WEST VIRGINIA
SECRETARY OF STATE
NATALIE E. TENNANT
ADMINISTRATIVE LAW DIVISION

Form #3

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2015 JUL 31 A 9:50

OFFICE WEST VIRGINIA
SECRETARY OF STATE

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

AGENCY: Department of Health and Human Resources TITLE NUMBER: 69

CITE AUTHORITY: W. Va. Code §§16-1-4 and 16-2N-2

AMENDMENT TO AN EXISTING RULE: YES ____ NO X

IF YES, SERIES NUMBER OF RULE BEING AMENDED: ____

TITLE OF RULE BEING AMENDED: ____

IF NO, SERIES NUMBER OF RULE BEING PROPOSED: 9

TITLE OF RULE BEING PROPOSED: Neonatal Abstinence Centers

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

Karen L Bowling

Authorized Signature

FISCAL NOTE FOR PROPOSED RULES

Rule Title: **NEONATAL ABSTINENCE CENTERS**

Type of Rule: **X** Legislative _____ Interpretive _____ Procedural

Agency: **Health and Human Resources**

Address: **One Davis Square**
Suite 100, East
Charleston, WV 25301

Phone Number: **304-558-2278** Email: kathy.m.lawson@wv.gov

Fiscal Note Summary

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

This rule implements a licensing and regulatory program for neonatal abstinence centers, a new license type that was created by HB 2999 during the 2015 Legislative Session. Based on the small projected number of centers, the Department anticipates that it will absorb this new program into an existing regulatory program, resulting in no additional staff. A minimal application and license fee will be assessed on any applications received, but the amount of revenue is projected to be negligible.

This fiscal note reflects the estimated costs and revenues associated with the implementation of a licensing and regulatory program for neonatal abstinence centers. This program would be licensed and regulated by the Office of Facility Licensure and Certification, within the Department of Health and Human Resources (Department). The Department estimates that the minimal costs associated with implementing this rule can be funded within existing budgets.

Fiscal Note Detail

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

Effect of Proposal	Fiscal Year		
	2015 Increase/Decrease (use"-")	2016 Increase/Decrease (use"-")	Fiscal Year (Upon Full Implementation)
1. Estimated Total Cost	0	0	0
Personal Services	0	0	0
Current Expenses	0	0	0
Repairs and Alterations	0	0	0
Buildings	0	0	0
Equipment	0	0	0
Land	0	0	0
Other Assets	0	0	0
2. Estimated Total Revenues	0	1,500	3,000

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

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

The Department expects to absorb this new program into an existing program because it does not anticipate a large number of applicants for this specialized facility type. The estimated revenue consists of license and application fees on two facilities in the first year and four upon full implementation.

Memorandum

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

Date 7/30/2015

Agency Department of Health and Human Resources

Authorized Representative Karen L. Bowling

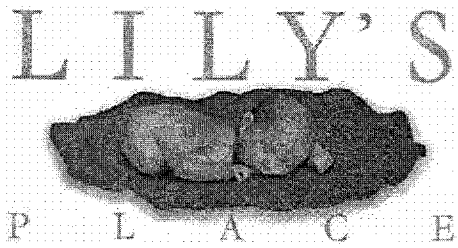
Proposed 69 CSR 9
Department of Health and Human Resources
Office of Inspector General
NEONATAL ABSTINENCE CENTERS

BRIEF SUMMARY

This rule establishes licensing and regulatory requirements for facilities that will operate as centers for the care and accommodation of infants with neonatal abstinence syndrome and neonatal opiate withdrawal syndrome. This rule provides for guidance in the operation of the facility as well as the standard of care for treatment of patients. The rule establishes definitions and creates requirements for licensure, the facility and its operation, staffing, patients' rights, care plans and interventions, as well as counselling, education and record retention.

STATEMENT OF CIRCUMSTANCES

The Legislature passed a law creating a license for a new type of facility to treat babies diagnosed with neonatal abstinence syndrome. The law requires that the Department of Health and Human Resources create a rule to address all aspects of the licensing, regulation, and operation of these types of centers. The rule is unique in that no other state issues a license for this type of stand-alone facility.



July 8, 2015

Office of Inspector General
WV DHHR
Building 6, Room 817B
State Capitol Complex
Charleston, WV 25305

Dear Secretary Bowling and Inspector General,

Please use this letter as my comment on the proposed rules for Neonatal Abstinence Centers.

Under 69-9-2 Definitions:

2.39 The definition of Neonatal Abstinence Center includes wording that would limit the length of stay to 30 days. Although that length of stay would be standard for a baby withdrawing from one substance, our experience shows that babies whose mothers are polysubstance abusers or those who are abusing Neurontin or other neurological agents, have lengths of stay that often extend beyond 30 days. We would recommend that the language be changed to allow physicians to determine the appropriate length of stay based on evidence-based practices and the baby's individual response to treatment.

2.40 The definition of NAS needs to be expanded as defined by the West Virginia Perinatal Partnership to include any substance that causes withdrawal symptoms in a baby. As written, the definition includes only opiates. This definition excludes infants suffering from a long list of substances that are not opiates, and in that way prevents the care and treatment of infants withdrawing from substances like marijuana, Neurontin, nicotine, anti-depressants (including SSRIs) and others. One thing we've learned in our treatment of babies is that as soon as we define a list of substances, others are invented. The law should be written to include those substances we are not yet aware of that would still cause a baby to suffer withdrawal symptoms.

Under 69-9-3 Certifications, etc…

3.10a. The renewal license will be issued for 1 year. We would request that renewals be for two (2) years.

Under 69-9-5 Administrative Organization

5.5 Administrator
Okay, so this is a big one.
5.5a. Finding someone to work as the executive director of a nonprofit is hard enough. He or she must have extensive experience in grant writing, business acumen, the ability to create and maintain a budget, public relations/marketing experience, social media and media relations proficiency, the ability to hire and manage a staff, and so much more. Finding someone with all these qualities who also has two to four years of experience in the direct care of neonatal or pediatric care at a nonprofit pay rate is next to impossible. With a Director of Nursing (Clinical Care plus Clinical Educator) and a Medical Director

handling the clinical side of an NAS Center, patient care is covered. The administrator needs to be more business oriented. I am the co-founder, literally created the organization from thin air with plenty of guidance and support from my colleagues and have been acting as the executive director since inception of Lily's Place. I have created the entire policies manual, which you guys reviewed and managed all operations since we opened, and I would not qualify as the organization's administrator as the rules are written. Neither would our Director of Nursing, Rhonda Edmunds, who has over 28 years of experience with neonates and drug exposed infants, but has a two-year nursing degree and doesn't handle any of the business side of things. As the Administrator, this person is the CEO of the organization. I wonder if any CEOs of other medical providers in the state have experience in direct care of patients. Probably not. That's why the CEO hires great staff. My recommendation would be that the Administrator have a bachelor's degree in an appropriate area of study, marketing/pr/social media/fundraising experience, and the ability to manage the financial side of the organization.

5.6 Advisory Council

5.6b. The rules say that the advisory council must be comprised of individuals served by the program. This is problematic because the primary patient is a newborn. The parents of the patients are addicts. The rules require the patient or addict to review program policies and procedures, review incidents and grievances, review administrative discharges, make recommendations for operational changes or improvements, be trained in patient confidentiality laws and regulations, keep records and working to assist NAS Centers in resolving problems.

We pride ourselves in the security measures we have put in place for the sake of our infants and staff. No one gets inside Lily's Place unless they are staff, are conducting business here (CPS workers, for example) or have a child as a patient. HIPPAA is our friend, and we follow the law to the letter. We use only first names with our patient's parents as a means of protecting our staff from intrusions into their personal lives via Facebook and other means. By opening our operating policies and procedures to those who are currently addicted or in recovery (part of recovery is relapse), we are opening up our security and operational rules to those who could use them to their advantage or share them with those who may misuse them. Allowing parents to review incidences and grievances or administrative discharges opens our staff up to potential harm. We conduct exit surveys with each family upon discharge to ask about problems and allow families to make suggestions. We monitor their level of satisfaction and make changes through our Quality Control Improvement Committee as appropriate. Although I think in most nursing care organizations (with the elderly, as an example) having an advisory council made up of patients is appropriate, for the safety and security of an NAS facility, we feel this is a liability.

5.7 Quality Improvement Committee

5.7c3. Clinical Care Manager and 5.7c4 Clinical Care Educator

When we first wrote our policies manual, we thought that we would employ a Clinical Care Manager to manage all the clinical employees and a Clinical Care Educator to help with educating parents. We have actually combined the position into a Director of Nursing to save on cost. The Director of Nursing is a nearly equal position to the Executive Director, and the DON handles human resources on the clinical side and manages all clinical employees, carries out the directives of the physicians, and works with nurses and our social worker to appropriately provide parents with our incredibly thorough education plan. Just as our Executive Director also has to be the business manager, so too our Director of Nursing has to fill both roles.

6.14p2 Director of Nursing or the registered nurse on duty.

LILY'S PLACE

6.14q. I think this must be a rule from a nursing home. First of all, we maintain a 3 patients to 1 nurse ratio with a Patient Care Assistant thrown in for additional support. And we have been required by DHHR to have eyes on the patient every 15 minutes. With these safeguards in place and our high patient to staff ratio (which is increased when our volunteer cuddlers are present), our babies are almost never unattended, and if they are, it is for less than 15 minutes. We do not allow staff to have phones in the patient area. Their phones are locked away in the break room. Parents are allowed to take cell phones in, but calls are not permitted. We have created and maintain a low-stimulus environment. Having phones in the room will deteriorate the environment that is required by these infants. We DO have indicator switches in each room that can be flipped on to notify nurses in the hallway that someone needs assistance, but they have never been used. The visiting parent just sticks his/her head out of the room, and someone is there to attend to them immediately.

6.8b. NFPA for health care facilities- Quite honestly this requirement is overkill. We are not conducting surgery or even drawing blood here. We are providing medication and therapeutic care and should not be lumped into the same category as hospitals. Without a waiver for this section, not a single NAS Center would be able to open. NAS Centers should meet the same fire and safety requirements as West Virginia's residential group homes, as created under DHHR rules. I have reviewed the rules/regulations online, and they are not appropriate for an NAS Center. If the rules under NFPA Chapter 15 are instituted, Lily's Place would use section 15.1.2, which states "An existing system that is not in strict compliance with the provisions of this code shall be permitted to be continued in use unless the authority having jurisdiction (OHFLAC) has determined that such use constitutes a distinct hazard to life."

7.10c I would add "non-emergency medical transport or the state" to the end of this in the event that the need is not an emergency.

7.12c. Live and learn. We have had parents who absolutely could not be sober, and we could not in good conscience send them out of the facility with their car keys. Our current procedure is to ask the parent to wait outside the patient area in our Education Center. His or her demeanor is assessed by our social worker and if she is unavailable by the baby's nurse. If either determine that the parent is in no condition to visit the baby, we confiscate the parent's car keys and call a taxi to take them to where they need to go. We felt it was a moral obligation to prevent a potential DUI.

9.2 and 9.3 have been combined at our facility under the title Director of Nursing.

9.4b. Must be two registered nurses on staff at all times per medicine administration rules of WV Board of Pharmacy and the DEA.

9.5a. I think the bachelor's degree wording was left out. Should read "Social worker must hold a bachelors degree and an unencumbered and valid WV Social Work License."

9.7d I would add clerical duties to volunteer tasks.

10.2g2. The babies are not hospitalized. I would use the word "treatment."

10.2i2. I would add "or give written consent."

11.8c. combine clinical educator and clinical care manager into Director of Nursing

69-9-12 Pharmacological interventions

12.1. This should say "Approved pharmacological treatment may include methadone, buprenorphine, Neurontin or as determined by the Medical Director." (We are constantly learning of new drugs being abused. It would be a shame to be unable to treat a baby because state code limited the treatment options.)

12.8d. Clinical Care Manager to Director of Nursing

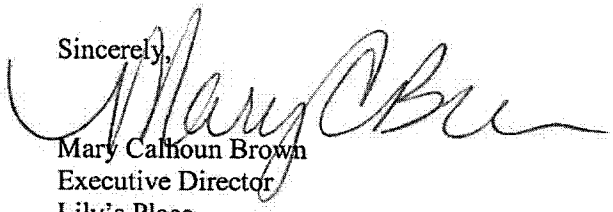
13.2h. I would add "as tolerated."

13.8. I would add "as tolerated."

14.2c. I would say "Provide access to individual and group therapy." A bachelor's level social worker may not be qualified to provide therapy in some instances, but she would certainly be able to make a referral and an appointment with a qualified counselor as appropriate."

Thank you for the opportunity to comment. Overall I think the rules are well done and appropriate.

Sincerely,



Mary Calhoun Brown
Executive Director
Lily's Place
1320 Seventh Ave
Huntington, WV 25701
304-523-5459

Cc: Secretary Karen Bowling

Rhonda Edmunds, RN
Director of Nursing
Lily's Place
Rt. 3 Box 140
Milton, WV 25541

DHHR Office of Inspector General
Building 6 Room 817B
State Capitol Complex
Charleston, WV 25305

To Whom It May Concern,

I have reviewed the proposed rules for Neonatal Abstinence Centers and am submitting my comments.

Under 69-9-2 Definitions:

2.39 NAS – This definition includes a time frame not to exceed 30 days. This is a problem because sometimes the babies require a longer time frame to complete the withdrawal process.

2.40 I would recommend the word opiate be removed from this definition so as not to limit those babies who are withdrawing from non-opioid substances.

2.42 My concern is that all evidence-based treatment that is non-pharmacological is not yet recognized by the American Academy of Pediatrics.

2.42 and 2.47 American Pediatric Association needs to be changed to American Academy of Pediatrics.

Under §69-9-3. Certification, Licensure, Approval and Exemption.

3.1.a I would recommend combining 3.1.a and 3.1.b to say: Treat symptoms of withdrawal in patients who have been prenatally drug exposed using both pharmacological and non-pharmacological interventions.

3.1.b. I would recommend omitting this.

Under §69-9-5. Administrative Organization.

5.5. I would recommend changing the title of Administrator to Executive Director.

5.5.a. In my opinion, the Administrator (or Executive Director) would not need to have experience in the field of neonatal or pediatric care. This person's role would be to develop policy and procedures for operation, establish and maintain security and maintenance of the building, management of the facility budget, fundraising and marketing, and to communicate with the board. This person would not have any direct patient contact or need for expertise in NAS.

5.6.b. I would not recommend that the advisory council consist of individuals served by the program since the patients are infants and the parents are suffering with addiction. It would not be wise for these individuals to have access to the facilities policies and procedures, or incidents and grievances. I do think it would be advantageous to the facility to have parents who would be willing to recommend operational changes and/or improvements and work to assist the center to identify, address and resolve problems.

5.7.a. I would recommend that the Quality Improvement Committee meet quarterly instead of monthly.

5.7.c.3 and 5.7.c.4 I would recommend combining the roles of the Clinical Care Manager and Clinical Care Educator to be the Director of Nursing.

Under §69-9-6. Physical Facility.

6.2.c. I would recommend that all doors providing entrance to secure areas of the center have key pad entrances; however, the front door to the center needs to be a keyed entrance for security purposes. If the security guard was making rounds outside and let a parent in the front door, they could look over his shoulder and get the code to the keypad entrance.

6.3.b. I would not recommend a changing table be a necessity in each nursery due to cost, space, safety and increased stimulation taking infant from crib to changing table. Diapers and clothes can be changed in the infant's crib.

6.3.c. I would recommend this be changed to read: the center shall provide adequate drawer, closet OR shelving space to accommodate clothing and personal items.

6.10.d. I would recommend adding: to wash or sanitize their hands after each direct contact and after engaging in any activity for which hand washing or hand sanitizing is indicated....

6.14.p.2. Change the Clinical Care Nurse to the Director of Nursing.

6.14.q. I would recommend changing the word unit in this sentence to patient care area. Unit may be confused as patient room and a phone would not be appropriate in each patient room due to overstimulation.

Under §69-9-7 Patient Rights and Parental/legal Representative Rights and Responsibilities.

7.9.a.8. I would recommend adding something that would allow parents to take their prescribed medication if needed while rooming-in overnight with the infant before discharge.

7.10.c. Since this may not be an emergent incidence, I would recommend using non-emergent transport or an ambulance.

Under §69-9-9.Staffing.

9.2 and 9.3 combining these roles into one with the name being Director of Nursing who would work with the Executive Director and report directly to the board.

9.4.b. I would recommend changing this to: There shall be one registered nurse per every 4 patients. There must be a minimum of two RNs on each shift. With the complexity of these infants, a one to 6 patient ratio would not best practice.

9.4.e. NRP certification is geared more to delivery room care of infants. A certification in S.T.A.B.L.E. within one year of employment would be more appropriate with these infants.

9.4.f.14. This could be a shared responsibility with the Director of Nursing.

9.6.c.1 PCAs should be certified or licensed as a PCA or CNA.

9.6.c.2 NALS certification for PCAs would not be necessary. Certification in S.T.A.B.L.E. within one year of employment would be more appropriate.

9.8.d. The center shall maintain, at a minimum, two RNs on-site at all times with the ability to increase when needed would be more appropriate.

9.9.c. At a minimum, it is my opinion, all employees participating in direct patient care should be trained in S.T.A.B.L.E., basic infant care, the effects of neonatal abstinence syndrome and how to care for those infants who are born prenatally exposed to drugs. Parenting skills is not necessary.

Under §69-9-10.Admission, Discharge and Transition

10.1.a.5. I would recommend the wording be changed to say: The patient has been established on medication for the symptoms of withdrawal. Not all facilities will choose to use the same weaning protocol with the 9 steps that we use here at Lily's Place.

10.1.d.1. Should be the patient or their infant.

10.2.g.1.b. Sometimes we have had to use the baby's baseline average as a guide to wean the medication. Oftentimes, that score is above an 8. I would recommend that this read: The patient must have a NAS score average of <8 or < their baseline average used for weaning at the Dr.'s discretion.

10.2.g.2. "Hospitalization" should be changed to "stay at the facility" since we are not a hospital.

Under §69-9-11. Plan of Care.

11.1. Is this on all infants or only those in the State's custody (whether voluntary or emergency)?

11.6.a.6. and 11.a.7. I would recommend that the Developmental History and Legal History be omitted since the patients are infants.

11.6.e.2.C. I would recommend adding "as long as the infant is on medication and during the observation period" because infants who are no longer on the medication and are waiting to be discharged because of social situations do not need to the scored every 3-4 hours.

11.6.e.2.H. Since we are not a hospital, we do not do the NPASS. These babies are in pain but not the kind of pain we are able to give pain medications for.

11.6.e.2.J. Abdominal girth is not a typical measurement that would be obtained or used to track the infant's growth.

11.6.e.2.A. The nurse aide should not be required to assist or observe the assessment. This is not conducive with time management.

11.6.e.2.B. This again is not always possible. Parents are welcome to observe the assessment and are taught about the Finnegan Scoring system; however, it is not practical to try to coordinate the two.

11.8.c. Is the Plan of Care and the Comprehensive Plan of Care used interchangeably?

Under §69-9-12. Pharmacological Interventions

12.1. Approved pharmacological treatment should also include clonidine, Neurontin, and zantac. It's difficult to limit the medications for treatment due to the newness of this process.

12.6.e.3. and 12.6.e.4. Is monthly and annual inventory necessary on individual prescriptions of methadone?

12.12.a. and 12.12.b. Under the guidelines of our Consulting Pharmacist, Gina Finley, we dispose of our unused and discontinued controlled substances by disposing of them in kitty litter. This disposal is witnessed and documented by 2 RNs.

Under §69-9-14. Parent Education and Counseling.

14.2.a. I think this should include the word "Attempt" to meet with mothers....

Thank you so much for the opportunity to comment on the rules. Please let me know if there is anything I can do to clarify any of my comments or be of any help to you as you proceed with the regulations.

Sincerely,

Rhonda Edmunds, RN
Director of Nursing
Lily's Place
304-523-5459

Marshall University
Joan C. Edwards School of Medicine
Department of Pediatrics
Joseph E. Evans, M.D., Chairman
Bob Miller, M.D., Associate Chair, Education
Yoram Elitsur, M.D., Associate Chair, Research

The enclosed document summarizes my comments on the legislation regarding NAS centers. Thank you for all of your efforts in helping establish these centers that will provide an additional resource for these infants and their families. If you were to have additional questions I may assist with, please feel free to contact me.

Sean Loudin

1600 Medical Center Drive, Suite 3500 • Huntington, West Virginia 25701-3655 • (304) 691-1386 • Fax (304) 691-1375

Sean Loudin MD

Comments on NAS Centers

Definitions:

2.39- Limiting time from 24 hours to 30 days is unwise. Infants respond differently to their exposure. Infants who were exposed to multiple substances throughout pregnancy are more difficult to wean and could require a stay longer than 30 days.

2.40- NAS definition is not just about opiates. My suggestion for the definition and that of the WV Perinatal Partnership is: When a baby has prenatal exposure to a neuroactive substance and exhibits clinical signs/symptoms of withdrawal, regardless of whether pharmacological treatment is required.

2.42 – Anywhere in the document the phrase "American Pediatric Association" appears it should be the American Academy of Pediatrics (aka AAP). (i.e. 2.47, 2.56

2.56 – For scoring systems the AAP just mentions that scoring systems may be used if they have been "published" NOT validated.

5.5 Administrator – The administrator should be a person who knows how to run a business/organization. Most people in the medical field do not have that experience. This person is the executive director who is responsible for meeting all of the requirements. This person should work closely with the medical director and nursing director to make sure the procedures are established and followed. They should not have to have neonatal or pediatric experience.

6.2.c – Double dead bolt locked entrances are secure as well for main entrance, and then additional layers of keypad access are acceptable

6.3.b – A changing table is not necessary as most babies can be changed in their own crib.

7.2.b – If the center is to not deny admission due to protected status, then the state of WV should be very proactive about having all payers accept this as a type of health care facility and offer reimbursement. As it stands now there are patients that are being denied admission because their medical coverage doesn't pay for their stay. The state they live in may impact as well, as patients from Ohio, Kentucky, Pennsylvania, Virginia, and Maryland would not be able to be admitted under current payer rules.

7.6 Informed consent – As it stands now, there is no informed consent process to treat infants in the hospital setting for NAS. It is medical necessity to treat an infant suffering from withdrawal. I would clarify what the need for informed consent is before requiring centers to obtain it. Does this mean that the center just needs to make it clear to legal representatives that this is an alternative to the care in the hospital, because it should be equivalent care that they get in the hospital, not a downgrade that is "risky" and therefore requiring a parent to take the risk of their infant in an NAS center.

7.10.c Refusal of Treatment – Why does the patient need to be returned to the hospital by ambulance. If the infant needs to be treated for withdrawal or additional therapy initiated to control withdrawal and the NAS center can provide that service, there is no need to return to the hospital. CPS should be notified that medical personnel feel that by refusing treatment this caregiver is putting their child's wellbeing in jeopardy.

9.1.b – What is meant by the center shall "employ" a medical director? Is the state mandating that the center provide the medical director a salary? If so how much? I serve as the medical director of Lily's Place and have never received a dime from Lily's Place.

9.1.c – While I agree that the medical director must be a pediatrician, I'm not sure a neonatologist is required. I think that one of the considerations the DHHR should make, is that when they are agreeing to license a NAS center that they have a medical director from an established NAS center be available to meet with the proposed medical director to make sure they are educated and vested in the process. The state is limited on the number of Neonatologists and their time to dedicate to the medical director role may vary considerably. Pediatricians who are willing to dedicate time and are vested in the care of NAS patients are capable of the medical director role.

Medical director should be NRP certified

9.2 and 9.3 – The Clinical Care Manager and Clinical Education Manager could be the same person.

9.4.b – The ratio of 1 RN to 6 babies is too high. For best care 1 to 3 is most ideal. Also there should be 2 RN's in house at ALL times.

10.1.a.5 – Not all NAS centers will be using the same weaning protocol. So defining which "step" a baby is on before they are admitted is impossible. There should be communication between the referring physician and the accepting physician as to the level of medical stability and whether the admission is appropriate.

10.2.g.1.b – This is assuming everyone will be using the Finnegan scoring system. Also this is very limiting for practitioners and payers. The AAP recognizes that infants can exhibit subacute withdrawal symptoms for at least 6 months. Therefore these infants will not be symptom free at discharge. They need to be medically stable to transition to the home environment and capable of handling various forms of stimulation. Meeting a certain number prior to discharge is not good medical practice. There are way to many other factors that must go into those decisions.

11.6 Comprehensive assessment – This section seems to be designed based on the EPSDT form. However this is used for foster children and their assessment. If there are babies admitted that do not need the EPSDT, then this comprehensive assessment is overkill. These patients should have just come from a hospital setting where they were under care of a board certified physician. Those assessments are made on a daily basis. This transition to a NAS center should be viewed as a continuation of care, NOT starting all over.

11.6.e.2.C – Now this dictates use of the Finnegan scoring system, rather than use of a published scoring system. Not everyone uses the Finnegan so don't dictate it's use.

11.6.e.2.H – NPASS is a hospital requirement. Is the DHHR aware of any studies that take into account NAS and how that effects the NPASS score. I am unaware of any correlations and the NAS scoring is assessing much more than the NPASS. The irritability that these babies experience is constantly being assessed so the NPASS seems to be doubling the work unnecessarily.

12.1 – Morphine may be the drug of choice for some hospitals around the state. Also there may be adjunct therapies such as Clonidine and some centers may use Phenobarbital. So list all drugs or have a phrase that allows

13.12.d.1 – First face to face meeting within 24 hours of admission would not then go with the physician rounding at least twice per week. If there is good communication before admission between the hospital and NAS center, it may be reasonable for having a 48 hour rule vs 24 hour rule. Again I think this is getting caught up around foster placement guidelines which may not apply in this situation.

129 Stamford Park Drive
Huntington, WV 25705
July 17, 2015

Secretary Karen Bowling
WV DHHR
Building 6, Room 817B
State Capitol Complex
Charleston, WV 25305

Dear Secretary Bowling:

I am writing concerning the proposed rules for Neonatal Abstinence Centers. I am the Volunteer Coordinator at Lily's Place in Huntington, WV, and serve on the Board of Directors of that facility. I am also an experienced volunteer and "cuddler" of infants suffering from pre-term drug exposure at Cabell-Huntington Hospital (CHH) in Huntington.

Several things caught my attention when reviewing the proposed rules.

69-9-2 Definitions

2.39. The wording when defining length of stay in a Neonatal Abstinence Center (30 days), is too restrictive. We have learned that our babies are often addicted to more than just opiates. Therefore, their length of stay at Lily's Place and at CHH is often longer than 30 days. Recently, we have found that exposure to Neurontin, not an opiate, produces another set of problems that these babies have to face.

2.4.0. The definition as written includes only opiates. These babies are sometimes addicted to many other addictive substances, including marijuana, nicotine, anti-depressants, and Neurontin.

69-9-5 Administrator

5.5. The requirement for the director of a NAS facility does not need to have four years' experience in working with these babies or experience in a pediatric care facility. This person needs a business background. A large part of this person's job is fund raising, managing personnel, and overseeing the day to day operation of the center, none of which require experience in working with drug exposed neonates. This would be similar to requiring CEO's of hospitals to be doctors or have medical training.

5.5c. This section delineates the duties of the Administrator, and none of them reflect the need for experience in a neonatal abstinence center. The Director of Nursing oversees the medical issues; the administrator handles the business side.

5.6 Advisory Council

5.6.a. Revise the first sentence, "Each center shall have an advisory council, *or board of directors*,..." Most 501©3's refer to their governing board as such.

5.6.b. This rule, as written, states that one of the members of this council should have been served by this program. Our patients are infants; therefore, this needs to be changed. The inclusion of a parent of a patient is not appropriate, either, based on the population we serve.

5.7 Quality Improvement Committee

5.7.c. 3 and 4. At Lily's Place, we have combined these two positions into one. Perhaps the verbiage could just be adjusted to reflect that these two positions *can be combined*, i.e. the Director of Nursing.

5.7.c.6. "Nurse Aide" isn't restrictive enough. This would leave the door open to anyone whether they're licensed by the State of WV or not. At the very least, this should say "patient care assistant or certified nursing assistant licensed in the State of West Virginia."

5.8.d. I would add "volunteer" to the list of those requiring a personnel file. We require similar training and each volunteer's file must include much of the same information, i.e. background check, fingerprints, and consent to be drug screened. There is a checklist on the front of every volunteer file that ensures that everything that the State requires is in that file.

Facility Security Requirements

6.2.c. The way this reads, the outside doors to the facility will be opened with a key pad code. While having a key pad that leads to the secure area of the building is good, allowing access from the outside with only a key pad seems risky, especially considering the population with whom we deal. Having a dead bolt to/from the outside is a safer option. At Lily's Place, the security guard on duty escorts our visitors in and out of the building.

6.3 Service Environment

6.3.b. Having a changing table in every room should not be a requirement. At Lily's Place and at CHH, our babies are changed in the crib itself. There is plenty of room to do it there. Also, not having to move them from one area to another decreases the stimuli they're receiving. Potentially, the rooms might not be large enough to provide a safe, clutter-free environment.

6.3.c. While providing some storage in the nurseries is important, having a closet in each baby's room isn't necessary. At Lily's Place we supply sleepers/gowns, etc., for our babies which are stored elsewhere. The drawers and bins in each room provide adequate storage space for additional clothing.

6.10. Infection Control

6.10.c. Include the volunteers in the first sentence: "The center shall prohibit employees *or volunteers* with a communicable disease…"

9.2 Clinical Care Manager

Once again, we have combined these positions into the Director of Nursing. There is no need for additional staffing in a small facility. If this suggestion is included earlier in the rules, (5.7.c – 3 & 4) it needs to be changed here, as well.

9.3e.1. This can be deleted or changed if the aforementioned rule is revised. This applies to the rest of the responsibilities listed in that section.

9.7 Volunteers

9.7.d. Add "and random drug screening" after "background check requirements."

9.7.c. I would make this addition: "Each volunteer shall receive training in therapeutic handling *and the characteristics of NAS to be able to report their observations to the RN or PCA on duty."*

9.7.d. I would make this addition: "Volunteers may only perform tasks related to therapeutic handling, housekeeping, *and clerical duties, unless deemed appropriate by the Director of Nursing."*

9.10 Personnel Records

9.10.a.4 At Lily's Place and at CHH, volunteers who work with drug exposed infants are required to have not only a current TB test but the Hepatitis B series of vaccinations, as well. This is as much for the volunteers' safety as for the babies with whom they work.

Thank you for allowing me to comment on the proposed rules. Those of us at Lily's Place are thrilled to have our own designation.

Very sincerely,

Marilyn M. Murdock

Marilyn M. Murdock, BA, MA
Volunteer Coordinator
Lily's Place

mmurdock27@hotmail.com
304-416-9900

Sara Murray, RN
Clinical Coordinator
Neonatal Therapeutic Unit
PO Box 429
Milton WV 25541

DHHR Office of Inspector General
Building 6, Room 817B
State Capitol Complex
Charleston, WV 25305

To Whom It May Concern,

Dr.Sean Loudin and I have reviewed the proposed rules for Neonatal Abstinence Centers. We are submitting our comments separately.

Under 69-9-2 Definitions:

2.39: The wording limits the length of stay for treatment to 30 days. Most opiate exposed infants who have no other exposures can be treated within the 30 day limit, however, our experience with poly substance abuse, especially Neurontin, has caused length of stay for these babies to increase dramatically. I feel the language should be changed to cover the myriad of drugs we are seeing combined with opiates and allow the physician and medical staff to determine when an infant is ready for discharge based on the each individual patient's response to treatment.

2.40: Neonatal Abstinence Syndrome definitions would be better understood as a group of symptoms rather than a group of problems. I would suggest changing the definition and replace "problems" with "symptoms". As mentioned above opiate withdrawal in babies is complicated by other addictive or companion drugs the mother consumes. Many of these drugs cause withdrawal in the neonate as well making treatment a challenge. I would change the wording from addictive "opiate" drugs to "addictive drugs". Neonatal Opiate Withdrawal Syndrome has not been officially adopted by the FDA to replace Neonatal Abstinence Syndrome and we have petitioned, in light of the many addictive drugs we are now seeing, if change is a must then Neonatal Withdrawal Syndrome would be more appropriate.

2.46: Recommend change from under 1 year of age to under six (6) months of age

2.47: Recommend change from American Pediatric Association to American Academy of Pediatrics.

Under 69-9-3. Certification, Licensure, Approval and Exemption

3.1.a: Recommend change chemical dependence to "symptoms of Neonatal Abstinence Syndrome".

3.1.b: Recommend omitting "from chemical dependence"

3.10.a: Recommend license renewal be for two (2) years

Under 69-9-5 Administrative Organization

5.5 Administrator: The administrator of the facility should not be required to have experience in Pediatric or Neonatal Care. This person is not involved in Clinical Care...basically the

Administrator/Executive Director needs to have experience in business management, grant writing, public relations, marketing, media relations, human resources, etc. The Clinical Care/Clinical Educator would cover the clinical management of the facility. Finding a manager type person with clinical experience would be like requiring the CEO of a hospital to be equally versed in business management and clinical care. My recommendation is the administrator have an appropriate bachelor's degree and experience in the business side of a Not for Profit Entity that best meets the needs of the facility whether the focus be grant writing, marketing or whatever best meets the business needs of the facility. This person will also have to gain understanding of all the regulatory compliance articles placed on the facility. There will be no time, nor will there be need for this person to be involved in Direct Patient care.

5.6 Advisory Council

I am not sure this would be appropriate for an NAS facility. If you remember our patients are infants which excludes them and their parents are addicts. I do agree with advisory councils in almost every area of patient care but I do not believe this would be feasible. For example, we have an advisory council at CHH in the NICU, we do not have one in the NTU. Most of our parents DO NOT even make their infant's initial pediatrician follow up days after discharge. The rule suggests they view policies and procedures. I think this puts the staff and infants at the facility in harm's way. Over the past months we have had parents involved in murder, robbery, showing up for visitation under the influence, abuse and neglect of a child and overdose. We should not make an addict privy to our security, narcotic and employee routines. It may sound harsh but the truth is harsh. All parents are treated kindly and asked to be involved with the care of their baby but I do not believe this council is appropriate. Perhaps a parent handbook with their rights and other things pertinent to their baby's stay would be more appropriate.

Exit interviews give the parent an opportunity to verbalize what we did well and what we could have done better. We take this very seriously. Also, the interaction with the parents by the staff is constant while the baby is a patient and they are in the building. Our building is very secure and once the patient is discharged the parent access to the building ends. We do not allow anyone in the building who does not have direct business with the facility. We have to do this for the safety of our employees and patients.

5.7, Quality Improvement Committee

5.7.c3. Clinical Manager and 5.7c4 Clinical Care Educator

When we first had the concept of a facility, we felt the two positions were needed, but as we progress and learned what we were doing we realized this could be a one person job. We rolled the two together and made the **Director of Nursing** position. This person functions on the clinical level as the Executive Director functions on the Business level. They are actually equal on the hierarchy with different roles.

This person should be competent and experienced in the care of the prenatally exposed infant. He/she will be responsible for the clinical excellence of the facility, therefore it would be unacceptable for the position not to require clinical expertise the care of prenatally exposed infants.

Recommendation the Clinical Manager and Clinical Care Coordinator be consolidated into the position Director of Nursing or Clinical Director and all language be changed to reflect the title.

6.14q. Having phones in the patient rooms is not necessary and not appropriate for our minimal stimulus environment. Parents may have their phones on them but are not allowed to take calls in the room. All phone ringers must be place on mute. Nurses phones are left in their lockers. There are call lights for emergency in each room. The nurses, if not in the room, are only steps away and can be at the bedside in moments.

6.8.b. This would be prohibitive to starting any new NAS facility. NFPA standards for medical facilities are inappropriate for a facility who only provides medication and therapeutic care. Under those regulations Lily's Place could fall under 15.1.2 for an existing facility but it would prohibit future facilities.

7.12.c Parent or caregiver under the influence of drugs.....This happens often and one recommendation would be no parent is sent out with car keys in hand to risk his/her life or that of the public. We have had parents removed from the patient care area and have called a relative or cab for their safe transportation. I would not mandate they are allowed to leave inebriated. We require documentation when this occurs.

9.2 and 9.3 We combined these positions into the Nursing Director position. This person responsible for the Clinical Excellence of the facility should have more than 2 years experience in pediatrics and must be clinically competent and experienced in the care of the prenatally exposed infant. This position is key to the success of the facility.

9.4.b. There shall be 1 RN for every six (6) patients. We require 2 RNs at all times because of narcotic administration(WV Board of Pharmacy and DEA rules for narcotic administration and waste) and complex assessment poly substance abuse babies require. We have come to realize with the complexity of these infants that 6 patients/ 1 RN is not appropriate.

I recommend the nursing to patient ratio be 1 RN per 4 babies.

9.4.e. NRP would not be necessary for nurses in this setting. NRP is designed for hospital and delivery room care. Neonatal Advanced Life Support would be acceptable but I would recommend all the nurses in an NAS facility be S.T.A.B.L.E. certified. This is what we(CHH) teach our referring hospitals. This allows the clinician to resuscitate,
stabilize and prepare a sick or distressed infant for transport when necessary to a hospital for care.

I would recommend S.T.A.B.L.E. or NALS certification with the preference being S.T.A.B.L.E

9.4.f.14. Initiating and updating plan of care should be done by the Nursing Director to ensure reliability and consistency. We found this works better and keeps the Nursing Director informed as to the care of the babies.

9.6.c.1. Personal Care Assistants should be required to complete and pass requirements for licensure in the state of WV for PCA or CNA (Certified nursing Assistants)

9.6.d.4 and 9.6.d.5 Recommend changing "efficient" to "proficient".

9.8.d. Both nurses should be licensed as Registered nurses to scheduled drugs be administered, counted and wasted.

9.9.b. Recommend adding S.T.A.B.L.E certification for Registered nurses and PCAs.

10.2.g.1.b. We have found with poly substance abuse a score of less than 8 is not always attainable. I would recommend changing this to:
The patient shall have an NAS score of 8 or less or may be discharge with higher average score at the discretion of the Physician and Nursing Director in collaboration.

10.2.g.2 Since infant is not "hospitalized" I would change to "throughout patient's **treatment**".

10.2.h Discharge Needs and After-Care

Should be added to this section: Appointment made for follow up visit with patients Primary Care Physician within 48 hours after discharge.

12.1 This statement should be expanded to include Clonidine, Neurontin or any medication deemed as appropriate for treatment. (We have and continue to discover multiple medications mothers are taking that require adjunct treatment. At the NTU and Lily's Place, we currently treat with Neurontin and Clonidine.)

12.10 Administration of Narcotic Medications

This section reinforces there must be two (2) registered nurses in the facility at all times.

Thank you for the opportunity to comment on the rules. Should you require further information on the Clinical Management of Prenatally Exposed Infants Dr. Sean Loudin, Rhonda Edmunds, RN and myself are available upon your request.

Sincerely,

Sara Murray, RN
Clinical Coordinator
Neonatal Therapeutic Unit
Co Founder and President of Board, Lily's Place
304-526-2371
Sara.murray@chhi.org

QUESTIONNAIRE

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

DATE: _____

TO: LEGISLATIVE RULE-MAKING REVIEW COMMITTEE

FROM:(*Agency Name, Address & Phone No.*) Department of Health and Human Resources
Office of Inspector General
Building 6, Room 817B
State Capitol Complex
Charleston, WV 25305
(304) 558-2278

LEGISLATIVE RULE TITLE: Neonatal Abstinence Centers

1. Authorizing statute(s) citation W. Va. Code §§16-1-4 and 16-2N-2

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

June 25, 2015

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

n/a

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

July 25, 2015

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

Attached X No comments received _____

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

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

Kathy Lawson, Inspector General
DHHR Office of Inspector General
Building 6 Room 817B
State Capitol Complex
Charleston, WV 25305
phone (304) 558-2278
fax (304) 558-1992
email Kathy.M.Lawson@wv.gov

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

n/a

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

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

n/a

b. Date of hearing or comment period:

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

n/a

d. Attach findings and determinations and reasons:

Attached

Title 69 Series 9
Neonatal Abstinence Syndrome Center
Legislative Rule
West Virginia Department of Health and Human Resources

Summary of Public Comments:

Comment #1

2.39. The wording when defining length of stay in a Neonatal Abstinence Center (30 days), is too restrictive. We have learned that our babies are often addicted to more than just opiates. Therefore, their length of stay at Lily's Place and at CHH is often longer than 30 days. Recently, we have found that exposure to Neurontin, not an opiate, produces another set of problems that these babies have to face.

Comment by Marilyn M. Murdock, BA, MA

Response #1

The Department finds clarification is needed, and changes were made related to the request.

Comment #2

2.39. The wording limits the length of stay for treatment to 30 days. Most opiate exposed infants who have no other exposures can be treated within the 30 day limit, however, our experiences with poly substance abuse, especially Neurontin, has caused length of stay for these babies to increase dramatically. I feel the language should be changed to cover the myriad of drugs we are seeing combined with opiates and allow the physician and medical staff to determine when an infant is ready for discharge based on each individual patient's response to treatment.

Comment by Sara Murray, RN

Response #2

The Department finds clarification is needed, and changes were made related to the request.

Comment #3

2.39. The definition of Neonatal Abstinence Center includes wording that would limit the length of stay to 30 days. Although that length of stay would be standard for a baby withdrawing from one substance, our experience shows that babies whose mothers are polysubstance abusers or those who are abusing, Neurontin or other neurological agents, have lengths of stay that often extend beyond 30 days. We would recommend that the language be changed to allow physicians to determine the appropriate length of stay based on evidence-based practices and the baby's individual response to treatment.

Comment by Mary Brown

Response #3

The Department finds clarification is needed, and changes were made related to the request.

Comment #4

2.39. Limiting time from 24 hours to 30 days is unwise. Infants respond differently to their exposure. Infants who were exposed to multiple substances throughout pregnancy are more difficult to wean and could require a stay longer than 30 days.

Comment by Sean Loudin MD FAAP

Response #4

The Department finds clarification is needed, and changes were made related to the request.

Comment #5

2.39. NAS – This definition includes a time frame not to exceed 30 days. This is a problem because sometimes the babies require a longer time frame to complete the withdrawal process.

Comment by Rhonda Edmunds, RN

Response #5

The Department finds clarification is needed, and changes were made related to the request.

Comment #6

2.40. The definition as written includes only opiates. These babies are sometimes addicted to many other addictive substances, including marijuana, nicotine, anti-depressants, and Neurontin.

Comment by Marilyn M. Murdock, BA, MA

Response #6

The Department finds clarification is needed, and changes were made related to the request.

Comment #7

2.40. The definition of NAS needs to be expanded as defined by the WV Perinatal Partnership to include any substance that causes withdrawal symptoms in a baby. As written, the definition includes only opiates. This definition excludes infants suffering from a long list of substances that are not opiates, and in that way prevents the care and treatment of infants withdrawing from substances like marijuana, Neurontin, nicotine, anti-depressants (including SSRIs) and others. One thing we've learned in our treatment of babies is that as soon as we define a list of substances, others are invented. The law should

be written to include those substances we are not yet aware of that would still cause a baby to suffer withdrawal symptoms.

Comment by Mary Brown

Response #7

The Department finds clarification is needed, and changes were made related to the request.

Response #8

2.40. Neonatal Abstinence Syndrome definitions would be better understood as a group of symptoms rather than a group of problems. I would suggest changing the definition and replace "problems" with "symptoms". As mentioned above opiate withdrawal in babies is complicated by other addictive or companion drugs the mother consumes. Many of these drugs cause withdrawal in the neonate as well making treatment a challenge. I would change the wording from addictive "opiate" drugs to "addictive drugs". Neonatal Opiate Withdrawal Syndrome has not been officially adopted by the FDA to replace Neonatal Abstinence Syndrome and we have petitioned, in light of the many addictive drugs we are now seeing, if change is a must then Neonatal Withdrawal Syndrome would be more appropriate.

Comment by Sara Murray, RN

Response #8

The Department finds clarification is needed, and changes were made related to the request.

Comment #9

2.40. NAS definition is not just about opiates. My suggestion for the definition and that of the WV Perinatal Partnership is: When a baby has prenatal exposure to a neuroactive substance and exhibits clinical signs/symptoms of withdrawal, regardless of whether pharmacological treatment is required.

Comment by Sean Loudin MD FAAP

Response #9

The Department finds clarification is needed, and changes were made related to the request.

Comment #10

2.40. I would recommend the word opiate be removed from this definition so as not to limit those babies who are withdrawing from non-opioid substances.

Comment by Rhonda Edmunds, RN

Response #10

The Department finds clarification is needed, and changes were made related to the request.

Comment #11

2.42. Anywhere in the document the phrase "American Pediatric Association" appears it should be the American Academy of Pediatrics (aka AAP). (i.e. 2.47, 2.56)

Comment by Sean Loudin MD FAAP

Response #11

The Department finds clarification is needed, and changes were made related to the request.

Comment #12

2.42, My concern is that all evidence-based treatment that is non-pharmacological is not yet recognized by the American Academy of Pediatrics

Comment by Rhonda Edmunds, RN

Response #12

The Department finds clarification is needed, and changes were made related to the request.

Comment #13

2.46. Recommend change from under 1 year of age to under six (6) months of age

Comment by Sara Murray, RN

Response #13

The Department finds clarification is needed, and changes were made related to the request.

Comment #14

2.47. Recommend change from American Pediatric Association to American Academy of Pediatrics.

Comment by Sara Murray, RN

Response #14

The Department finds clarification is needed, and changes were made related to the request.

Comment #15

2.47 and 2.42. American Pediatric Association needs to be changed to American Academy of Pediatrics

Comment by Rhonda Edmunds, RN

Response #15

The Department finds clarification is needed, and changes were made related to the request.

Comment #16

2.56. For scoring systems the AAP just mentions that scoring systems may be used if they have been "published" NOT validated.

Comment by Sean Loudin MD FAAP

Response #16

The Department finds clarification is needed, and changes were made related to the request.

Comment #17

3.1.a. Recommend change chemical dependence to "symptoms of Neonatal Abstinence Syndrome".

Comment by Sara Murray, RN

Response #17

The Department finds clarification is needed, and changes were made related to the request.

Comment #18

3.10.a. I would recommend combining 3.1.a. and 3.1.b. to say: Treat symptoms of withdrawal in patients who have been prenatally drug exposed using both pharmacological and non-pharmacological interventions.

Comment by Rhonda Edmunds, RN

Response #18

The Department finds clarification is needed, and changes were made related to the request.

Comment #19

3.1.b. Recommend omitting "from chemical dependence"

Comment by Sara Murray, RN

Response #19

The Department finds clarification is needed, and changes were made related to the request.

Comment #20

3.1.b. I would recommend omitting this.

Comment by Rhonda Edmunds, RN

Response #20

The Department finds clarification is needed, and changes were made related to the request.

Comment #21

3.10.a. Recommend license renewal be for two (2) years

Comment by Sara Murray, RN

Response #21

No changes were required in response to this comment.

Comment #22

3.10.a. The renewal license will be issued for 1 year. We would request that renewals be for two (2) years.

Comment by Mary Brown

Response #22

No changes were required in response to this comment.

Comment #23:

5.5. The requirement for the director of the NAS facility does not need to have four years' experience in working with these babies or experience in a pediatric care facility. This person needs a business background. A large part of this person's job is fund raising, managing personnel, and overseeing the day to day operation of the center, none of which require experience in working with drug exposed neonates. This would be similar to requiring CEO's of hospitals to be doctors or have medical training.

Comment by Marilyn M. Murdock, BA, MA

Response #23

The Department finds clarification is needed, and changes were made related to the request.

Comment #24

5.5. I would recommend changing the tile of Administrator to Executive Director.

Comment by Rhonda Edmunds, RN

Response #24

No changes were required in response to this comment.

Comment #25

5.5. The administrator of the facility should not be required to have experience in Pediatric or Neonatal Care. This person is not involved in Clinical Care…basically the Administrator/Executive Director needs to have experience in business management, grant writing, public relations, marketing, media relations, human resources, etc. The Clinical Care/Clinical Educator would cover the clinical management of the facility. Finding a manager type person with clinical experience would be like requiring the CEO of a hospital to be equally versed in business management and clinical care. My recommendation is the administrator have an appropriate bachelor's degree and experience in the business side of a Not for Profit Entity that best meets the needs of the facility whether the focus be grant writing, marketing or whatever best meets the business needs of the facility. This person will also have to gain understanding of all the regulatory compliance articles placed on the facility. There will be no time, nor will there be need for this person to be involved in Direct Patient care.

Comment by Sara Murray, RN

Response #25

The Department finds clarification is needed, and changes were made related to the request.

Comment #26

5.5. Administrator – The administrator should be a person who knows how to run a business/organization. Most people in the medical field do not have that experience. This person is the executive director who is responsible for meeting all of the requirements. This person should work closely with the medical director and nursing director to make sure the procedures are established and followed. They should not have to have neonatal or pediatric experience.

Comment by Sean Loudin MD FAAP

Response #26

The Department finds clarification is needed, and changes were made related to the request.

Comment #27

5.5.a. Okay, so this is a big one.

Finding someone to work as the executive director of a nonprofit is hard enough. He or she must have extensive experience in grant writing, business acumen, the ability to create and maintain a budget, public relations/marketing experience, social media and media relations proficiency, the ability to hire

and manage a staff, and so much more. Finding someone with all these qualities who also has a two 5o four years of experience in the direct care of neonatal or pediatric care at a nonprofit pay rate is next to impossible. With a Director of Nursing (Clinical Care plus Clinical Educator) and a Medical Director handling the clinical side of the NAS Center, patient care is covered. The administrator needs to be more business oriented. I am the co-founder, literally created the organization from thin air with plenty of guidance and support from my colleagues and have been acting as the executive direct since inception of Lily's Place. I have created the entire policies manual, which you guys reviewed and managed all operations since we opened, and would not qualify as the organization's administrator as the rules are written. Neither would our Director of Nursing, Rhonda Edmunds, who has over 28 years experience with neonates and drug exposed infants, but has a two-year nursing degree and doesn't handle any of the business side of things. As the administrator, this person is the CEO of the organization. I wonder if any CEO's of other medical providers in the state have experience in direct care of patients. Probably not. That's why the CEO hires great staff. My recommendation would be that the Administrator have a bachelor's degree in an appropriate area of study, marketing/pr/social media/fundraising experience, and the ability to manage the financial side of the organization.

Comment by Mary Brown

Response #27

The Department finds clarification is needed, and changes were made related to the request.

Comment #28

5.5.a. In my opinion, the Administrator (or Executive Director) would not need to have experience in the field of neonatal or pediatric care. This person's role would be to develop policy and procedures for operation, establish and maintain security and maintenance of the building, management of the facility budget, fundraising and marketing, and to communicate with the board. This person would not have any direct patient contact or need for expertise in NAS.

Comment by Rhonda Edmunds, RN

Response #28

The Department finds clarification is needed, and changes were made related to the request.

Comment #29

5.5.c. This section delineates the duties of the Administration, and none of them reflect the need for experience in a neonatal abstinence center. The Director of Nursing oversees the medical issues; the administrator handles the business side.

Comment made by Marilyn M. Murdock, BA, MA

Response #29

The Department finds clarification is needed, and changes were made related to the request.

Comment #30

5.6. Advisory Council.

I am not sure this would be appropriate for an NAS facility. If you remember our patients are infants which excludes them and their parents are addicts. I do agree with advisory councils in almost every area of patient care but I do not believe this would be feasible. For example, we have an advisory council at CHH in the NICU, we do not have one in the NTU. Most of our parents DO NOT even make their infant's initial pediatrician follow up days after discharge. The rule suggests they view policies and procedures. I think this puts the staff and infants at the facility in harm's way. Over the past months we have had parents involved in murder, robbery, showing up for visitation under the influence, abuse and neglect of a child and overdose. We should not make an addict privy to our security, narcotic and employee routines. It may sound harsh but the truth is harsh. All parents are treated kindly and asked to be involved with the care of their baby but I do not believe this council is appropriate. Perhaps a parent handbook with their rights and other things pertinent to their baby's stay would be more appropriate.

Exit interviews give the parent an opportunity to verbalize what we did well and what we could have done better. We take this very seriously. Also, the interaction with the parents by the staff is constant while the baby is a patient and they are in the building. Our building is very secure and once the patient is discharged the parent access to the building ends. We do not allow anyone in the building who does not have direct business with the facility. We have to do this for the safety of our employees and patients.

Comment by Sara Murray, RN

Response #30

The Department finds clarification is needed, and changes were made related to the request.

Comment #31

5.6.a. Revise the first sentence, "Each center shall have an advisory council, or board of directors, ..." Most 501Comment by Mary Brown3's refer to their governing board as such.

Comment by Marilyn M. Murdock, BA, MA

Response #31

The Department finds clarification is needed, and changes were made related to the request.

Comment #32

5.6.b. This rule, as written, states that one of the members of this council should have been served by this program. Our patients are infants; therefore, this needs to be changed. This inclusion of a parent of a patient is not appropriate, either, based on the population we serve.

Comment by Marilyn M. Murdock, BA, MA

Response #32

The Department finds clarification is needed, and changes were made related to the request.

Comment #33

5.6.b. The rules say that the advisory council must be comprised of individuals served by the program. This is problematic because the primary patient is a newborn. The parents of the patients are addicts. The rules require the patient or addict to review program policies and procedures, review incidents and grievances, review administrative discharges, make recommendations for operational changes or improvements, be trained in patient confidentiality laws and regulations, keep records and working to assist NAS Centers in resolving problems.

We pride ourselves in the security measures we have put in place for the sake of our infants and staff. No one gets inside Lily's Place unless they are staff, are conducting business hers (CPS workers, for example) or have a child as a patient. HIPAA is our friend, and we follow the law to the letter. We use only first names with our patient's parents as a means of protecting our staff from intrusions into their personal lives via Facebook and other means. By opening our operation policies and procedures to those who are currently addicted or in recovery (part of recovery is relapse), we are opening up our security and operational rules to those who could use them to their advantage or share them with those who may misuse them. Allowing parents to review incidences and grievances or administrative discharges opens our staff up to potential problems and allows families to make suggestions. We monitor their level of satisfaction and make changes through our Quality Control Improvement Committee as appropriate. Although I think in most nursing care organizations (with the elderly, as an example) having an advisory council made up of patients is appropriate, for the safety and security of the NAS facility, we feel this is a liability.

Comment by Mary Brown

Response #33

The Department finds clarification is needed, and changes were made related to the request.

Comment #34

5.6.b.I would not recommend that the advisory council consist of individuals served by the program since the patients are infants and the parents are suffering with addiction. It would not be wise for these individuals to have access to the facilities policies and procedures, or incidents and grievances. I do think it would be advantageous to the facility to have parents who would be willing to recommend operational changes and /or improvements and work to assist the center to identify, address and resolve problems.

Comment by Rhonda Edmunds, RN

Response #34

The Department finds clarification is needed, and changes were made related to the request.

Comment #35

5.7.a. I would recommend that the Quality Improvement Committee meet quarterly instead of monthly.

Comment by Rhonda Edmunds, RN

Response #35

The Department finds clarification is needed, and changes were made related to the request.

Comment #36

5.7.c.3. and 4. At Lily's Place, we have combined these two positions into one. Perhaps the verbiage could just be adjusted to reflect that these two positions can be combined, i.e., the Director of Nursing.

Comment by Marilyn M. Murdock, BA, MA

Response #36

The Department finds clarification is needed, and changes were made related to the request.

Comment #37

5.7.c.3. and 4. When we first had the concept of a facility, we felt the two positions were needed, but as we progress and learned what we were doing we realized this could be a one person job. We rolled the two together and made the Director of Nursing position. This person functions on the clinical level as the Executive Director functions on the Business level. They are actually equal on the hierarchy with different roles.

This person should be competent and experienced in the care of the prenatally exposed infant.

He/she will be responsible for the clinical excellence of the facility, therefore it would be unacceptable for the position not to require clinical expertise the care of prenatally exposed infants.

Recommendation the Clinical Manager and Clinical Care Coordinator be consolidated into the position Director of Nursing or Clinical Director and all language be changed to reflect the title.

Comment by Sara Murray, RN

Response #37

The Department finds clarification is needed, and changes were made related to the request.

Comment #38

5.7.c.3. and 5.7.c.4. When we first wrote our policies manual, we thought that we would employ a Clinical Care Manager to manage all the clinical employees and the Clinical Care Educator to help with educating parents. We have actually combined the position into a Director of Nursing to save on cost. The Director of Nursing is a nearly equal position to the Executive Director, and the DON handles human resources on the clinical side and manages all clinical employees, carriers out the directives of the physicians, and works with the nurses and our social worker to appropriately provide parents with our incredibly thorough education plan. Just as our Executive Director also has to be the business manager, so too our Director of Nursing has to fill both roles.

Comment by Mary Brown

Response #38

The Department finds clarification is needed, and changes were made related to the request.

Comment #39

5.7.c.3. and 5.7.c.4. I would recommend combining the roles of the Clinical Care Manager and Clinical Care Educator to be the Director of Nursing.

Comment by Rhonda Edmunds, RN

Response #39

The Department finds clarification is needed, and changes were made related to the request.

Comment #40

5.7.c.6. "Nurse Aide" isn't restrictive enough. This would leave the door open to anyone whether they're licensed by the State of WV or not. At the very least, this should say "patient care assistant or certified nursing assistant licensed in the State of West Virginia."

Comment by Marilyn M. Murdock, BA, MA

Response #40

The Department finds clarification is needed, and changes were made related to the request.

Comment #41

5.8.d. I would add "volunteer" to the list of those requiring a personnel file. We require similar training and each volunteer's file must include much of the same information, i.e., background check, fingerprints, and consent to be drug screened. There is a checklist on the front of every volunteer file that ensures that everything that the State requires is in that file.

Comment by Marilyn M. Murdock, BA, MA

Response #41

Centers are required to maintain personnel records for volunteers in Section 9.9.b. of this rule.

Comment #42

6.2.c. The way this reads, the outside doors to the facility will be opened with a key pad code. While have a key pad that leads to the secure area of the building is good, allowing access from the outside with only a key pad seems risky, especially considering the population with whom we deal. Having a dead bolt to/from the outside is a safer option. At Lily's Place, the security guard on duty escorts our visitors in and out of the building.

Comment by Marilyn M. Murdock, BA, MA

Response #42

The Department finds clarification is needed, and changes were made related to the request.

Comment #43

6.2.c. Double dead bolt locked entrances are secure as well for main entrance, and then additional layers of keypad access are acceptable

Comment by Sean Loudin MD FAAP

Response #43

The Department finds clarification is needed, and changes were made related to the request.

Comment #44

6.2.c. I would recommend that all doors providing entrance to secure areas of the center have key pad entrances; however, the front door to the center needs to be a keyed entrance for security purposes. If the security guard was making rounds outside and let a parent in the front door, they could look over his shoulder and get the code to the keypad entrance.

Comment by Rhonda Edmunds, RN

Response #44

The Department finds clarification is needed, and changes were made related to the request.

Comment #45

6.3.b. Having a changing table in everyone should not be a requirement. At Lily's Place and at CHH, our babies are changed in the crib itself. There is plenty of room to do it there. Also, not having to move them from one area to another decreases the stimuli they're receiving. Potentially, the rooms might not be large enough to provide a safe, clutter-free environment.

Comment by Marilyn M. Murdock, BA, MA

Response #45

The Department finds clarification is needed, and changes were made related to the request.

Comment #46

6.3.b. A changing table is not necessary as most babies can be changed in their own crib.

Comment by Sean Loudin MD FAAP

Response #46

The Department finds clarification is needed, and changes were made related to the request.

Comment #47

6.3.b. I would not recommend a changing table be a necessity in each nursery due to cost, space, safety and increased stimulation taking infant from crib to changing table. Diapers and clothes can be changed in the infant's crib.

Comment by Rhonda Edmunds, RN

Response #47

The Department finds clarification is needed, and changes were made related to the request.

Comment #48

6.3.c. While providing some storage in the nurseries is important, having a closet in each baby's room isn't necessary. At Lily's Place we supply sleepers/gowns, etc., for our babies which are stored elsewhere. The drawers and bins in each room provide adequate storage space for additional clothing.

Comment by Marilyn M. Murdock, BA, MA

Response #48

The Department finds clarification is needed, and changes were made related to the request.

Comment #49

6.3.c. I would recommend this be changed to read: the center shall provide adequate drawer, closet OR shelving space to accommodate clothing and personal items.

Comment by Rhonda Edmunds, RN

Response #49

The Department finds clarification is needed, and changes were made related to the request.

Comment #50

6.8.b. This would be prohibitive to starting any new NAS facility. NFPA standards for medical facilities are inappropriate for a facility who only provides medication and therapeutic care. Under those regulations Lily's Place could fall under 15.1.2 for an existing facility but it would prohibit future facilities.

Comment by Sara Murray, RN

Response #50

The Department finds clarification is needed, and changes were made related to the request.

Comment #51

6.8.b. NFPA for health care facilities – Quite honestly this requirement is overkill. We are not conducting surgery or even drawing blood here. We are providing medication and therapeutic care and should not be lumped into the same category as hospitals. Without a waiver for this section, not a single NAS Center would be able to open. NAS Centers should meet the same fire and safety requirements as West Virginia's residential group homes, as created under DHHR rules. I have reviewed the rules/regulations online, and they are not appropriate for an NAS Center. If the rules under NFPA Chapter 15 are instituted, Lily's Place would use section 15.1.2, which states "An existing system that is not in strict compliance with the provisions of this code shall be permitted to be continued in use unless the authority having jurisdiction (OHFLAC) has determined that such use constitutes a distinct hazard to life."

Comment by Mary Brown

Response #51

The Department finds clarification is needed, and changes were made related to the request.

Comment #52

6.10.c. Include the volunteers in the first sentence: "The center shall prohibit employees or volunteers with a communicable disease…"

Comment by Marilyn M. Murdock, BA, MA

Response #52

The Department finds clarification is needed, and changes were made related to the request.

Comment #53

6.10.d. I would recommend adding: to wash or sanitize hands after each direct contact and after engaging in any activity for which hand washing or hand sanitizing is indicated…

Comment by Rhonda Edmunds, RN

Response #53

The Department finds clarification is needed, and changes were made related to the request.

Comment #54

6.14.p.2. Director of Nursing or the Registered Nursing on Duty.

Comment by Mary Brown

Response #54

The Department finds clarification is needed, and changes were made related to the request.

Comment #55

6.14.p.2. Change the Clinical Care Nurse to the Director of Nursing.

Comment by Rhonda Edmunds, RN

Response #55

The Department finds clarification is needed, and changes were made related to the request.

Comment #56

6.14.q. Having phones in the patient rooms is not necessary and not appropriate for our minimal stimulus environment. Parents may have their phones on them but are not allowed to take calls in the room. All phone ringers must be place on mute. Nurses phones are left in their lockers. There are call lights for emergency in each room. The nurses, if not in the room, are only steps away and can be at the bedside in moments.

Comment by Rhonda Edmunds, RN

Response #56

The Department finds clarification is needed, and changes were made related to the request.

Comment by Sara Murray, RN

Comment #57

6.14.q. I think this must be a rule from a nursing home. First of all, we maintain a 3 patients to 1 nurse ratio with a Patient Care Assistant thrown in for additional support. And we have been required by DHHR to have eyes on the patient every 15 minutes. With these safeguards in place and our high patient to staff ratio (which is increased when our volunteer cuddlers are present), our babies are almost never unattended, and if they are, it is for less than 15 minutes. We do not allow staff to take cell phones in the patient area. Their phones are locked away in the break room. Parents are allowed to take cell phone in, but calls are not permitted. We have created and maintain a low-stimulus environment. Having phones in the room will deteriorate the environment that is required by these infants. We DO have indicator switches in each room that can be flipped on to notify nurses in the hallway that someone needs assistance, but they have never been used. The visiting parent just sticks his/her head out of the room, and someone is there to attend to them immediately.

Comment by Mary Brown

Response #57

The Department finds clarification is needed, and changes were made related to the request.

Comment #58

6.14.q. I would recommend changing the word unit in this sentence to patient care area. Unit may be confused as patient room and a phone would not be appropriate in each patient room due to overstimulation.

Comment by Rhonda Edmunds, RN

Response #58

The Department finds clarification is needed, and changes were made related to the request.

Comment #59

7.2.b. If the center is to not deny admission due to protected status, then the state of WV should be very proactive about having all payers accept this as a type of health care facility and offer reimbursement. As it stands now there are patients that are being denied admission because their medical coverage doesn't pay for their stay. The state they live in may impact as well, as patients from Ohio, Kentucky, Pennsylvania, Virginia, and Maryland would not be able to be admitted under current payer rules.

Comment by Sean Loudin MD FAAP

Response #59

The Department finds clarification is needed, and changes were made related to the request.

Comment #60

7.6. Informed consent – As it stands now, there is no informed consent process to treat infants in the hospital setting for NAS. It is medical necessity to treat an infant suffering from withdrawal. I would clarify what the need for informed consent is before requiring centers to obtain it. Does this mean that the center just needs to make it clear to legal representatives that this is an alternative to the care in the hospital, because it should be equivalent care that they get in the hospital, not a downgrade that is "risky" and therefore requiring a parent to take the risk of their infant in an NAS center.

Comment by Sean Loudin MD FAAP

Response #60

No changes were required in response to this comment.

Comment #61

7.9.a.8. I would recommend adding something that would allow parents to take their prescribed medication if needed while rooming-in overnight with the infant before discharge.

Comment by Rhonda Edmunds, RN

Response #61

The Department finds clarification is needed, and changes were made at Section 7.9.a.15. of this rule.

Comment #62

7.10.c. I would add "non-emergency medical transport or the state" to the end of this in the event that the need is not an emergency.

Comment by Mary Brown

Response #62

The Department finds clarification is needed, and changes were made related to the request.

Comment #63

7.10.c. Refusal of Treatment – Why does the patient need to be returned to the hospital by ambulance. If the infant needs to be treated for withdrawal or additional therapy initiated to control withdrawal and the NAS center can provide that service, there is no need to return to the hospital. CPS should be notified that medical personnel feel that by refusing treatment this caregiver is putting their child's wellbeing in jeopardy.

Comment by Sean Loudin MD FAAP

Response #63

The Department finds clarification is needed, and changes were made related to the request.

Comment #64

7.10.c. Since this may not be an emergent incidence, I would recommend using non-emergent transport or an ambulance.

Comment by Rhonda Edmunds, RN

Response #64

The Department finds clarification is needed, and changes were made related to the request.

Comment #65

7.12.c. Parent or caregiver under the influence of drugs.....This happens often and one recommendation would be no parent is sent out with car keys in hand to risk his/her life or that of the public. We have had parents removed from the patient care area and have called a relative or cab for their safe transportation. I would not mandate they are allowed to leave inebriated. We require documentation when this occurs.

Comment by Sara Murray, RN

Response #65

No changes were made to this rule in response to this comment.

Comment #66

7.12.c. Live and learn. We have had parents who absolutely could not be sober, and we could not in good conscience send them out of the facility with their car keys. Our current procedure is to ask the parent to wait outside the patient area in our Education Center. His or her demeanor is assessed by our social worker and if she is unavailable by the baby's nurse. If either determine that the parent is in no condition to visit the baby, we confiscate the parent's keys and call a taxi to take them to where they need to go. We felt it was a moral obligation to prevent a potential DUI.

Comment by Mary Brown

Response #66

The Department finds clarification is needed, and changes were made related to the request.

Comment #67

9.1.b. What is meant by the center shall "employ" a medical director? Is the state mandating that the center provide the medical director a salary? If so how much? I serve as the medical director of Lily's Place and have never received a dime from Lily's Place.

Comment by Sean Loudin MD FAAP

Response #67

The Department finds clarification is needed, and changes were made related to the request.

Comment #68

9.1.c. While I agree that the medical director must be a pediatrician, I'm not sure a neonatologist is required. I think that one of the considerations the DHHR should make, is that when they are agreeing to license a NAS center that they have a medical director from an established NAS center be available to meet with the proposed medical director to make sure they are educated and vested in the process. The state is limited on the number of Neonatologists and their time to dedicate to the medical director role may vary considerably. Pediatricians who are willing to dedicate time and are vested in the care of NAS patients are capable of the medical director role.

Comment by Sean Loudin MD FAAP

Response #68

The Department finds clarification is needed, and changes were made related to the request.

Comment #69

9.2. and 9.3. We combined these positions into the Nursing Director position. This person responsible for the Clinical Excellence of the facility should have more than 2 years experience in pediatrics and must be clinically competent and experienced in the care of the prenatally exposed infant. This position is key to the success of the facility.

Comment by Sara Murray, RN

Response #69

The Department finds clarification is needed, and changes were made related to the request.

Comment #70

9.2 and 9.3. Have been combine at our facility under the title of Director of Nursing

Comment by Mary Brown

Response #70

The Department finds clarification is needed, and changes were made related to the request.

Comment #71

9.2. Clinical Care Manager

Once again, we have combined these positions into the Director of Nursing. There is no need for additional staffing in a small facility. If this suggestions in included earlier in the rules, (5.7.c – 3 & 4) it

needs to be changed there, as well.

Comment by Mary Brown

Response #71

The Department finds clarification is needed, and changes were made related to the request.

Comment #72

9.2 and 9.3. The Clinical Care Manager and Clinical Education Manager could be the same person.

Comment by Sean Loudin MD FAAP

Response #72

The Department finds clarification is needed, and changes were made related to the request.

Comment #73

9.2 and 9.3. Combining these roles into one with the name being Director of Nursing who would work with the Executive Director and report directly to the board.

Comment by Rhonda Edmunds, RN

Response #73

The Department finds clarification is needed, and changes were made related to the request.

Comment #74

9.3.e.1. This can be deleted or changed if the aforementioned rule is revised. This applies to the rest of the responsibilities in this section.

Comment by Marilyn M. Murdock, BA, MA

Response #74

The Department finds clarification is needed, and changes were made related to the request.

Comment #75

9.4.b. There shall be 1 RN for every six (6) patients. We require 2 RNs at all times because of narcotic administration (WV Board of Pharmacy and DEA rules for narcotic administration and waste) and complex assessment poly substance abuse babies require. We have come to realize with the complexity of these infants that 6 patients/ 1 RN is not appropriate.

I recommend the nursing to patient ratio be 1 RN per 4 babies.

Comment by Sara Murray, RN

Response #75

The Department finds clarification is needed, and changes were made related the staffing ratio part of the request. No changes were required in response to the comment concerning two registered nurses being available at all times.

Comment #76

9.4.b. Must be two registered nurses on staff at all times per medicine administration rules of WV Board of Pharmacy and the DEA.

Comment by Mary Brown

Response #76

No changes were required in response to the comment.

Comment #77

9.4.b. The ratio of 1 RN to 6 babies is too high. For best care 1 to 3 is most ideal. Also there should be 2 RN's in house at ALL times.

Comment by Sean Loudin MD FAAP

Response #77

The Department finds clarification is needed, and changes were made related the staffing ratio part of the request. No changes were required in response to the comment concerning two registered nurses being available at all times.

Comment #78

9.4.b. I would recommend changing this to: There shall be one registered nurse per every 4 patients. There must be a minimum of two RNs on each shift. With the complexity of these infants, a one to 6 patient ratio would not be best practice.

Comment by Rhonda Edmunds, RN

Response #78

The Department finds clarification is needed, and changes were made related the staffing ratio part of the request. No changes were required in response to the comment concerning two registered nurses being available at all times.

Comment #79

9.4.e. NRP would not be necessary for nurses in this setting. NRP is designed for hospital and delivery room care. Neonatal Advanced Life Support would be acceptable but I would recommend all the nurses in an NAS facility be S.T.A.B.L.E. certified. This is what we (CHH) teach our referring hospitals. This allows the clinician to resuscitate, stabilize and prepare a sick or distressed infant for transport when necessary to a hospital for care.

I would recommend S.T.A.B.L.E. or NALS certification with the preference being S.T.A.B.L.E

Comment by Sara Murray, RN

Response #79

The Department finds clarification is needed, and changes were made related to the request.

Comment #80

9.4.e. NRP certification is geared more to delivery room care of infants. A certification in S.T.A.B.L.E. within one year of employment would be more appropriate with these infants.

Comment by Rhonda Edmunds, RN

Response #80

The Department finds clarification is needed, and changes were made related to the request.

Comment #81

9.4.f.14. Initiating and updating plan of care should be done by the Nursing Director to ensure reliability and consistency. We found this works better and keeps the Nursing Director informed as to the care of the babies.

Comment by Sara Murray, RN

Response #81

No changes were required in response to the comment.

Comment #82

9.4.f.14. This could be a shared responsibility with the Director of Nursing.

Comment by Rhonda Edmunds, RN

Response #83

No changes were required in response to the comment.

Comment #83

9.5.a. I think a bachelor's degree wording was left out. Should read "Social worker must home a bachelor's degree and an unencumbered and valid WV Social Work License."

Comment by Mary Brown

Response #83

No changes were required in response to the comment.

Comment #84

9.6.c.1. Personal Care Assistants should be required to complete and pass requirements for licensure in the state of WV for PCA or CNA (Certified nursing Assistants)

Comment by Sara Murray, RN

Response #84

No changes were required in response to the comment.

Comment #85

9.6.c.1. PCAs should be certified or licensed as a PCA or CNA.

Comment by Rhonda Edmunds, RN

Response #85

No changes were required in response to the comment.

Comment #86

9.6.c.2. NALS certification of PCAs would not be necessary. Certification in S.T.A.B.L.E. within one year of employment would be more appropriate.\

Comment by Rhonda Edmunds, RN

Response #86

No changes were required in response to the comment.

Comment #87

9.6.d.4. and 9.6.d.5. Recommend changing "efficient" to "proficient".

Comment by Sara Murray, RN

Response #87

The Department finds clarification is needed, and changes were made related to the request.

Comment #88

9.7.a. Add "and random drug screening" after "background check requirements."

Comment by Marilyn M. Murdock, BA, MA

Response #88

No changes were required in response to the comment.

Comment #89

9.7.c. I would make this addition: "Each volunteer shall receive training in therapeutic handling and the characteristics of NAS to be able to report their observations to the RN or PCA on duty."

Comment by Marilyn M. Murdock, BA, MA

Response #89

The Department finds clarification is needed, and changes were made related to the request.

Comment #90

9.7.d. I would make this addition: "Volunteers may only perform tasks related to therapeutic handling, housekeeping, and clerical duties, unless deemed appropriate by the Director of Nursing."

Comment by Marilyn M. Murdock, BA, MA

Response #90

The Department finds clarification is needed, and changes were made related to the request.

Comment #91

9.7.d. I would add clerical duties to volunteer tasks.

Comment by Mary Brown

Response #91

The Department finds clarification is needed, and changes were made related to the request.

Comment #92

9.8.d. Both nurses should be licensed as Registered nurses to scheduled drugs be administered, counted and wasted.

Comment by Sara Murray, RN

Response #92

The Department finds clarification is needed, and changes were made related to the request.

Comment #93

9.8.d. The center shall maintain, at a minimum, two RNs on-site at all times with the ability to increase when needed would be more appropriate.

Comment by Rhonda Edmunds, RN

Response #93

No changes were required in response to the comment.

Comment #94

9.9.b. Recommend adding S.T.A.B.L.E certification for Registered nurses and PCAs.

Comment by Sara Murray, RN

Response #94

The Department finds clarification is needed, and changes were made related to the request.

Comment #95

9.9.c. At a minimum, it is my opinion, all employees participating in direct patient care should be trained in S.T.A.B.L.E., basic infant care, the effects of neonatal abstinence syndrome and how to care for those infants who are born prenatally exposed to drugs. Parenting skills is not necessary.

Comment by Rhonda Edmunds, RN

Response #95

The Department finds clarification is needed, and changes were made related to the request.

Comment #96

9.10.a.4. Personnel Records

At Lily's Place and at CHH, volunteers who work with drug exposed infants are required to have not only a current TB test but the Hepatitis B series of vaccinations, as well. This is as much for the

volunteers' safety as for the babies with whom they work.

Comment made by Marilyn M. Murdock, BA, MA

Response #96

No changes were required in response to the comment.

Comment #97

10.1.a.5. Not all NAS centers will be using the same weaning protocol. So defining which "step" a baby is on before they are admitted is impossible. There should be communication between the referring physician and the accepting physician as to the level of medical stability and whether the admission is appropriate.

Comment by Sean Loudin MD FAAP

Response #97

The Department finds clarification is needed, and changes were made related to the request.

Comment #98

10.1.a.5. I would recommend the wording be change to say: The patient has been established on medication for the symptoms of withdrawal. Not all facilities will choice to use the same weaning protocol with the 9 steps that we use here at Lily's Place.

Comment by Rhonda Edmunds, RN

Response #98

The Department finds clarification is needed, and changes were made related to the request.

Comment #99

10.1.d.1. Should be the patient or their infant.

Comment by Rhonda Edmunds, RN

Response #99

The Department finds clarification is needed, and changes were made related to the request.

Comment #100

10.2.g.1.b. We have found with poly substance abuse a score of less than 8 is not always attainable. I would recommend changing this to: The patient shall have an NAS score of 8 or less or may be

discharge with higher average score at the discretion of the Physician and Nursing Director in collaboration.

Comment by Sara Murray, RN

Response #100

The Department finds clarification is needed, and changes were made related to the request.

Comment #101

10.2.g.1.b. This is assuming everyone will be using the Finnegan scoring system. Also this is very limiting for practitioners and payers. The AAP recognizes that infants can exhibit subacute withdrawal symptoms for at least 6 months. Therefore these infants will not be symptom free at discharge. They need to be medically stable to transition to the home environment and capable of handling various forms of stimulation. Meeting a certain number prior to discharge is not good medical practice. There are way to many other factors that must go into those decisions.

Comment by Sean Loudin MD FAAP

Response #101

The Department finds clarification is needed, and changes were made related to the request.

Comment #102

10.2.g.1.b. Sometimes we have had to use the baby's baseline average as a guide to wean the medication. Oftentimes, that score is above an 8. I would recommend that this read: The patient must have a NAS score average of <8 or their baseline average used for weaning at the Dr.'s discretion.

Comment by Rhonda Edmunds, RN

Response #102

The Department finds clarification is needed, and changes were made related to the request.

Comment #103

10.2.g.2. Since infant is not "hospitalized" I would change to "throughout patient's treatment".

Comment by Sara Murray, RN

Response # 103

The Department finds clarification is needed, and changes were made related to the request.

Comment #104

10.2.g.2. The babies are not hospitalized. I would use the work "treatment."

Comment by Mary Brown

Response #104

The Department finds clarification is needed, and changes were made related to the request.

Comment #105

10.2.g.2. "Hospitalization" should be changed to "stay at the facility" since we are not a hospital.

Comment by Rhonda Edmunds, RN

Response #105

The Department finds clarification is needed, and changes were made related to the request.

Comment #106

10.2.h. Discharge Needs and After-Care

Should be added to this section: Appointment made for follow up visit with patients Primary Care Physician within 48 hours after discharge.

Comment by Sara Murray, RN

Response #106

The Department finds clarification is needed, and changes were made related to the request.

Comment #107

10.2.i.2. I would add "or given written consent."

Comment by Mary Brown

Response #107

No changes were required in response to the comment.

Comment #108

11.1. Is this on all infants or only those in State's custody (whether voluntary or emergency)?

Comment by Rhonda Edmunds, RN

Response #108

No changes were required in response to the comment.

Comment #109

11.6. Comprehensive assessment – This section seems to be designed based on the EPSDT form. However this is used for foster children and their assessment. If there are babies admitted that do not need the EPSDT, then this comprehensive assessment is overkill. These patients should have just come from a hospital setting where they were under care of a board certified physician. Those assessments are made on a daily basis. This transition to a NAS center should be viewed as a continuation of care, NOT starting all over.

Comment by Sean Loudin MD FAAP

Response #109

No changes were required in response to the comment.

Comment #110

11.6.a.6 and 11.a.7. I would recommend that the Developmental History and Legal History be omitted since the patients are infants.

Comment by Rhonda Edmunds, RN

Response #110

The Department finds clarification is needed, and changes were made related to the request.

Comment #111

11.6.e.2.C. Now this dictates use of the Finnegan scoring system, rather than use of a published scoring system. Not everyone uses the Finnegan so don't dictate its use.

Comment by Sean Loudin MD FAAP

Response #111

The Department finds clarification is needed, and changes were made related to the request.

Comment #112

11.6.e.2.C. I would recommend adding "as long as the infant is on medication and during the observation period" because infants who are no longer on the mediation and are waiting to be discharged because of social situations do not need to be scored every 3-4 hours.

Comment by Rhonda Edmunds, RN

Response #112

The Department finds clarification is needed, and changes were made related to the request.

Comment #113

11.6.e.2.H. NPASS is a hospital requirement. Is the DHHR aware of any studies that take into account NAS and how that effects the NPASS score. I am unaware of any correlations and the NAS scoring is assessing much more than the NPASS. The irritability that these babies experience is constantly being assessed so the NPASS seems to be doubling the work unnecessarily.

Comment by Sean Loudin MD FAAP

Response #113

The Department finds clarification is needed, and changes were made related to the request.

Comment #114

11.6.e.2.H. Since we are not a hospital, we do not do the NPASS. These babies are in pain but not the kind of pain we are able to give pain medications for.

Comment by Rhonda Edmunds, RN

Response #114

The Department finds clarification is needed, and changes were made related to the request.

Comment #115

11.6.e.2.J. Abdominal girth is not a typical measurement that would be obtained or used to track the infants growth.

Comment by Rhonda Edmunds, RN

Response #115

The Department finds clarification is needed, and changes were made related to the request.

Comment #116

11.6.e.2.A. The nurse aide should not be required to assist or observe the assessment. This is not conducive to time management.

Comment by Rhonda Edmunds, RN

Response #116

The Department finds clarification is needed, and changes were made related to the request.

Comment #117

11.6.e.2.B. This again is not always possible. Parents are welcome to observe the assessment and are taught the Finnegan Scoring system; however, it is not practical to try to coordinate the two.

Comment by Rhonda Edmunds, RN

Response #117

The Department finds clarification is needed, and changes were made related to the request.

Comment #118

11.8.c. Combine clinical educator and clinical care manager into Director of Nursing

Comment by Mary Brown

Response #118

The Department finds clarification is needed, and changes were made related to the request.

Comment #119

11.8.c. Is this Plan of Care and the Comprehensive Plan of Care used interchangeably?

Comment by Rhonda Edmunds, RN

Response #119

The Department finds clarification is needed, and changes were made related to the request.

Comment #120

12.1. This statement should be expanded to include Clonidine, Neurontin or any medication deemed as appropriate for treatment. (We have and continue to discover multiple medications mothers are taking that require adjunct treatment. At the NTU and Lily's Place, we currently treat with Neurontin and Clonidine.)

Comment by Sara Murray, RN

Response #120

The Department finds clarification is needed, and changes were made related to the request.

Comment #121

12.1. This should say "Approved pharmacological treatment may include methadone, buprenorphine, Neurontin or as determined by the Medical Director." (We are constantly learning of new drugs being abused. It would be a shame to be unable to treat a baby because the state code limited the treatment options.)

Comment by Mary Brown

Response #121

The Department finds clarification is needed, and changes were made related to the request.

Comment #122

12.1. Morphine may be the drug of choice for some hospitals around the state. Also there may be adjunct therapies such as Clonidine and some centers may use Phenobarbital. So list all drugs or have a phrase that allows.

Comment by Sean Loudin MD FAAP

Response #122

The Department finds clarification is needed, and changes were made related to the request.

Comment #123

12.1. Approved pharmacological treatment should also include clonidine, Neurontin, and zantac. It's difficult to limit the medications for treatment due to the newness of this process.

Comment by Rhonda Edmunds, RN

Response #123

The Department finds clarification is needed, and changes were made related to the request.

Comment #124

12.6.e.3. and 12.6.e.4. Is monthly and annual inventory necessary on individual prescriptions of methadone?

Comment by Rhonda Edmunds, RN

Response #124

The Department finds clarification is needed, and changes were made related to the request.

Comment #125

12.8.d. Clinical Care Manager to Director of Nursing *(This comment referenced 12.8.d. and it should have referenced 12.8.e.)*

Comment by Mary Brown

Response #125

The Department finds clarification is needed, and changes were made related to the request.

Comment #126

12.10. Administration of Narcotic Medications

This section reinforces there must be two (2) registered nurses in the facility at all times.

Comment by Sara Murray, RN

Response #126

The Department finds clarification is needed, and changes were made related to the request.

Comment #127

12.12.a. and 12.12.b. Under the guidelines of our Consulting Pharmacist, Gina Finley, we dispose of our unused and discontinued controlled substances by disposing of them in kitty litter. This disposal is witnessed and documented by 2 RNs.

Comment by Rhonda Edmunds, RN

Response #127

No changes were required in response to the comment.

Comment #128

13.2.h. I would add "as tolerated."

Comment by Mary Brown

Response #128

The Department finds clarification is needed, and changes were made related to the request.

Comment #129

13.8. I would add "as tolerated."

Comment by Mary Brown

Response #129

The Department finds clarification is needed, and changes were made related to the request.

Comment #130

13.12.d.1. First face to face meeting within 24 hours of admission would not then go with the physician rounding at least twice per week. If there is good communication before admission between the hospital and NAS center, it may be reasonable for having a 48 hour rule vs 24 hour rule. Again I think this is getting caught up around foster placement guidelines which may not apply in this situation.

Comment by Sean Loudin MD FAAP

Response #130

No changes were required in response to the comment.

Comment #131

14.2.a. I think this should include the word "Attempt" to meet with mothers…

Comment by Rhonda Edmunds, RN

Response #131

The Department finds clarification is needed, and changes were made related to the request.

Comment #132

14.2.c. I would say "Provide access to individual and group therapy." A bachelor's level social worker may not be qualified to provide therapy in some instances, but she would certainly be able to make a referral and an appointment with a qualified counselor as appropriate."

Comment by Mary Brown

Response #132

The Department finds clarification is needed, and changes were made related to the request.

TITLE 69
LEGISLATIVE RULES
WEST VIRGINIA DEPARTMENT OF HEALTH AND HUMAN RESOURCES

SERIES 9
NEONATAL ABSTINENCE CENTERS

§69-9-1. GENERAL PROVISIONS.

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 centers located within the state of West Virginia.

1.2. Authority. W. Va. §§16-1-4 and 16-2N-2.

1.3. Filing Date.

1.4. Effective Date.

1.5. Application. This rule applies to neonatal abstinence 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.

1.6. Variances.

1.6.a. The department may grant a variance from any provision of this rule if is determines:

1.6.a.1. Strict compliance would impose a substantial hardship on the licensee;

1.6.a.2. The licensee will otherwise meet the intent of the rule; and

1.6.a.3. A variance will not result in less protection of the health, safety and welfare of the patients.

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

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

1.7. Enforcement. This rule is enforced by the secretary of the Department of Health and Human Resources or his or her lawful designee.

§69-9-2. DEFINITIONS.

2.1. Abuse. 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. A disease characterized by an individual pursuing reward and/or relief of 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. An individual designated by the governing body 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. An authorized disclosure of an individual's history with the Department as an identified adult or child abuse maltreator.

2.5. Annual Inspection. For the purpose of this rule, each neonatal abstinence syndrome center shall be inspected annually during an elapsed time frame of nine to 15 months.

2.6. Applicant. 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. The maximum number of beds a neonatal abstinence syndrome center is licensed to offer for residential care and occupancy.

2.8. Care Plan. 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. 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. 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. Any action that results in, or has the appearance of resulting in, personal, organizational, or professional gain.

2.12. Critical Incident or Adverse Event. 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. A neonatal abstinence syndrome center's failure to meet a specific requirement under the provisions of this rule, an explicit statement that the requirement was not met, and the evidence to support the decision of noncompliance.

2.14. Department. West Virginia Department of Health and Human Resources.

2.15. Director. The director of the Office of Health Facility Licensure and Certification.

2.16. Diversion Control Plan. A required plan developed by the neonatal abstinence syndrome center to minimize the diversion of methadone or other medications to illicit use.

2.17. Employee. Any person who performs personal services for the neonatal abstinence syndrome center in exchange for monetary compensation where such personal services, including the results to be accomplished as well as the details and the means by which the results are accomplished, are controlled and

directed by the neonatal abstinence syndrome center, where monetary compensation is effected through the neonatal abstinence syndrome center's payroll system.

2.18. Experimental Research. 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.

2.19. Facility. The physical building in which a neonatal abstinence syndrome center services are provided.

2.20. Family. A group of two or more persons related by blood, marriage, significant relationship, or adoption.

2.21. For-Cause Inspection. 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.

2.22. Governing Body. 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.

2.23. Grievance. 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.

2.24. Harm. 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 transient in nature.

2.25. Immediate Jeopardy. 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.

2.26. Individualized Plan of Care. 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.

2.27. Informed Consent. 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 they agree to the treatment.

2.28. Interdisciplinary Team. 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. 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. The document issued by the state oversight agency 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. When applied to a person, 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, means the facility is licensed by the state oversight agency.

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

2.33. Medical Director. 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 direct supervision.

2.34. Medication Error. 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. The deliberate misplacement, exploitation or wrongful use of a patient's belongings or money.

2.36. Neglect. 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. The period of time covering the first 28 days after birth.

2.38. Neonatal Abstinence Center. 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. Stays exceeding 30 days shall be based on the physician's recommendation to determine the appropriate length of stay based on documented evidence-based practices, and the infant's individual response to treatment.

2.39. Neonatal Abstinence Syndrome (NAS). 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. 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. 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. The state oversight agency responsible to enforce this rule.

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

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

2.45. Pharmacological Treatment. Pharmacological treatment is indicated to relieve moderate to severe

signs of NAS 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. An individual licensed to practice 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 Osteopathy pursuant to W. Va. Code §30-14-1 et seq.

2.47. Plan of Care. 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. A written description of the actions the neonatal abstinence syndrome center intends to take to correct and prevent the reoccurrence of violations of a rule or policy identified by the designated state oversight agency during an investigation or survey.

2.49. Program Sponsor. The person named in the application for certification and 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. Child or Adult Protective Services operating under the West Virginia Department of Health and Human Resources.

2.51. Repeat Deficiency. 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. Secretary. The secretary of the West Virginia Department of Health and Human Resources, or his or her designee.

2.53. Scoring System. A formal, validated method for assessing NAS severity. The Finnegan, modified Finnegan, or other validated scoring method that is recognized by the American Academy of Pediatrics, or a nationally recognized organization with expertise in neonatal abstinence syndrome.

2.54. State Oversight Agency. The Office of Health Facility Licensure and Certification.

2.55. Variance. A formal agreement between state oversight agency and the neonatal abstinence 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.

2.56. Volunteer. Individuals who perform services without pay.

§69-9-3. CERTIFICATION, LICENSURE, APPROVAL AND EXEMPTION.

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

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

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

3.1.c. 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, rules and regulations; and shall be licensed by the designated state oversight agency.

3.3. Hospitals licensed under "Hospital Licensure" (64 CSR 12), behavioral health centers licensed under "Behavioral Health Centers Licensure" (64 CSR 11), and opioid treatment facilities licensed under "Regulation of Opioid Treatment Programs" (69 CSR 7), and which provide opioid treatment to adults, 18 years or older, are exempt from this rule.

3.4. Licensed neonatal abstinence centers are exempt from state licensure rules regulating hospitals (64 CSR 12), behavioral health centers (64 CSR 11), nursing homes (64 CSR 13), chronic pain management clinics (69 CSR 8) and opioid treatment centers (69 CSR 7).

3.5. Licensure Process and Fees.

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

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

3.5.a.2. Obtain from the state oversight agency a license authorizing the operation of the neonatal abstinence syndrome center.

3.5.b. For neonatal abstinence syndrome centers in operation in the state of West Virginia on June 7, 2015, they must make an application for license to the state oversight agency within one year of the effective date of this rule.

3.6. License Application.

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

3.6.a.1. A completed application as established by the state oversight agency;

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

3.6.a.3. Copies of all required policies and procedures; and

3.6.a.4. The applicable filing fee.

3.6.b. 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.a. All initial and renewal fee 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 in full prior to the issuance of the license.

3.7.b. The neonatal abstinence syndrome center shall pay for the cost of the initial inspection made by the state oversight agency 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.a. Upon receipt of an application for an initial license to operate as a neonatal abstinence syndrome center, the state oversight agency 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.b. If the inspection reveals violations, deficiencies or shortcomings on the part of the neonatal abstinence center, the state oversight agency shall advise the program sponsor. The program sponsor may submit a written plan of correction demonstrating compliance with the cited deficiencies. The state oversight agency may conduct follow up inspections, if required.

3.8.c. Following an application review, onsite inspection or inspections, and approval of any subsequent written plans of correction, 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 state oversight agency shall issue a license in one of three categories:

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

3.8.e. 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 state oversight agency, unless the provisional recommendation is that of the state fire marshal.

3.9. Denial of License.

3.9.a. The state oversight agency may deny an application for an initial or renewed license when:

3.9.a.1. The state oversight agency determines the application is deficient in any respect;

3.9.a.2. The neonatal abstinence syndrome center will not be or is not operated in accordance with state standards, rules, and procedures;

3.9.a.3. 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.a.4. The neonatal abstinence syndrome center has made misrepresentations in obtaining certification or licensure.

3.9.b. If the state oversight agency determines not to issue a license, the secretary shall notify the applicant in writing of the denial and the basis for the decision.

3.9.c. A neonatal abstinence syndrome center may protest the denial of a new or renewed license pursuant to the administrative procedures in section 3, subsection 11 of this rule.

3.10. Renewal or Amended License.

3.10.a. Renewal License. A renewal license shall be issued when a neonatal abstinence syndrome center is in substantial compliance with this rule and expires not more than one year from the date of issuance.

3.10.a.1. The program sponsor of a neonatal abstinence syndrome center shall submit an application for a renewed license to the state oversight agency not less than 60 days prior to the expiration of the current license.

3.10.a.2. After the state oversight agency 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.b. Amended License. The program sponsor shall notify the secretary 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 a license amendment.

3.11. Administrative Due Process.

3.11.a. Any person aggrieved by an order by the state oversight agency based on this rule may request in writing a hearing by the secretary.

3.11.b. All hearings shall be conducted in accordance with the Department of Health and Human Resources rule, "Rules of Procedure for Contested Case Hearings and Declaratory Rulings" (69 CSR 1), a copy of which may be obtained from the Secretary of State.

§69-9-4. STATE OVERSIGHT AGENCY AUTHORITY; POWERS AND DUTIES.

4.1. The secretary has designated the Office of Health Facility Licensure and Certification within the Department of Health and Human Resources to act as the state oversight agency, as defined in this rule.

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

4.3. The duties and powers of the state oversight agency include, but are not limited to, the following:

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

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

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

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

4.3.e. Deny initial, amended and renewed licenses to neonatal abstinence centers upon the

determination that the program is not qualified;

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

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

4.3.h. Receive and act upon patient complaints, appeals and grievances;

4.3.i. 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, employees of a neonatal abstinence syndrome center;

4.3.j. Issue a directed plan of correction when a neonatal abstinence facility fails to develop an acceptable plan of correction;

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

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

4.4. Annual Inspections.

4.4.a. Each neonatal abstinence syndrome center shall be inspected annually by the oversight state agency. Inspections shall include, but are not limited to:

4.4.a.1. Observations of service delivery;

4.4.a.2. Review of life safety and environmental conditions;

4.4.a.3. Review of clinical and administrative records;

4.4.a.4. Review of policies and procedures;

4.4.a.5. Review of personnel files, criminal background checks, qualifications, staff education and staff training; and

4.4.a.6. Interviews with staff, administrators, volunteers, families, and legal representatives.

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

4.4.c. Within 10 working days of the completion of the inspection, the state oversight agency shall issue a written report. The written report or statement of deficiencies will detail the findings of the annual inspection, and a determination of compliance.

4.4.d. The state oversight agency may permit the neonatal abstinence syndrome center to develop a plan of correction based on the finding of the statement of deficiencies.

4.4.e. Based upon the neonatal abstinence center's previous substantial compliance with this rule, and the current inspection report, the state oversight agency may waive the requirement for an onsite inspection for issuance of an amended license.

4.5. For Cause Inspections and Complaints.

4.5.a. The state oversight agency 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.

4.5.b. Any person may file a complaint with the state oversight agency alleging a violation of applicable laws, rules, or policies by a neonatal abstinence center.

4.5.c. The state oversight agency may conduct unannounced inspections of a neonatal abstinence center named in a complaint and any other investigations deemed necessary to determine the validity of a complaint.

4.5.d. At the time of any on-site investigation activities, the state oversight agency shall notify the program sponsor or administrator of the general reason for the investigation.

4.5.e. Within 10 working days of the investigation, the state oversight agency 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 rule that forms the basis for the violation.

4.5.f. The state oversight agency may permit the neonatal abstinence center to develop a plan of correction to address any cited violations or deficiencies.

4.5.g. The state oversight agency may issue a directed plan of correction for implementation by the neonatal abstinence center to correct any violations or deficiencies.

4.5.h. The state oversight agency 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 state oversight agency 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.

4.6. Plans of Correction.

4.6.a. Within 10 working days of the completion of the inspection, the state oversight agency shall issue a written report. The written report or statement of deficiencies will detail the findings of the annual inspection, and a determination of compliance.

4.6.b. The state oversight agency may permit the neonatal abstinence syndrome center to develop a plan of correction based on the finding of the statement of deficiencies.

4.6.c. The state oversight agency may issue a directed plan of correction for implementation by the neonatal abstinence syndrome center to correct any violations or deficiencies.

4.6.d. Within 10 working days after receipt of the inspection report, program sponsor or administrator shall submit to the state oversight agency 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:

4.6.d.1. Any action taken or procedures proposed to correct the deficiencies and prevent their reoccurrence;

4.6.d.2. The date of completion of each action taken or to be taken; and

4.6.d.3. The signature of the head of the governing body or his or her designee.

4.6.e. The proposed plan of correction shall be approved, modified or rejected by the state oversight agency in writing.

4.6.f. The neonatal abstinence center may make modifications to the plan at a later date in conjunction with the state oversight agency.

4.6.g. The state oversight agency shall state the reasons for rejection or modification of any plan of correction.

4.6.h. The program sponsor or administrator shall submit a revised plan of correction to the secretary within 10 working days of receipt of a rejection by the state oversight agency.

4.6.i. The neonatal abstinence center shall immediately correct a violation that severely risks the health or safety of a patient or other persons.

4.6.j. The state oversight agency shall determine if the satisfactory corrections have been made and advise the program sponsor of any compliance or continued deficiencies in writing.

4.6.k. The state oversight agency may conduct an onsite revisit to determine compliance with the plan of correction.

4.7. Penalties.

4.7.a. The state oversight agency may impose a fine, suspend or revoke a license or take other action as deemed appropriate to address any violations or deficiencies.

4.7.b. The state oversight agency may suspend or revoke a license of any neonatal abstinence center for violating the prohibition of this rule.

4.7.c. The state oversight agency 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:

4.7.c.1. The state oversight agency makes a determination that fraud or other illegal action has been committed;

4.7.c.2. The state oversight agency has violated federal, state or local law relating to building, health, fire protection, safety, sanitation or zoning;

4.7.c.3. The neonatal abstinence syndrome center conducts practices that jeopardize the health, safety, welfare or clinical treatment of a patient;

4.7.c.4. The neonatal abstinence center has failed or refused to submit reports or make records available as requested by the state oversight agency; or

4.7.c.5. The neonatal abstinence center has refused to provide access to its location or records as requested by the state oversight agency.

4.7.d. If a license for a neonatal abstinence center has been revoked, the state oversight agency 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.

4.8. Informal Dispute Resolution.

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

4.8.b. The neonatal abstinence syndrome center shall submit a request for an informal dispute resolution to the state oversight agency with the plan of correction.

4.8.c. The request for an informal dispute resolution must be received within 10 working days of receipt of the inspection or investigation report.

4.8.d. The state oversight agency will maintain policies and procedures for conducting informal dispute resolutions.

4.8.e. 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.

4.8.f. All communications during an informal dispute resolution are confidential and cannot be used by or against the licensee or the state oversight agency in the event a formal hearing takes place.

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

4.8.h. The state oversight agency may make an independent informal dispute resolution process available to the neonatal abstinence center.

4.9. Inspection Reports and Records.

4.9.a. Neonatal Abstinence Center Responsibilities.

4.9.a.1. 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 to patients and visitors.

4.9.a.2. The center shall post a notice of the availability of the survey and inspection reports in a place readily accessible to patients and visitors.

4.9.a.3. Any person shall have the right to review the most recent and past state inspection and complaint reports with the plan of correction.

4.9.b. State Oversight Agency Responsibilities.

4.9.b.1. The state oversight agency 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.

4.9.b.2. The information in reports or records shall be available to the public except for the following:

4.9.b.2.A. Information regarding complaints and subsequent investigations that is deemed confidential by any provision of this rule or applicable state or federal laws;

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

4.9.b.2.C. Information required to be kept confidential by state or federal law.

4.9.b.3. 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:

4.9.b.3.A. Applications and exhibits;

4.9.b.3.B. Inspection reports;

4.9.b.3.C. Reports of investigations conducted in response to complaints; and

4.9.b.3.D. Any other report filed with or issued by the director pertaining to the compliance of a neonatal abstinence center with applicable laws and rules.

4.9.b.4. 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.

4.9.b.5. The director shall treat a report of inspection of a center as public information from the time an acceptable plan of correction is submitted.

4.9.b.6. 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.

4.9.b.7. Other records and reports shall be treated as public information from the time they are submitted to or issued by the director.

4.9.b.8. 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 state oversight agency 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.

§69-9-5. 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.a. The program sponsor is the person named in the application for certification and licensure of a neonatal abstinence syndrome center.

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

5.3.d. 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.

5.4.a. 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.

5.4.b. The governing body may be a board, a single entity or ownership or a partnership.

5.5. Administrator.

5.5.a. The administrator of the center shall have:

5.5.a.1. 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, or

5.5.a.2. 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.

5.5.b. 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.c. The duties of the administrator include, but are not limited to:

5.5.c.1. Development of policies and procedures for operation of the center;

5.5.c.2. Maintenance and security of the center;

5.5.c.3. Employment, credentialing, evaluation, scheduling, training and management of staff;

5.5.c.4. Protection of patient rights;

5.5.c.5. Conformity of the program with confidentiality laws and regulations;

5.5.c.6. Security of medication storage and safe handling of medications;

5.5.c.7. Management of the facility budget;

5.5.c.8. Implementation of a quality improvement committee;

5.5.c.9. Implementation of governing body policy; and

5.5.c.10. Communication with the governing body.

5.6. Advisory Council.

5.6.a. 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.b. The advisory council shall consist of individuals previously served by the program, at least one staff representative and interested community 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.c. The advisory council shall not have access to any patient identifying information.

5.6.d. The advisory council shall meet at least quarterly in an area where there are no patients present.

5.6.e. Quarterly, the advisory council shall:

5.6.e.1. Review program policies and procedures annually, or as proposed for revision;

5.6.e.2. Make recommendations for operational changes or improvements;

5.6.e.3. Be trained in patient confidentiality laws and regulations;

5.6.e.4. Keep records of meetings and describe business conducted, members present and members absent; and

5.6.e.5. Work to assist the neonatal abstinence center in identifying, addressing and resolving problems.

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

5.6.g. The advisory council shall report any recommendations Quality Improvement Committee.

5.7. Quality Improvement Committee.

5.7.a. The Quality Improvement Committee shall meet at least quarterly to identify problems or service deficits, and develop plans to correct areas of concern.

5.7.b. 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.c. The Quality Improvement Committee shall consist of, at a minimum, the:

5.7.c.1. Administrator;

5.7.c.2. Medical Director;

5.7.c.3. Director of Nursing;

5.7.c.4. Registered Professional Nurse; and

5.7.c.5. Patient Care Assistant.

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

5.7.d.1. Review both critical and noncritical incidents;

5.7.d.2. Address reports of and allegations of abuse and neglect;

5.7.d.3. Conduct case review;

5.7.d.4. Address grievances;

5.7.d.5. Establish standards and measurable outcomes, analyze outcome data as self-assessment;

5.7.d.6. Review any recommendations submitted by the Advisory Council; and

5.7.d.7. Provide feedback to the governing board.

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

5.7.e.1. Safety review;

5.7.e.2. Medication administration review; and

5.7.e.3. Security review.

5.8. Contractual Relationships.

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

5.8.b.1. Roles and responsibilities of participants;

5.8.b.2. Services to be provided;

5.8.b.3. Provisions for training and technical support as necessary;

5.8.b.4. Duration of the contract, including delineation of follow up services;

5.8.b.5. Methods for resolving disputes;

5.8.b.6. Documentation necessary for, and means of reporting to, funding or oversight bodies;

5.8.b.7. Conditions for termination; and

5.8.b.8. Expected outcomes as appropriate.

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

5.8.c.1. Roles and responsibilities of the organization and the contracting party;

5.8.c.2. Documentation required of the contracting individual or service with time lines for provision of the documentation;

5.8.c.3. Services to be provided;

5.8.c.4. Provision of appropriate liability or malpractice insurance either by the contractor or contracting party;

5.8.c.5. Procedures for exchange of information;

5.8.c.6. Definition of the patients to be served and the services to be provided;

5.8.c.7. Time lines for provision of service;

5.8.c.8. Methods for resolving disputes;

5.8.c.9. Terms of payment;

5.8.c.10. Assurances that the contracting party shall adhere to state and federal requirements of confidentiality; and

5.8.c.11. Expected outcomes as appropriate.

5.8.d. 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.d.1. Evidence of clinical training;

5.8.d.2. Evidence of appropriate licensure or certification;

5.8.d.3. Evidence of malpractice or liability insurance as specified in the contract;

5.8.d.4. Evidence of ability to conduct business in the state of West Virginia; and

5.8.d.5. Evidence of state and federal fingerprint-based criminal background check.

5.8.e. 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.e.1. Evidence of clinical training;

5.8.e.2. Evidence of licensure;

5.8.e.3. Evidence of state and federal fingerprint-based criminal background check;

5.8.e.4. Evidence of liability insurance; and

5.8.e.5. Evidence of a license to operate a business in the State of West Virginia.

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

§69-9-6. PHYSICAL FACILITY.

6.1. Facility Construction and Renovation.

6.1.a. 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.b. The plans shall include the drawings and specification for the architectural, structural, and mechanical design for the construction or renovation.

6.1.c. The state oversight agency shall advise the program sponsor whether approval has been granted within 30 days from the date of receipt of the plans.

6.1.d. In the event the plans for the project are not approved, the state oversight agency shall set forth in writing the reasons for the disapproval and provide the program sponsor the opportunity to correct any deficiencies.

6.1.e. Construction or extensive renovation of a facility may not begin until the secretary has issued final approval of the plans.

6.1.f. All centers must meet all other requirements of applicable federal or state regulatory or oversight agencies.

6.2. Facility Security Requirements.

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

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

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

6.2.e. All visitors must present valid government-issued photo identification to be permitted entrance

into the facility;

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

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

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

6.3. Service Environment.

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

6.3.b. 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.c. The center shall provide adequate storage space to accommodate clothing and personal items.

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

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

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

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

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

6.4. Laundry and Linens.

6.4.a. 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.b. 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.c. The center shall provide clean waterproof mattresses or mattress covers that are non-absorbent.

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

6.4.e. The center shall provide each patient with individual towels, wash cloths, and bedding.

6.5. Nursing Equipment and Sterile Supplies.

6.5.a. The center shall have the sufficient quantity and type of nursing equipment to meet the

individual care needs for each patient.

6.5.b. 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.c. 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.d. All equipment shall be maintained in accordance with the provisions of this rule.

6.5.e. Clean nursing equipment and sterile supplies shall be stored in a clean work room or store room that does not permit patient contact.

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

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

6.5.h. Damaged supplies and utensils shall not be used.

6.6. Housekeeping and Maintenance.

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

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

6.6.b.1. All equipment is operable and in a safe working condition;

6.6.b.2. The interior and exterior of the building is safe; and

6.6.b.3. The grounds are maintained in a presentable condition free from rubbish and other health hazards of a similar nature.

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

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

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

6.6.f. 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.

6.7. Storage of Supplies.

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

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

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

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

6.8.a. The center shall be located within fifteen minutes of a hospital with a neonatal care program.

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

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

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

6.8.e. 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.e.1. This requirement applies to new construction, additions, renovations, or alterations to an existing center.

6.8.e.2. 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.e.3. The director shall approval all plans prior to beginning construction.

6.8.e.4. 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.e.5. The project shall be inspected during the construction phase by a registered professional architect or his or her representative.

6.8.e.6. The requirement for a registered architect may be waived by the director depending on the scope of the project.

6.8.e.7. 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.e.8. Minor renovations that do not alter floor plans, impact on safety or require the services of a design professional may not require approval of the director.

6.8.e.9. 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.f. 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.g. The center shall request in writing a pre-opening inspection no less than thirty (30) days prior to the proposed opening date.

6.8.h. 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.a. 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.b. The site shall be located in an environment that is free from flooding and excessive noise sources such as railroads, freight yards, traffic arteries and airports.

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

6.9.d. 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.e. The site shall be accessible to physicians, emergency services and other necessary services.

6.9.f. 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.g. The road shall connect directly to a paved hard surface highway.

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

6.9.i. Parking areas shall be sufficient according to the latest edition of the Guidelines for Design and Construction of Health Care Facilities according to by Facilities Guidelines Institute (FGI) and published by American Society for Healthcare Engineering (ASHE).

6.9.j. Local building codes and zoning restrictions shall be followed.

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

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

6.10.b.1. Investigate, control, and prevent infection in the center;

6.10.b.2. 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.b.3. 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.c. 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.d. 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.e. Personnel shall handle, store, process and transport linens in order to prevent the spread of infection.

6.10.f. 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.a. The center shall have procedures and contracts for disposing of bio-hazardous waste.

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

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

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

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

6.11.g. 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.a. 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.b. The facility shall have as its source of water, a public water system that complies with West Virginia Division of Health Rules, Public Water Systems, 64CSR3, or water well that complies with West Virginia Division of Health Rules, Water Well Regulations, 64CSR19 and Water Well Design Standards, 64CSR46.

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

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

6.12.e. The temperatures shall be appropriate for comfortable use but shall not exceed 110 degrees Fahrenheit.

6.12.f. 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.a. Sewage disposal shall be in accordance with West Virginia Division of Health Rules, Sewage System Rules, and West Virginia Division of Health Rules, Sewage Treatment and Collection System Design Standards, 64CSR47.

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

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

6.14.b. 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.c. 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.d. 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.e. 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.f. 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.g. There shall be copies of the disaster and emergency preparedness plan at all staff stations or emergency control stations.

6.14.h. 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.i 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.j. The center shall have a written plan and procedures for transferring casualties and uninjured patients.

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

6.14.m. The center shall have information regarding methods of fire containment.

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

6.14.o. 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.p. 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.p.1. The administrator;

6.14.p.2. The Director of Nursing or the registered professional nurse on duty;

6.14.p.3. The maintenance director or safety director;

6.14.p.4. The physician on-site or on-call; and

6.14.p.5. Other appropriate personnel.

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

6.14.t. The internal disaster plan shall be rehearsed at least annually.

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

6.14.v. 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.

§69-9-7. PATIENT RIGHTS AND PARENTAL/LEGAL REPRESENTATIVE RIGHTS AND RESPONSIBILITIES.

7.1. Policies and Procedures.

7.1.a. 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.b. 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.c. The center shall make its policies and procedures available upon request to legal representatives, including legal representatives of potential patients.

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

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

7.2. Civil Rights.

7.2.a. 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.b. 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.a. 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.b. 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.c. 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.d. The center shall ensure all alleged violations involving mistreatment, abuse, neglect, and misappropriation of property, including injuries of unknown origin are reported to the state oversight agency immediately, and no later than within 24 hours. In addition, the facility shall submit a five-day follow up report. These shall be submitted in the format developed by the state oversight agency.

7.3.e. 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.f. 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.g. 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.h. The center shall protect patients from abuse, neglect and misappropriation of property during the investigation of any allegations.

7.3.i. 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.j. 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.a. 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, as developed and approved by the Department.

7.4.b. 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 parent 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.

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

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

7.5.b. 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.c. 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.a. 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.b. Legal representatives shall be informed of their rights and responsibilities in writing, prior to admission.

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

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

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

7.7.b. 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.a. The center shall assure confidential treatment of each patient's personal and medical records and may approve or refuse 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.b. Upon an oral or written 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.c. The center may charge a fee for labor, supplies, and postage 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.d. 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.e. 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 representative and shall post a notice of their availability.

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

7.8.g. 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.a. 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.a.1. Regular visitation hours;

7.9.a.2. Off-hours visitation to accommodate working parents;

7.9.a.3. Visitor identification;

7.9.a.4. Monitoring and documenting the visitation;

7.9.a.5. Hand washing and protective clothing covers when handling patients;

7.9.a.6. Limiting the items (bags, purses, jackets) visitors may take into the center and/or into the visitation area;

7.9.a.7. Prohibiting illegal substances on the premises of the center;

7.9.a.8. Prohibiting prescription and non-prescription medications and supplements on the premises of the center;

7.9.a.9. Prohibiting weapons of any kind on the premises of the center;

7.9.a.10. Identifying where visitation is permitted within the center;

7.9.a.11. Identifying circumstances that may prohibit or limit visitation rights of parents, legal representatives and/or family;

7.9.a.12. Detailing how visitors will be identified, logged in and monitored;

7.9.a.13. Informing and educating visitors of the visitation policy and other relevant policies;

7.9.a.14. Handling visitors that do not abide by the visitation policies and other relevant policies of the center.; and

7.9.a.15. Addressing any medical needs of parents or guardians who stay overnight with their infant.

7.9.b. The center shall provide all parents, legal representatives, and family with a copy of the

center's visitation policy.

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

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

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

7.9.f. Mothers 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.a. 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.b. 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, and offer alternative treatments, and continue to provide all other services.

7.10.c. 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 state oversight agency and the protective services agency shall be notified.

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

7.10.e. 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.f. 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.a. The center must have a 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.b. The policy must address how the center will manage the complaint process in a timely and objective manner.

7.11.c. 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 state oversight agency.

7.11.d. 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 state protective services agency and the state oversight agency, including address and phone number for filing complaints.

7.11.e. Information about how to file a complaint with the state protective services and state oversight agencies shall be posted in locations easily accessible by staff and visitors.

7.11.f. 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.g. 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.h. The policy must be posted in a location that is accessible to visitors.

7.12. Issues with Parental Participation.

7.12.a. 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.b. 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.c. If a parent arrives to care for his or her patient, 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 of the center. The center must have policies and procedures to identify how these situations will be handled.

§69-9-8. INCIDENTS AND INCIDENT REPORTING.

8.1. Critical Incidents.

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

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

8.1.c. 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.c.1. Allegations of abuse, neglect, mistreatment, misappropriation;

8.1.c.2. Medication errors;

8.1.c.3. Removal of a staff member from duty pending an investigation;

8.1.c.4. Behavior likely to lead to serious injury or significant property damage;

8.1.c.5. Involvement with law enforcement;

8.1.c.6. Possession of illicit substances, including alcohol;

8.1.c.7. Possession of a weapon;

8.1.c.8. Injuries requiring medical treatment;

8.1.c.9. Reaction to medication or food requiring medical treatment;

8.1.c.10. Dietary errors with a negative outcome;

8.1.c.11. Removal of a patient from the nursery without authorization;

8.1.c.12. Fire;

8.1.c.13. Drug diversion;

8.1.c.14. Incident due to a lack of employee oversight;

8.1.c.15. Injuries of unknown origin;

8.1.c.16. Unusual occurrences, or

8.1.c.17. Any incident that has a significant and negative impact on the patient.

8.2. Critical Incident Reporting and Investigation.

8.2.a. The center shall complete a written report of any critical incident or accident in which a patient is involved, either inside or outside of the center.

8.2.b. The report shall include the:

8.2.b.1. Date of the occurrence;

8.2.b.2. Time of the occurrence;

8.2.b.3. Place of the occurrence;

8.2.b.4. Details of the occurrence; and

8.2.b.5. Date and signature of the reviewing physician.

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

§69-9-9. STAFFING.

9.1. Medical Director.

9.1.a. The center shall designate, in writing, a physician accountable to the governing body to serve

as medical director.

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

9.1.c. 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.d. The medical director is responsible for:

9.1.d.1. Reviewing policies, procedures, and guidelines to ensure adequate, comprehensive services;

9.1.d.2. Coordinating medical care provided, including the attending physician, in the center so it is adequate and appropriate;

9.1.d.3. Assisting in the evaluation of credentialing and re-credentialing of licensed independent practitioners, physician assistants and nurse practitioners to determine whether they will be authorized to practice within the organization by recommendation;

9.1.d.4. Approving in-service training programs; and

9.1.d.5. 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.a. The neonatal abstinence syndrome center shall employ a Director of Nursing with the following minimum qualifications:

9.2.a.1. 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.a.2. The Director of Nursing shall have at least two years of experience in the medical care of neonatal or pediatric patients.

9.2.b. The Director of Nursing shall be responsible for:

9.2.b.1. Assisting in the development of staff performance evaluations;

9.2.b.2. Supervising day-to-day clinical operations of the center, including but not limited to practice standards and quality improvement;

9.2.b.3. Developing and implementing programs and related materials based on best practices in collaboration with the Medical Director;

9.2.b.4. Assure competency and consistency in care and guides clinical practice through resource development, educational opportunities, consultation and research;

9.2.b.5. Developing and monitoring benchmark standards and tools to evaluate and achieve

success in clinical objectives;

9.2.b.6. Reviewing the effectiveness of practice modalities and develops performance measures and indicators to assess success.

9.2.b.7. Continuously monitoring outcomes and approaches to ensure quality performance and outcomes;

9.2.b.8. Assisting in the development of educational materials to address deficiencies in the operation of the center; and

9.2.b.9. Coordinating outreach and education to referring centers or entities.

9.3. Registered Professional Nurse.

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

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

9.3.e. Registered professional nurses shall have a Neonatal Advanced Life Support (NALS) or S.T.A.B.L.E. certification within one year of employment.

9.3.f. Registered professional nurses shall be responsible for:

9.3.f.1. Overseeing care and treatment of patients provided by patient care assistants;

9.3.f.2. Checking neonatal abstinence syndrome symptoms score once per shift, and as needed;

9.3.f.3. Participating in physician rounds for all assigned patients;

9.3.f.4. Administering medications according to physician's orders;

9.3.f.5. Verifying and documenting administration and dosage of all medications, including opiates, administered by another registered professional nurse;

9.3.f.6. Initiating emergency resuscitation measures, according to patient protocols;

9.3.f.7. Monitoring for adherence to feeding and treatment protocols;

9.3.f.8. Reporting all patient medical concerns to the physician;

9.3.f.9. Reporting all social concerns to the social worker;

9.3.f.10. Assuming care and treatment of patients requiring closer monitoring;

9.3.f.11. Communicating with parents and caregivers in a non-judgmental environment;

9.3.f.12. Maintaining confidentiality in all matters pertaining to patient and family care and treatment;

9.3.f.13. Providing education and support to parents and caregivers; and

9.3.f.14. Initiating and updating plan of care.

9.4. Social Worker.

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

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

9.4.c. Social worker shall be responsible to:

9.4.c.1. Coordinate and collaborate with the social work departments at all admitting hospitals;

9.4.c.2. Visit with and provide information to parents about the center;

9.4.c.3. Coordinate and give tours of the center to qualifying parents;

9.4.c.4. Work with the registered professional nurse during the admission process;

9.4.c.5. Review the center rules with parents;

9.4.c.6. Work with families to identify the existing needs and strengths for providing care;

9.4.c.7. Introduce the family to the clinical team at the center;

9.4.c.8. Ensure all families receive necessary training;

9.4.c.9. Provide parent and family training for non-medical issues;

9.4.c.10. Gather and record information regarding the family and patient social status;

9.4.c.11. Be the liaison to Patient Protective Services;

9.4.c.12. Help identify patients who should be remanded into state custody;

9.4.c.13. Coordinate local substance abuse prevention programs;

9.4.c.14. Prepares and maintains records for the patient's chart regarding social and parental strengths and needs; and

9.4.c.15. 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.a. The facility shall 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.b. Personal care assistants shall not be assigned to more than three patients.

9.5.c. Personal care assistants shall meet the following educational requirements:

9.5.c.1. A high school diploma, or equivalent; and

9.5.c.2. A current Neonatal Advanced Life Support (NALS) or S.T.A.B.L.E. certification within one year of employment.

9.5.d. The center shall provide a comprehensive orientation to each personal care assistants to at a minimum to:

9.5.d.1. Provide an in-depth understanding of all policies and procedures of the center;

9.5.d.2. Report allegations abuse, neglect, misappropriation and fraud;

9.5.d.3. Report drug diversion concerns;

9.5.d.4. Become proficient in therapeutic handling; and

9.5.d.5. Become proficient in neonatal abstinence syndrome symptom scoring.

9.5.e. Personal care assistants shall be responsible for:

9.5.e.1. Caring for patients with neonatal abstinence syndrome under direct supervision of a registered professional nurse;

9.5.e.2. Providing general patient care including, vital signs, bathing, feeding, and diapering.

9.5.e.3. Maintaining low stimulus environment at all times;

9.5.e.4. Scoring patients using the neonatal abstinence syndrome scoring method;

9.5.e.5. Using therapeutic handling to comfort and decrease stimulus;

9.5.e.6. Directing any concerns to the registered professional nurse immediately;

9.5.e.7. Maintaining confidentiality in all matters pertaining to patient and family care and treatment;

9.5.e.8. Documenting care provided in the patient's chart; and

9.5.e.9. Reporting end of shift status to the registered professional nurse.

9.6. Volunteers.

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

9.6.b. No one under the age of 18 may volunteer.

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

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

9.7. Staffing Ratios.

9.7.a. The center shall maintain a personal care assistant staffing ratio to meet the acuity level of the patients.

9.7.b. 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.c. 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.d. 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.a. The center shall ensure all employees are specifically trained to meet the needs of the patients with neonatal abstinence syndrome.

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

9.8.c. At a minimum, all employees shall be trained in:

9.8.c.1. Patient development;

9.8.c.2. Neonatal Advanced Life Support (NALS) or S.T.A.B.L.E within one year of employment;

9.8.c.3. First aid;

9.8.c.4. Basic patient care; and

9.8.c.5. The effects of neonatal abstinence syndrome on the patient.

9.8.d. Prior to completion of the training, the new employee shall be scheduled to work with only fully trained employees.

9.9. Personnel Records.

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

9.9.a.1. A dated application;

9.9.a.2. Reference verification;

9.9.a.3. Evaluations of work performance;

9.9.a.4. Tuberculosis screening prior to hire and every five years;

9.9.a.5. Current license, registration, or certification status if applicable to the job;

9.9.a.6. A summary of the employee's in-service training for the previous two years;

9.9.a.7. Any center specific required forms;

9.9.a.8. A job description signed by the employee; and

9.9.a.9. Records required to be retained for criminal background checks as defined by the provisions of this rule.

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

9.9.b.1. A dated application;

9.9.b.2. Reference verification;

9.9.b.3. Evaluations of work performance;

9.9.b.4. Tuberculosis screening prior to hire and every five years;

9.9.b.5. Current license, registration, or certification status, if applicable to the job;

9.9.b.6. A summary of the volunteer's in-service training for the previous two years;

9.9.b.7. Any center specific required forms;

9.9.b.8. A job description signed by the volunteer; and

9.9.b.9. 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 center shall be subject to the provisions of the Article 49, Chapter 16 of the W. Va. Code, or the West Virginia Clearance for Access: Registry and Employment Screening Act, and subsequent promulgated rules.

§69-9-10. ADMISSION, DISCHARGE AND TRANSITION.

10.1. Admission.

10.1.a. A center may accept an admission under the following criteria:

10.1.a.1. The patient is recommended or referred by physician;

10.1.a.2. The patient is in stable condition;

10.1.a.3. The patient has a diagnosis of neonatal abstinence syndrome without other unrelated health conditions; and

10.1.a.4. The patient has an adjusted age of 36 weeks of gestation, and is under the age of four months old.

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

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

10.1.d. 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.d.1. Visit their infant at a frequency determined by the physician and the parents;

10.1.d.2. Participate in the care of the patient while present;

10.1.d.3. Learn the patient's stress cues and how to address them;

10.1.d.4. Learn and practice the minimal stress protocol for the patient experiencing withdrawal;

10.1.d.5. Attends parenting classes provided or arranged for by the center;

10.1.d.6. Attends weekly or biweekly meetings with the social worker, nursing staff and when necessary, the physician.

10.1.d.7. Participate in education provided regarding discharge; and

10.1.d.8. Provide contact information where they can be reached at any time.

10.2. Discharge.

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

10.2.b. Discharge planning shall begin upon admission.

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

10.2.d. Discharges must have a physician's order.

10.2.e. Situations for Appropriate Discharge.

10.2.e.1.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.e.2. The patient reaches the maximum benefit from the services of the center;

10.2.e.3. The patient no longer meets the eligibility criteria; or

10.2.e.4. The patient has needs exceeding the resources of the center.

10.2.f. Discharge Criteria:

10.2.f.1. The patient must meet the following criteria prior to discharge from the center:

10.2.f.1.A. The patient shall be weaned off pharmacological interventions for at least 72 hours;

10.2.f.1.B. The patient shall have a NAS score average of less than 8 or may be discharged with a higher average score at the discretion of the physician; and

10.2.f.1.C. Clearance by child protective services, if applicable.

10.2.f.2. Parental education will be an ongoing process throughout the patient's hospitalization treatment.

10.2.f.3. Parents and/or legal representatives will meet criteria on the Parental Discharge Agreement and received clearance from protective services for discharge.

10.2.f.4. Parents and/or legal representatives will receive instruction for therapeutic handling.

10.2.f.5. All caregivers are required to receive training on the:

10.2.f.5.A. Period of purple crying;

10.2.f.5.B. Caring for drug exposed patients;

10.2.f.5.C. Therapeutic handling; and

10.2.f.5.D. Discharge and aftercare.

10.2.g. Discharge Needs and After-Care.

10.2.g.1. An assessment shall be completed to determine whether the patient has access to appropriate baby items for daily care in the home.

10.2.g.2. An assessment shall be completed to determine whether the patient has access to health, medical, nutritional, social, crisis, and emergency support in the home.

10.2.g.3. 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.g.4. Patients shall be referred to all appropriate community-based supports by the date of discharge as part of the after-care plan.

10.2.h. Discharge for Going Home with a Person other than the Biological Mother.

10.2.h.1. 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.h.2. 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 the custody of protective services, there must be an additional release form in the chart and the protective services representative must be present.

10.2.h.3. No patient is to be discharged to any person, other than the biological mother or legal representative, without signed consent unless the patient is in the custody of the Department.

10.2.h.4. The person picking up the patient must have all the appropriate legal documents and deemed appropriate by the social worker of the facility.

10.2.h.5. 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.h.6. The center's registered professional nurse will accompany 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.h.7. Document to whom the patient was discharged and complete any state required minor release reports.

10.3. Transfer.

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

§69-9-11. 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. The initial comprehensive assessment will result in the development of the initial plan of care. The initial plan of care will include an initial comprehensive assessment and an initial comprehensive summary of findings. The initial plan of care and implementation of services must begin at the earliest opportunity immediately after the initial assessment, no later than 24 hours after admission.

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

11.6.a. The comprehensive assessment shall include:

11.6.a.1. Physical and medical assessment;

11.6.a.2. Demographic information and custody status;

11.6.a.3. Presenting problems and reason for referral;

11.6.a.4. Medical history;

11.6.a.5. Social history;

11.6.a.6. Developmental history;

11.6.a.7. Exposure history;

11.6.a.8. Summary of family strengths and weaknesses;

11.6.a.9. Treatment and medication orders;

11.6.a.10. Nutritional and dietary needs;

11.6.a.11. Summary of presenting problems and foci for treatment;

11.6.a.12. Behavioral status and needs; and

11.6.a.13. Any other special needs or accommodations.

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

11.6.b.1. Review of adaptive behavior;

11.6.b.2. Review of need for special accommodations or adaptive technology; and

11.6.b.3. Special or unique behavioral issues.

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

11.6.d. 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.d.1. Recommendations for health screenings or treatment;

11.6.d.2. A diagnosis;

11.6.d.3. Recommendations for further assessment as appropriate;

11.6.d.4. Recommendations for clinical behavioral health treatment;

11.6.d.5. Recommendations for interventions to be made in the home environment;

11.6.d.6. Recommendations for placement and aftercare upon discharge;

11.6.d.7. Recommendations for family visitation unless contraindicated clinically or legally; and

11.6.d.8. Recommendations for rights restrictions.

11.6.e. Medical and Physical Assessments.

11.6.e.1. Medical and physical assessments must occur upon admission and ongoing assessment must occur at various times throughout the day, week and month.

11.6.e.2. Medical and physical assessments must include, at a minimum, the following:

11.6.e.2.A. A head to toe physical assessment must be completed upon admission and daily once per shift;

11.6.e.2.B. Vital signs and temperature must be completed upon admission and daily once per shift;

11.6.e.2.C. 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.e.2.D. Skin integrity for mottling or breakdown;

11.6.e.2.E. Respiratory status;

11.6.e.2.F. Breathing sounds;

11.6.e.2.G. Cardiovascular system;

11.6.e.2.H. Brief neurological exam; and

11.6.e.2.I. Weight, length, and head circumference.

11.6.e.3. Twice Daily Assessment.

11.6.e.3.A. 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.e.3.B. 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.a. A diagnosis;

11.7.b. A prognosis;

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

11.7.d. Recommendations for continued assessment;

11.7.e. Recommendations for behavioral health treatment;

11.7.f. Recommendations interventions needed in the home environment;

11.7.g. Recommendations for placement and aftercare upon discharge;

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

11.7.i. Recommendations for rights restrictions.

11.8. Plan of Care.

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

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

11.8.b.1. Treatment to be provided for health screenings, pharmacological interventions, and non-pharmacological interventions;

11.8.b.2. Nutritional interventions;

11.8.b.3. Continued assessment needs and schedule;

11.8.b.4. Behavioral health treatment and interventions;

11.8.b.5. Interventions for in the home environment;

11.8.b.6. Interventions for any other underlying medical problems;

11.8.b.7. Description of all services to be provided;

11.8.b.8. Family visitation schedule unless contraindicated clinically or legally;

11.8.b.9. Rights restrictions to be implemented; and

11.8.b.10. Consent and approval of the parent or legal representative, as appropriate.

11.8.c. 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.d. 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.e. Development of the Plan of Care. The Plan of Care shall include, at a minimum, the following:

11.8.e.1. Plan to strengthen the relationship between patient and family, if clinically and legally appropriate;

11.8.e.2. Identify the goals of each service to be provided;

11.8.e.3. Identify the services to be provided to achieve all identified goals;

11.8.e.4. Identify pharmacological and non-pharmacological treatments and interventions prescribed by the physician;

11.8.e.5. Identify therapeutic and other behavioral health interventions to be provided;

11.8.e.6. Identify dietary and other health services to be provided;

11.8.e.7. Identify services provided by outside providers or entities;

11.8.e.8. Discharge and permanency plan;

11.8.e.9. Identify the person(s) responsible for all services and interventions provided; and

11.8.e.10. Identify the frequency for all services and interventions provided.

11.8.f. 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.f.1. Review of each goal and its current status;

11.8.f.2. Identification of problems preventing progress and strategies to address these problems;

11.8.f.3. Modifications to the made to the plan;

11.8.f.4. Summary of interventions provided to date; and

11.8.f.5. Review of discharge plan.

§69-9-12. 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 consents until the center obtains a current physician's order. At no time shall this period exceed 24 hours.

12.4. Only the program physician 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 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.a. Ensure responsible handling and secure storage of all medications kept at the facility;

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

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

12.6.d. Ensure the security of medications to prevent diversion;

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

12.6.e.1. Receipt records;

12.6.e.2. Initial inventory;

12.6.e.3. Monthly inventory;

12.6.e.4. Counting of all controlled substances;

12.6.e.5. Perpetual logs;

12.6.e.6. Administration;

12.6.e.7. Documenting wastage;

12.6.e.8. Documentation of patient charts;

12.6.e.9. Disposal of controlled substances; and

12.6.e.10. Transferring of controlled substances among registrants.

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

12.6.g. 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.h. Ensure all medication is administered in accordance with its approved product labeling.

12.7. Medication Errors.

12.7.a. All medication errors will be addressed and reported immediately upon discovery.

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

12.7.b.1. Complete a physical assessment of the patient's condition;

12.7.b.2. Provide any and all first aid, and contact emergency medical services;

12.7.b.3. Place patient on cardio respiratory monitor, if opiate error;

12.7.b.4. Notify the physician immediately;

12.7.b.5. Document and read back physician orders; and

12.7.b.6. Once patient is stable notify the Administrator, Director of Nursing, state protective services agency, and the state oversight agency.

12.7.c. Medication errors are considered a critical incident and must be reported to the state oversight agency.

12.8. Medication Storage and Handling.

12.8.a. Each and every time controlled substances change hands or are used, documentation must be generated and maintained.

12.8.b. State and federal laws require all controlled substance records be maintained for a period of five years.

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

12.8.e. 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.

12.8.f. All employees shall receive annual training in the handling of narcotics.

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

12.8.h. All centers must follow proper storage requirements for ensuring security of medications, including but not limited to:

12.8.h.1. All controlled substances in a building must be stored in a permanently affixed, securely double locked and substantially built safe or cabinet;

12.8.h.2. The process or system for security of controlled substances must be commensurate with the quantity and types of controlled substances stocked; and

12.8.h.3. Controlled substances must not be left out or unattended at any time.

12.9. Handling Diversion, Loss and Theft.

12.9.a. A loss or theft must be immediately reported to the Drug Enforcement Administration, Board of Pharmacy, and the state oversight agency.

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

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

12.10.c. 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.d. Both licensed nurses shall sign the individual narcotic record book.

12.11. Medication Disposal.

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

12.11.b.1. Log must have the center's name and address indicated;

12.11.b.2. Date of disposal or destruction;

12.11.b.3. Time of disposal or destruction;

12.11.b.4. Patient's name;

12.11.b.5. Drug name, drug dosage, and quantity disposed of or destroyed;

12.11.b.6. Reason for disposal or destruction;

12.11.b.7. Signature of the person, who shall be a licensed professional, preparing the report and performing the disposal or destruction; and

12.11.b.8. Signature of the witness, who shall be a licensed professional, as to the report and disposal or destruction.

12.11.c. Controlled substances must be disposed of or destroyed beyond reclamation.

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

§69-9-13. 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.a. Swaddling;

13.2.b. C-Position;

13.2.c. Head to Toe Movement;

13.2.d. Vertical Rocking;

13.2.e. Clapping;

13.2.f. Feeding;

13.2.g. Controlling the Environment; and

13.2.h. 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.

13.9. Feeding.

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

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

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

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

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

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

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

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

13.11. Transportation.

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

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

13.12. Physician and Physician Extender Services.

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

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

13.12.c. Physician visits. The physician shall:

13.12.c.1. Review the patient's total plan of care, including medications and treatments, and examine the patient personally at each visit required under the provision of this rule;

13.12.c.2. Write, sign and date progress notes at each visit; and

13.12.c.3. Sign and date all orders.

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

13.12.d.1. Within 24 hours of admission; and

13.12.d.2. At least twice per week, or more frequently as indicated by the needs of the patient.

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

13.12.f. 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.g. 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.g.1. Is licensed by the State;

13.12.g.2. Is acting within the scope of practice as defined by W. Va. Code §30-3-1 et seq; and

13.12.g.3. Is under the supervision of the physician.

§69-9-14. PARENT EDUCATION AND COUNSELING.

14.1. The center shall provide or arrange for engagement, assessment, therapeutic services, and linkage to community supports and services as part of the discharge and transition planning. Primary focus will be mothers, 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.a. Meet, or document attempts to meet, with mothers, 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.b. Complete biopsychosocial assessment of mother, family, and/or the legal representative that includes the use of drugs and alcohol;

14.2.c. Provide access to individual and group therapy, individual and group supportive intervention, and psychoeducational services to mothers, families, and/or legal representatives;

14.2.d. Assist mothers in obtaining needed supports by establishing linkage including but not limited to employment, housing, social service benefits;

14.2.e. Develop and arrange services and supports for the mother, family, and/or legal representative upon discharge, including but not limited to behavioral and physical health services and recovery supports; and

14.2.f. Coordinate linkage with, and support by, peer support and recovery coaches.

§69-9-15. 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, and accessible.

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.a. 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.b. 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.

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

15.8.a. Biographical information;

15.8.b. Copies of the custody and/or guardianship records;

15.8.c. Court ordered restrictions for the patient;

15.8.d. Reason for the referral;

15.8.e. Admission intake forms;

15.8.f. Discharge plan;

15.8.g. Aftercare plan for ongoing and future service needs;

15.8.h. Psychological, medical, toxicological, diagnostic and psychosocial evaluations;

15.8.i. Assessment information;

15.8.j. Plan of care, including goals of service;

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

15.8.l. Copies of all signed, written consent forms;

15.8.m. Routine documentation of ongoing services;

15.8.n. Documentation of incidents;

15.8.o. Documentation of medication administration records;

15.8.p. Documentation of treatment administration records;

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

15.8.r. Closing summary of discharge.

15.9. Medical records shall be stored in a secure place.

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

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

15.11.a. Patient;

15.11.b. His or her parents, as legally appropriate;

15.11.c. Legal representative;

15.11.d. Attorney, as legally appropriate;

15.11.e. Employees, as needed to provide care; and

15.11.f. Others as permitted by state or federal law.