

PROCEDURES FOR RULE ENFORCEMENT

MH LICENSURE & CERTIFICATION SECTION

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CLIA Waivers and Glucometer Disinfection

The Clinical Laboratory Improvement Amendments of 1988 (CLIA) law establishes quality standards for all laboratory testing to ensure the accuracy, reliability and timeliness of patient test results regardless of where the test is performed. Tests may be waived from regulatory oversight if they meet certain requirements established by the statute.

In 1992, regulations were published to implement CLIA. In the regulations, waived tests were defined as simple laboratory examinations and procedures that are cleared by the Food and Drug Administration (FDA) for home use, employ methodologies that are so simple and accurate as to render the likelihood of erroneous results negligible, or pose no reasonable risk of harm to the patient if the test is performed incorrectly. Specific tests are listed in the regulation¹.

Glucose monitoring devices cleared by the FDA specifically for home use are included in the list of waived tests. Licensed mental health facilities performing blood glucose monitoring must have a CLIA waiver to be in compliance. For questions regarding obtaining a CLIA waiver, refer providers to the DHSR CLIA Section at (919)855-4620.

- NOTE: CLIA waivers are also needed for certain urine tests often used in Methadone Clinics. We don't generally survey for this requirement, but you may see evidence of the waiver while conducting a survey.

In addition to application for a CLIA waiver, providers must comply with the infection control requirements when using a glucometer. The CDC states the HBV (Hepatitis B Virus) can survive for at least one week in dried blood on environmental surfaces or on contaminated instruments. A glucometer may be contaminated with blood and body fluids during routine use. The CDC recommendation is that each consumer has their own individual glucometer.

If a shared glucometer is in use, it is imperative that the machine be disinfected between each client's testing utilizing the manufacturer's instructions for the specific glucometer. Directions for glucometer disinfection vary between manufacturers and models within brands. Facility staff should be familiar with which glucometer manufacturer(s) the facility uses and the cleaning procedures recommended by that manufacturer(s).

¹ For a full list of waived tests visit: <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/TVDRegulatoryAssistance/ucm124202.htm>
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Community Respite Services for Individuals of All Disability Groups: 10A NCAC 27G. 5100

1. Scope

"Community respite is a service which provides periodic relief for a family or family substitute on a temporary basis."

- The rule specifies "family substitute" which would include other licensed providers.
- A license is required for respite services when two or more clients are served concurrently or one or two children, two adults or any combination of clients are served more than 240 hours a month.
- Although the respite rules allow children and adults to receive services from the same respite provider, the core rules specify that children and adolescents can NOT share a bedroom with an adult **10A NCAC 27G .0202 (d) (9) Facility Design and Equipment.**
- Billing is not a consideration for licensure, any provider meeting the above respite conditions is required to be licensed regardless of billing or payment source.
- Endorsement is separate from licensure and DHSR has no authority or involvement in endorsement decisions by LMEs. Community Respite is not an endorsed service.
- Respite services may be provided for less than 24 hours. There is no time limit on how long the client may stay in respite. The rule states "temporary" meaning the client should have an identified permanent placement or efforts should be documented that a permanent placement is being sought for the client.
- Facilities that are dually licensed as 5100 and 5600 have designated beds for each service and cannot flex beds into or out of respite.
- Facilities providing 1300, 1700 and 5000 services cannot be dually licensed for 5100 services. The level of therapeutic intervention required in these programs is not consistent with the "periodic relief" provided by respite services. Facilities licensed to provide 5000 services are locked, institutional settings. Children or adolescents needing short term treatment may be served in a .1300 or .1700 facility, but the facility must remain in compliance with all the .1300 or .1700 rules.

2. Staff

- Although the rule states the Program Director will determine the appropriate age of staff, the core rules apply to respite programs as well. **10A NCAC 27G .0202 (b) (1) Personnel Requirements** requires staff to be at least 18 years of age.
- The minimum staffing rules specify "two staff members be available in the immediate area." Immediate area is not defined by statute but is considered to be the premises of the licensed facility unless otherwise specified by facility policy.
- The emergency back up procedures as specified in **10A NCAC 27G .5102 (c) (3)** do not apply when only one client is present.

3. Operations

- 10A NCAC 27G .5103 (b) states "only the program director or his designee shall arrange respite care." The rule does not specify any restrictions on the delegation of this duty. However, the core rules **10A NCAC 27G .0203 Competencies of Qualified Professionals and Associate Professionals and .0204 Competencies and Supervision of Paraprofessionals** specify the competencies required by qualified professionals, associate professionals and paraprofessional staff.
- Clients need treatment plans in accordance with **10A NCAC 27G .0205 Assessment and Treatment /Habilitation or Service Plan.** A copy of the Person Centered Plan or treatment plan should be available for review. The 5100 respite rules do not exempt facilities from the core rule requirements.

Construction: Locking Requirements for Level IV and PRTF

Locking Requirements for Level IV (10A NCAC 27G .1800) and PRTF (10A NACA 27G .1900) programs:

- **10A NCAC 27G .1800 (Level IV)** is required to be a “physically secured” facility. This requires meeting the NC State Building Code for Institutional-Unrestrained Occupancy—I-2 Occupancy—and must be locked per Section 1003.3.1.8 Exception #5. This allows doors to be locked as long as staff carries keys at all times.
- **10A NCAC 27G .1900 (PRTF)** is required to be “staff secured”. The provider may also decide to be “physically secured”. This building must also meet the NC State Building Code for Institutional-Unrestrained Occupancy—I-2 Occupancy—but they are allowed to be “staff secured”. If the provider chooses to be “physically secured”, they must meet the locking requirements of the Level IV building above. If the provider chooses to be “staff secured”, the building has the option of being locked as in the Level IV, or providing a lesser degree of security such as delayed egress, magnetic locking system or no locking system at all, simply “staff secured.”

Criminal Record Checks: Access to Records (created 2/18/2015)

The Division of Health Service Regulation (DHSR) recognizes a potential discrepancy between G.S. 122C-25 which states, in part, "...in the course of an inspection...representatives of the Secretary may review...the personnel records of those individuals employed by the licensable facility..." and G.S. 122C-80 which states, in part, that "...all criminal history information [regarding personnel] received by the provider is confidential and may not be disclosed, except to the applicant..."

For the reasons set out below, DHSR staff ***are authorized*** to review criminal history information for employees of the licensable facility:

Despite the language addressing the confidentiality of criminal history records contained in G.S. 122C-80, the statutes empowering the Secretary to perform the duties involved in licensing such facilities clearly anticipate access to such records. In general, G.S. 122C-23 states that the Secretary "shall issue a license if the Secretary finds that the person complies with this Article and the rules of the Commission and Secretary." In addition, G.S. 122C-24 states that the Secretary "may deny, suspend, amend or revoke a license in any case in which the Secretary finds that there has been substantial failure to comply with any provision of this Article or other applicable statutes or any applicable rule adopted pursuant to these statutes."

G.S. 122C-80 requires facilities to conduct criminal background checks on certain employees. Thus, in order to perform the functions of the statutes, the Department must have access to the criminal records history received by the facility in order to ensure at least two requirements of licensure 1) that the facility actually performed the check as required by law and 2) that the facility properly utilized the information obtained in making its decision to hire an employee with a criminal record.

The Department may access such records to comply with statutory licensure responsibilities so long as those reviewing the records do not further disclose the confidential information to any other party not legally entitled to such information. This interpretation is consistent with the State Bureau of Investigation's (SBI) interpretation on access to criminal record checks.

Day Treatment

1. Day Treatment in Public School Setting: Public Schools need to obtain a license to provide day treatment if the service is provided separately from DPI (Department of Public Instruction) educational services. Day treatment is billed separately. If a school expects to bill day treatment, they need a license.
2. Point of clarification: G.S. 122C-22(3) exempts state and federally operated “facilities” from licensure. Consultation with DHSR, DMH, and the AGs office agrees that this refers to state and federally operated **mental health facilities**. (Not any state or federally operated facility, such as the Department of Transportation)
3. Licensing Day Treatment in a Public School Setting: Public schools must designate a specific area (i.e. classrooms) where day treatment services will be provided. When a child leaves the designated area to attend other activities, they are no longer receiving Day Treatment services. The entire school setting should not be licensed.

Day Treatment for Children and Adolescents: Building Code Classifications

In response to inquiries concerning the building code requirements for day treatment programs for children and adolescents (10 NCAC 27G .1400) the construction section in coordination with the NC Department of Insurance has provided the information below.

Building Requirements:

- Located in a building that meets classification of Educational Occupancy under the North Carolina State Building Code (NCSBC).
 - NOTE: The current edition of the NCSBC has an alternative for this use allowing the building to meet I-4 – Child Day Care. This Building Code classification is more stringent and requires a higher degree of safety features (i.e. sprinkler features). It can be appropriate for this Licensure Program.
 - NOTE: There is an exception to the Educational Occupancy classification in the Building Code for Child Care Facilities that provide accommodations for eight or fewer persons with no more than five preschool aged children to be classified as R-3. The construction office does not allow this option based on the fact that the license for Day Programs notes “zero” as the licensed capacity. In addition DHSR cannot regulate that the capacity is held to a maximum of eight at all times.

Zoning Approval:

- The jurisdiction must allow for this Group E – Educational Occupancy use in the location of the building.

Death of a Licensee: Individual Licensed Facility

1. MHL receives information a Licensee has died.
2. Team Leader should contact management or staff at facility to:
 - Determine if clients are currently admitted to facility and being served
 - Determine who is currently in charge & managing daily operations
 - Determine plans for continued operation or closure
 - Determine who has legal rights to make decisions regarding licensure changes for this facility
 - Advise prospective new licensee of process for change of ownership
3. Items needed for Change of Ownership.
 - Change application
 - Proof of death
 - Proof of legal rights to take over ownership of facility:
 - Will
 - Executor of the estate sends letter indicating notice of Change of Ownership along with proof they are the legal Executor of the estate
 - Attorney's office sends letter with legal proof of rights

Facility Based Crisis & Non-Hospital Medical Detox

Current Licensure Options:

1. 10A NCAC 27G .5000: Facility Based Crisis for individuals of all disability groups
 - This is a stand alone facility licensed through DHSR.
 - The 23-hour observation chairs can be part of this service.
 - This is an I-2 (Institutional 2) building, and requires sprinklers and other building code requirements.
 - If the facility takes involuntary clients, it must be locked. Providers must comply with requirements in 10A NCAC 26C .0100 in order to request and be designated as a facility allowed to serve involuntary clients.
 - The facility does not have to be locked if it takes only voluntary clients.
 - A provider may offer detox services as part of their facility based services program. If they expect more than half of their program to be detox, and/or they market their program as offering non-hospital medical detox services, then they must have a .3100 license.
 - If a facility is licensed for non-hospital detox and facility based crisis, they may interchange the beds, but must be staffed at the higher level required.

2. 10A NCAC 27G .3100: Non-Hospital Medical Detox
 - This is a stand alone facility licensed through DHSR.
 - This is an I-2 (Institutional 2) building, and requires sprinklers and other building code requirements.
 - If the facility takes involuntary clients, it must be locked. Providers must comply with requirements in 10A NCAC 26C .0100 in order to request and be designated as a facility allowed to serve involuntary clients.
 - The facility is does not have to be locked if it takes only voluntary clients.
 - If the provider wishes to provide facility based crisis services, as well as non-hospital medical detox, they need to obtain a .5000 license.
 - If a facility is licensed for non-hospital detox and facility based crisis, they may interchange the beds, but must be staffed at the higher level required.

Fire and Disaster Drills: 10A NCAC 27G. 0207

NOTE: The procedures below are for state licensed facilities only; they do not apply to ICF/IID facilities. ICF/IID staff should adhere to the federal survey guidelines within CFR 483.470(i).

1. Fire and Disaster Plans

Written fire plans and area disaster plans approved by the local authority are required prior to initial licensure as outlined by 10A NCAC 27G .0207. The local authority is the local Emergency Management (EM) Office. For facilities trying to contact the "local authority," North Carolina's Division of Emergency Management has a list of phone numbers for each county's Emergency Management (EM) office on their web site. Their web site is www.ncem.org. Click the "counties" link on the left hand side of the page.

- NOTE: Although approval from the local authority is specified in rule, there are no guidelines for local EM offices to approve written fire and disaster plans however, local EM offices will review written fire and disaster plans. Therefore, initial surveyors should ensure written fire and disaster plans are reviewed by the local authority.

2. Fire Drills

Fire drills are to be conducted quarterly on each shift as stated in 10A NCAC 27G .0207 (c). Drills are to be conducted under conditions which simulate fire emergencies. This necessitates that the fire drills:

- Involve a complete evacuation of the building
- Occur quarterly on each shift.

3. Disaster Drills

Disaster drills are to be conducted quarterly on each shift as stated in 10A NCAC 27G .0207 (c). Disaster drills may be conducted on the same day provided it is clear they are two separate drills. In this case, documentation of the drills should clearly document both the Disaster and Fire.

Examples

Below are examples of possible "shift" scenarios for fire and disaster drills. Please note: these are only a few examples and are not all inclusive. Providers must ensure they are conducting and documenting drills per their shift schedule.

- If the provider reports they have one shift Monday through Friday, and one Saturday and Sunday, surveyors would expect to see two fire/disaster drills per quarter; one in the Mon-Fri time period and one in the Sat-Sun time period.
- If the provider reports they have live in staff and every two months they get a break for the weekend, surveyors would expect to see two fire/disaster drills per quarter; one during the live in shift time and one during the relief shift time.
- If the provider reports that they have three shifts per day, surveyors would expect to see three fire/disaster drills per quarter; one for each shifts time period.

Letters of Support

Overview

Revisions to North Carolina General Statute 122C-23.1 became effective August 13, 2005. This provision requires prospective providers of residential services to submit a letter of support from their Local Management Entity with their license application to the Division of Health Service Regulation. This letter must be from the LME in whose catchment area the facility is located.

The statute states, in part:

(5) That it is necessary to protect the general welfare and lives, health, and property of the people of the State for the local management entity (LME) to verify that additional beds are needed in the LME's catchment area before new residential treatment facilities are licensed. This process is established to ensure that unnecessary costs to the State do not result, residential treatment facility beds are available where needed, and that individuals who need care in residential treatment facilities may have access to quality care.

Applicable

- New licensure application for a residential facility
- Change in service code for an existing residential facility license to another residential service.
- Change of location of an existing residential license relocating **outside** of the county in which facility originally licensed.

Not Applicable

- Licensure application or change application for any non-residential facility (i.e., day treatment, outpatient, etc.)
- Change in ownership of an existing residential license
- Change in location of an existing residential license **within** the county in which facility originally licensed.
- Increase or decrease in capacity for a residential facility.

Medication Administration in Day Activities for Adults

The day activity service is designed to promote individual independence. Clients attend these programs from a variety of residential situations, including both supervised and independent living. During the initial licensure application process, the day activity licensee will be asked to identify their approach to medication administration.

Facility does administer, manage or store medications:

The facility will be responsible for the medication requirements outlined in **10A NCAC 27G .0209**.

Facility does NOT administer, manage or store medications:

The licensee will have policies and procedure in place to ensure the following:

1. Each client admitted to the program will have a self administration order on file at the day treatment program if they will be taking medications during the time spent at the day activity program.
2. Individual clients will be responsible for the storage and management of their medications.

Medication: Self Administration 10A NCAC 27G. 0209

The medication process provides opportunities for teaching and learning. Many people assume an individual with disabilities is totally dependent and has little to offer in the medication process. Although individuals will vary in their abilities to participate, they should be involved to the best of their ability as outlined in *Medication Administration, A Course for Unlicensed Personnel in Community Facilities* published by NC DHHS DMH/DD/SAS.

Self administration of medications should be based on an assessment of the client's ability. Self administration practices are individualized to meet the treatment needs of the client. This can range from the client assuming limited responsibility for their medications to being totally independent in administration, storage and re-filling of medications.

1. Physician's Order

A physician's order authorizing the client to self administer medications shall be maintained in the facility and available for review as required by 10A NCAC 27G .0209 (c) (2).

2. Maintaining a Medication Administration Record (MAR)

A current MAR with each medication transcribed correctly is required by 10A NCAC 27G .0209 (c) (4). Self administered individual doses are not required to be documented in rule; therefore, the facility can document "self administration" across the daily blocks usually used for staff initials.

Maintaining a current and accurate MAR provides the facility with a listing of all current medication orders and serves as a reference for staff to assist the client and assess the client's compliance with medications.

3. Medication Storage

10A NCAC 27G .0209 (e) (1) (A) requires medications to be stored in a securely locked manner. This requirement does not extend to medications self administered by clients. 10A NCAC 27G .0209(e)(1)(e) states medications shall be stored "...in a secure manner if approved by a physician for a client to self-medicate." Facility policy and the client's functioning level should dictate medication storage options. The medications may be maintained either in the facility medication storage area or in a secured location in the client's room. Clients may use medi-planners (or "pill boxes") to organize their medications. Clients must be independent in placing the medications into the medi-planner and the original packaging for the medications must be maintained in the facility for reference. Facility staff may not fill medi-planners as this would be considered dispensing.

4. Staff Training

Facility staff must have medication training to ensure clients are taking medications as ordered by the physician. 10A NCAC 27G .0209 (c) (3) requires that medications are administered only by trained staff. Staff are responsible for monitoring clients who self administer their medications. On-going assessment of the client's understanding of their medication needs and capabilities is critical to fostering independence and ensuring compliance with medications. Staff must have documentation of training to meet these needs as required in 10A NCAC 27G .0204 (c).

Medication: Use and Storage of Stock Prescription Medication

In programs such as Facility Based Crisis, a physician involved in the operation of the facility may obtain a DEA certification which permits the use and maintenance of stock prescription medications. There is no prohibition in the mental health licensure or pharmacy rules against maintaining stock prescription medications for administration to individual clients. One dose can be administered from a stock supply to an individual client by the facility staff when ordered by a physician².

10A NCAC 27G .0209 (a) Medication Requirements states:

(4) Other than for emergency use, facilities shall not possess a stock of prescription legend drugs for the purpose of dispensing without hiring a pharmacist and obtaining a permit from the NC Board of Pharmacy. Physicians may keep a small locked supply of prescription drug samples. Samples shall be dispensed, packaged and labeled in accordance with state law and this rule.

10A NCAC 27G .0103 General Definitions states:

(2) "Administering medication" means direct application of a drug to the body of a client by injection, inhalation, ingestion, or any other means.

The NC Board of Pharmacy defines dispensing in the NC Pharmacy Practice Act 90-85.3

(f) "Dispense" means preparing and packaging a prescription drug or device in a container and labeling the container with information required by State and federal law. Filling or refilling drug containers with prescription drugs for subsequent use by a patient is "dispensing". Providing quantities of unit dose prescription drugs for subsequent administration is "dispensing".

Pharmacy Rule 21 NCAC 46-1401 (b).

21 NCAC 46 .1401 REGISTRATION AND PERMITS

(a) Registration Required. All places providing services which embrace the practice of pharmacy shall register with the North Carolina Board of Pharmacy as provided in G.S. 90-85.21 and acquire a permit to do so. Application for such registration and permit shall be on forms provided by the Board. If the Board is satisfied that proper facilities and adequately trained and properly licensed personnel have been obtained which will assure compliance with all laws regulating the compounding and distribution of drugs, the practice of pharmacy and the rules of the Board, a permit shall be issued by the Board attesting such registration.

(b) Exemptions. Nothing in these rules shall be construed to require the registration with the Board of those health care facilities in which there occurs only the administration of drugs.

² This standard operating procedure was developed based upon consultation with the NC Board of Pharmacy Executive Director Jay Campbell in June 2013. For additional information regarding pharmacy regulations please visit: <http://www.ncbop.org/>

Psychiatric Residential Treatment Facility (PRTF): 10A NCAC 27G .1900 (revised 3/20/2015)

A PRTF is defined as a psychiatric residential treatment facility other than a hospital, which provides psychiatric services to individuals under age 21 in an inpatient setting. PRTFs are licensed by the state of North Carolina, but they must also adhere to certain federal requirements. In addition, if the PRTF is locked, they must follow the requirements for judicial review in NCGS 122C-224, which is copied at the end of this SOP.

Education and PRTFs

In August 2014, NCGS 122C 23.1(b) was adopted by the general assembly. It states PRTFs "... shall meet all the requirements of a qualified nonpublic school under Article 39 of Chapter 115C of the General Statutes and of a Nonpublic Exceptional Children's Program as defined in G.S. 122C-450(a)(2)." Following is information about the law and protocol to follow:

Educational Requirements of the PRTF:

All private psychiatric residential treatment facilities (PRTFs), including hospital based PRTFs are required to meet the requirements of a Nonpublic Exceptional Children's Program as defined in G.S. 122C-450(a)(2). Current PRTF providers must obtain approval by June 30, 2015. If they do not obtain approval in that time frame, we will communicate with DPI and review the license for appropriate action.

New PRTF providers are issued a 6-month license and must obtain approval as a Nonpublic Exceptional Children's Program within 6 months of the date of the initial license. If they have not received approval within the 6 months, we will communicate with DPI and review the license for appropriate action.

Federal Requirements of the PRTF:

1. Complete and send Attestation Statement to the State Medicaid Agency (SMA) yearly, by July 21. DMA sends to Acute and Home Care, and they enter the attestation into ASPEN. DMA provider services will send a reminder out on an annual basis in March.
2. Comply with the Condition of Participation on the use of restraint and seclusion (483.350 – 483.376): Orders, Monitoring, and Assessment regulations are more prescriptive than state licensure rule
3. Pursuant to 483.354 – a psychiatric residential treatment facility must meet requirements in 42 CFR Part 441 Subpart D – Inpatient Psychiatric Services for Individuals Under Age 21 in Psychiatric Facilities or Programs for requirements 441.151 through 441.182. These requirements are audited by DMA through the LME-MCO.
4. Report serious occurrences to the SMA and the State-designated P&A per 483.374 (b). Serious occurrences include a resident's death, serious injury to a resident, suicide attempt. Report all deaths to the CMS RO office as required in 483.374(c) by close of business the next day. Pursuant to the letter from DMA dated 6-21-13, the CMS address for death reporting is: NC_DeathReports@cms.hhs.gov
Reporting serious occurrences through the IRIS system will meet the requirement for reporting to the State Medicaid Agency. Providers must separately notify DRNC of serious occurrences, suicide attempts, and death.

Federal Requirements for review during survey process

483.374	<p>Attestation of facility compliance: Check to see if attestation is in place. Each facility must attest in writing that the facility is in compliance with CMS’ standards governing the use of restraint and seclusion. The attestation must be signed by the facility director. <i>In the event of changes of ownership a new director, the facility must re-attest. The attestation should include minimally:</i></p> <ul style="list-style-type: none"> a. Facility name and location b. Total number of facility beds c. Number of Medicaid residents in facility d. Number of residents for who the Psych under 21 is paid for by another state e. A Statement acknowledging the rights of the State Survey Agency ... f. A statement that the facility will submit a new attestation of compliance in the event that the facility director is no longer in such position. g. Name of individual and position of individual signing the attestation. h. The date that the attestation was signed.
483.358(c):	<p>Order for Seclusion or Restraint: Physician or other licensed practitioner orders restraint: This includes MD, Doctor of Osteopathy, Psychologist, Physician’s Assistant, or Family Nurse Practitioner</p>
483.358(d)	<p>Orders Received for Seclusion or Restraint: Verbal orders must be received by a registered nurse or other licensed staff (<i>i.e. licensed practical nurse</i>) while staff is <u>initiating the emergency safety intervention or immediately after safety situation ends.</u></p>
483.362	<p>Monitoring of the resident in and immediately after restraint. <i>Clinical staff trained in the use of emergency safety intervention must be physically present continually assessing and monitoring the physical and psychological well being of the resident and the safe use of restraint throughout the duration of the emergency safety intervention.</i></p>
483.358(f)	<p>Assessment post Seclusion or Restraint: Within 1 hour of the initiation of the emergency safety intervention a physician or other licensed practitioner must conduct a face to face assessment of the physical and psychological well being of the resident. This is limited to Medical Doctors, Doctor of Osteopathy, Physician Assistant, Family Nurse Practitioner, or Registered Nurse <i>trained in the use of emergency safety.</i> Assessment to include the residents: <i>physical and psychological status, behavior, appropriateness of the intervention measures and any complications resulting from the intervention.</i> The Registered Nurse was added as per DMH/DD/SAS Implementation Update #63, 11/2/2009. **Note a PHD Psychologist, or Psy. D cannot perform the 1-hour assessment.</p>
483.374(b)	<p>1) Reporting of serious occurrences: The facility must report to both the State Medicaid agency and the Protection and Advocacy system no later than close of business the next business day after each serious occurrence. Reportable serious occurrences include:</p> <ul style="list-style-type: none"> a. A resident’s death b. A serious injury to a resident as defined in (483.352) – <i>(Any significant impairment of the physical condition to the resident as determined by the qualified medical personnel. This includes, but is not limited to, burns lacerations, bone fractures, substantial hematoma, and injuries to internal organs, whether self inflicted or inflicted someone else.)</i>

	<p>c. A resident’s suicide attempt. ** Report to Protection and Advocacy system should include: name of resident, description of the occurrence and name, street address, and telephone of the facility.</p> <p>2) Staff must document that each serious occurrence was reported to both the state Medicaid agency and the state designated Protection and Advocacy system.</p> <p>3) Facilities must report the death of any resident to CMS regional office by no later than the close of business the next business day after the resident’s death.</p> <p>4) Staff must document in the resident’s record that the death was reported to the CMS office.</p>
483.376 (f)	<p>1. Training components (483.376 (a) (1) – (3)) are required on a semiannual basis. (Non-physical interventions and the use of physical restraints) *Training required annually in 10A NCAC 27E .0108(a)</p> <p>2. Training component (483.376 (b) is required on an annual basis. *Cardiopulmonary resuscitation required to be “current” in 10A NCAC 27G .0202(h)</p>

NC General Statute Requirements for review during survey process	
122C-224	<p>Judicial review of voluntary admission.</p> <p>1. When a minor is admitted to a 24-hour facility where the minor will be subjected to the same restrictions on his freedom of movement present in the State facilities for the mentally ill, or to similar restrictions, a hearing shall be held by the district court in the county in which the 24-hour facility is located within 15 days of the day that the minor is admitted to the facility. A continuance of not more than five days may be granted.</p> <p>2. Before the admission, the facility shall provide the minor and his legally responsible person with written information describing the procedures for court review of the admission and informing them about the discharge procedures. They shall also be informed that, after a written request for discharge, the facility may hold the minor for 72 hours during which time the facility may apply for a petition for involuntary commitment.</p> <p>3. Within 24 hours after admission, the facility shall notify the clerk of court in the county where the facility is located that the minor has been admitted and that a hearing for concurrence in the admission must be scheduled. At the time notice is given to schedule a hearing, the facility shall notify the clerk of the names and addresses of the legally responsible person and the responsible professional.</p> <p>4. When a minor is admitted to a 24-hour facility where the minor will be subjected to the same restrictions on his freedom of movement present in the State facilities for the mentally ill, or to similar restrictions, a hearing shall be held by the district court in the county in which the 24-hour facility is located within 15 days of the day that the minor is admitted to the facility. A continuance of not more than five days may be granted.</p>

Residential Facilities: .5600C Facilities Previously Licensed as DDA Homes.

House Bill 387 became effective June 15, 2001. As a result of this legislation, all group homes for developmentally disabled adults (DDA) previously licensed under G.S. 131D were required to be licensed pursuant to G.S. 122C. DDA licenses were transferred to .5600C licenses. When the change occurred, House Bill 387 allowed for certain DDA rules to remain in effect. Below are the rules that were grandfathered.

House Bill 387 states:

1. “ ... A group home for developmentally disabled adults licensed under Article 1 of Chapter 131D of the General Statutes and transferred to licensure under G.S. 122C-3(14) e. shall be deemed to have met the building code requirements for licensure as a supervised living facility...”
 - DDA rule 10A NCAC 13H .0604(g) states “the manager and family must have bedrooms separate from the residents...” Therefore providers and their family are able to live in the facility with the residents provided they have bedrooms separate from the residents.
 - DDA rule 10A NCAC 13H .1301(c) states “the total number of residents assigned to a room shall not exceed the number authorized for that particular room.” Therefore there can be more than 2 clients in a bedroom provided spatial requirements are met.
2. “... Supervised living facility for developmentally disabled adults’ means a residential facility, as defined in G.S. 122C-3(14), which has two to nine developmentally disabled adult residents...”
 - These homes can have greater than 6 (but no more than 9) clients in the facility. Their license would indicate the licensed capacity.

Residential Facilities: .5600 Facilities

Frequently Asked Questions:

- Can staff live in a 5600A, B, C, D, E?
 - There is nothing in rule stating a staff cannot live in these facilities. These facilities are required, per construction, to be single family dwellings; therefore, the licensee/provider cannot live in one section of the house and have another section for the licensed facility. This would be considered a multi-family dwelling.
- When should there be more than one staff?
 - Additional staff may be needed in order for staff “to respond to individualized client needs.” (.5602a)
- What is the composition of a treatment team?
 - There is nothing in rule that identifies the composition of the treatment team. The treatment plan includes client outcomes and strategies to achieve those expectations.
- What is required for unsupervised time?
 - The rule states that a client cannot have unsupervised time unless the treatment plan documents that the client is capable of remaining in the home or community unsupervised. Therefore, because the treatment plan is expected to identify client outcomes and strategies to achieve those outcomes, the unsupervised time should be related to the expected client outcomes.
 - The rule requires a minimum of an annual review to ensure the client continues to be capable of unsupervised time, therefore simply a doctor’s note without any indication of a review of the client’s behavior is not sufficient. .

10A NCAC 27G .5600(c)(6) – 5600F (AFL)

Facilities licensed as a 5600F (or AFL) are “... in a private residence, which serves no more than three adult clients whose primary diagnoses is mental illness but may also have other disabilities, or three adult clients or three minor clients whose primary diagnoses is developmental disabilities but may also have other disabilities who live with a family and the family provides the service... This facility shall also be known as alternative family living or assisted family living (AFL).”

- AFL Exemptions³
 - These facilities are exempt from the following rule areas:
10A NCAC 27G .0201 (a)(1)(2),(3),(4),(5)(A)&(B); (6); (7)(A),(B),(E),(F),(G),(H); (8); (11); (13); (15); (16); (18) and (b); 10A NCAC 27G .0202(a),(d),(g)(1)(i); 10A NCAC 27G .0203; 10A NCAC 27G .0205 (a),(b); 10A NCAC 27G .0207 (b),(c); 10A NCAC 27G .0208 (b),(e); 10A NCAC 27G .0209[(c)(1) – non-prescription medications only] (d)(2),(4); (e)(1)(A),(D),(E);(f);(g); and 10A NCAC 27G .0304 (b)(2),(d)(4).
 - Exemption from Assessment -10A NCAC 27G .0205(a)(b): AFLs are exempt from assessment.
 - Exemption from Qualified Professional (QP)/Associate Professional (AP) competency -10A NCAC 27G .0203: Although AFLs are exempt from the Competency rule regarding QPs and APs, they are not exempt from 10A NCAC 27G .0204—Competencies and Supervision of paraprofessionals. This rule requires that paraprofessionals must be supervised by an AP or a QP, therefore a AFL is expected to have an AP or QP for supervision. If there is non-compliance related to a lack of clinical intervention by a QP or AP or demonstrated QP/AP incompetence, this would be cited in the specific rule area of the failure.
- Indoor Space Requirements; 27G .0304(d)

³ See appendix B for full text of all exempt rules.
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- These rules apply to clients only. Since an AFL is a private residence, questions often arise as to whether or not the requirements for bedrooms and other indoor space requirements apply to all living in the home. The rules apply to client space only; therefore the rules regarding the amount of space do not apply for any member of the family living in the private residence.

Smoking Prohibitions: G.S. 122C-6

1. Signs

Facilities shall conspicuously post signs clearly stating that smoking is prohibited inside the facility. The signs may include the international 'No Smoking' symbol, which consists of a pictorial representation of a burning cigarette enclosed in a red circle with a red bar across it as outlined in G.S 122C-6 (b) (1).

2. Smoking Areas

Facilities shall direct any person who is smoking inside the facility to extinguish the lighted smoking product (Note: G.S. 122C-6 (a) defines 'inside' as "a fully enclosed area".) A DHSR Mental Health Licensure and Certification memorandum to mental health providers dated September 21, 2007 and a DHSR Public notice – Regarding Resident Safety dated March 23, 2007 explained that open and screened in porches would not be considered fully enclosed areas. A "fully enclosed area" would include an area containing a roof, walls and one or more doors. Enclosed sheds, garages or outbuildings on the facility property are included under the general statute. In addition, the term "facility" does not include the entire building but only the part of the building that is licensed under G.S. 122C. Non-licensed areas such as separate apartments, independent living, etc., would not be affected by this law.

3. Written Notice

Facilities shall provide written notice to individuals upon admittance that smoking is prohibited inside the facility and obtain the signature of the individual or the individual's representative acknowledging receipt of the notice as outlined in G.S 122C-6 (b) (2).

Determining the amount of the penalty.

G.S. 122C-6(c) states: "The Department may impose an administrative penalty not to exceed two hundred dollars (\$200.00) for **each** violation on any person who owns, manages, operates, or otherwise controls a facility and fails to comply with subsection (b) of this section..." (emphasis added) Therefore, facilities are fined for each violation of one of the items listed in subsection (b). In keeping with internal policies, MH Branch fines are \$100.00 per violation, ICF/MR Branch fines are \$200.00 per violation. See table below. Each "YES" = separate fine.

Were required signs posted?	YES	NO
Was there any evidence of smoking within the facility?	YES	NO
Was written notice provided upon admission? ⁴	YES	NO

⁴ For clients admitted after August 1, 2007.
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Substance Abuse: .4100, .5600E & .3600 Programs

.4100: Therapeutic Homes for Individuals with Substance Abuse Disorders and Their Children

- Capacity: Children are not considered part of capacity. However, as per .4104, bedrooms must be 80 sq. ft. for children over age six and for clients, must have 60 sq. ft. for pre-school age children, and 40 sq. ft. for infants and toddlers.
- These facilities often have many units and/or cottages. This is the way they were designed. We do not expect staff to be in each cottage. Staff are often in a central apartment.
- Treatment plans for children: These are not always required. The rules specify substance abuse prevention for children, but the child is expected to receive “age appropriate therapeutic services” as appropriate to his or her needs.

.5600E: Halfway House for Adults with Substance Abuse Problems

- Capacity: These homes are allowed to be licensed for greater than 6 individuals.

.3600: Outpatient Opioid Treatment

1. DMH/DD/SAS Contact for .3600 – Outpatient Narcotic Addiction Treatment:
Spencer Clark: Spencer.Clark@dhhs.nc.gov
2. DMH/DD/SAS designee role:
 - Routine site visits.
 - Quarterly meetings with all methadone clinic directors
 - Approves new licensure of .3600’s, as per 10A NCAC 27G.3604(d)⁵
3. DHSR/DMH/DD/SAS Collaboration
 - DHSR will forward statements of deficiencies resulting from Outpatient Opioid program surveys to designated DMH/DD/SAS staff
 - DHSR will contact DMH/DD/SAS with non- rule based issues arising during survey or complaints regarding Outpatient Opioid programs that are not relevant to state licensure rules.
 - DHSR staff and DMH/DD/SAS will coordinate any joint surveys or investigations as necessary.

⁵ 10A NCAC 27G.3604(d): Compliance With State Authority Regulations. Each facility shall be approved by the North Carolina State Authority for Opioid Treatment, DMH/DD/SAS, which is the person designated by the Secretary of Health and Human Services to exercise the responsibility and authority within the state for governing the treatment of addiction with an opioid drug, including program approval, for monitoring compliance with the regulations related to scope, staff, and operations, and for monitoring compliance with Section 1923 of P.L. 102-321. The referenced material may be obtained from the Substance Abuse Services Section of DMH/DD/SAS.

Appendix A: Acronym List

Acronym	Definition
ACO	ASPEN Central Office
ACTS	ASPEN Complaint Tracking System
ADVP	Adult Developmental & Vocational Program
AFL	Alternate Family Living
AG	Attorney General
AP	Associate Professional
BPAS	Business Process Automated System
CHOW	Change of Ownership
CIU	Complaint Intake Unit
CMHC	Community Mental Health Centers
CON	Certificate of Need
COP	Condition of Participation
DFS	Division of Facility Services
DHHS	Department of Health and Human Services
DHSR	Division of Health Service Regulation
DIL	Denial of Initial Licensure
DMA	Division of Medical Assistance
DMH	Division of Mental Health
DSS	Department of Social Services
FID	Facility Identification Number
HCPR	Health Care Personnel Registry
ICF/IID	Intermediate Care Facility for Individuals with Intellectual Disabilities
ICR	Informal Conference Response
ITO	Isolation/ Time Out
ITR	Intent to Revoke
LME	Local Management Entity
LP	Licensed Professional
LSC	Life Safety Code
MAR	Medication Administration Record
MFF	Master Facility File
MH/DD/SAS	Mental Health/Developmental Disability/Substance Abuse Services
MHL	Mental Health Licensure
MHL&C	Mental Health Licensure and Certification
MR	Mentally Retarded
MTD	Motion to Dismiss
NCAC	North Carolina Administrative Code
NCGS	North Carolina General Statutes
NIB	Non Imposed B
NOR	Notice of Revocation
OAH	Office of Administrative Hearings
PHS	Pre Hearing Statement
POC	Plan of Correction
POD	Principles of Documentation

POP	Plan of Protection
PRTF	Psychiatric Residential Treatment Facility
PSR	Psychosocial Rehab
QA	Quality Assurance
QMRP	Qualified Mental Retardation Professional
QP	Qualified Professional
RIE	Revocation In Effect
SA	Special Assistance
SACOT	Substance Abuse Comprehensive Outpatient Treatment
SAIOP	Substance Abuse Intensive Outpatient Program
SOA	Suspension of Admissions
SOD	Statement of Deficiencies
SOP	Standard Operating Procedure
SS	Summary Suspension
TBI	Traumatic Brain Injury
TILP	Training in Lieu of Penalty
TRO	Temporary Restraining Order

Appendix B: 10A NCAC 27G .5600F – Rule Exemptions

Facilities licensed as a 5600F (or AFL) are “... in a private residence, which serves no more than three adult clients whose primary diagnoses is mental illness but may also have other disabilities, or three adult clients or three minor clients whose primary diagnoses is developmental disabilities but may also have other disabilities who live with a family and the family provides the service... This facility shall also be known as alternative family living or assisted family living (AFL).”

These facilities are exempt from the following rule areas: 10A NCAC 27G .0201 (a)(1)(2),(3),(4),(5)(A)&(B); (6); (7)(A),(B),(E),(F),(G),(H); (8); (11); (13); (15); (16); (18) and (b); 10A NCAC 27G .0202(a),(d),(g)(1)(i); 10A NCAC 27G .0203; 10A NCAC 27G .0205 (a),(b); 10A NCAC 27G .0207 (b),(c); 10A NCAC 27G .0208 (b),(e); 10A NCAC 27G .0209[(c)(1) – non-prescription medications only] (d)(2),(4); (e)(1)(A),(D),(E);(f);(g); and 10A NCAC 27G .0304 (b)(2),(d)(4).

Below is the full text of the rule areas listed above. Facilities licensed as a .5600F (or AFL) are exempt from the rules areas highlighted in yellow. They must remain in compliance with all other rules.

10A NCAC 27G .0201 GOVERNING BODY POLICIES

(a) The governing body responsible for each facility or service shall develop and implement written policies for the following:

- (1) delegation of management authority for the operation of the facility and services;
- (2) criteria for admission;
- (3) criteria for discharge;
- (4) admission assessments, including:
 - (A) who will perform the assessment; and
 - (B) time frames for completing assessment.
- (5) client record management, including:
 - (A) persons authorized to document;
 - (B) transporting records;
 - (C) safeguard of records against loss, tampering, defacement or use by unauthorized persons;
 - (D) assurance of record accessibility to authorized users at all times; and
 - (E) assurance of confidentiality of records.
- (6) screenings, which shall include:
 - (A) an assessment of the individual's presenting problem or need;
 - (B) an assessment of whether or not the facility can provide services to address the individual's needs; and
 - (C) the disposition, including referrals and recommendations;
- (7) quality assurance and quality improvement activities, including:
 - (A) composition and activities of a quality assurance and quality improvement committee;
 - (B) written quality assurance and quality improvement plan;
 - (C) methods for monitoring and evaluating the quality and appropriateness of client care, including delineation of client outcomes and utilization of services;
 - (D) professional or clinical supervision, including a requirement that staff who are not qualified professionals and provide direct client services shall be supervised by a qualified professional in that area of service;
 - (E) strategies for improving client care;
 - (F) review of staff qualifications and a determination made to grant treatment/habilitation privileges;
 - (G) review of all fatalities of active clients who were being served in area-operated or contracted residential programs at the time of death;

- (H) adoption of standards that assure operational and programmatic performance meeting applicable standards of practice. For this purpose, "applicable standards of practice" means a level of competence established with reference to the prevailing and accepted methods, and the degree of knowledge, skill and care exercised by other practitioners in the field;
 - (8) use of medications by clients in accordance with the rules in this Section;
 - (9) reporting of any incident, unusual occurrence or medication error;
 - (10) voluntary non-compensated work performed by a client;
 - (11) client fee assessment and collection practices;
 - (12) medical preparedness plan to be utilized in a medical emergency;
 - (13) authorization for and follow up of lab tests;
 - (14) transportation, including the accessibility of emergency information for a client;
 - (15) services of volunteers, including supervision and requirements for maintaining client confidentiality;
 - (16) areas in which staff, including nonprofessional staff, receive training and continuing education;
 - (17) safety precautions and requirements for facility areas including special client activity areas; and
 - (18) client grievance policy, including procedures for review and disposition of client grievances.
- (b) Minutes of the governing body shall be permanently maintained.

History Note: Authority G.S. 122C-26; 143B-147;
Eff. May 1, 1996.

10A NCAC 27G .0202 PERSONNEL REQUIREMENTS

- (a) All facilities shall have a written job description for the director and each staff position which:
- (1) specifies the minimum level of education, competency, work experience and other qualifications for the position;
 - (2) specifies the duties and responsibilities of the position;
 - (3) is signed by the staff member and the supervisor; and
 - (4) is retained in the staff member's file.
- (b) All facilities shall ensure that the director, each staff member or any other person who provides care or services to clients on behalf of the facility:
- (1) is at least 18 years of age;
 - (2) is able to read, write, understand and follow directions;
 - (3) meets the minimum level of education, competency, work experience, skills and other qualifications for the position; and
 - (4) has no substantiated findings of abuse or neglect listed on the North Carolina Health Care Personnel Registry.
- (c) All facilities or services shall require that all applicants for employment disclose any criminal conviction. The impact of this information on a decision regarding employment shall be based upon the offense in relationship to the job for which the applicant is applying.
- (d) Staff of a facility or a service shall be currently licensed, registered or certified in accordance with applicable state laws for the services provided.
- (e) A file shall be maintained for each individual employee indicating the training, experience and other qualifications for the position, including verification of licensure, registration or certification.
- (f) Continuing education shall be documented.
- (g) Employee training programs shall be provided and, at a minimum, shall consist of the following:
- (1) general organizational orientation;
 - (2) training on client rights and confidentiality as delineated in 10A NCAC 27C, 27D, 27E, 27F and 10A NCAC 26B;
 - (3) training to meet the mh/dd/sa needs of the client as specified in the treatment/habilitation plan; and
 - (4) training in infectious diseases and bloodborne pathogens.

(h) Except as permitted under 10a NCAC 27G .5602(b) of this Subchapter, at least one staff member shall be available in the facility at all times when a client is present. That staff member shall be trained in basic first aid including seizure management, currently trained to provide cardiopulmonary resuscitation and trained in the Heimlich maneuver or other first aid techniques such as those provided by Red Cross, the American Heart Association or their equivalence for relieving airway obstruction.

(i) The governing body shall develop and implement policies and procedures for identifying, reporting, investigating and controlling infectious and communicable diseases of personnel and clients.

History Note: Authority G.S. 122C-26;
Eff. May 1, 1996;
Temporary Amendment Eff. January 3, 2001;
Temporary Amendment Expired October 13, 2001;
Temporary Amendment Eff. November 1, 2001;
Amended Eff. April 1, 2003.

10A NCAC 27G .0203 COMPETENCIES OF QUALIFIED PROFESSIONALS AND ASSOCIATE PROFESSIONALS

(a) There shall be no privileging requirements for qualified professionals or associate professionals.

(b) Qualified professionals and associate professionals shall demonstrate knowledge, skills and abilities required by the population served.

(c) At such time as a competency-based employment system is established by rulemaking, then qualified professionals and associate professionals shall demonstrate competence.

(d) Competence shall be demonstrated by exhibiting core skills including:

- (1) technical knowledge;
- (2) cultural awareness;
- (3) analytical skills;
- (4) decision-making;
- (5) interpersonal skills;
- (6) communication skills; and
- (7) clinical skills.

(e) Qualified professionals as specified in 10A NCAC 27G .0104 (18)(a) are deemed to have met the requirements of the competency-based employment system in the State Plan for MH/DD/SAS.

(f) The governing body for each facility shall develop and implement policies and procedures for the initiation of an individualized supervision plan upon hiring each associate professional.

(g) The associate professional shall be supervised by a qualified professional with the population served for the period of time as specified in Rule .0104 of this Subchapter.

History Note: Authority G.S. 122C-26;
Temporary Adoption Eff. January 1, 2001;
Temporary Adoption Expired October 13, 2001;
Temporary Adoption Eff. November 1, 2001;
Eff. April 1, 2003.

10A NCAC 27G .0205 ASSESSMENT AND TREATMENT/HABILITATION OR SERVICE PLAN

(a) An assessment shall be completed for a client, according to governing body policy, prior to the delivery of services, and shall include, but not be limited to:

- (1) the client's presenting problem;
- (2) the client's needs and strengths;
- (3) a provisional or admitting diagnosis with an established diagnosis determined within 30 days of admission, except that a client admitted to a detoxification or other 24-hour medical program shall have an established diagnosis upon admission;
- (4) a pertinent social, family, and medical history; and
- (5) evaluations or assessments, such as psychiatric, substance abuse, medical, and vocational, as appropriate to the client's needs.

(b) When services are provided prior to the establishment and implementation of the treatment/habilitation or service plan, hereafter referred to as the "plan," strategies to address the client's presenting problem shall be documented.

(c) The plan shall be developed based on the assessment, and in partnership with the client or legally responsible person or both, within 30 days of admission for clients who are expected to receive services beyond 30 days.

(d) The plan shall include:

- (1) client outcome(s) that are anticipated to be achieved by provision of the service and a projected date of achievement;
- (2) strategies;
- (3) staff responsible;
- (4) a schedule for review of the plan at least annually in consultation with the client or legally responsible person or both;
- (5) basis for evaluation or assessment of outcome achievement; and
- (6) written consent or agreement by the client or responsible party, or a written statement by the provider stating why such consent could not be obtained.

History Note: Authority G.S. 122C-26; 130A-144; 130A-152; 143B-147;
Eff. May 1, 1996;
Recodified from 10 NCAC 14V .0203 to 10 NCAC 14V .0205 Eff. January 3, 2001.

10A NCAC 27G .0207 EMERGENCY PLANS AND SUPPLIES

(a) A written fire plan for each facility and area-wide disaster plan shall be developed and shall be approved by the appropriate local authority.

(b) The plan shall be made available to all staff and evacuation procedures and routes shall be posted in the facility.

(c) Fire and disaster drills in a 24-hour facility shall be held at least quarterly and shall be repeated for each shift. Drills shall be conducted under conditions that simulate fire emergencies.

(d) Each facility shall have basic first aid supplies accessible for use.

History Note: Authority G.S. 122C-26; 143B-147;
Eff. May 1, 1996;
Recodified from 10 NCAC 14V .0205 to 10 NCAC 14V .0207 Eff. January 3, 2001.

10A NCAC 27G .0208 CLIENT SERVICES

(a) Facilities that provide activities for clients shall assure that:

- (1) space and supervision is provided to ensure the safety and welfare of the clients;
- (2) activities are suitable for the ages, interests, and treatment/habilitation needs of the clients served; and
- (3) clients participate in planning or determining activities.

(b) Facilities or programs designated or described in these Rules as "24-hour" shall make services available 24 hours a day, every day in the year, unless otherwise specified in the rule.

(c) Facilities that serve or prepare meals for clients shall ensure that the meals are nutritious.

(d) When clients who have a physical handicap are transported, the vehicle shall be equipped with secure adaptive equipment.

(e) When two or more preschool children who require special assistance with boarding or riding in a vehicle are transported in the same vehicle, there shall be one adult, other than the driver, to assist in supervision of the children.

History Note: Authority G.S. 122C-26; 122C-112; 122C-146; 130A-361; 143B-147;
Eff. May 1, 1996;
Recodified from 10 NCAC 14V .0206 to 10 NCAC 14V .0208 Eff. January 3, 2001;
Temporary Amendment Eff. January 3, 2001;
Amended Eff. August 1, 2002.

10A NCAC 27G .0209 MEDICATION REQUIREMENTS

(a) Medication dispensing:

- (1) Medications shall be dispensed only on the written order of a physician or other practitioner licensed to prescribe.
- (2) Dispensing shall be restricted to registered pharmacists, physicians, or other health care practitioners authorized by law and registered with the North Carolina Board of Pharmacy. If a permit to operate a pharmacy is not required, a nurse or other designated person may assist a physician or other health care practitioner with dispensing so long as the final label, container, and its contents are physically checked and approved by the authorized person prior to dispensing.
- (3) Methadone for take-home purposes may be supplied to a client of a methadone treatment service in a properly labeled container by a registered nurse employed by the service, pursuant to the requirements of 10A NCAC 26E .0306 SUPPLYING OF METHADONE IN TREATMENT PROGRAMS BY RN. Supplying of methadone is not considered dispensing.
- (4) Other than for emergency use, facilities shall not possess a stock of prescription legend drugs for the purpose of dispensing without hiring a pharmacist and obtaining a permit from the NC Board of Pharmacy. Physicians may keep a small locked supply of prescription drug samples. Samples shall be dispensed, packaged, and labeled in accordance with state law and this Rule.

(b) Medication packaging and labeling:

- (1) Non-prescription drug containers not dispensed by a pharmacist shall retain the manufacturer's label with expiration dates clearly visible;
- (2) Prescription medications, whether purchased or obtained as samples, shall be dispensed in tamper-resistant packaging that will minimize the risk of accidental ingestion by children. Such packaging includes plastic or glass bottles/vials with tamper-resistant caps, or in the case of unit-of-use packaged drugs, a zip-lock plastic bag may be adequate;
- (3) The packaging label of each prescription drug dispensed must include the following:
 - (A) the client's name;
 - (B) the prescriber's name;
 - (C) the current dispensing date;
 - (D) clear directions for self-administration;
 - (E) the name, strength, quantity, and expiration date of the prescribed drug; and
 - (F) the name, address, and phone number of the pharmacy or dispensing location (e.g., mh/dd/sa center), and the name of the dispensing practitioner.

(c) Medication administration:

- (1) Prescription or non-prescription drugs shall only be administered to a client on the written order of a person authorized by law to prescribe drugs. **EXEMPTION APPLIES TO NON-PRESCRIPTION MEDICATIONS ONLY**
- (2) Medications shall be self-administered by clients only when authorized in writing by the client's physician.
- (3) Medications, including injections, shall be administered only by licensed persons, or by unlicensed persons trained by a registered nurse, pharmacist or other legally qualified person and privileged to prepare and administer medications.
- (4) A Medication Administration Record (MAR) of all drugs administered to each client must be kept current. Medications administered shall be recorded immediately after administration. The MAR is to include the following:
 - (A) client's name;
 - (B) name, strength, and quantity of the drug;
 - (C) instructions for administering the drug;
 - (D) date and time the drug is administered; and
 - (E) name or initials of person administering the drug.
- (5) Client requests for medication changes or checks shall be recorded and kept with the MAR file followed up by appointment or consultation with a physician.

(d) Medication disposal:

- (1) All prescription and non-prescription medication shall be disposed of in a manner that guards against diversion or accidental ingestion.

(2) Non-controlled substances shall be disposed of by incineration, flushing into septic or sewer system, or by transfer to a local pharmacy for destruction. A record of the medication disposal shall be maintained by the program. Documentation shall specify the client's name, medication name, strength, quantity, disposal date and method, the signature of the person disposing of medication, and the person witnessing destruction.

(3) Controlled substances shall be disposed of in accordance with the North Carolina Controlled Substances Act, G.S. 90, Article 5, including any subsequent amendments.

(4) Upon discharge of a patient or resident, the remainder of his or her drug supply shall be disposed of promptly unless it is reasonably expected that the patient or resident shall return to the facility and in such case, the remaining drug supply shall not be held for more than 30 calendar days after the date of discharge.

(e) Medication Storage:

(1) All medication shall be stored:

(A) in a securely locked cabinet in a clean, well-lighted, ventilated room between 59° and 86° F.;

(B) in a refrigerator, if required, between 36° and 46° F. If the refrigerator is used for food items, medications shall be kept in a separate, locked compartment or container;

(C) separately for each client;

(D) separately for external and internal use;

(E) in a secure manner if approved by a physician for a client to self-medicate.

(2) Each facility that maintains stocks of controlled substances shall be currently registered under the North Carolina Controlled Substances Act and shall be in compliance with the North Carolina Controlled Substances Act, G.S. 90, Article 5, including any subsequent amendments.

(f) Medication review:

(1) If the client receives psychotropic drugs, the governing body or operator shall be responsible for obtaining a review of each client's drug regimen at least every six months. The review shall be to be performed by a pharmacist or physician. The on-site manager shall assure that the client's physician is informed of the results of the review when medical intervention is indicated.

(2) The findings of the drug regimen review shall be recorded in the client record along with corrective action, if applicable.

(g) Medication education:

(1) Each client started or maintained on a medication by an area program physician shall receive either oral or written education regarding the prescribed medication by the physician or their designee. In instances where the ability of the client to understand the education is questionable, a responsible person shall be provided either oral or written instructions on behalf of the client.

(2) The medication education provided shall be sufficient to enable the client or other responsible person to make an informed consent, to safely administer the medication and to encourage compliance with the prescribed regimen.

(3) The area program physician or designee shall document in the client record that education for the prescribed psychotropic medication was offered and either provided or declined. If provided, it shall be documented in what manner it was provided (either orally or written or both) and to whom (client or responsible person).

(h) Medication errors. Drug administration errors and significant adverse drug reactions shall be reported immediately to a physician or pharmacist. An entry of the drug administered and the drug reaction shall be properly recorded in the drug record. A client's refusal of a drug shall be charted.

History Note: Authority G.S. 90-21.5; 90-171.20(7),(8); 90-171.44; 122C-26; 143B-147;
Eff. May 1, 1996;
Recodified from 10 NCAC 14V .0207 to 10 NCAC 14V .0209 Eff. January 3, 2001.

10A NCAC 27G .0304 FACILITY DESIGN AND EQUIPMENT

(a) Privacy: Facilities shall be designed and constructed in a manner that will provide clients privacy while bathing, dressing or using toilet facilities.

(b) Safety: Each facility shall be designed, constructed and equipped in a manner that ensures the physical safety of clients, staff and visitors.

(1) All hallways, doorways, entrances, ramps, steps and corridors shall be kept clear and unobstructed at all times.

(2) All mattresses purchased for existing or new facilities shall be fire retardant.

(3) Electrical, mechanical and water systems shall be maintained in operating condition.

(4) In areas of the facility where clients are exposed to hot water, the temperature of the water shall be maintained between 100-116 degrees Fahrenheit.

(5) All indoor areas to which clients have routine access shall be well-lighted. Lighting shall be adequate to permit occupants to comfortably engage in normal and appropriate daily activities such as reading, writing, working, sewing and grooming.

(c) Comfort Zone: Each 24-hour facility shall provide heating and air-cooling equipment to maintain a comfort range between 68 and 80 degrees Fahrenheit.

(1) This requirement shall not apply to therapeutic (habilitative) camps and other 24-hour facilities for six or fewer clients.

(2) Facilities licensed prior to October 1, 1988 shall not be required to add or install cooling equipment if not already installed.

(d) Indoor space requirements: Facilities licensed prior to October 1, 1988 shall satisfy the minimum square footage requirements in effect at that time. Unless otherwise provided in these Rules, residential facilities licensed after October 1, 1988 shall meet the following indoor space requirements:

(1) Client bedrooms shall have at least 100 square feet for single occupancy and 160 square feet when two clients occupy the bedroom.

(2) Where bassinets and portable cribs for infants are used, a minimum of 40 square feet per bassinet or portable crib shall be provided.

(3) No more than two clients may share an individual bedroom regardless of bedroom size.

(4) In facilities with overnight accommodations for persons other than clients, such accommodations shall be separate from client bedrooms.

(5) No client shall be permitted to sleep in an unfinished basement or in an attic.

(6) In a residential facility licensed under residential building code standards and without elevators, bedrooms above or below the ground level shall be used only for individuals who are capable of moving up and down the steps independently.

(7) Minimum furnishings for client bedrooms shall include a separate bed, bedding, pillow, bedside table, and storage for personal belongings for each client.

(8) Only clients of the same sex may share a bedroom except for children age six or below, and married couples.

(9) Children and adolescents shall not share a bedroom with an adult.

(10) At least one full bathroom for each five or fewer persons including staff of the facility and their family shall be included in each facility.

(11) Each facility, except for a private home provider, shall have a reception area for clients and visitors and private space for interviews and conferences with clients.

(12) The area in which therapeutic and habilitative activities are routinely conducted shall be separate from sleeping areas.

(e) Where strict conformance with current requirements would be impractical, or because of extraordinary circumstances, new programs, or unusual conditions, DFS may approve alternate methods, procedures, design criteria and functional variations from the physical plant requirements when the facility can effectively demonstrate to DFS's satisfaction that the:

(1) intent of the physical plant requirements are met; and

(2) variation does not reduce the safety or operational effectiveness of the facility.

Eff. May 1, 1996;
Temporary Amendment Eff. January 3, 2001;
Amended Eff. August 1, 2002.

Appendix C: Building Code Zoning Classifications - Requirements for Licensure Categories

Program Code 10 NCAC 27G	Facility Type	Residential/ Institutional 24 hour programs	Building Classification	Code
.1100	Partial Hospitalization for individuals who are acutely mentally ill	No	Group B – Business Occupancy (Adults) Group E – Educational or I4 (Minors)	a
.1200	Psychosocial Rehab for individuals with Severe and Persistent Mental Illness	No	Group B – Business Occupancy	a
.1300	Residential Treatment for Children or Adolescents	Yes	Residential – Classification dependent on number & ambulation status	b
.1400	Day Treatment for Children and Adolescents with Emotional or Behavioral Disturbances	No	Group E – Educational Occupancy or I-4	a
.1700	Residential Treatment Staff Secure for Children or Adolescents	Yes	Residential – Classification dependent on number & ambulation status	d
.1800	Intensive Residential Treatment for Children or Adolescents	Yes	Institutional Occupancy	e
.1900	Psychiatric Residential Treatment for Children and Adolescents	Yes	Institutional Occupancy	f
.2100	Specialized Community Residential Centers for Individuals with Developmental Disabilities	Yes	Residential or Institutional Occupancy	g
.2200	Before/After School and Summer Developmental Day Services for Children with or at Risk for Developmental Delays, Developmental Disabilities, or Atypical Development	No	Group E- Educational or I-4	a
.2300	Adult Developmental and Vocational Program for Individuals with Developmental Disabilities	No	Group B- Business Occupancy	a
.2400	Developmental Day Services for Children with or at Risk for Developmental Delays, Developmental Disabilities or Atypical Development	No	Group E- Educational or I-4	a
.3100	Nonhospital Medical Detoxification for Individuals who are Substance Abusers	Yes	Institutional Occupancy	h
.3200	Social Setting Detoxification for Substance Abusers	Yes	Residential or Institutional Occupancy	i
.3300	Outpatient Detoxification for Substance Abuse	No	Group B – Business Occupancy	a
.3400	Residential Treatment/Rehabilitation for Individuals with Substance Abuse Disorders	Yes	Residential or Institutional Occupancy	i
.3500	Outpatient Facilities for Individuals with Substance Abuse Disorders	No	Group B- Business Occupancy	a
.3600	Outpatient Opioid Treatment	No	Group B- Business Occupancy	a
.3700	Day Treatment Facilities for Individuals with Substance Abuse Disorders	No	Group B- Business Occupancy Group E – Educational or I4 (Minors)	a
.4100	Residential Recovery Programs for Individuals with Substance Abuse Disorders and their Children	Yes	Typically Group R – Residential	j
.4300	Therapeutic Community	Yes	Typically Group R –	k

			Residential	
.4400	Substance Abuse Intensive Outpatient Program (SAIOP)	No	Group B – Business Occupancy (Adults) Group E – Educational or I4 (minors)	a
.4500	Substance Abuse Comprehensive Outpatient Treatment Program (SACOT)	No	Group B- Business Occupancy	a
.5000	Facility Based Crisis Services for Individuals of All Disability Groups	Yes	Institutional Occupancy	l
.5100	Community Respite Services for Individuals of All Disability Groups	Yes	Typically Residential depending on number of residents	m
.5200	Residential Therapeutic (Habilitative) Camps for Children and Adolescents of All Disability Groups	Yes	Wilderness Camp Settings	p
.5400	Day Activity For Individuals of All Disability Groups	No	Group B- Business Occupancy Group E – Educational or I4 (Minors)	a
.5500	Sheltered Workshops For Individuals of All Disability Groups	No	Group B- Business Occupancy	a
.5600	Supervised Living For Individuals of All Disability Groups	Yes	Residential	o
.6000	Inpatient Hospital Treatment for Individuals who have Mental Illness or Substance Abuse Disorders	Yes	Institutional Occupancy	l

Code	Program Type / Description
a	Day Program
b	Level II Clients
c	This program has been deleted
d	Level II clients (previously part of the .1300 program)
e	Level IV clients. Required to be a secured facility and Institutional – Unrestrained Occupancy (previously part of the .1500 program)
f	PRTF clients. May be staff secured or locked; still Institutional – Unrestrained Occupancy (previously part of the .1500 program)
g	Usually these are ICF/IID facilities and required to have a Certificate of Need (CON)
h	Institutional Occupancy since providing medical treatment
i	Typically not in a six bed facility since requires CON
j	Program is for women and their children. Usually in apartment/motel situation but if less than six could be a home
K	Program is for adults and is usually in apartment/ motel situation but if less than six could be in a home
l	Requires Institutional Occupancy since requiring treatment
m	Typically is a resident with another residential program. Could be part of a larger facility not residential
n	Support Services, not residential
o	Has six different programs. .5600A; .5600B; .5600C are limited to maximum of 6 clients. .5600F is limited to maximum of 3 clients in private residence.
p	Residential Camp
q	Any program not listed is not a licensed program by Mental Health

Programs typically licensed in Single-Family Dwellings and falling under G.S. 168 are: .1300, .1700, .2100, .5100 & .5600.