RRC STAFF OPINION

PLEASE NOTE: THIS COMMUNICATION IS EITHER 1) ONLY THE RECOMMENDATION OF AN RRC STAFF ATTORNEY AS TO ACTION THAT THE ATTORNEY BELIEVES THE COMMISSION SHOULD TAKE ON THE CITED RULE AT ITS NEXT MEETING, OR 2) AN OPINION OF THAT ATTORNEY AS TO SOME MATTER CONCERNING THAT RULE. THE AGENCY AND MEMBERS OF THE PUBLIC ARE INVITED TO SUBMIT THEIR OWN COMMENTS AND RECOMMENDATIONS (ACCORDING TO RRC RULES) TO THE COMMISSION.

AGENCY: Medical Care Commission

RULE CITATION: 10A NCAC 13B .3801, .3903, .4103, .4104, .4106, .4305, .4603, .4801, .4805, .5102, .5105, .5406, .5408, .5411

RECOMMENDED ACTION:

Approve, but note staff's comment

X Object, based on:

X Lack of statutory authority (All Rules)

Unclear or ambiguous

Unnecessary

Failure to comply with the APA

Extend the period of review

COMMENT:

These rules set standards for the licensing of hospitals, and are before RRC as part of the agency's scheduled readoption. The rules cover a broad array of aspects including hospital staffing, administration, and the provision of medical care. Among other things, these rules include detailed requirements that hospitals hire and maintain certain personnel, job responsibilities and required credentials for such personnel, requirements and policy statements relating to the preservation of medical records, standards for the provision of emergency services, standards for organization of neonatal care, requirements for the establishment and review of safety standards for imaging services, requirements for the establishment and review of written infection control policies and procedures, and staffing and discharge requirements for inpatient rehabilitation facilities.

Brian Liebman
Commission Counsel
Issued August 5, 2022

It is staff's opinion that the set of rules before you exceeds the grasp of the agency's statutory authority. The Medical Care Commission ("MCC" or the "Commission") draws its rulemaking authority from G.S. 131E-79(a), which states: "The Commission shall promulgate rules **necessary to implement this Article**[,]" referring to Article 5 of Chapter 131E, titled the "Hospital Licensure Act."

Review of the Hospital Licensure Act reveals that while certain provisions of Article 5 go on to discuss *inter alia*, aspects of license enforcement, requirements for granting or denying hospital privileges, discharge from facilities, and confidentiality of medical records, the statute generally directs *the hospital*, rather than MCC, to develop the policies, procedures, and requirements that are a condition of licensure. Hospitals must submit any plans and specifications for their facilities to MCC upon application for a license, and MCC may request information related to hospital operations during the application process, but MCC is not empowered to specifically set those requirements, policies, and procedures by rule.

Moreover, the rules before you delve into issues that are not specifically governed by the Hospital Licensure Act, and as such cannot be "necessary to implement" those statutes. *Inter alia*, there is no statutory requirement that a hospital maintain the position of nurse executive (Rule .3801) or medical director (Rule .4104), or maintain certain levels of inpatient rehabilitation staffing (Rule .5408). There are no statutory requirements related to preservation of medical records, other than that they are confidential and are not public records under Chapter 132 (Rule .3903). There are no statutory requirements related to establishment of emergency services procedures (Rule .4103). The word "neonatal" does not appear within Article 5 (Rule .4305), nor does any reference to radiological services (Rules .4801 and .4805). Part 4 of Article 5 deals with discharge from hospitals, yet only makes requirements related to a patient's refusal to leave, and fair billing practices. There are no discharge criteria required by Article 5 (Rule .5406).

To this, the agency makes two principal responses. MCC argues that its authority to adopt the rules before you stems from G.S. 131E-75, which is the title and purpose section of the Hospital Licensure Act. Therein, the legislature directed that Article 5's purpose was to "establish hospital licensing requirements which promote public health, safety and welfare and to provide for the development, establishment and enforcement of basic standards for the care and treatment of patients in hospitals." G.S. 131E-75(b) (2021). Thus, the agency contends that in determining whether to issue, deny, or take any other action with respect to a hospital's

license, it is "required to assess if a hospital is meeting the 'requirements which promote public health, safety, and welfare….'" and is consequently *required* to establish "operational minimum standards"—a phrase that does not appear within Article 5 of Chapter 131E—for hospitals through rulemaking. The agency goes on to argue that there is no requirement for the General Assembly to specifically enumerate "every area of rule promulgation with any of the agencies creating rules for licensing," bolstering its point by referring to several allegedly equivalent statutory provisions.

As an initial matter, with respect to the agency's reference to other rules not currently before RRC, staff cannot and does not opine as to whether those agencies have authority under their respective statutes to adopt the cited rules. The scope of this opinion is limited to the Rules submitted for review by MCC. Here, the agency is authorized only to "promulgate rules necessary to implement" Article 5 of Chapter 131E. G.S. 131E-79(b) (2021). While the agency is correct that G.S. 131E-75 enunciates the *purpose* of the other provisions of Article 5, this language cannot be read as an open-ended grant of *authority* for MCC to promulgate any rule that could conceivably "promote public health, safety and welfare" or concern the "basic standards for the care and treatment of patients in hospitals" outside of the boundaries of the statutory scheme. As noted above, the rules impose deep, granular requirements upon hospitals with respect to issues that are at best tangentially referenced within the bounds of Article 5, and at worst mentioned nowhere within these statutes. Thus, it is staff's opinion that G.S. 131E-75(b) is not an adequate statutory basis for the rules before you.

Finally, MCC appears to argue that it has additional rulemaking authority for these rules under G.S. 143B-165(6), which states:

> (6) The Commission [MCC] has the duty to adopt rules and regulations and standards with respect to the different types of hospitals to be licensed under the provisions of **Article 13A of Chapter 131** of the General Statutes of North Carolina (emphasis added).

The General Assembly repealed Chapter 131 and replaced it with Chapter 131E in 1983. Specifically, the pre-existing Hospital Licensing Act (Article 13A, Chapter 131) was replaced with the Hospital Licensure Act (Article 5, Chapter 131E), which contained the current text of G.S. 131E-79(a) providing MCC with rulemaking authority. While the current iteration of the statutory scheme replaces Article 13A of Chapter 131, there is no evidence that the legislature intended, by citing to the repealed statutes, to refer to Article 5, Chapter 131E. *See Lundsford v. Mills*, 367 N.C. 618, 623, 766 S.E.2d 297, 301 (2014) (in ascertaining legislative intent, one

should "give effect to the words actually used in a statute and not . . . delete words used or . . . insert words not used."). Contrarily, the legislature refers explicitly to Chapter 131E elsewhere within G.S. 143B-165. *See, e.g.*, G.S. 131E-165(11) (2021) ("The Commission is authorized to adopt such rules as may be necessary to carry out the provisions of Part C of Article 6, and Article 10, of Chapter 131E of the General Statutes of North Carolina."). If the legislature wished for G.S. 143B-165 to refer to Article 5 of Chapter 131E, it could have amended the statutory text. As it chose not to, but rather included a new, independent grant of rulemaking authority within Article 5, it is staff's opinion that G.S. 143B-165(6) does not provide MCC with an additional source of rulemaking authority with respect to hospital licensure.

Consequently, staff recommends RRC object for lack of statutory authority.

Brian Liebman
Commission Counsel
Issued August 5, 2022

10A NCAC 13B .3801 is readopted as published in 36:12 NCR 1029-1032 as follows:

SECTION .3800 - NURSING SERVICES

10A NCAC 13B .3801 NURSE EXECUTIVE

(a) Whether the facility utilizes a centralized or decentralized organizational structure, a nurse executive shall be responsible for the coordination of nursing organizational functions.

(b) A nurse executive shall develop facility wide patient care programs, ~~policies~~ policies, and procedures that describe how the nursing care needs of patients are assessed, ~~met~~ met, and evaluated.

(c) The nurse executive shall develop and adopt, subject to the approval of the facility, a set of administrative policies and procedures to establish a framework to accomplish required functions.

(d) There shall be scheduled ~~meetings,~~ meetings ~~at least~~ every 60 ~~days,~~ days of the members of the nursing staff to evaluate the quality and efficiency of nursing services. Minutes of these meetings shall be maintained.

(e) The nurse executive shall be responsible for:

(1) the development of a written organizational plan which describes the levels of accountability and responsibility within the nursing organization;

(2) identification of standards and policies and procedures related to the delivery of nursing care;

(3) planning for and the evaluation of the delivery of nursing care delivery system;

(4) establishment of a mechanism to validate qualifications, knowledge, and skills of nursing personnel;

(5) provision of orientation and educational opportunities related to expected nursing ~~performance,~~ performance and maintenance of records pertaining thereto;

(6) implementation of a system for performance evaluation;

(7) provision of nursing care services in conformance with ~~the North Carolina Nursing Practice Act;~~ G.S. 90-171.20(7) and G.S. 90-171.20(8);

(8) assignment of nursing staff to clinical or managerial responsibilities based upon educational preparation, in conformance with licensing laws and an assessment of current competence; and

(9) staffing nursing units with ~~sufficient~~ personnel in accordance with a written ~~plan.~~ plan of care to meet the needs of the patients.

History Note: *Authority G.S. 131E-75(b); 131E-79;*
Eff. January 1, ~~1996.~~ 1996;
Readopted Eff. July 1, 2022.

10A NCAC 13B .3903 is readopted as published in 36:12 NCR 1029-1032 as follows:

10A NCAC 13B .3903 PRESERVATION OF MEDICAL RECORDS

(a) The manager of medical records service shall maintain medical records, whether original, computer media, or microfilm, for ~~a minimum of~~ 11 years following the discharge of an adult patient.

(b) The manager of medical records shall maintain medical records of a patient who is a minor until the patient's 30th birthday.

(c) If a hospital discontinues operation, its management shall make known to the Division where its records are stored. Records shall be stored in a business offering retrieval services for ~~at least~~ 11 years after the closure date.

~~(d) The hospital shall give public notice prior to destruction of its records, to permit former patients or representatives of former patients to claim the record of the former patient. Public notice shall be in at least two forms: written notice to the former patient or their representative and display of an advertisement in a newspaper of general circulation in the area of the facility.~~

~~(e)~~(d) The manager of medical records may authorize the microfilming of medical records. Microfilming may be done on or off the premises. If done off the premises, the facility shall provide for the confidentiality and safekeeping of the records. The original of microfilmed medical records shall not be destroyed until the medical records department has had an opportunity to review the processed film for content.

~~(f)~~(e) Nothing in this Section shall be construed to prohibit the use of automation in the medical records service, provided that all of the provisions in this Rule are met and the information is readily available for use in patient care.

~~(g)~~(f) Only personnel authorized by ~~state~~ State laws and Health Insurance Portability and Accountability Act (HIPAA) regulations shall have access to medical records. Where the written authorization of a patient is required for the release or disclosure of health information, the written authorization of the patient or authorized representative shall be maintained in the original record as authority for the release or disclosure.

~~(h)~~(g) Medical records are the property of the hospital, and they shall not be removed from the facility jurisdiction except through a court order. Copies shall be made available for authorized purposes such as insurance claims and physician review.

History Note: *Authority G.S. ~~90-21.20B;~~ 131E-75(b); 131E-79; 131E-97;*
Eff. January 1, 1996;
Amended Eff. July 1, ~~2009.~~ 2009;
Readopted Eff. July 1, 2022.

10A NCAC 13B .4103 is readopted as published in 36:12 NCR 1029-1032 as follows:

10A NCAC 13B .4103 PROVISION OF EMERGENCY SERVICES

(a) Any ~~of any~~ facility providing emergency services shall establish and maintain policies requiring ~~appropriate~~ medical screening, treatment and transfer services for any individual who presents to the facility emergency department and on whose behalf treatment is requested regardless of that person's ability to pay for medical services and without delay to inquire about the individual's method of payment.

(b) Any facility providing emergency services under the rules of this Section shall install, ~~operate~~ operate, and maintain, on a 24-hour per day basis, an emergency two-way radio ~~licensed by the Federal Communications Commission in the Public Safety Radio Service~~ capable of ~~establishing~~ accessing the North Carolina Voice Interoperability Plan for Emergency Responders (VIPER) radio network for voice ~~radio~~ communication with ~~ambulance units~~ EMS providers transporting patients to ~~said~~ the facility or ~~having any written procedure or agreement for handling emergency services with the local ambulance service, rescue squad or other trained medical~~ or provide on-line medical direction for EMS personnel.

(c) All communication equipment shall be in compliance with ~~current~~ the rules ~~established by North Carolina Rules for Basic Life Support/Ambulance Service (10 NCAC 3D .1100) adopted by reference with all subsequent amendments. Referenced rules are available at no charge from the Office of Emergency Medical Services, 2707 Mail Service Center, Raleigh, N.C. 27699-2707.~~ set forth in 10A NCAC 13P, Emergency Medical Services and Trauma Rules.

History Note: *Authority G.S. 131E-75(b); 131E-79;*
Eff. January 1, ~~1996.~~ 1996;
Readopted Eff. July 1, 2022.

10A NCAC 13B .4104 is readopted as published in 36:12 NCR 1029-1032 as follows:

10A NCAC 13B .4104 MEDICAL DIRECTOR

(a) The governing body shall establish the qualifications, duties, and authority of the director of emergency services. Appointments shall be recommended by the medical staff and approved by the governing body.

(b) The medical staff credentials committee shall approve the mechanism for emergency privileges for physicians employed for brief periods of time such as evenings, ~~weekends~~ weekends, or holidays.

(c) Level I and II emergency services shall be directed and supervised by a ~~physician with experience in emergency care.~~ physician.

(d) Level III services shall be directed and supervised by a ~~physician with experience in emergency care or through a multi-disciplinary medical staff committee. The chairman of this committee shall serve as director of emergency medical services.~~ physician.

History Note: *Authority G.S. 131E-75(b); 131E-79; 131E-85(a);*
RRC objection due to lack of statutory authority Eff. July 13, 1995;
Eff. January 1, ~~1996.~~ 1996;
Readopted Eff. July 1, 2022.

10A NCAC 13B .4106 is readopted as published in 36:12 NCR 1029-1032 as follows:

10A NCAC 13B .4106 POLICIES AND PROCEDURES

Each emergency department shall establish written policies and procedures ~~which~~ that specify the scope and conduct of patient care to be provided in the emergency areas. They shall include the following:

(1) the location, storage, and procurement of medications, blood, supplies, equipment and the procedures to be followed in the event of equipment failure;

(2) the initial management of patients with burns, hand injuries, head injuries, fractures, multiple injuries, poisoning, animal bites, gunshot or stab ~~wounds~~ wounds, and other acute problems;

(3) the provision of care to an unemancipated minor not accompanied by a parent or guardian, or to an unaccompanied unconscious patient;

(4) management of alleged or suspected child, ~~elder~~ elder, or adult abuse;

(5) the management of pediatric emergencies;

(6) the initial management of patients with actual or suspected exposure to radiation;

(7) management of alleged or suspected rape victims;

(8) the reporting of individuals dead on arrival to the proper authorities;

(9) the use of standing orders;

(10) tetanus and rabies prevention or prophylaxis; and

(11) the dispensing of medications in accordance with ~~state~~ State and federal laws.

History Note: *Authority G.S. 131E-75(b); 131E-79;*
Eff. January 1, ~~1996.~~ 1996;
Readopted Eff. July 1, 2022.

10A NCAC 13B .4305 is readopted as published in 36:12 NCR 1029-1032 as follows:

10A NCAC 13B .4305 ORGANIZATION OF NEONATAL SERVICES

(a) The governing body shall approve the scope of all neonatal services and the facility shall classify its capability in providing a range of neonatal services using the following criteria:

(1) LEVEL I: Full-term and pre-term neonates that are stable without complications. This may ~~include,~~ include infants who are small for gestational age or large for gestational age neonates.

(2) LEVEL II: Neonates or infants that are stable without complications but require special care and frequent feedings; infants of any weight who no longer require Level III or LEVEL IV neonatal services, but who still require more nursing hours than normal infant. This may include infants who require close observation in a licensed acute care ~~bed~~ bed.

(3) LEVEL III: Neonates or infants that are high-risk, small (or approximately 32 and less than 36 completed weeks of gestational age) but otherwise healthy, or sick with a moderate degree of illness that are admitted from within the hospital or transferred from another facility requiring intermediate care services for sick infants, but not requiring intensive care. The beds in this level may serve as a "step-down" unit from Level IV. Level III neonates or infants require less constant nursing care, but care does not exclude respiratory support.

(4) LEVEL IV (Neonatal Intensive Care Services): High-risk, medically unstable or critically ill neonates approximately under 32 weeks of gestational age, or infants, requiring constant nursing care or supervision ~~not limited to~~ that includes continuous cardiopulmonary or respiratory support, complicated surgical procedures, or other intensive supportive interventions.

(b) The facility shall provide for the availability of equipment, supplies, and clinical support services.

(c) The medical and nursing staff shall develop and approve policies and procedures for the provision of all neonatal services.

History Note: *Authority G.S. 131E-75(b); 131E-79;*
Eff. January 1, 1996;
Temporary Amendment Eff. March 15, 2002;
Amended Eff. April 1, ~~2003.~~ 2003;
Readopted Eff. July 1, 2022.

10A NCAC 13B .4603 is readopted as published in 36:12 NCR 1029-1032 as follows:

10A NCAC 13B .4603 SURGICAL AND ANESTHESIA STAFF

~~(a)~~ The facility shall develop processes ~~which require that~~ that require each individual ~~provides~~ provide only those services for which proof of licensure and competency can be demonstrated. The facility shall require that:

~~(b) The facility shall require that:~~

(1) when anesthesia is administered, a ~~qualified~~ physician is ~~immediately~~ available in the facility to provide care in the event of a medical emergency;

(2) a roster of practitioners with a delineation of current surgical and anesthesia privileges is available and maintained for the service;

(3) an on-call schedule of surgeons with privileges to be available at all times for emergency surgery and for post-operative clinical management is maintained;

(4) the operating room is supervised by a ~~qualified~~ registered nurse or doctor of medicine or osteopathy; and

(5) an operating room register which shall include date of the operation, name and patient identification number, names of surgeons and surgical assistants, name of anesthetists, type of anesthesia given, pre- and post-operative diagnosis, type and duration of surgical procedure, and the presence or absence of complications in surgery is maintained.

History Note: *Authority G.S. 131E-75(b); 131E-79; 131E-85;*
Eff. January 1, ~~1996.~~ 1996;
Readopted Eff. July 1, 2022.

10A NCAC 13B .4801 is readopted as published in 36:12 NCR 1029-1032 as follows:

SECTION .4800 - DIAGNOSTIC IMAGING

10A NCAC 13B .4801 ORGANIZATION

(a) Imaging services shall be under the supervision of a full-time radiologist, consulting radiologist, or a ~~physician~~ physician. ~~experienced in the particular imaging modality and the~~ The physician in charge ~~must~~ shall have the credentials required by facility policies.

(b) ~~Activities of the imaging service may include radio-therapy.~~ Radio-therapy is a type of imaging service.

(c) All imaging equipment shall be operated under professional supervision by ~~qualified~~ personnel trained in the use of imaging equipment and knowledgeable of all applicable safety precautions required by the North Carolina Department of ~~Environment and Natural Resources,~~ Health and Human Services, Division of ~~Environmental~~ Health Service Regulation, Radiation Protection ~~Section.~~ Section set forth in 10A NCAC 15, hereby incorporated by reference including subsequent amendments. ~~Copies of regulations are available from the N.C. Department of Environment and Natural Resources, Radiation Protection Section, 3825 Barrett Drive, Raleigh, NC 27609 at a cost of sixteen dollars ($16.00) each~~.

History Note: *Authority G.S. 131E-75(b); 131E-79;*
RRC objection due to lack of statutory authority and ambiguity Eff. July 13, 1995;
Eff. January 1, ~~1996.~~ 1996;
Readopted Eff. July 1, 2022.

10A NCAC 13B .4805 is readopted as published in 36:12 NCR 1029-1032 as follows:

10A NCAC 13B .4805 SAFETY

(a) The facility shall require that all imaging equipment is operated under the supervision of a physician and by qualified personnel.

(b) The facility shall require that proper caution is exercised to protect all persons from exposure to radiation.

(c) Safety inspections of the imaging department, including equipment, shall be conducted by the North Carolina Division of ~~Environmental Health,~~ Health Service Regulation, Radiation Protection ~~Services~~ Section. Copies of the report shall be available for review by the Division.

(d) The governing authority shall appoint a radiation safety committee. The committee shall ~~include but is not limited to:~~ include:

(1) a physician experienced in the handling of radio-active isotopes and their therapeutic use; and

(2) other representatives of the medical staff.

(e) All radio-active isotopes, whether for diagnostic, therapeutic, or research purposes shall be received, handled, and disposed of in accordance with the requirements of the North Carolina Department of ~~Environment and Natural Resources,~~ Health and Human Services, Division of ~~Environmental Health,~~ Health Service Regulation, Radiation Protection ~~Services Section.~~ Section set forth in 10A NCAC 15, hereby incorporated by reference including subsequent amendments. ~~Copies of regulations are available from the North Carolina Department of Environment, Health, and Natural Resources, Division of Radiation Protection, 3825 Barrett Drive, Raleigh, NC 27609 at a cost of six dollars ($6.00) each.~~

History Note: *Authority G.S. 131E-75(b); 131E-79;*
Eff. January 1, ~~1996.~~ 1996;
Readopted Eff. July 1, 2022.

10A NCAC 13B .5102 is readopted as published in 36:12 NCR 1029-1032 as follows:

10A NCAC 13B .5102 POLICY AND PROCEDURES

(a) Each facility department or service shall establish and maintain written infection control policies and procedures. These shall ~~include but are not limited to:~~ include:

(1) the role and scope of the service or department in the infection control program;

(2) the role and scope of surveillance activities in the infection control program;

(3) the methodology used to collect and analyze data, maintain a surveillance program on nosocomial infection, and the control and prevention of infection;

(4) the specific precautions to be used to prevent the transmission of infection and isolation methods to be utilized;

(5) the method of sterilization and storage of equipment and supplies, including the reprocessing of disposable items;

(6) the cleaning of patient care areas and equipment;

(7) the cleaning of non-patient care areas; and

(8) exposure control plans.

(b) The infection control committee shall approve all infection control policies and procedures. The committee shall review all policies and procedures ~~at least~~ every three years and indicate the last date of review.

(c) The infection control committee shall meet ~~at least~~ quarterly and maintain minutes of meetings.

History Note: *Authority G.S. 131E-75(b); 131E-79;*
Eff. January 1, ~~1996.~~ 1996;
Readopted Eff July 1, 2022.

10A NCAC 13B .5105 is readopted as published in 36:12 NCR 1029-1032 as follows:

10A NCAC 13B .5105 STERILE SUPPLY SERVICES

The facility shall provide for the following:

(1) decontamination and sterilization of equipment and supplies;

(2) monitoring of sterilizing equipment on a routine schedule;

(3) establishment of policies and procedures for the use of disposable items; and

(4) establishment of policies and procedures addressing shelf life of stored sterile items.

History Note: *Authority G.S. 131E-75(b); 131E-79;*
Eff. January 1, ~~1996.~~ 1996;
Readopted Eff. July 1, 2022.

10A NCAC 13B .5406 is readopted as published in 36:12 NCR 1029-1032 as follows:

10A NCAC 13B .5406 DISCHARGE CRITERIA FOR INPATIENT REHABILITATION FACILITIES OR UNITS

(a) Discharge planning shall be an integral part of the patient's treatment plan and shall begin upon admission to the facility. After established goals have been reached, or a determination has been made that care in a less intensive setting would be appropriate, or that further progress is unlikely, the patient shall be discharged to an appropriate setting. Other reasons for discharge may include an inability or unwillingness of patient or family to cooperate with the planned therapeutic program or medical complications that preclude a further intensive rehabilitative effort. The facility shall involve the patient, family, staff ~~members~~ members, and referral sources in discharge planning.

(b) The case manager shall facilitate the discharge or transfer process in coordination with the facility social worker.

(c) If a patient is being referred to another facility for further care, ~~appropriate~~ documentation of the patient's current status shall be forwarded with the patient. A ~~formal~~ discharge summary shall be forwarded within 48 hours following discharge and shall include the reasons for referral, the diagnosis, functional limitations, services provided, the results of services, referral action ~~recommendations~~ recommendations, and activities and procedures used by the patient to maintain and improve functioning.

History Note: *Authority G.S. 131E-75(b); 131E-79;*
Eff. March 1, ~~1996.~~ 1996;
Readopted Eff. July 1, 2022.

10A NCAC 13B .5408 is readopted as published in 36:12 NCR 1029-1032 as follows:

10A NCAC 13B .5408 COMPREHENSIVE INPATIENT REHABILITATION PROGRAM STAFFING REQUIREMENTS

(a) The staff of the inpatient rehabilitation facility or unit shall ~~include at a minimum:~~ include:

(1) the inpatient rehabilitation facility or unit shall be supervised by a rehabilitation ~~nurse.~~ nurse as defined in Rule .5401 of this Section. The facility shall ~~identify the nursing skills necessary to meet the needs of the rehabilitation patients in the unit and~~ assign staff qualified to meet those needs;

(2) the minimum nursing hours per patient in the rehabilitation unit shall be 5.5 nursing hours per patient day. At no time shall direct care nursing staff be less than two full-time equivalents, one of which must be a registered nurse;

(3) the inpatient rehabilitation unit shall employ or provide by contractual agreements ~~sufficient~~ therapist to provide ~~a minimum of~~ three hours of specific (physical, occupational or speech) or combined rehabilitation therapy services per patient day;

(4) physical therapy assistants and occupational therapy assistants shall be supervised on-site by physical therapists or occupational therapists;

(5) rehabilitation aides shall have documented training appropriate to the activities to be performed and the occupational licensure laws of his or her supervisor. The overall responsibility for the on-going supervision and evaluation of the rehabilitation aide remains with the registered nurse as identified in Subparagraph (a)(1) of this Rule. Supervision by the physical therapist or by the occupational therapist is limited to that time when the therapist is on-site and directing the rehabilitation activities of the aide; and

(6) hours of service by the rehabilitation aide are counted toward the required nursing hours when the aide is working under the supervision of the nurse. Hours of service by the rehabilitation aide are counted toward therapy hours during that time the aide works under the immediate, on-site supervision of the physical therapist or occupational therapist. Hours of service shall not be dually counted for both services. Hours of service by rehabilitation aides in performing nurse-aide duties in areas of the facility other than the rehabilitation unit shall not be counted toward the 5.5 hour minimum nursing requirement described for the rehabilitation unit.

(b) Additional personnel shall be provided as required to meet the needs of the patient, as defined in the comprehensive inpatient rehabilitation evaluation.

History Note: *Authority G.S. 131E-75(b);131E-79;*
RRC Objection due to lack of statutory authority Eff. January 18, 1996;
Eff. May 1, ~~1996.~~ 1996;
Readopted Eff. July 1, 2022.

10A NCAC 13B .5411 is repealed through readoption as published in 36:12 NCR 1029-1032 as follows:

10A NCAC 13B .5411 PHYSICAL FACILITY REQUIREMENTS/INPATIENT REHABILITATION FACILITIES OR UNIT

History Note: *Authority G.S. 131E-79;*
Eff. March 1, ~~1996.~~ 1996;
Repealed Eff. July 1, 2022.

RRC STAFF OPINION

PLEASE NOTE: THIS COMMUNICATION IS EITHER 1) ONLY THE RECOMMENDATION OF AN RRC STAFF ATTORNEY AS TO ACTION THAT THE ATTORNEY BELIEVES THE COMMISSION SHOULD TAKE ON THE CITED RULE AT ITS NEXT MEETING, OR 2) AN OPINION OF THAT ATTORNEY AS TO SOME MATTER CONCERNING THAT RULE. THE AGENCY AND MEMBERS OF THE PUBLIC ARE INVITED TO SUBMIT THEIR OWN COMMENTS AND RECOMMENDATIONS (ACCORDING TO RRC RULES) TO THE COMMISSION.

AGENCY: Medical Care Commission

RULE CITATION: 10A NCAC 13B .4805

RECOMMENDED ACTION:

Approve, but note staff's comment

X Object, based on:

Lack of statutory authority

X Unclear or ambiguous

Unnecessary

Failure to comply with the APA

Extend the period of review

COMMENT:

This Rule, which is also covered by another staff opinion recommending objection for lack of statutory authority, imposes safety requirements for use of imaging equipment using radioactive materials. In paragraph (c), MCC requires the hospital's governing authority to appoint a radiation safety committee and specifies that membership shall include "a physician approved by the medical staff experienced in the handling of radio-active isotopes and their therapeutic use[.]" Despite making this staffing requirement, the Rule does not specify what experience is required to satisfy the requirement. As such, it is staff's opinion that the Rule is unclear and ambiguous, and staff recommends objection to the Rule on that basis.

Brian Liebman
Commission Counsel
Issued August 5, 2022

10A NCAC 13B .4805 is readopted with changes as published in 36:12 NCR 1029-1032 as follows:

10A NCAC 13B .4805 SAFETY

(a) The facility shall require that all imaging equipment is operated under the supervision of a physician and by qualified personnel.

(b) The facility shall require that ~~proper~~ caution is exercised to protect all persons from exposure to radiation.

~~(c) Safety inspections of the imaging department, including equipment, shall be conducted by the North Carolina Division of Environmental Health, [Health Service Regulation,] Radiation Protection Services Section. Copies of the report shall be available for review by the Division.~~

(d) The governing authority shall appoint a radiation safety committee. The committee shall ~~include but is not limited to:~~ include:

(1) a physician approved by the medical staff experienced in the handling of radio-active isotopes and their therapeutic use; and

(2) other representatives of the medical staff.

(e) All radio-active isotopes, whether for diagnostic, therapeutic, or research purposes shall be received, handled, and disposed of in accordance with the requirements of the North Carolina Department of ~~Environment and Natural Resources,~~ Health and Human Services, Division of ~~Environmental Health,~~ Health Service Regulation, Radiation Protection ~~Services Section.~~ Section set forth in 10A NCAC 15, hereby incorporated by reference including subsequent amendments. ~~Copies of regulations are available from the North Carolina Department of Environment, Health, and Natural Resources, Division of Radiation Protection, 3825 Barrett Drive, Raleigh, NC 27609 at a cost of six dollars ($6.00) each.~~

History Note: *Authority G.S. 131E-75(b); 131E-79;*
Eff. January 1, ~~1996.~~ 1996;
Readopted Eff. September 1, 2022.