Fiscal Impact Analysis of
Permanent Rule Readoption without Substantial Economic Impact

Agency Proposing Rule Change
North Carolina Medical Care Commission

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Impact Summary
Federal Government Entities: No Impact
State Government entities: No Impact
Local Government Entities: No Impact
Small Business: No Impact
Substantial Impact: No Impact

Title of Rules Changes and Statutory Citations
10A NCAC 13B

Section .1900 – Supplemental Rules for the Licensure of the Skilled: Intermediate: Adult Care Home Beds in a Hospital
- Definitions 10A NCAC 13B .1902 (Readopt)
- Adult Care Home Personnel Requirements 10A NCAC 13B .1915 (Readopt)
- Training 10A NCAC 13B .1918 (Readopt)
- Required Spaces 10A NCAC 13B .1925 (Readopt)

Section .3000 – General Information
- Definitions 10A NCAC 13B .3001 (Readopt)
- General Requirements 10A NCAC 13B .3101 (Readopt)
- Itemized Charges 10A NCAC 13B .3110 (Readopt)

Section .3200 -- General Hospital Requirements
- Transfer Agreement 10A NCAC 13B .3204 (Readopt)
- Discharge of Minor or Incompetent 10A NCAC 13B .3205 (Readopt)

Section .3300 – Patient’s Bill of Rights
- Minimum Provisions of Patient’s Bill of Rights 10A NCAC 13B .3302 (Readopt)
- Procedure 10A NCAC 13B .3303 (Readopt)

Section .5400 – Comprehensive Inpatient Rehabilitation
- Additional Requirements for Traumatic Brain Injury Patients 10A NCAC 13B .5412 (Readopt)
- Additional Requirements for Spinal Cord Injury Patients 10A NCAC 13B .5413 (Readopt)

*See proposed text of these rules in Appendix 1
Statutory Authority

G.S. 131E-79-169

Background and Purpose

Under authority of G.S. 150B-21-3A, Periodic review and expiration of existing rules, the Medical Care Commission, Rules Review Commission and the Joint Legislative Administrative Procedure Oversight Committee approved the Subchapter report with classifications for the rules located at 10A NCAC 13B—Rules for the Licensing of Hospitals on February 10, 2017, May 18, 2017, and July 22, 2017, respectively. A total of 13 rules were determined necessary with substantive public interest and therefore subject to readoptions as new rules. The Medical Care Commission is proposing to readopt 13 hospital licensure rules. These rules are a collection of the supplemental rules for the licensure of skilled nursing, intermediate, and adult care home beds in a hospital, comprehensive rehabilitation, and general information regarding hospital licensure. Of those 13 rules, eight are proposed for readoption with substantive changes. (10A NCAC 13B .1902, .1918, .1925, .3001, .3101, .3302, .5412, and .5413).

Five rules are proposed for readoption without substantive changes and will not be discussed in this analysis. (10A NCAC 13B .1915, .3110, .3204, .3205, and .3303).

There are 119 licensed hospitals in North Carolina, of which 21 are combination facilities licensed for Skilled Nursing Beds. There are also five licensed Comprehensive Inpatient Rehabilitation Hospitals and 21 Rehabilitation Units within Acute Care Hospital facilities. The rule readoptions presented in this fiscal analysis will be the third phase of the hospital rule readoptions required by G.S. 150B-21.3.A. The readoptions will update rules that, in some cases, have not been updated in 29 years. The readoptions will update practices and language, address previous Rules Review Commission objections, and implement technical changes. Changes will also allow reference to the General Statute. When a hospital offers nursing facility or adult care home long-term care services, the services shall be included under one hospital license. The general requirements included in this Subchapter shall apply when applicable but in addition the nursing facility care and adult care home care unit must meet the supplemental requirements of this Section. A hospital stakeholder group was put together to assist in rule readoption by providing expertise on hospital processes, current standards of practice, and to ensure hospitals have an opportunity to provide input as we move forward with the readoption process.

Rules Summary and Anticipated Fiscal Impact

Rule 13B .1902 – Definitions

The agency is proposing to readopt this rule with substantive changes. This rule lists definitions that apply throughout the Subchapter and is being changed to update definitions, delete definitions that are no longer used in the Subchapter, to relocate definitions to other existing rules, and to reference definitions in the General Statute. Generally, the definitions in the statute are the same as those used in the rule. There are several minor differences that are noted in the General Statute definitions, but those minor differences do not materially change the scope of the definition and are not any more stringent than the definitions in the current rule. The definitions in the General Statute will always prevail. Two definitions are not utilized in the Subchapter and were deleted.

In addition, the agency removed redundancy by deleting definitions for Existing Facility and New Facility. Those definitions are in Rule 10A NCAC 13B .6102 and .6105 of this Subchapter.

Fiscal Impact:

Federal Government Entities: No Impact
Rule 13B .1918 – Training

The agency is proposing to readopt this rule with substantive changes. The rule was last amended in 1991. This rule identifies training requirements for Nurse Aide I patient care employees. This rule previously specified curriculum content for nurse aide training programs and subjected the programs to approval by DHSR. It also specified the breakdown of educational hours between classroom hours and supervised practical experience. The rule also allowed nurse aides who had formerly been fully qualified under the nurse aide training requirements to re-instate their requirements by passing an approved competency evaluation test.

The new changes incorporate the training and competency evaluation standards for Nurse Aide 1 that are contained in 42 CFR 483, Subpart D. The referenced standards establish the requirements for the state approved Nurse Aide 1 training and evaluation program. Regardless of the facility of employment, all Nurse Aide 1s who meet the required training and evaluation are eligible to be put on the Nurse Aide 1 Registry. Therefore, the current baseline incorporates the changes already made to the Nurse Aide 1 registry requirements. The fiscal note for Nurse Aide Registry changes, 10A NCAC 13 .0301 is available at https://ncosbm.s3.amazonaws.com/s3fs-public/documents/files/DHHS07082015.pdf, details the cost associated with the initial switch to the current program. The new rules, 10A NCAC 13 .0301, were designed to result in the public receiving safer/more competent hands-on, direct patient/resident/client care.

DHSR does not require any additional training above the minimum and therefore does not expect any additional costs for training above the current minimum standards. However, a facility or program may go above the minimum training standards for Nurse Aide Is, if they so desire. In the event a new training topic needs to the added to the Nurse Aide I trainings curriculum, approved trainers will not change class time. While new training objectives would be added to the existing class time, there is a possibility that new materials would be required to be purchased in order to teach new skills. However, these are unknown at this time and would be expected to be minimal.

Facilities are responsible for providing their initial facility specific orientation exclusive of the 75-hour training requirement and for checking the Nurse Aide Registry to ensure potential Nurse Aide Is are on the registry prior to employment.

In addition, changes to the rule require training programs to establish a policy for retention of attendance and subject matter covered during the training. This information is currently retained by the training programs. We are instructing them to document their policy for doing so for compliance purposes. Dependent on current practices, there may be some minimal staff time/cost involved in establishing a retention schedule regarding attendance and subject matter covered during the training. There are currently 261 state-approved Nurse Aide I training programs. Changes to this rule won’t result in any modification to the training program or process.

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Rule 13B .1925 – Required Spaces
The agency is proposing to readopt this rule with substantive changes. This rule lists the space requirements for a combination facility (nursing facility within a hospital) and is changed to update requirements, make technical changes, and to reorganize text. Space requirements are being relocated from Rule 10A NCAC 13B .1902 to this Rule. This change will pull similar information together in one location.

Technical changes include changing language to update “washrooms” to “bath areas” and deleting the reference to 10 A NCAC 13B .1902 as it was no longer applicable. This was a technical change and is not expected to have an impact. Lockers and movable wardrobes were added to the rule as additional options in lieu of closets. Closets, lockers or wardrobes space are not counted against the space requirements for bedrooms. The current requirement is one closet or wardrobe per bed. The lockers will give facilities an additional option they can use in lieu of closets or wardrobes. Some of the old facilities may still utilize lockers instead of closets or wardrobes. The nursing home wing in a hospital is required to follow the nursing facility standards regarding space identified in 10A NCAC 13D .3201. It is unknown how many facilities, if any, will take advantage of the additional options. The overall requirements regarding space, closets, or wardrobes in combination facilities remains unchanged. These changes will not expand the scope of this rule or result in any additional administrative or staff time and is unlikely to have financial implications for combination facilities.

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Rule 13B .3001 -- Definitions
The agency is proposing to readopt this rule with substantive changes. This rule lists definitions that apply throughout the Subchapter and are being changed to satisfy previous Rules Review Commission objections, to update definitions and terminology, and to reference the General Statute. Changes were also made to remove repealed statutes and update statute location. There were nine definitions the Rules Review Commission objected to regarding lack of authority. All were definitions that were defined in the general statute. The nine definitions were replaced with references to the general statute. Changing the definition to referencing the statute does not make any material changes to the definitions or expand or decrease the scope of the definition. Furthermore, the definitions in the statutes constitute the current baseline because the definitions in the general statutes take legal precedence over the current definitions written in rules because the statute is the higher-level authority. Two definitions were relocated from an existing rule to eliminate redundancy. The definition of Special Care units was condensed into three categories. Those three categories are inclusive of all the items identified in the current rule.

As the current baseline includes the definitions as found in the general statutes, there is no impact to this rule change and it does not require any additional actions by the facility or staff.

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Substantial Impact: No Impact

**Rule 13B.3101 – General Requirements**
The agency is proposing to readopt this rule with substantive changes. This rule lays out general requirements regarding licensure, lease, and bed changes. Changes to the rule establish 30 days as the standard for prior notification of licensure changes. Facilities are currently required to notify the agency in writing at any time prior to the occurrence of licensure changes. The change to the rule will establish a consistent timeframe to make notification. There were also several technical changes. These changes will not result in any increase in administrative or staff time and are unlikely to have any fiscal implications.

**Fiscal Impact:**
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- Substantial Impact: No Impact

**Rule 13B.3302 – Minimum Provisions of Patient’s Bill of Rights**
The agency is proposing to readopt this rule with substantive changes. This rule establishes minimal provisions of patient’s bill of rights. The rule is changed to consolidate language regarding the patients right to information with the patients access to medical records. This change will combine related information and eliminate redundancy. In addition, the agency made several technical changes to take out ambiguous language. There was no expansion or reduction to the provision of the patient bill of rights and the changes won’t result in any administrative or facility costs.

**Fiscal Impact:**
- Federal Government Entities: No Impact
- State Government entities: No Impact
- Local Government Entities: No Impact
- Small Business: No Impact
- Substantial Impact: No Impact

**Rule 13B.5412 – Additional Requirements for Traumatic Brain Injury Patients**
The agency is proposing to readopt this rule with substantive changes. This rule establishes additional requirements for inpatient rehabilitation facilities providing services to persons with traumatic brain injuries. It is being changed to resolve the conflict between the rule and the current standards of practice, and to reflect current standards of care regarding nursing, physical, occupational, and speech therapy hours. The current rule was last amended in 1996 and is highly prescriptive without offering flexibility for hospitals to encourage the efficient use of resources. The rule also does not have any basis in evidence based practice standards that contribute to better patient outcomes.

During the readoption process for these rules, DHSR asked stakeholder groups for input regarding current rules. The stakeholder group was composed of staff from rehabilitation units at acute care hospitals as well as staff from rehabilitation hospitals. Two members of the stakeholder group, both staff at rehabilitation facilities, acknowledged that the standard of practice regarding nursing, physical, occupational, and speech therapy for traumatic brain injury patients is to provide nursing, physical, occupational, and speech therapy hours to meet the needs of the patient in accordance with the patient assessment, treatment plan, and physician orders.
The current rules required a minimum of 6.5 nursing hours per patient day and that direct care nursing staff required at least 2 FTEs, one of which is a registered nurse. According to the CMS Measures Inventory Tool, nursing care hours per patient day is the number of productive hours worked by nursing staff, including RNs, LPNs/LVNs, and UAP (unlicensed assistive personnel) with direct patient care responsibilities per patient day for each in-patient unit in a calendar month. While evidence suggests that higher nursing staffing ratios can have impacts on patient outcomes including patient readmission rates, preventable events such as falls and pressure ulcers, and medical and medication errors, other factors also must be taken into account when developing optimal nursing hours per patient day levels such as patient complexity and acuity and nursing skill mix. Due to these reasons, the rule as currently written does not ensure efficient, high quality care for traumatic brain injury patients, which is the intent of the rule. According to reports from stakeholder groups, this rule is both incredibly onerous and does not represent current practices and has not been followed for some time due to these reasons.

The range of traumatic brain injuries (TBI) is wide and the severity of the injury may vary widely from a mild concussion to severe memory loss and extended period of unconsciousness after injuries. However, this condition is wide ranging – in 2014, there were about “2.87 million TBI-related emergency department (ED) visits, hospitalizations, and deaths” that occurred in the United States. The leading cause of TBIs were falls, which disproportionately affect children aged 0-4 and older adults aged 75 years and older. “Motor vehicle crashes were the leading cause of hospitalizations for adolescents and adults aged 15 to 44 years of age.”

“Inpatient TBI rehabilitation practice remains highly variable, which, in part, reflects lack of empirical evidence of how the complex interweaving of rehabilitations from different professionals, in conjunction with patient prognostic factors (e.g. comorbidities, injury severity), influences recovery.” More research is necessary to determine standardized rehabilitation options across traumatic brain injury patients. Due to the range of symptoms that may occur in TBI patients, each patient should have a care plan that is individualized to them based on their specific needs. However, there is evidence to suggest that similar treatment options based on cognitive functions and other assessments such as the Comprehensive Severity Index that takes into account a patient’s comorbidities and severity of illness are more able to be standardized. However, due to the complexity of these factors for every patient, these decisions are generally individualized to each patient based on their cognitive function level and comorbidities as part of their care plan developed by their medical team.

As part of current practice and federal regulations for conditions of payment under the inpatient rehabilitation facility prospective payment system for Medicare and Medicaid, rehabilitation facilities are to furnish through the use of qualified personnel, rehabilitation nursing, physician therapy, and occupational therapy, plus as needed, speech-language pathology, social services, psychological services.

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4 https://www.cdc.gov/traumaticbraininjury/get_the_facts.html
5 https://www.cdc.gov/traumaticbraininjury/get_the_facts.html
6 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4516907/
7 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4516907/
(including neuropsychological services), and orthotic and prosthetic services. In addition, federal regulation 42 CFR 412.622 (ii) requires intensive rehabilitation therapy programs to generally consist of at least three hours of therapy per day, at least five days per week. However, as noted in stakeholder meetings, meeting these targets also depends on the patient’s ability to tolerate these therapies.

A change was also made to eliminate the medical director qualifications because of an existing Rules Review Commission objection. The Rules Review Commission determined that the agency has no authority to set the medical director qualifications. In order to receive reimbursement for Medicare and Medicaid patients, facilities are responsible for providing the appropriate director of rehabilitation per 42 CFR 412.29(g).

As federal regulations already require hospitals to be organized and staffed to provide care according to a patient’s assessment and plan of care developed by their medical team as well as the fact that existing rules have not been practiced for some time as they are outdated, the current baseline already reflects the new rules. The new rule also allows hospitals the flexibility to provide care without negatively impacting in any way the wellbeing of the patient. It is unlikely that there will be any additional fiscal impact from this rule update. This readoption also will not result in any changes to current practices or processes and is unlikely to have any fiscal implications for administrative/professional staff, state, or local staff.

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**Rule 13B .5413 – Additional Requirements for Spinal Cord Injury Patients**

The agency is proposing to readopt this rule with substantive changes. This rule establishes additional requirements for inpatient rehabilitation facilities providing services to persons with spinal cord injury. It is being changed to resolve the conflict between the outdated rule and the current standards of practice, as well as reflect current standards of care regarding nursing, physical, occupational, and speech therapy hours. Current industry standards for intensive rehabilitation therapy programs generally consist of at least three hours of therapy per day at least five days per week.

An estimated 291,000 people are living with SCI in the United States today. In the United States alone, approximately 17,730 new SCI cases occur each year. Most new spinal cord injuries affect men, who account for 78% of new cases. The average age at the time of injury is 43 years. Most spinal cord injuries are caused by car crashes, followed closely by falls and violent acts. The average Acute Care hospital stay is 11 days. Rehabilitation facility stays average 31 days.8

The previously mentioned stakeholder group also provided expertise regarding spinal cord patient care standards. They acknowledged that the standard of practice regarding nursing care and physical, occupational, and speech therapy for spinal cord patients is to provide physical, occupational, and speech therapy hours to meet the needs of the patient in accordance with the patient assessment, treatment plan, and physician orders.

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Doctors determine the appropriate level of care and treatment plan for SCI patients. Hospitals determine the appropriate level of staffing to meet treatment plan. The current rules required a minimum of 6.0 nursing hours per patient day and that direct care nursing staff required at least 2 FTEs, one of which is a registered nurse. Similarly to the reasons listed for the traumatic brain injury patients, the care of spinal cord patients is also extremely varied based on their individual injuries and comorbidities. Therefore, it is not an efficient or effective practice to mandate minimum numbers of nursing hours per patient day for such a general population. The current rule standards are also not supported by evidence-based practice.

The following current federal regulations set the current industry standards. 42 CFR 482.56 requires hospitals that provide rehabilitation to be organized and staffed to ensure the health and safety of patients. Federal regulation 42 CFR 412.29 as a condition for payment for Medicare and Medicaid patients under the inpatient rehabilitation facility prospective payment system, rehabilitation facilities are to furnish through the use of qualified personnel, rehabilitation nursing, physical therapy, and occupational therapy, plus as needed, speech-language pathology, social services, psychological services (including neuropsychological services), and orthotic and prosthetic services.

In addition, a change was made to eliminate the medical director qualifications because of an existing Rules Review Commission objection. The Rules Review Commission determined that the agency has no authority to set the medical director qualifications. Similarly to traumatic brain injury patients, facilities are responsible for providing the appropriate medical director to meet the needs of patients per 42 CFR 412.29(g).

While changes to rules reflect current practices, it is unlikely that there will be any fiscal impact. Acute care hospitals with rehabilitation units and rehabilitation facilities are currently complying with the federal regulations. Hospitals are required to be in compliance with the federal requirements set forth in the Medicare Conditions of Participation (CoP) in order to receive Medicare/Medicaid payment. This readoption will not result in any changes to current standards, practices, or processes and is unlikely to have any fiscal implications for administrative/professional staff, state, or local staff.

**Fiscal Impact:**
- Federal Government Entities: No Impact
- State Government entities: No Impact
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**Impact Summary**

These readoptions update rules to account for current practices and language, remove ambiguity, address previous Rule Review Commission objections, and implement technical changes. Changes also allow reference to the General Statute where appropriate. The changes reflect current practices and eliminates the conflict between current standards of practice and rules 13B .5412 and .5413. It is unlikely that there will be any fiscal impact. Updates to current standards or processes is unlikely to have any fiscal implications for facilities since rehabilitation facilities currently adhere to the standards. Changes made to reference the statute will have no impact, as the statutes will always prevail. There were no new requirements added, or changes in scope. It is unlikely changes will have any fiscal impact on facility cost, administrative cost, patient costs, or impact state or local staff.
10A NCAC 13B .1902 is proposed for readoption with substantive changes as follows:

**10A NCAC 13B .1902 DEFINITIONS**

The following definitions shall apply throughout this Section, unless text otherwise clearly indicates to the contrary:

1. **"Accident"** means something occurring by chance or without intention which has caused physical or mental harm to a patient, resident, or employee.

2. **"Administer"** means the direct application of a drug to the body of a patient by injection, inhalation, ingestion or other means, as defined in G.S. 90-87.

3. **"Administrator"** means the person who has authority for and is responsible to the governing board for the overall operation of a facility.

4. **"Brain injury long-term care"** is defined as an interdisciplinary, intensive maintenance program for patients who have incurred brain damage caused by external physical trauma and who have completed a primary course of rehabilitative treatment and have reached a point of no gain or progress for more than three consecutive months. Services are provided through a medically supervised interdisciplinary process and are directed toward maintaining the individual at the optimal level of physical, cognitive, and behavioral functioning.

5. **"Capacity"** means the maximum number of patient or resident beds which the facility is licensed to maintain at any given time. This number shall be determined as follows:
   (a) Bedrooms shall have minimum square footage of 100 square feet for a single bedroom and 80 square feet per patient or resident in multi-bedded rooms. This minimum square footage shall not include space in toilet rooms, washrooms, closets, vestibules, corridors, and built-in furniture.
   (b) Dining, recreation and common use areas available shall total no less than 25 square feet per bed for skilled nursing and intermediate care beds and no less than 30 square feet per bed for adult care home beds. Such space must be contiguous to patient and resident bedrooms.

6. **"Combination Facility"** means any hospital with nursing home beds which is licensed to provide more than one level of care such as a combination of intermediate care and/or skilled nursing care and adult care home care.

7. **"Convalescent Care"** means care given for the purpose of assisting the patient or resident to regain health or strength.

8. **"Department"** means the North Carolina Department of Health and Human Services.

9. **"Director of Nursing"** means the nurse who has authority and responsibility for all nursing services and nursing care.

10. **"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," as defined in G.S. 90-87.

(44)(9) "Drug" means substances:

(a) recognized in the official United States Pharmacopoeia, official National Formulary, or
    any supplement to any of them;

(b) intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in
    man or other animals;

(c) intended to affect the structure or any function of the body of man or other animals, i.e.,
    substances other than food; and

(d) intended for use as a component of any article specified in (a), (b), or (c) of this
    Subparagraph, but does not include devices or their components, parts, or accessories.

as defined in G.S. 90-87.

(42)(10) "Duly Licensed" means holding a current and valid license as required under the General Statues of
    North Carolina.

(13) "Existing Facility" means a licensed facility; or a proposed facility, proposed addition to a licensed
    facility or proposed remodeled licensed facility that will be built according to plans and
    specifications which have been approved by the department through the preliminary working
    drawings stage prior to the effective date of this Rule.

(14) "Exit Conference" means the conference held at the end of a survey, inspection or investigation, but
    prior to finalizing the same, between the department's representatives who conducted the survey,
    inspection or investigation and the facility administration representative(s).

(45)(11) "Incident" means an intentional or unintentional action, occurrence or happening which is likely
    to cause or lead to physical or mental harm to a patient, resident, or employee.

(16)(12) "Licensed Practical Nurse" means a nurse who is duly licensed as a practical nurse under G.S. 90,
    Article 9A, as defined in G.S. 90-171.30 or G.S. 90-171.32.

(17) "Licensee" means the person, firm, partnership, association, corporation or organization to whom a
    license has been issued.

(18)(13) "Medication" means drug as defined in (42) Item (9) of this Rule.

(19) "New Facility" means a proposed facility, a proposed addition to an existing facility or a proposed
    remodeled portion of an existing facility that is constructed according to plans and specifications
    approved by the department subsequent to the effective date of this Rule. If determined by the
    department that more than one half of an existing facility is remodeled, the entire existing facility
    shall be considered a new facility.

(20)(14) "Nurse Aide" means any individual providing nursing or nursing-related services to patients in a
    facility, and is not a licensed health professional, a qualified dietitian or someone who volunteers to
    provide such services without pay, and who is listed in a nurse aide registry approved by the
    Department.
(21) "Nurse Aide Trainee" means an individual who has not completed an approved nurse aide training course and competency evaluation and is demonstrating knowledge, while performing tasks for which they have been found proficient in by an instructor. These tasks shall be performed under the direct supervision of a registered nurse. The term does not apply to volunteers.

(22) "Nursing Facility" means that portion of a nursing home certified under Title XIX of the Social Security Act (Medicaid) as in compliance with federal program standards for nursing facilities. It is often used as synonymous with the term "nursing home" which is the usual prerequisite level for state licensure for nursing facility (NF) certification and Medicare skilled nursing facility (SNF) certification.

(23) "Nurse in Charge" means the nurse to whom duties for a specified number of patients and staff for a specified period of time have been delegated, such as for Unit A on the 7-3 or 3-11 shift.

(24) "On Duty" means personnel who are awake, dressed, and responsive to patient needs and physically present in the facility performing assigned duties.

(25) "Patient" means any person admitted for care to a skilled nursing or intermediate care facility.

(26) "Physician" means a person licensed under G.S. Chapter 90, Article 1 to practice medicine in North Carolina, as defined in G.S. 90-9.1 or G.S. 90-9.2.

(27) "Qualified Dietitian" means a person who meets the standards and qualifications established by the Committee on Professional Registration of the American Dietetic Association included in "Standards of Practice" seven dollars and twenty-five cents ($7.25) or "Code of Ethics for the Profession of Dietetics" two dollars and fifteen cents ($2.15), American Dietetic Association, 216 W. Jackson Blvd., Chicago, IL 60606-6995, as defined in 42 CFR 483.60(a)(1), herein incorporated by reference including subsequent amendments and editions. Electronic copies of 42 CFR 483.60 can be obtained free of charge at https://www.ecfr.gov/cgi-bin/textidx?SID=1260800a39929487f0ca55b0ab5e710b&mc=true&tpl=/ecfrbrowse/Title42/42cfrv5_02.tpl#0.

(28) "Registered Nurse" means a nurse who is duly licensed as a registered nurse under as defined in G.S. 90, Article 9A.

(29) "Resident" means any person admitted for care to an adult care home, as defined in G.S.131D-2.1.

(30) "Sitter" means an individual employed to provide companionship and social interaction to a particular resident or patient, usually on a private duty basis.

(31) "Supervisor-in-Charge" means a duly licensed nurse to whom supervisory duties have been delegated by the Director of Nursing.

(32) "Ventilator dependence" means physiological dependency by a patient on the use of a ventilator for more than eight hours a day.

History Note: Filed as a Temporary Amendment Eff. October 1, 1990 For a Period of 142 Days to Expire on February 28, 1991;
Authority G.S. 131E-79;
Eff. February 1, 1986;
Amended Eff. February 1, 1993; December 1, 1991; March 1, 1991; March 1, 1990; 1990;

10A NCAC 13B .1918 is proposed for readoption with substantive changes as follows:

10A NCAC 13B .1918 TRAINING
(a) A licensed facility shall provide for all patient or resident care employees a planned orientation and continuing education program emphasizing patient or resident assessment and planning, activities of daily living, personal grooming, rehabilitative nursing or restorative care, other patient or resident care policies and procedures, patients' rights, and staff performance expectations. Attendance and subject matter covered shall be documented for each session, retained in accordance with policy established by the facility, and available for licensure inspections.
(b) The administrator shall assure that each employee is oriented within the first week of employment to the facility's philosophy and goals.
(c) Each employee shall have specific on-the-job training as necessary for the employee to properly perform his individual job assignment.
(d) Unless otherwise prohibited, a nurse aide trainee may be employed to perform the duties of a nurse aide for a period of time not to exceed four months. During this period of time the nurse aide trainee shall be permitted to perform only those tasks for which minimum acceptable competence has been demonstrated and documented on a skills check-off record. Job applicants for nurse aide positions who were formerly qualified nurse aides but have not been gainfully employed as such for a period of 24 consecutive months or more shall be employed only as nurse aide trainees and must re-qualify as nurse aides within four months of hire by successfully passing an approved competency evaluation. Any individual, nursing home, or education facility may offer Department approved vocational education for nursing home nurse aides. An accurate record of nurse aide qualifications shall be maintained for each nurse aide used by a facility and shall be retained in the general personnel files of the facility in accordance with policy established by the facility.
(e) The curriculum content required for nurse aide education programs shall be subject to approval by the Division of Health Service Regulation and shall include, as a minimum, basic nursing skills, personal care skills, cognitive, behavioral and social care, basic restorative services, and patients' rights. Successful course completion shall be determined by passing a competency evaluation test. The minimum number of course hours shall be 75 of which at least 20 hours shall be classroom and at least 40 hours of supervised practical experience. The initial orientation to the facility shall be exclusive of the 75 hour training program. Competency evaluation shall be conducted in each of the following areas:
   (1) Observation and documentation,
(2) Basic nursing skills,
(3) Personal care skills,
(4) Mental health and social service needs,
(5) Basic restorative services, and
(6) Residents' Rights.

(f) Successful course completion and skill competency shall be determined by competency evaluation approved by the Department. Commencing July 1, 1989, nurse aides who had formerly been fully qualified under nurse aide training requirements may re-establish their qualifications by successfully passing a competency evaluation test.

History Note: Filed as a Temporary Rule Eff. October 1, 1990 For a Period of 142 Days to Expire on February 28, 1991; Authority G.S. 131E-79; 42 U.S.C. 1396 r (b)(5); Eff. February 1, 1986; Amended Eff. March 1, 1991; March 1, 1990; Readopted Eff. April 1, 2020.

10A NCAC 13B .1925 is proposed for readoption with substantive changes as follows:

10A NCAC 13B .1925 REQUIRED SPACES
The total space requirements shall be those set forth in Rule 1902(5) of this Section. Physical therapy and occupational therapy space shall not be included in these totals. (a) A combination or nursing facility shall meet the following requirements for bedrooms, dining, recreation, and common use areas:

(1) Single bedrooms shall be provided with not less than 100 square feet of floor area;
(2) bedrooms with more than one bed shall be provided with not less than 80 square feet of floor area per bed;
(3) dining, recreation, and common use areas shall:
   (A) total not less than 25 square feet of floor area per bed for skilled nursing and intermediate care beds;
   (B) total not less than 30 square feet of floor area per bed for adult care home beds; and
   (C) be contiguous to patient and resident bedrooms.
(b) Floor space for the following rooms, areas, and furniture shall not be included in the floor areas required by Paragraph (a) of this Rule:

(1) toilet rooms;
(2) vestibules;
(3) bath areas;
(4) closets, lockers, or moveable wardrobes;
10A NCAC 13B .3001 is proposed for readoption with substantive changes as follows:

10A NCAC 13B .3001  DEFINITIONS
Notwithstanding Section .1900 of this Subchapter, the following definitions shall apply throughout this Section unless the context clearly indicates to the contrary:

(1) "Appropriate" means suitable or fitting, or conforming to standards of care as established by professional organizations.

(2) "Authority having jurisdiction" means the Division of Health Service Regulation.

(3) "Certified Dietary Manager" or "CDM" means an individual who is certified by the Certifying Board of the Dietary Managers and meets the standards and qualification as referenced in the "Dietary Manager Training Program Requirements." These standards include any subsequent amendments and editions of the referenced manual. Copies of the "Dietary Manager Training Program Requirements" may be purchased for fifteen dollars ($15.00) from the Dietary Managers Association, 406 Surry Woods Dr., St. Charles, IL 60174, or obtained free of charge at https://www.cbdmonline.org/.

(4) "Competence" means the state or quality of being able to perform specific functions well; skill; ability.

(5) "Comprehensive" means covering completely, inclusive; large in scope or content.

(6) “Construction documents” means final building plans and specifications for the construction of a facility that a governing body submits to the Construction Section for approval as specified in Rule .3102 of this Subchapter.

(7) “Construction Section” means the Construction Section of the Division of Health Service Regulation.

(8)(9) "Continuous" means ongoing or uninterrupted, 24 hours per day.

(7)(9) "CRNA" means a Certified Registered Nurse Anesthetist as credentialed by the Council on Certification of Nurse Anesthetists and recognized by the Board of Nursing in 21 NCAC 36 .0226, defined in G.S. 90-171.21(d)(4).

(8)(10) "Credentialed" means that the individual having a given title or position has been credited with the right to exercise official responsibilities to provide specific patient care and treatment services, within defined limits, based primarily upon the individual's license, education, training, experience, competence, and judgment.
"Department" means the Department of Health and Human Services.

"Dietetics" means the integration and application of principles derived from the science of nutrition, biochemistry, physiology, food and management and from behavioral and social sciences to achieve and maintain optimal nutritional status, as defined in G.S. 90-352.

"Dietitian" means an individual who is licensed according to as defined in G.S. 90, Article 25, or is registered by the Commission on Dietetic Registration (CDR) of the American Dietetic Association (ADA) according to the standards and qualifications as referenced in the second edition of the "Accreditation/Approval Manual for Dietetic Education Programs", "The Registration Eligibility Application for Dietitians" and subsequent amendments or editions of the reference material. Copies of the "Accreditation/Approval Manual for Dietetic Education Programs" may be purchased for twenty-one dollars and ninety-five cents ($21.95) plus three dollars ($3.00) minimum shipping and handling from ADA 216 W. Jackson Blvd., Chicago, IL 60606-9-6995, Article 25.

"Dietetic Technician Registered" or "DTR" means an individual who is registered by the Commission on Dietetic Registration (CDR) of the American Dietetic Association (ADA) according to the standards and qualifications as referenced in the second edition of the "Accreditation/Approval Manual for Dietetic Education Programs" which is incorporated by reference including any subsequent amendments and editions. Copies of the "Accreditation/Approval Manual for Dietetic Education Programs" may be purchased for twenty-one dollars and ninety-five cents ($21.95) plus three dollars ($3.00) minimum for shipping and handling from the ADA 216 W. Jackson Blvd., Chicago, IL 60606-9-6995, as defined in G.S. 90-352.

"Direct Supervision" means the state of being under the immediate control of a supervisor, manager, or other person of authority.

"Division" means the Division of Health Service Regulation.

"Facility" means a hospital as defined in G.S. 131E-76.

"Free standing facility" means a facility that is physically separated from the primary hospital building or separated by a three hour fire containment wall.

"Full-time equivalent" means a unit of measure of employee work time that is equal to the number of hours that one full-time employee would work during one calendar year if the employee worked eight hours a day, five days a week, and 52 weeks a year; i.e. 2,080 hours per year.

"Governing body" means the authority as defined in G.S. 131E-76.

"Imaging" means a reproduction or representation of a body or body part for diagnostic purposes by radiologic intervention that may include conventional fluoroscopic exam, magnetic resonance, nuclear or radio-isotope scan.

"Invasive procedure" means a procedure involving puncture or incision of the skin, insertion of an instrument or foreign material into the body (excluding venipuncture and intravenous therapy).
"LDRP" (labor, delivery, recovery, post-partum) means a specific single occupancy obstetrical use room counted as a licensed bed.

"License" means formal permission to provide services as granted by the State.

"Medical staff" means the formal organization that is comprised of all of those individuals who have sought and obtained clinical privileges in a facility. Those members of the medical staff who regularly and routinely admit patients to a facility constitute the active medical staff.

"Mission statement" means a written statement of the philosophy and beliefs of the organization or hospital as approved by the governing body.

"Neonate" means the newborn from birth to one month.

"NP" means a Nurse Practitioner as defined in G.S. 90-6, G.S. 90-8.2, 90-18(14), 90-18(14), and 90-18.2.

"Nurse executive" means a registered nurse who is the director of nursing services or a representative of decentralized nursing management staff, as defined in Rule 21 NCAC 36.0109.

"Nurse midwife" means a Certified Nurse Midwife as defined in G.S. 90, Article 10, G.S.90-171.21 (4).

"Nursing facility" means that portion of a hospital that is approved to provide skilled nursing care, as defined in G.S. 131E.116 (2).

"Nursing staff" means the registered nurses, licensed practical nurses, nurse aides, and others under nurse supervision, who provide direct patient care. The term also includes clerical personnel who work in clinical areas under nurse supervision.

“Nutrition and Dietetic Technician Registered” means as defined by the Academy of Nutrition and Dietetics. A copy of the requirements can be obtained at https://www.eatrightpro.org/about-us/what-is-an-rdn-and-dtr/what-is-a-nutrition-and-dietetics-technician-registered at no cost.

"Nutrition therapy" ranges from intervention and counseling on diet modification to administration of specialized nutrition therapies as determined necessary to manage a condition or treat illness or injury. Specialized nutrition therapies include supplementation with medical foods, enteral and parenteral nutrition. Nutrition therapy integrates information from the nutrition assessment with information on food and other sources of nutrients and meal preparation consistent with cultural background and socioeconomic status.

"Observation bed" means a bed used for no more than 24-hours, to evaluate and determine the condition and disposition of a patient and is not considered a part of the hospital's licensed bed capacity.

"Patient" means any person receiving diagnostic or medical services at a hospital.

"Pharmacist" means a person licensed according to G.S. 90, Article 4A, by the N.C. Board of Pharmacy to practice pharmacy, as defined in G.S. 90-85.3.

"Physical Rehabilitation Services" means any combination of physical therapy, occupational therapy, speech therapy, or vocational rehabilitation.
"Physician" means a person licensed according to G.S. 90, Article 1, by the N.C. Board of Medical Examiners to practice medicine, as defined in G.S.90-9.1 or G.S. 90-9.2.

"Provisional license" means a hospital license recognizing significantly less than full compliance with the licensure rules.

"Qualified" means having complied with the specific conditions for employment or the performance of a function.

"Reference" means to use in consultation to obtain information.

"Special Care Unit" means a designated unit or area of a hospital with a concentration of qualified professional staff and support services that provide intensive or extraordinary care on a 24-hour basis to critically ill patients; these units may include but are not limited to Cardiac Care, Medical or Surgical Intensive Care Unit, Cardiac or Thoracic Intensive Care Unit, Burn Intensive Care Unit, Neurologic Intensive Care Unit or Pediatric Intensive Care Unit. that includes a critical care unit, an intermediate care unit, or a pediatric care unit.

"Unit" means a designated area of the hospital for the delivery of patient care services.

**History Note:**
Authority G.S. 131E-79;  
RRC Objection due to lack of Statutory Authority Eff. July 13, 1995;  
Eff. January 1, 1996;  

10A NCAC 13B .3101 is proposed for readoption with substantive changes as follows:

**10A NCAC 13B .3101 GENERAL REQUIREMENTS**

(a) An application for licensure shall be submitted to the Division prior to a license being issued or patients admitted.

(b) An existing facility shall not sell, lease, or subdivide a portion of its bed capacity without the approval of the Division.

(c) Application forms may be obtained by contacting the Division.

(d) The Division shall be notified in writing 30 days prior to the occurrence of any of the following:

   (1) addition or deletion of a licensable service;
   (2) increase or decrease in bed capacity;
   (3) change of chief executive officer;
   (4) change of mailing address;
   (5) ownership change; or
   (6) name change.

(e) Each application shall contain the following information:

   (1) legal identity of applicant;
(2) name or names under which used to present the hospital or services are presented to the public;
(3) name of the chief executive officer;
(4) ownership disclosure;
(5) bed complement;
(6) bed utilization data;
(7) accreditation data;
(8) physical plant inspection data; and
(9) service data.
(f) A license shall include only facilities or premises within a single county.

History Note: Authority G.S. 131E-79;
Eff. January 1, 1996;
Amended Eff. April 1, 2003, 2003;

10A NCAC 13B .3302 is proposed for readoption with substantive changes as follows:

**10A NCAC 13B .3302 MINIMUM PROVISIONS OF PATIENT'S BILL OF RIGHTS**

This Rule does not apply to patients in licensed nursing facility beds since these individuals are granted rights pursuant to G.S. 131E-117. A patient in a facility subject to this Rule has the following rights:

1. A patient has the right to respectful care given by competent personnel.
2. A patient has the right, upon request, to be given the name of his attending physician, the names of all other physicians directly participating in his or her care, and the names and functions of other health care persons having direct contact with the patient.
3. A patient has the right to privacy concerning his or her own medical care program. Case discussion, consultation, examination, and treatment are considered confidential and shall be conducted discreetly.
4. A patient has the right to have all records pertaining to his medical care treated as confidential except as otherwise provided by law or third party contractual arrangements.
5. A patient has the right to know what facility rules and regulations apply to his or her conduct as a patient.
6. A patient has the right to expect emergency procedures to be implemented without unnecessary delay.
7. A patient has the right to good quality care and high professional standards that are continually maintained and reviewed.
(8)(7) A patient has the right to full information in laymen’s terms, concerning his diagnosis, treatment and prognosis, including information about alternative treatments and possible complications. When it is not possible or medically advisable to give such information to the patient, the information shall be given on his or her behalf to the patient’s designee.

(9) (8) Except for emergencies, a physician must obtain necessary informed consent prior to the start of any procedure or treatment, or both.

(10) (9) A patient has the right to be advised when a physician is considering the patient as a part of a medical care research program or donor program. Informed consent must be obtained prior to actual participation in such a program. The patient or legally responsible party, may, at any time, may refuse to continue in any such program to which they have previously given informed consent. An Institutional Review Board (IRB) may waive or alter the informed consent requirement if it reviews and approves a research study in accordance with federal regulations for the protection of human research subjects including U.S. Department of Health and Human Services (HHS) regulations under 45 CFR Part 46 and U.S. Food and Drug Administration (FDA) regulations under 21 CFR Parts 50 and 56. For any research study proposed for conduct under an FDA "Exception from Informed Consent Requirements for Emergency Research" or an HHS "Emergency Research Consent Waiver" in which the waiver of informed consent is waived but community consultation and public disclosure about the research are required, any facility proposing to be engaged in the research study shall also verify that the proposed research study has been registered with the North Carolina Medical Care Commission. When the IRB reviewing the research study has authorized the start of the community consultation process required by the federal regulations for emergency research, but before the beginning of that process, notice of the proposed research study by the facility shall be provided to the North Carolina Medical Care Commission. The notice shall include:

(a) the title of the research study;
(b) a description of the research study, including a description of the population to be enrolled;
(c) a description of the planned community consultation process, including currently proposed meeting dates and times;
(d) an explanation of the way that people choosing not to participate in instructions for opting out of the research study may opt out; and
(e) contact information including mailing address and phone number for the IRB and the principal investigator.

The Medical Care Commission may publish all or part of the above information in the North Carolina Register, and may require the institution proposing to conduct the research study to attend a public meeting convened by a Medical Care Commission member in the community where the proposed research study is to take place to present and discuss the study or the community consultation process proposed.
A patient has the right to refuse any drugs, treatment or procedure offered by the facility, to the extent permitted by law, and a physician shall inform the patient of his or her right to refuse any drugs, treatment or procedures and of the medical consequences of the patient's refusal of any drugs, treatment or procedure.

A patient has the right to assistance in obtaining consultation with another physician at the patient's request and expense.

A patient has the right to medical and nursing services without discrimination based upon race, color, religion, sex, sexual orientation, gender identity, national origin or source of payment.

A patient who does not speak English shall have access, when possible, access to an interpreter.

A facility shall provide a patient, or patient designee, upon request, access to all information contained in the patient's medical records. A patient or his or her designee has the right to have all records pertaining to his or her medical care treated as confidential except as otherwise provided by law or third party contractual arrangements. A patient's access to medical records may be restricted by the patient's attending physician. If the physician restricts the patient's access to information in the patient's medical record, the physician shall record the reasons on the patient's medical record. Access shall be restricted only for sound medical reason. A patient's designee may have access to the information in the patient's medical records even if the attending physician restricts the patient's access to those records.

A patient has the right not to be awakened by hospital staff unless it is medically necessary.

The patient has the right to be free from duplication of medical and nursing procedures as determined by the attending physician.

The patient has the right to medical and nursing treatment that avoids unnecessary physical and mental discomfort.

When medically permissible, a patient may be transferred to another facility only after he or his next of kin or other legally responsible representative has received complete information and an explanation concerning the needs for and alternatives to such a transfer. The facility to which the patient is to be transferred must first have accepted the patient for transfer.

The patient has the right to examine and receive a detailed explanation of his bill.

The patient has a right to full information and counseling on the availability of known financial resources for his health care.

A patient has the right to be informed upon discharge of his or her continuing health care requirements following discharge and the means for meeting them.

A patient shall not be denied the right of access to an individual or agency who is authorized to act on his or her behalf to assert or protect the rights set out in this Section.

A patient has the right to be informed of his rights at the earliest possible time in the course of his or her hospitalization.
A patient has the right to designate visitors who shall receive the same visitation privileges as the patient's immediate family members, regardless of whether the visitors are legally related to the patient.

History Note: Authority G.S. 131E-75; 131E-79; 143B-165;
RRC Objection due to ambiguity Eff. July 13, 1995;
Eff. January 1, 1996;
Temporary Amendment Eff. April 1, 2005;
Amended Eff. January 1, 2011; May 1, 2008; November 1, 2005; 2005;

10A NCAC 13B .5412 is proposed for readoption with substantive changes as follows:

**10A NCAC 13B .5412 ADDITIONAL REQUIREMENTS FOR TRAUMATIC BRAIN INJURY PATIENTS**

Inpatient rehabilitation facilities providing services to patients with traumatic brain injuries shall meet the requirements in this Rule in addition to those identified in this Section, provide staff to meet the needs of patients in accordance with the patient assessment, treatment plan, and physician orders.

1. Direct-care nursing personnel staffing ratios established in Rule .5408 of this Section shall not be applied to nursing services for traumatic brain injury patients in the inpatient, rehabilitation facility or unit. The minimum nursing hours per traumatic brain injury patient in the unit shall be 6.5 nursing hours per patient day. At no time shall direct care nursing staff be less than two full-time equivalents, one of which shall be a registered nurse.

2. The inpatient rehabilitation facility or unit shall employ or provide by contractual agreements physical, occupational or speech therapists in order to provide a minimum of 4.5 hours of specific or combined rehabilitation therapy services per traumatic brain injury patient day.

3. The facility shall provide special facilities or have access to special equipment to meet the needs for patients with traumatic brain injury, including specially designed wheelchairs, tilt tables and standing tables.

4. The medical director of an inpatient traumatic brain injury program shall have two years management in a brain injury program, one of which may be in a clinical fellowship program and board eligibility or certification in the medical specialty of the physician's training.

5. The facility shall provide the consulting services of a neuropsychologist.

6. The facility shall provide continuing education in the care and treatment of brain injury patients for all staff.
The size of the brain injury program shall be adequate to support a comprehensive, dedicated ongoing brain injury program.

History Note: Authority G.S. 131E-79;
RRC Objection due to lack of statutory authority Eff. January 18, 1996;
Eff. May 1, 1996;

10A NCAC 13B .5413 is proposed for readoption with substantive changes as follows:

10A NCAC 13B .5413 ADDITIONAL REQUIREMENTS FOR SPINAL CORD INJURY PATIENTS

Inpatient rehabilitation facilities providing services to persons with spinal cord injuries shall meet the requirements in this Rule in addition to those identified in this Section, provide staff to meet the needs of patients in accordance with the patient assessment, treatment plan, and physician orders.

(1) Direct care nursing personnel staffing ratios established in Rule .5408 of this Section shall not be applied to nursing services for spinal cord injury patients in the inpatient rehabilitation facility or unit. The minimum nursing hours per spinal cord injury patient in the unit shall be 6.0 nursing hours per patient day. At no time shall direct care nursing staff be less than two full-time equivalents, one of which shall be a registered nurse.

(2) The inpatient rehabilitation facility or unit shall employ or provide by contractual agreements physical, occupational or speech therapists in order to provide a minimum of 4.0 hours of specific or combined rehabilitation therapy services per spinal cord injury patient day.

(3) The facility shall provide special facility or have access to special equipment to meet the needs of patients with spinal cord injury, including specially designed wheelchairs, tilt tables and standing tables.

(4) The medical director of an inpatient spinal cord injury program shall have either two years experience in the medical care of persons with spinal cord injuries or six months minimum in a spinal cord injury fellowship.

(5) The facility shall provide continuing education in the care and treatment of spinal cord injury patients for all staff.

(6) The facility shall provide specific staff training and education in the care and treatment of spinal cord injury.

(7) The size of the spinal cord injury program shall be adequate to support a comprehensive, dedicated ongoing spinal cord injury program.

History Note: Authority G.S. 131E-79;