Burgos, Alexander N

Subject: FW: Submission of Permanent Rule Follow Up Matter Rules - 10A NCAC 13B

From: Liebman, Brian R <brian.liebman@oah.nc.gov>
Sent: Thursday, July 13, 2023 2:07 PM
To: Pfeiffer, Nadine <nadine.pfeiffer@dhhs.nc.gov>
Cc: Hill, Greta D <greta.hill@dhhs.nc.gov>; Burgos, Alexander N <alexander.burgos@oah.nc.gov>
Subject: RE: Submission of Permanent Rule Follow Up Matter Rules - 10A NCAC 13B

Nadine,

Just a heads up, given how long these rules have been on the agenda, I am issuing a staff opinion recommending approval. I didn't want you to see it and think I'd double crossed you and was recommending a continued objection. 😊

Best,
Brian

Brian Liebman
Counsel to the North Carolina Rules Review Commission
Office of Administrative Hearings
(984)236-1948
brian.liebman@oah.nc.gov

Burgos, Alexander N

From: Pfeiffer, Nadine
Sent: Wednesday, July 12, 2023 12:06 PM
To: Rules, Oah
Cc: McGhee, Dana; Burgos, Alexander N; Liebman, Brian R
Subject: Rules for July RRC meeting
Attachments: 10A NCAC 13B .3801.docx; 10A NCAC 13B .3903.docx; 10A NCAC 13B .4103.docx; 10A NCAC 13B .4104.docx; 10A NCAC 13B .4106.docx; 10A NCAC 13B .4305.docx; 10A NCAC 13B .4603.docx; 10A NCAC 13B .4801.docx; 10A NCAC 13B .4805.docx; 10A NCAC 13B .5102.docx; 10A NCAC 13B .5105.docx; 10A NCAC 13B .5406.docx; 10A NCAC 13B .5408.docx; 10A NCAC 13B .5411.docx

Attached for the July 20, 2023 RRC meeting are the revised rules for the RRC's agenda follow-up matter for the N.C. Medical Care Commission for rules 10A NCAC 13B .3801, .3903, .4103, .4104, .4106, .4305, .4603, .4801, .4805, .5102, .5105, .5406, .5408, and .5411. Brian informed me he is recommending approval of these rules and they are all ready to go.

Thank you.

Nadine Pfeiffer
Rules Review Manager
Division of Health Service Regulation
NC Department of Health and Human Services

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10A NCAC 13B .3801 is readopted with changes 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.~~ functions as required in Paragraph (e) of this Rule.

(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)~~(2) planning for and the evaluation of the delivery of nursing care ~~delivery~~ system;

~~(4)~~(3) establishment of a mechanism to validate qualifications, knowledge, and skills of nursing personnel;

~~(5)~~(4) provision of orientation and educational opportunities related to expected nursing ~~performance,~~ performance and maintenance of records pertaining thereto;

~~(6)~~(5) implementation of a system for performance evaluation;

~~(7)~~(6) 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)~~(7) 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)~~(8) 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;~~ 143B-165;*
Eff. January 1, ~~1996.~~ 1996;
Readopted Eff. August 1, 2023.

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

10A NCAC 13B .3903 PRESERVATION OF MEDICAL RECORDS

(a) The manager of the medical records service shall maintain medical ~~records,~~ records that were created when the patient was an adult, whether original, computer media, or ~~microfilm,~~ digital archived 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.~~ that were created when the patient was a minor, whether original, computer media, or digital archived, until the patient's 30th birthday. If a minor patient is readmitted as an adult, the manager of the medical records shall maintain medical records according to Paragraph (a) of this Rule.

(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.~~ date or according to Paragraph (b) of this Rule if the patient was a minor.

~~(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~~ digital archiving of medical records. ~~Microfilming~~ Digital archiving 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~~ digital archived medical records shall not be destroyed until the medical records department has had an opportunity to review the ~~processed film~~ digital record 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 the Health Insurance Portability and Accountability Act (HIPAA) ~~regulations~~ found in 42 CFR 482, which is incorporated by reference including subsequent amendments and editions, shall have access to medical records. This regulation may be obtained free of charge at https://www.govinfo.gov/help/cfr. 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~~ shall remain the property of the hospital, 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; 143B-165;*
Eff. January 1, 1996;
Amended Eff. July 1, ~~2009.~~ 2009;

Readopted Eff. August 1, 2023.

10A NCAC 13B .4103 is readopted with changes 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;~~ 143B-165;*
Eff. January 1, ~~1996.~~ 1996;
Readopted Eff. August 1, 2023.

10A NCAC 13B .4104 is readopted with changes 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); 143B-165;*
RRC objection due to lack of statutory authority Eff. July 13, 1995;
Eff. January 1, ~~1996.~~ 1996;
Readopted Eff. August 1, 2023.

10A NCAC 13B .4106 is readopted with changes 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~~ 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;~~ 143B-165;*
Eff. January 1, ~~1996.~~ 1996;
Readopted Eff. August 1, 2023.

10A NCAC 13B .4305 is readopted with changes 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 neonates who are large for gestational ~~age neonates.~~ age.

(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~~ 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~~ or approximately 32 and less than 36 completed weeks of gestational ~~age)~~ 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~~ 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;~~ 143B-165;*
Eff. January 1, 1996;
Temporary Amendment Eff. March 15, 2002;
Amended Eff. April 1, ~~2003.~~ 2003;
Readopted Eff. August 1, 2023.

10A NCAC 13B .4603 is readopted with changes 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; 143B-165;*
Eff. January 1, ~~1996.~~ 1996;
Readopted Eff. August 1, 2023.

10A NCAC 13B .4801 is readopted with changes 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;~~ 143B-165;*
RRC objection due to lack of statutory authority and ambiguity Eff. July 13, 1995;
Eff. January 1, ~~1996.~~ 1996;
Readopted Eff. August 1, 2023.

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)~~(c) 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)~~(d) 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;~~ 143B-165;*
Eff. January 1, ~~1996.~~ 1996;
Readopted Eff. August 1, 2023.

10A NCAC 13B .5102 is readopted with changes 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 the following written infection control policies and ~~procedures. These shall include but are not limited to:~~ [~~include:~~] procedures:

(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;~~ 143B-165;*
Eff. January 1, ~~1996.~~ 1996;
Readopted Eff August 1, 2023.

10A NCAC 13B .5105 is readopted with changes 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;~~ 143B-165;*
Eff. January 1, ~~1996.~~ 1996;
Readopted Eff. August 1, 2023.

10A NCAC 13B .5406 is readopted with changes 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 of care have been reached, or a determination by the interdisciplinary care team has been made ~~that care~~ ~~in a less intensive setting would be appropriate,~~ to return to the setting from which the patient was admitted, or that further progress is unlikely, the patient shall be discharged to ~~an appropriate setting.~~ another inpatient or residential health care facility that can address the patient's needs including skilled nursing homes, assisted living facilities, nursing homes, or other hospitals. 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~~ community-based services such as home health services, hospice or palliative care, respiratory services, rehabilitation services to include occupational therapy, physical therapy, and speech therapy, end stage renal disease, nutritional, medical equipment and supplies, transportation services, meal services, and household services such as housekeeping 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;~~ 143B-165;*
Eff. March 1, ~~1996.~~ 1996;
Readopted Eff. August 1, 2023.

10A NCAC 13B .5408 is readopted with changes 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;~~ the needs of the patient;

(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~~ therapists 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)~~(4) 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)~~(5) 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;~~ 143B-165;*
RRC Objection due to lack of statutory authority Eff. January 18, 1996;
Eff. May 1, ~~1996.~~ 1996;
Readopted Eff. August 1, 2023.

10A NCAC 13B .5411 is repealed through readoption with changes 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;~~ 143B-165;*
Eff. March 1, ~~1996.~~ 1996;
Repealed Eff. August 1, 2023.

Burgos, Alexander N

Subject: FW: Submission of Permanent Rule Follow Up Matter Rules - 10A NCAC 13B

From: Liebman, Brian R <brian.liebman@oah.nc.gov>
Sent: Wednesday, July 12, 2023 12:01 PM
To: Pfeiffer, Nadine <nadine.pfeiffer@dhhs.nc.gov>
Cc: Hill, Greta D <greta.hill@dhhs.nc.gov>; Burgos, Alexander N <alexander.burgos@oah.nc.gov>
Subject: RE: Submission of Permanent Rule Follow Up Matter Rules - 10A NCAC 13B

Sounds good. Thanks, Nadine!

Brian Liebman
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(984)236-1948
brian.liebman@oah.nc.gov

From: Pfeiffer, Nadine <nadine.pfeiffer@dhhs.nc.gov>
Sent: Wednesday, July 12, 2023 11:46 AM
To: Liebman, Brian R <brian.liebman@oah.nc.gov>
Cc: Hill, Greta D <greta.hill@dhhs.nc.gov>; Burgos, Alexander N <alexander.burgos@oah.nc.gov>
Subject: RE: Submission of Permanent Rule Follow Up Matter Rules - 10A NCAC 13B

Thank you, Brian. That wording change does make sense. Our apologies for not seeing that sooner. Will revise Rule .5406 further and will send all the rules to Dana and Alex (and cc you) for the meeting on July 20th.

Nadine Pfeiffer
Rules Review Manager
Division of Health Service Regulation
NC Department of Health and Human Services

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From: Liebman, Brian R <brian.liebman@oah.nc.gov>
Sent: Wednesday, July 12, 2023 11:35 AM
To: Pfeiffer, Nadine <nadine.pfeiffer@dhhs.nc.gov>

Cc: Hill, Greta D <greta.hill@dhhs.nc.gov>; Burgos, Alexander N <alexander.burgos@oah.nc.gov>
Subject: RE: Submission of Permanent Rule Follow Up Matter Rules - 10A NCAC 13B

Hi Nadine,

Everything looks good except for .5406. The second sentence in (a) still reads a little strangely, and I think you may need to delete a few more words. Currently as edited it says: "After goals of care have been reached, or a determination by the interdisciplinary care team has been made **that care** to return to the setting from which the patient was admitted, or that further progress is unlikely…." I think the bolded "that care" needs to be deleted.

That's the last change I have. If you want to make this minor change, and then send the final versions of all of these rules to Dana and Alex for filing, I'll let them know I'm recommending approval and these are ready to go.

Thanks,
Brian

Brian Liebman
Counsel to the North Carolina Rules Review Commission
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Burgos, Alexander N

Subject: FW: Submission of Permanent Rule Follow Up Matter Rules – 10A NCAC 13B

From: Pfeiffer, Nadine <nadine.pfeiffer@dhhs.nc.gov>
Sent: Wednesday, July 5, 2023 11:52 AM
To: Liebman, Brian R <brian.liebman@oah.nc.gov>
Cc: Burgos, Alexander N <alexander.burgos@oah.nc.gov>; Hill, Greta D <greta.hill@dhhs.nc.gov>; Conley, Azzie <azzie.conley@dhhs.nc.gov>; Harms, Jeff <jeff.harms@dhhs.nc.gov>; Sylvester, Tammy <tammy.sylvester@dhhs.nc.gov>
Subject: RE: Submission of Permanent Rule Follow Up Matter Rules – 10A NCAC 13B

Brian,
Thank you!!!!!!!!!! I am currently involved with a high priority issue so giving me until next Friday gives me some breathing room.

Thank you so much!!!

Nadine Pfeiffer
Rules Review Manager
Division of Health Service Regulation
NC Department of Health and Human Services

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Raleigh, NC 27699-2701

From: Liebman, Brian R <brian.liebman@oah.nc.gov>
Sent: Wednesday, July 5, 2023 11:44 AM
To: Pfeiffer, Nadine <nadine.pfeiffer@dhhs.nc.gov>
Cc: Burgos, Alexander N <alexander.burgos@oah.nc.gov>; Hill, Greta D <greta.hill@dhhs.nc.gov>; Conley, Azzie <azzie.conley@dhhs.nc.gov>; Harms, Jeff <jeff.harms@dhhs.nc.gov>; Sylvester, Tammy <tammy.sylvester@dhhs.nc.gov>
Subject: Re: Submission of Permanent Rule Follow Up Matter Rules – 10A NCAC 13B

Nadine,

Unless you foresee some issue arising with making these changes, the Friday before the meeting would be fine. Otherwise, if you anticipate that we'll need to hash out something further, let me know asap.

Sorry I didn't specify in the email.

Brian Liebman
Counsel to the North Carolina Rules Review Commission

Office of Administrative Hearings
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From: Pfeiffer, Nadine <nadine.pfeiffer@dhhs.nc.gov>
Sent: Wednesday, July 5, 2023 11:39:32 AM
To: Liebman, Brian R <brian.liebman@oah.nc.gov>
Cc: Burgos, Alexander N <alexander.burgos@oah.nc.gov>; Hill, Greta D <greta.hill@dhhs.nc.gov>; Conley, Azzie <azzie.conley@dhhs.nc.gov>; Harms, Jeff <jeff.harms@dhhs.nc.gov>; Sylvester, Tammy <tammy.sylvester@dhhs.nc.gov>
Subject: RE: Submission of Permanent Rule Follow Up Matter Rules – 10A NCAC 13B

Thank you, Brian. We will make the minor rule corrections and get them back to you as quickly as we can. Is there a timeframe you need these by?

Nadine Pfeiffer
Rules Review Manager
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From: Liebman, Brian R <brian.liebman@oah.nc.gov>
Sent: Wednesday, July 5, 2023 11:25 AM
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Cc: Burgos, Alexander N <alexander.burgos@oah.nc.gov>; Hill, Greta D <greta.hill@dhhs.nc.gov>; Conley, Azzie <azzie.conley@dhhs.nc.gov>; Harms, Jeff <jeff.harms@dhhs.nc.gov>; Sylvester, Tammy <tammy.sylvester@dhhs.nc.gov>
Subject: RE: Submission of Permanent Rule Follow Up Matter Rules – 10A NCAC 13B

Hi Nadine,

Thanks for sending these over. In general, I think I will be able to recommend that the amendments made satisfy the Commission's objections. That includes Rule .4805. In reviewing the Rules, however, I noticed a few minor issues that I think you'll want to correct:

In all rules, I think you should delete the references to 131E-75(b) and 131E-79. As we discussed at length last year, neither of these statutes gives MCC relevant rulemaking authority.

Rule .3801 – in (c), line 11, I think you only meant to delete the punctuation after "functions". Add the word back in.

Rule .4103 – in (b), lines 12-13, I think as edited you have two back to back instances of "or".

Rule .4106 - in (1), line 6, add an oxford comma after "equipment".

Rule .5102 – on line 5, the term "includes" is open ended and connotes unstated requirements. Suggest adding on line 4: "…maintain the following written infection control policies…" and deleting "These shall include:" on line 5.

Rule .5406 – in (a), line 7, I think there's been a formatting error. Did you mean to delete "that care in a less intensive setting"? As currently written the rule says "…a determination by the interdisciplinary care team has been made that care in a less intensive setting to return to the setting from which was admitted". Also, did you mean "the setting from which the patient was admitted"?

In (a), line 13, consider "such as" rather than "include, but not limited to". In any case please omit "but not limited to".

Rule .5408 – (a)(3), line 14, I think you need to finesse the language a little. As written: "…shall employ or provide by contractual agreements therapist to provide three hours…" Maybe make that "therapists"?

Hope you all had a great 4th of July!

Best,
Brian

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From: Pfeiffer, Nadine <nadine.pfeiffer@dhhs.nc.gov>
Sent: Monday, July 3, 2023 11:41 AM
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Subject: Submission of Permanent Rule Follow Up Matter Rules – 10A NCAC 13B

Brian,
On June 29th, H190 was signed into law as S.L. 2023-65. In Section 4.1 of this law were amendments to G.S. 143B-165 for the Medical Care Commission's powers and duties. A follow-up matter on the RRC's agenda following the RRC's August 18, 2022 meeting has been the Licensing of Hospital's rules in 10A NCAC 13B due to outstanding objections for lack of statutory authority for all the rules and an addition objection for ambiguity for a rule.

Attached for your review are the 14 Licensing of Hospital rules in 10A NCAC 13B that have been revised to satisfy these longstanding objections. The history notes have been updated to add G.S. 143B-165 that was amended by S.L. 2023-65. In addition, the text of rule 10A NCAC 13B .4305 has been revised for clarity.

Should you have any questions regarding the attachments, or should you have any follow up questions or concerns, please feel free to contact me.

Nadine Pfeiffer

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GENERAL ASSEMBLY OF NORTH CAROLINA
SESSION 2023

SESSION LAW 2023-65
HOUSE BILL 190

AN ACT MAKING TECHNICAL, CONFORMING, AND OTHER MODIFICATIONS TO LAWS PERTAINING TO THE DEPARTMENT OF HEALTH AND HUMAN SERVICES AND TO MAKE TECHNICAL AND CONFORMING CHANGES TO SESSION LAW 2023-14.

The General Assembly of North Carolina enacts:

PART I. LAWS PERTAINING TO THE DIVISION OF AGING AND ADULT SERVICES

AUTHORIZATION FOR SECRETARY OF HEALTH AND HUMAN SERVICES TO ADOPT AND ENFORCE RULES TO IMPLEMENT EMERGENCY SOLUTIONS GRANT PROGRAM

SECTION 1.1. Article 3 of Chapter 143B of the General Statutes is amended by adding a new section to read:

"**§ 143B-139.1A. Secretary of Health and Human Services; rules to implement the Emergency Solutions Grant Program.**

The Secretary of Health and Human Services may adopt rules to implement the Emergency Solutions Grant Program. The Department of Health and Human Services shall enforce any rules adopted under this section."

ALIGNMENT OF STATE-COUNTY SPECIAL ASSISTANCE PROGRAM WITH FEDERAL REGULATIONS/REMOVAL OF PROPERTY TAX THRESHOLD WHEN DETERMINING ELIGIBILITY

SECTION 1.2. G.S. 108A-41 reads as rewritten:

"**§ 108A-41. Eligibility.**

…

(c) When determining whether a person has insufficient resources to provide a reasonable subsistence compatible with decency and health, there shall be excluded from consideration the person's primary place of residence and the land on which it is situated, and in addition there shall be excluded real property contiguous with the person's primary place of ~~residence in which the property tax value is less than twelve thousand dollars ($12,000).~~residence.

…."

EQUALIZATION OF STATE-COUNTY SPECIAL ASSISTANCE PAYMENTS FOR RECIPIENTS RESIDING IN LICENSED FACILITIES APPROVED TO ACCEPT STATE-COUNTY SPECIAL ASSISTANCE AND RECIPIENTS RESIDING IN IN-HOME LIVING ARRANGEMENTS

SECTION 1.3. G.S. 108A-47.1(a) reads as rewritten:

"(a) The Department of Health and Human Services ~~may~~ shall use funds from the existing State-County Special Assistance budget to provide Special Assistance payments to eligible individuals 18 years of age or older in in-home living arrangements. The standard monthly

payment to individuals enrolled in the Special Assistance in-home program shall be one hundred percent (100%) of the monthly payment the individual would receive if the individual resided in an adult care home and qualified for Special ~~Assistance, except if a lesser payment amount is appropriate for the individual as determined by the local case manager.~~ Assistance. The Department shall implement Special Assistance in-home eligibility policies and procedures to assure that in-home program participants are those individuals who need and, but for the in-home program, would seek placement in an adult care home facility. The Department's policies and procedures shall include the use of ~~a functional~~ an assessment."

PART II. LAWS PERTAINING TO THE DIVISION OF CENTRAL MANAGEMENT AND SUPPORT

CONTRACTING REFORM

SECTION 2.1. Section 2 of S.L. 2022-52 reads as rewritten:

"**SECTION 2.(a)** Contract Time and Continuity. – In efforts to support the continuity of services provided by ~~nonprofit grantees receiving state and federal funds,~~ a nonprofit grantee receiving State or federal funds or any combination of State and federal funds through a financial assistance contract, the Department of Health and Human Services (Department) shall enter into a contract agreement for a minimum of ~~a two-year contract agreement~~ two years with such nonprofit ~~grantees/recipients~~ grantee if ~~all of~~ the following requirements are met:

(1) The nonprofit ~~grantee/recipient~~ grantee is receiving nonrecurring ~~funding~~ funds for each year of a fiscal biennium.

(2) The nonprofit ~~grantee/recipient~~ grantee is receiving recurring ~~funding.~~funds for each year of a fiscal biennium.

(3) The nonprofit grantee is receiving any combination of recurring and nonrecurring funds for each year of a fiscal biennium.

~~(3)~~(4) Multiyear contracts are not otherwise prohibited by the funding source.

"**SECTION 2.(a1)** ~~Nonprofit grantees/recipients~~ Option for Contract Extension. – A nonprofit grantee receiving recurring federal grant ~~funding shall have~~ funds through a financial assistance contract has the option to extend the contract for up to one additional year at the end of the ~~contract's~~ initial term of the contract if all of the following requirements are met:

(1) The extension is mutually agreed upon by the Department and the nonprofit grantee, through a written amendment as provided for in the ~~General Terms and Conditions.~~terms and conditions of the contract.

(2) Funding for the contract remains available.

"**SECTION 2.(a2)** Automatic Contract Extension. – The Department shall allow any nonprofit ~~grantee/recipient~~ grantee receiving recurring or nonrecurring ~~state and/or~~ State or federal ~~funding~~ funds, or any combination of State and federal funds, through a financial assistance contract for each year of a fiscal biennium to automatically activate a limited-time ~~extensions~~ contract extension for a period of up to three months ~~for~~ to preserve continuity of services when a formal contract extension or renewal process has not been completed within 10 business days ~~of~~ after the ~~subsequent contract start date if all of~~ expiration of the original contract; provided, however, that all of the following requirements are met:

(1) The nonprofit ~~grantee/recipient~~ grantee is receiving recurring ~~funding~~ funds, or nonrecurring ~~state and/or federal funding~~ State or federal funds, or any combination of nonrecurring State and federal funds, for each year of a fiscal biennium.

(2) The nonprofit ~~grantee/recipient~~ grantee has received an unqualified audit report on its most recent financial audit when an audit is required by G.S. 159-34 or 09 NCAC 03M.

(3) The nonprofit ~~grantee/recipient~~ grantee has a track record of timely performance and financial reporting to the Department as required by the contract.

(4) The nonprofit ~~grantee/recipient~~ grantee has not been identified by the Department as having a record of noncompliance with requirements of any funding source used to support the contract and has not received an undisputed notice of such noncompliance from the Department. For purposes of this requirement, noncompliance does not include issues stemming from late execution of a contract or mutually agreed upon changes to scope of work or deliverables, and undisputed notice of noncompliance does not include notice of noncompliance where the nonprofit grantee has provided written evidence of actual compliance to the Department within 30 days ~~of~~ after receipt of a notice of noncompliance.

(5) The nonprofit ~~grantee/recipient~~ grantee has been in operation for at least five years.

In the event of an automatic contract extension pursuant to this subsection, the terms of the expired contract shall govern the relationship and obligations of the party until the end of the three-month contract extension period or until the execution of a formal contract extension or renewal, whichever occurs first.

…

"**SECTION 2.(c)** Negotiated Overhead Rates. – The negotiation, determination, or settlement of the reimbursable amount of overhead under cost-reimbursement type contracts is accomplished on an individual contract basis and is based upon the federally approved indirect cost rate. For ~~vendors who~~ grantees, including nonprofit grantees, that (i) are receiving financial assistance and do not have a federally approved indirect cost ~~rate,~~ rate from a federal agency or (ii) have a previously negotiated but expired rate, the Department may allow the grantee, in accordance with 2 C.F.R. § 200.332(a)(4) or 2 C.F.R. § 200.414(f), ~~the de minimis rate of ten percent (10%) of modified total direct costs shall apply.~~to use the de minimis rate or ten percent (10%) of modified total direct costs. Alternatively, the grantee may negotiate or waive an indirect cost rate with the Department. If State or federal law or regulations establish a limitation on the amount of funds the grantee may use for administrative purposes, then that limitation controls, in accordance with 2 C.F.R. § 200.414(c)(3)."

PART III. LAWS PERTAINING TO THE DIVISION OF CHILD AND FAMILY WELL-BEING

CONFORMING CHANGES RELATED TO ESTABLISHMENT OF NEW DIVISION

SECTION 3.1. G.S. 7B-1402 reads as rewritten:

"**§ 7B-1402. Task Force – creation; membership; vacancies.**

(a) There is created the North Carolina Child Fatality Task Force within the Department of Health and Human Services for budgetary purposes only.

(b) The Task Force shall be composed of 36 members, 12 of whom shall be ex officio members, four of whom shall be appointed by the Governor, 10 of whom shall be appointed by the Speaker of the House of Representatives, and 10 of whom shall be appointed by the President Pro Tempore of the Senate. The ex officio members other than the Chief Medical Examiner may designate representatives from their particular departments, divisions, or offices to represent them on the Task Force. In making appointments or designating representatives, appointing authorities and ex officio members shall use best efforts to select members or representatives with sufficient knowledge and experience to effectively contribute to the issues examined by the Task Force and, to the extent possible, to reflect the geographical, political, gender, and racial diversity of this State. The members shall be as follows:

(1) The Chief Medical Examiner.
(2) The Attorney General.
(3) The Director of the Division of Social ~~Services.~~Services, Department of Health and Human Services.
(4) The Director of the State Bureau of Investigation.
(5) The Director of the ~~Maternal and Child Health Section of the~~ Division of Public Health, Department of Health and Human Services.
(6) The chair of the Council for Women and Youth Involvement.
(7) The Superintendent of Public Instruction.
(8) The Chairman of the State Board of Education.
(9) The Director of the ~~Division of Mental Health, Developmental Disabilities, and Substance Abuse Services.~~Division of Child and Family Well-Being, Department of Health and Human Services.

…."

SECTION 3.2. G.S. 7B-1404(b) reads as rewritten:

"(b) The State Team shall be composed of the following 11 members of whom nine members are ex officio and two are appointed:

(1) The Chief Medical Examiner, who shall chair the State ~~Team;~~Team.
(2) The Attorney ~~General;~~General.
(3) The Director of the Division of Social Services, Department of Health and Human ~~Services;~~Services.
(4) The Director of the State Bureau of ~~Investigation;~~Investigation.
(5) The Director of the Division of ~~Maternal and Child Health of the~~ Public Health, Department of Health and Human ~~Services;~~Services.
(6) The Superintendent of Public ~~Instruction;~~Instruction.
(7) The Director of the Division ~~of Mental Health, Developmental Disabilities, and Substance Abuse Services,~~ of Child and Family Well-Being, Department of Health and Human ~~Services;~~Services.
(8) The Director of the Administrative Office of the ~~Courts;~~Courts.
(9) The pediatrician appointed pursuant to G.S. 7B-1402(b) to the Task ~~Force;~~Force.
(10) A public member, appointed by the ~~Governor; and~~Governor.
(11) The Team Coordinator.

The ex officio members other than the Chief Medical Examiner may designate a representative from their departments, divisions, or offices to represent them on the State Team."

SECTION 3.3. G.S. 122C-113(b1) reads as rewritten:

"(b1) The Secretary shall cooperate with the State Board of Education and the Division of Juvenile Justice of the Department of Public Safety in coordinating the responsibilities of the Department of Health and Human Services, the State Board of Education, the Division of Juvenile Justice of the Department of Public Safety, and the Department of Public Instruction for adolescent substance abuse programs. The Department of Health and Human Services, through its Division of Mental Health, Developmental Disabilities, and Substance Abuse ~~Services,~~ Services and its Division of Child and Family Well-Being, in cooperation with the Division of Juvenile Justice of the Department of Public Safety, shall be responsible for intervention and treatment in non-school based programs. The State Board of Education and the Department of Public Instruction, in consultation with the Division of Juvenile Justice of the Department of Public Safety, shall have primary responsibility for in-school education, identification, and intervention services, including student assistance programs."

SECTION 3.4. G.S. 122C-142.2(g) reads as rewritten:

"(g) The Rapid Response Team shall be comprised of representatives of the Department of Health and Human Services from the Division of Social Services; the Division of Mental

Health, Developmental Disabilities, and Substance Abuse Services; the Division of Child and Family Well-Being; and the Division of Health Benefits. Upon receipt of a notification from a director, the Rapid Response Team shall evaluate the information provided and coordinate a response to address the immediate needs of the juvenile, which may include any of the following:

(1) Identifying an appropriate level of care for the juvenile.
(2) Identifying appropriate providers or other placement for the juvenile.
(3) Making a referral to qualified services providers.
(4) Developing an action plan to ensure the needs of the juvenile are met.
(5) Developing a plan to ensure that relevant parties carry out any responsibilities to the juvenile."

PART IV. LAWS PERTAINING TO THE DIVISION OF HEALTH SERVICE REGULATION

MEDICAL CARE COMMISSION CLARIFICATION OF POWERS AND DUTIES

SECTION 4.1. G.S. 143B-165 reads as rewritten:

"**§ 143B-165. North Carolina Medical Care Commission – creation, powers and duties.**

There is hereby created the North Carolina Medical Care Commission of the Department of Health and Human Services with the power and duty to ~~promulgate~~ adopt rules ~~and regulations~~ to be followed in the construction and maintenance of public and private hospitals, medical centers, and ~~related~~ facilities ~~with the power and duty~~ regulated under Chapters 131D and 131E of the General Statutes; to adopt, amend and rescind rules ~~and regulations~~ under and not inconsistent with the laws of the State as necessary to carry out the provisions and purposes of this ~~Article.~~Article; and to protect the health, safety, and welfare of the individuals served by these facilities.

(1) The North Carolina Medical Care Commission ~~has the duty to~~ shall adopt statewide plans for the construction and maintenance of hospitals, medical centers, and ~~related facilities,~~ facilities regulated under Chapters 131D and 131E of the General Statutes, or such other plans as may be found desirable and necessary ~~in order~~ to meet the requirements and receive the benefits of any applicable federal ~~legislation with regard thereto.~~legislation.
(2) The Commission ~~is authorized to~~ may adopt such rules ~~and regulations~~ as may be necessary to carry out the intent and purposes of Article ~~13~~ 4 of Chapter ~~131~~ 131E of the General ~~Statutes of North Carolina.~~Statutes.
~~(3) The Commission may adopt such reasonable and necessary standards with reference thereto as may be proper to cooperate fully with the Surgeon General or other agencies or departments of the United States and the use of funds provided by the federal government as contained and referenced in Article 13 of Chapter 131 of the General Statutes of North Carolina.~~
(4) The Commission ~~shall have~~ has the power and duty to approve projects in the amounts of grants-in-aid from funds supplied by the federal and State governments for the planning and construction of hospitals and other related medical facilities ~~according to the provisions of Article 13~~ in accordance with Articles 4 and 5 of Chapter ~~131~~ 131E of the General ~~Statutes of North Carolina.~~Statutes.
(5) Repealed by Session Laws 1981 (Regular Session, 1982), c. 1388, s. 3.
(6) The Commission ~~has the duty to~~ shall adopt rules ~~and regulations and standards with respect to~~ establishing standards for the licensure, inspection, and operation of, and the provision of care and services by, the different types of hospitals to be licensed under ~~the provisions of Article 13A~~ Articles 2 and 5 of Chapter ~~131~~ 131E of the General ~~Statutes of North Carolina.~~Statutes.

(7) The Commission ~~is authorized and empowered to~~ may adopt such ~~rules and regulations,~~ rules, not inconsistent with the laws of this State, as may be required by the federal government ~~for~~ to secure federal grants-in-aid for medical facility services and ~~licensure which may be made available to the State by the federal government.~~ licensure. This section ~~is to~~ shall be liberally construed in order that the State and its citizens may benefit from such grants-in-aid.

(8) The Commission shall adopt such ~~rules and regulations,~~ rules, consistent with the provisions of this Chapter. All rules ~~and regulations not inconsistent with the provisions of this Chapter heretofore~~ adopted by the ~~North Carolina Medical Care~~ Commission since the enactment of Chapter 131E of the General Statutes that are not inconsistent with the provisions of this Chapter shall remain in full force and effect ~~unless and~~ until repealed or superseded by action of the ~~North Carolina Medical Care~~ Commission. All rules ~~and regulations~~ adopted by the Commission shall be enforced by the Department of Health and Human Services.

(9) The Commission ~~shall have the power and duty to~~ may adopt rules ~~and regulations with regard to~~ concerning emergency medical services in accordance with the provisions of Article ~~26~~ 7 of Chapter ~~130~~ 131E and Article 56 of Chapter 143 of the General ~~Statutes of North Carolina.~~Statutes.

(10) The Commission ~~shall have the power and duty to~~ shall adopt rules for the operation of nursing homes, as defined by Article 6 of Chapter 131E of the General Statutes.

(11) The Commission ~~is authorized to~~ may adopt ~~such~~ rules as ~~may be~~ necessary to ~~carry out the provisions of Part C of Article 6, and Article 10,~~ establish standards for the licensure, inspection, and operation of, and the provision of care and services by, facilities licensed under Articles 6 and 10 of Chapter 131E of the General ~~Statutes of North Carolina.~~Statutes.

(12) The Commission shall adopt ~~rules, including temporary rules pursuant to G.S. 150B-13,~~ rules providing for the accreditation of facilities that perform mammography procedures and for laboratories evaluating screening pap smears. Mammography accreditation standards shall address, but are not limited to, the quality of mammography equipment used and the skill levels and other qualifications of personnel who administer mammographies and personnel who interpret mammogram results. The Commission's standards shall be no less stringent than those established by the United States Department of Health and Human Services for Medicare/Medicaid coverage of screening mammography. These rules shall also specify procedures for waiver of these accreditation standards on an individual basis for any facility providing screening mammography to a significant number of patients, but only if there is no accredited facility located nearby. The Commission may grant a waiver subject to any conditions it deems necessary to protect the health and safety of patients, including requiring the facility to submit a plan to meet accreditation standards.

(13) The Commission ~~shall have the power and duty to~~ shall adopt rules establishing standards for the ~~inspection and licensure of~~ licensure, inspection, and operation of, and the provision of care and services by, adult care ~~homes and operation of adult care~~ homes, as defined by Article 1 of Chapter 131D of the General Statutes, and for personnel requirements of staff employed in adult care homes, except ~~where~~ when rule-making authority is assigned by law to the Secretary.

(14) The Commission shall adopt rules establishing standards for the following with respect to facilities used as multiunit assisted housing with services, as defined by Article 1 of Chapter 131D of the General Statutes:

a. Registration and deregistration.
b. Disclosure statements.
c. Agreements for services.
d. Personnel requirements.
e. Resident admissions and discharges."

PART V. LAWS PERTAINING TO THE DIVISION OF MENTAL HEALTH, DEVELOPMENTAL DISABILITIES, AND SUBSTANCE ABUSE SERVICES

TECHNICAL CHANGES/POPULATIONS COVERED BY LME/MCOS

SECTION 5.1.(a) G.S. 122C-115 reads as rewritten:

"**§ 122C-115. Duties of counties; appropriation and allocation of funds by counties and cities.**

…

(e) Beginning ~~on the date that capitated contracts under Article 4 of Chapter 108D of the General Statutes begin,~~ July 1, 2021, LME/MCOs shall cease managing Medicaid services for all Medicaid recipients ~~other than recipients described in G.S. 108D-40(a)(1), (4), (5), (6), (7), (10), (11), (12), and (13).~~ who are enrolled in a standard benefit plan.

(e1) Until BH IDD tailored plans become operational, all of the following shall occur:

(1) LME/MCOs shall continue to manage the Medicaid services that are covered by the LME/MCOs under the combined 1915(b) and (c) waivers for Medicaid recipients ~~described in G.S. 108D-40(a)(1), (4), (5), (6), (7), (10), (11), (12), and (13).~~who are covered by the those waivers and who are not enrolled in a standard benefit plan.

(2) The Division of Health Benefits shall negotiate actuarially sound capitation rates directly with the LME/MCOs based on the change in composition of the population being served by the LME/MCOs.

(3) Capitation payments under contracts between the Division of Health Benefits and the LME/MCOs shall be made directly to the LME/MCO by the Division of Health Benefits.

(f) ~~Entities~~ LME/MCOs operating the BH IDD tailored plans under G.S. 108D-60 may continue to manage the behavioral health, intellectual and developmental disability, and traumatic brain injury services for any Medicaid recipients ~~described in G.S. 108D-40(a)(4), (5), (7), (10), (11), (12), and (13) under any contract with the Department in accordance with G.S. 108D-60(b).~~who are not enrolled in a BH IDD tailored plan."

SECTION 5.1.(b) G.S. 108D-60(b) reads as rewritten:

"(b) The Department may contract with entities operating BH IDD tailored plans under a capitated or other arrangement for the management of behavioral health, intellectual and developmental disability, and traumatic brain injury services for any recipients ~~excluded from PHP coverage under G.S. 108D-40(a)(4), (5), (7), (10), (11), (12), and (13).~~who are not enrolled in a BH IDD tailored plan."

SECTION 5.1.(c) G.S. 122C-3 reads as rewritten:

"**§ 122C-3. Definitions.**

The following definitions apply in this Chapter:

…

(2b) ~~"Behavioral~~ Behavioral health and intellectual/developmental disabilities tailored ~~plan"~~ plan or ~~"BH~~ BH IDD tailored ~~plan" has the same meaning as~~ plan. – As defined in G.S. 108D-1.

…

(29b) ~~"Prepaid~~ Prepaid health ~~plan" has the same meaning as~~ plan. – As defined in G.S. 108D-1.

…

(35b) Specialty services. – Services that are provided to consumers from low-incidence populations.

~~(35c) State or Local Consumer Advocate. The individual carrying out the duties of the State or Local Consumer Advocacy Program Office in accordance with Article 1A of this Chapter.~~

(35d) Standard benefit plan. – As defined in G.S. 108D-1.

(35e) State Plan. – The State Plan for Mental Health, Developmental Disabilities, and Substance Abuse Services.

~~(35e)~~(35f) State resources. – State and federal funds and other receipts administered by the Division.

…."

CHANGES TO EFFECTUATE RENAMING OF DIVISION

SECTION 5.2.(a) G.S. 143B-138.1(a)(4) reads as rewritten:

"(4) Division of Mental Health, Developmental Disabilities, and Substance ~~Abuse~~ Use Services."

SECTION 5.2.(b) Throughout the General Statutes, the Revisor of Statutes shall replace the phrase "Division of Mental Health, Developmental Disabilities, and Substance Abuse Services" with the phrase "Division of Mental Health, Developmental Disabilities, and Substance Use Services."

SECTION 5.2.(c) Throughout the General Statutes, the Revisor of Statutes shall replace the phrase "MH/DD/SAS" with the phrase "MH/DD/SUS."

PART VI. LAWS PERTAINING TO THE DIVISION OF PUBLIC HEALTH

EXPANSION OF PERMISSIBLE USES FOR NEWBORN SCREENING EQUIPMENT REPLACEMENT AND ACQUISITION FUND

SECTION 6.1. G.S. 130A-125(d) reads as rewritten:

"(d) The Newborn Screening Equipment Replacement and Acquisition Fund (Fund) is established as a nonreverting fund within the Department. Thirty-one dollars ($31.00) of each fee collected pursuant to subsection (c) of this section shall be credited to this Fund and applied to the Newborn Screening Program to be used as directed in this subsection. The Department shall not use monies in this Fund for any purpose other than to ~~purchase or replace~~ purchase, replace, maintain, or support laboratory instruments, equipment, and information technology systems used in the Newborn Screening Program. The Department shall notify and consult with the Joint Legislative Commission on Governmental Operations whenever the balance in the Fund exceeds the following threshold: the sum of (i) the actual cost of new equipment necessary to incorporate conditions listed on the RUSP into the Newborn Screening Program and (ii) one hundred percent (100%) of the replacement value of existing equipment used in the Newborn Screening Program. Any monies in the Fund in excess of this threshold shall be available for expenditure only upon an act of appropriation by the General Assembly."

EXPANSION OF QUALIFIED PROFESSIONALS ELIGIBLE TO SERVE AS COUNTY MEDICAL EXAMINERS

SECTION 6.2. G.S. 130A-382 reads as rewritten:

"**§ 130A-382. County medical examiners; appointment; term of office; vacancies; training requirements; revocation for cause.**

(a) The Chief Medical Examiner shall appoint two or more county medical examiners for each county for a three-year term. In appointing medical examiners for each county, the Chief Medical Examiner shall give preference to physicians licensed to practice medicine in this State but may also appoint ~~licensed~~ the following professionals:

(1) Dentists, physician assistants, nurse practitioners, nurses, or ~~emergency~~ physical therapists as long as the appointee is licensed to practice in this State.

(2) Emergency medical ~~technician~~ technicians or paramedics credentialed under G.S. 131E-159.

(3) Pathologists' assistants certified by the American Society for Clinical Pathology.

(4) Pathologists' assistants or medicolegal death investigators certified by a nationally recognized certifying body determined by the Chief Medical Examiner to have an appropriate certification process for pathologists' assistants or medicolegal death investigators to demonstrate readiness to serve as a county medical examiner.

A medical examiner may serve more than one county. The Chief Medical Examiner may take jurisdiction in any case or appoint another medical examiner to do so.

(a1) During a state of emergency declared by the Governor or by a resolution of the General Assembly pursuant to G.S. 166A-19.20, or by the governing body of a municipality or county pursuant to G.S. 166A-19.22, the Chief Medical Examiner may appoint temporary county medical examiners to serve until the expiration of the declared state of emergency. In appointing temporary county medical examiners pursuant to this subsection, the Chief Medical Examiner may appoint any individual determined by the Chief Medical Examiner to have the appropriate training, education, and experience to serve as a county medical examiner during a declared state of emergency.

…."

PART VII. LAWS PERTAINING TO THE DIVISION OF SOCIAL SERVICES

ALIGNMENT OF TIME LINE FOR COUNTY TANF PLAN SUBMISSIONS

SECTION 7.1.(a) G.S. 108A-24(1e) reads as rewritten:

"(1e) "County Plan" is the ~~biennial~~ triennial Work First Program plan prepared by each Electing County pursuant to this Article and submitted to the Department for incorporation into the State Plan that also includes the Standard Work First Program."

SECTION 7.1.(b) G.S. 108A-27.3(a)(12) reads as rewritten:

"(12) Develop, adopt, and submit to the Department a ~~biennial~~ triennial County Plan;"

SECTION 7.1.(c) G.S. 108A-27.4(a) reads as rewritten:

"(a) Each Electing County shall submit to the Department, according to the schedule established by the Department and in compliance with all federal and State laws, rules, and regulations, a ~~biennial~~ triennial County Plan."

AMENDMENT OF CHILD ABUSE AND NEGLECT SCHOOL POSTERS

SECTION 7.2.(a) G.S. 115C-12(47) reads as rewritten:

"(47) Duty Regarding Child Abuse and Neglect. – The State Board of Education, in consultation with the Superintendent of Public Instruction, shall adopt a rule requiring information on child abuse and neglect, including age-appropriate information on sexual abuse, to be provided by public school units to students in grades six through 12. This rule shall also apply to high schools under the control of The University of North Carolina. Information shall be provided in

the form of (i) a document provided to all students at the beginning of each school year and (ii) a display posted in visible, high-traffic areas throughout each public secondary school. The document and display shall include, at a minimum, the following information:

a. Likely warning signs indicating that a child may be a victim of abuse or neglect, including age-appropriate information on sexual abuse.

b. The telephone number used for reporting abuse and neglect to the department of social services in the county in which the school is located, in accordance with G.S. 7B-301.

c. A statement that information reported pursuant to sub-subdivision b. of this subdivision shall be held in the strictest confidence, to the extent permitted by law, pursuant to G.S. 7B-302(a1).

~~d. Available resources developed pursuant to G.S. 115C-105.51, including the anonymous safety tip line application.~~"

SECTION 7.2.(b) This section is effective when it becomes law and applies beginning with the 2023-2024 school year.

AUTHORIZATION FOR APPLICATION OF FEDERALLY MANDATED TOOLS TO ENFORCE CHILD SUPPORT PAYMENTS

SECTION 7.3.(a) G.S. 110-129 reads as rewritten:

"**§ 110-129. Definitions.**

As used in this Article:

…

(6a) "Financial Management Services" (FMS) means the unit of the U.S. Department of the Treasury, which, under federal law, offsets certain federal payments to satisfy support arrears.

…

(9a) "Internal Revenue Service" (IRS) means the unit of the U.S. Department of the Treasury, which, under federal law, offsets income tax refunds against certain support arrears.

…

(12a) "Offset" means withholding by the IRS or FMS of all or part of an income tax refund or certain federal payments due an obligor and remitting payments to the federal Office of Child Support Enforcement for transmittal to the State.

…."

SECTION 7.3.(b) G.S. 110-129.1(a) reads as rewritten:

"(a) In addition to other powers and duties conferred upon the Department of Health and Human Services, Child Support Enforcement Program, by this Chapter or other State law, the Department shall have the following powers and duties:

…

(10) Certify obligors to the federal Office of Child Support Enforcement for the Passport Denial Program under G.S. 110-143.

(11) Certify to the federal Office of Child Support Enforcement determinations that an obligor in a IV-D case owes support arrears in an amount equal to or greater than the federally mandated thresholds for offset of federal income tax refunds under 42 U.S.C. § 664(b)(2) if the arrears are assigned to the State and 45 C.F.R. § 303.72(a)(2) if the arrears are not assigned to the State.

(12) Certify obligors to the federal Office of Child Support Enforcement for the Administrative Offset Program under G.S. 110-144."

SECTION 7.3.(c) Article 9 of Chapter 110 of the General Statutes is amended by adding the following new sections to read:

"**§ 110-143. Passport Denial Program.**

(a) Participation. – The Department of Health and Human Services shall participate in the federal Passport Denial Program for the denial, revocation, or limitation of an obligor's passports under 42 U.S.C. § 654(31) and 42 U.S.C. § 652(k).

(b) Certification. – The Department shall annually certify to the federal Office of Child Support Enforcement (OCSE) an obligor in a IV-D case whose support arrears exceed the federally mandated threshold in 42 U.S.C. § 654(31). The OCSE shall transmit the certification to the U.S. Department of State pursuant to the federal Passport Denial Program.

(c) Notice. – The Department shall send written notice of the certification to the obligor at the obligor's last known address. The notice shall advise the obligor of all of the following:

(1) The amount of the arrears as of the date of the notice.

(2) The possibility that the obligor's passport may be denied, revoked, or restricted by the U.S. Department of State.

(3) The procedure to contest the certification.

(d) Appeal. – Within 60 days of the date the notice is placed in the mail to the obligor, the obligor may file a contested case petition with the North Carolina Office of Administrative Hearings to contest the certification. The contested case shall be conducted in accordance with Article 3 of Chapter 150B of the General Statutes. The obligor may contest the certification only if one of the following applies:

(1) An arrearage does not exist.

(2) An arrearage does exist, but never exceeded the federally mandated threshold.

(3) There is a claim of mistaken identity.

(e) Withdrawal of Certification. – The Department shall notify the OCSE if the obligor's support arrears are paid in full.

"**§ 110-144. Administrative Offset Program.**

(a) Participation. – The Department of Health and Human Services shall participate in the federal Administrative Offset Program for the offset of certain federal payments under 31 C.F.R. § 285.1.

(b) Certification. – The Department shall annually certify to the federal Office of Child Support Enforcement (OCSE) an obligor in a IV-D case whose support arrears are (i) equal to or greater than one hundred fifty dollars ($150.00) if the arrears are assigned to the State and (ii) equal to or greater than five hundred dollars ($500.00) if the arrears are not assigned to the State.

(c) Notice. – At least 30 days before certification, the Department shall send written notice of the certification to the obligor at the obligor's last known address. The notice shall advise the obligor of all of the following:

(1) The amount of the arrears as of the date of the notice.

(2) The possibility that the obligor may have certain federal payments offset by FMS.

(3) The procedures to contest the certification.

Without further notice to the obligor, the Department shall provide OCSE with updates to adjust the amount of arrears to reflect any payments or additional arrears that accrue after the date of certification.

(d) Appeal. – Within 60 days of the date the notice is placed in the mail to the obligor, the obligor may file a contested case petition with the North Carolina Office of Administrative Hearings to contest the certification. The contested case shall be conducted in accordance with Article 3 of Chapter 150B of the General Statutes. The obligor may contest the certification only if either of the following applies:

(1) The amount of arrears stated in the notice is incorrect.

(2) There is a claim of mistaken identity."

AUTHORIZATION FOR DSS TO GRANT EXCEPTIONS FOR EQUIVALENT CHILD WELFARE TRAINING COMPLETED IN ANOTHER STATE

SECTION 7.4. G.S. 131D-10.6A reads as rewritten:

"**§ 131D-10.6A. Training by the Division of Social Services required.**

…

(b) The Division of Social Services shall establish minimum training requirements for child welfare services staff. The minimum training requirements established by the Division are as follows:

(1) Child welfare services workers shall complete a minimum of 72 hours of preservice training before assuming direct client contact responsibilities. In completing this requirement, the Division of Social Services shall ensure that each child welfare worker receives training on family centered practices and State and federal law regarding the basic rights of individuals relevant to the provision of child welfare services, including the right to privacy, freedom from duress and coercion to induce cooperation, and the right to parent.

(2) Child protective services workers shall complete a minimum of 18 hours of additional training that the Division of Social Services determines is necessary to adequately meet training needs.

(3) Foster care and adoption workers shall complete a minimum of 39 hours of additional training that the Division of Social Services determines is necessary to adequately meet training needs.

(4) Child welfare services supervisors shall complete a minimum of 72 hours of preservice training before assuming supervisory responsibilities and a minimum of 54 hours of additional training that the Division of Social Services determines is necessary to adequately meet training needs.

(5) Child welfare services staff shall complete 24 hours of continuing education annually. In completing this requirement, the Division of Social Services shall provide each child welfare services staff member with annual update information on family centered practices and State and federal law regarding the basic rights of individuals relevant to the provision of child welfare services, including the right to privacy, freedom from duress and coercion to induce cooperation, and the right to parent.

(c) The Division of Social Services may grant an exception in whole or in part to the requirement under subdivision ~~(1) of this subsection~~ (b)(1) of this section to child welfare workers who ~~satisfactorily~~ meet either of the following:

(1) Satisfactorily complete or are enrolled in a masters or bachelors program after July 1, 1999, from a North Carolina social work program accredited pursuant to the Council on Social Work Education. The program's curricula must cover the specific preservice training requirements as established by the Division of Social Services.

(2) Have child welfare work experience in another state and have completed child welfare training equivalent to training in this State.

(d) The Division of Social Services shall ensure that training opportunities are available for county departments of social services and consolidated human service agencies to meet the training requirements of ~~this subsection.~~subsection (b) of this section."

CLARIFICATION OF WHO SETS MAXIMUM DAILY RATE FOR ADULT DAY CARE SERVICES

SECTION 7.5. G.S. 143B-153(2a)b.3. reads as rewritten:

"3. Maximum rates of payment for the provision of social services, except there shall be no maximum statewide reimbursement

rate for adult day care services, adult day health services, and the associated transportation services, as these reimbursement rates shall be determined ~~at the local level~~ by the county department of social services or a designee of the board of county commissioners to allow flexibility in responding to local variables."

PART VIII. LAWS PERTAINING TO THE DIVISION OF VOCATIONAL REHABILITATION SERVICES

CHANGES TO EFFECTUATE RENAMING OF DIVISION

SECTION 8.1. G.S. 108A-26 reads as rewritten:

"**§ 108A-26. Certain financial assistance and in-kind goods not considered in determining assistance paid under Chapters 108A and 111.**

Financial assistance and in-kind goods or services received from a governmental agency, or from a civic or charitable organization, shall not be considered in determining the amount of assistance to be paid any person under Chapters 108A and 111 of the General Statutes provided that such financial assistance and in-kind goods and services are incorporated in the rehabilitation plan of such person being assisted by the Division of ~~Vocational Rehabilitation Services~~ Employment and Independence for People with Disabilities or the Division of Services for the Blind of the Department of Health and Human Services, except where such goods and services are required to be considered by federal law or regulations."

SECTION 8.2. G.S. 111-11.1 reads as rewritten:

"**§ 111-11.1. Jurisdiction of certain Divisions within the Department of Health and Human Services.**

For the purpose of providing rehabilitative services to people who are visually impaired, the Division of Services for the Blind and the Division of ~~Vocational Rehabilitation Services~~ Employment and Independence for People with Disabilities shall develop and enter into an agreement specifying which agency can most appropriately meet the specific needs of this client population. If the Divisions cannot reach an agreement, the Secretary of Health and Human Services shall determine which Division can most appropriately meet the specific needs of this client population."

SECTION 8.3. G.S. 122C-22(a)(7) reads as rewritten:

"(7) Persons subject to rules and regulations of the Division of ~~Vocational Rehabilitation Services.~~Employment and Independence for People with Disabilities."

SECTION 8.4. G.S. 131D-2.3 reads as rewritten:

"**§ 131D-2.3. Exemptions from licensure.**

The following are excluded from this Article and are not required to be registered or obtain licensure under this Article:

(1) Facilities licensed under Chapter 122C or Chapter 131E of the General ~~Statutes;~~Statutes.

(2) Persons subject to rules of the Division of ~~Vocational Rehabilitation Services;~~Employment and Independence for People with Disabilities.

(3) Facilities that care for no more than four persons, all of whom are under the supervision of the United States Veterans ~~Administration;~~Administration.

(4) Facilities that make no charges for housing, amenities, or personal care service, either directly or ~~indirectly; and~~indirectly.

(5) Institutions that are maintained or operated by a unit of government and that were established, maintained, or operated by a unit of government and exempt from licensure by the Department on September 30, 1995."

SECTION 8.5. G.S. 143-545.1(a) reads as rewritten:

"(a) Policy. – Recognizing that disability is a natural part of human experience, the State establishes as its policy that individuals with physical and mental disabilities should be able to participate to the maximum extent of their abilities in the economic, educational, cultural, social, and political activities available to all citizens of the State. To implement this policy, the Department of Health and Human Services shall establish and operate comprehensive and accountable programs of vocational rehabilitation and independent living for persons with disabilities. These programs are to be administered by the Division of ~~Vocational Rehabilitation Services~~ Employment and Independence for People with Disabilities in collaboration with the Division of Services for the Blind, which conducts vocational rehabilitation and independent living programs for individuals who are blind or visually impaired, pursuant to Chapter 111 of the General Statutes and the rules of the Commission for the Blind adopted pursuant to G.S. 143B-157. The programs so provided shall be administered according to the following principles:

…."

SECTION 8.6. G.S. 143-547 reads as rewritten:

"**§ 143-547. Subrogation rights; withholding of information a misdemeanor.**

…

(b) In furnishing a person rehabilitation services, including medical case services under this Chapter, the Division of ~~Vocational Rehabilitation Services~~ Employment and Independence for People with Disabilities is subrogated to the person's right of recovery from:

(1) Personal insurance;
(2) Worker's Compensation;
(3) Any other person or personal injury caused by the other person's negligence or wrongdoing; or
(4) Any other source.

(c) The Division of ~~Vocational Rehabilitation Services'~~ Employment and Independence for People with Disabilities' right to subrogation is limited to the cost of the rehabilitation services provided by or through the Division for which a financial needs test is a condition of the service provisions. Those services that are provided without a financial needs test are excluded from these subrogation rights.

(d) The Division of ~~Vocational Rehabilitation Services~~ Employment and Independence for People with Disabilities may totally or partially waive subrogation rights when the Division finds that enforcement would tend to defeat the client's process of rehabilitation or when client assets can be used to offset additional Division costs.

(e) The Division of ~~Vocational Rehabilitation Services~~ Employment and Independence for People with Disabilities may adopt rules for the enforcement of its rights of subrogation.

(f) It is a Class 1 misdemeanor for a person seeking or having obtained assistance under this Part for himself or another to willfully fail to disclose to the Division of ~~Vocational Rehabilitation Services~~ Employment and Independence for People with Disabilities or its attorney the identity of any person or organization against whom the recipient of assistance has a right of recovery, contractual or otherwise."

SECTION 8.7. G.S. 143-548 reads as rewritten:

"**§ 143-548. Vocational State Rehabilitation Council.**

(a) There is established the Vocational State Rehabilitation Council (Council) in support of the activities of the Division of ~~Vocational Rehabilitation Services~~ Employment and Independence for People with Disabilities to be composed of not more than 18 appointed members. Appointed members shall be voting members except where prohibited by federal law or regulations. The Director of the Division of ~~Vocational Rehabilitation Services~~ Employment and Independence for People with Disabilities and one vocational rehabilitation counselor who is an employee of the Division shall serve ex officio as nonvoting members. The President Pro

Tempore of the Senate shall appoint six members, the Speaker of the House of Representatives shall appoint six members, and the Governor shall appoint five or six members. The appointing authorities shall appoint members of the Council after soliciting recommendations from representatives of organizations representing a broad range of individuals with disabilities. Terms of appointment shall be as specified in subsection (d1) of this section. Appointments shall be made as follows:

…

(b1) Additional Qualifications. – In addition to ensuring the qualifications for membership prescribed in subsection (a) of this section, the appointing authorities shall ensure that a majority of Council members are individuals with disabilities and are not employed by the Division of ~~Vocational Rehabilitation Services.~~Employment and Independence for People with Disabilities.

…."

PART IX. MISCELLANEOUS

MODIFICATION OF EDUCATIONAL REQUIREMENTS FOR REGISTERED ENVIRONMENTAL HEALTH SPECIALISTS

SECTION 9.1.(a) G.S. 90A-53 reads as rewritten:

"**§ 90A-53. Qualifications and examination for registration as an environmental health specialist or environmental health specialist intern.**

(a) The Board shall issue a certificate to a qualified person as a registered environmental health specialist or a registered environmental health specialist intern. A certificate as a registered environmental health specialist or a registered environmental health specialist intern shall be issued to any person upon the Board's determination that the ~~person:~~person satisfies all of the following criteria:

(1) Has made application to the Board on a form prescribed by the Board and paid a fee not to exceed one hundred dollars ~~($100.00);~~($100.00).

(2) Is of good moral and ethical character and has signed an agreement to adhere to the Code of Ethics adopted by the ~~Board;~~Board.

(3) Meets any of the following combinations of education and practice experience standards:

a. Graduated ~~from a baccalaureate~~ with a bachelor's degree or postgraduate degree from a program that is accredited by the National Environmental Health Science and Protection Accreditation Council ~~(EHAC) and has one or more years of experience in the field of environmental health practice; or~~(EHAC).

b. Graduated ~~from a baccalaureate or postgraduate degree program that is accredited by an accrediting organization recognized by the United States Department of Education, Council for Higher Education Accreditation (CHEA)~~ with a bachelor's degree or postgraduate degree and ~~meets both of the following:~~

~~1.~~ ~~Earned~~ earned a minimum of 30 semester hours or ~~its equivalent~~ 45 quarter hours in the ~~physical or biological sciences; and~~physical, biological, natural, life, or health sciences and has one

~~2.~~ ~~Has two~~ or more years of experience in the field of environmental health practice.

c. Graduated ~~from a baccalaureate program rated as acceptable by the Board and meets both of the following:~~with a bachelor's degree or postgraduate degree in public health and has one or more years of experience in the field of environmental health practice.

1. ~~Earned a minimum of 30 semester hours or its equivalent in the physical or biological sciences; and~~
2. ~~Has two or more years of experience in the field of environmental health practice.~~

(4) Has satisfactorily completed a course in specialized instruction and training approved by the Board in the practice of environmental ~~health;~~health.

(5) Repealed by Session Laws 2009-443, s. 4, effective August 7, 2009.

(6) Has passed an examination administered by the Board designed to test for competence in the subject matters of environmental health sanitation. The examination shall be in a form prescribed by the Board and may be oral, written, or both. The examination for applicants shall be held annually or more frequently as the Board may by rule prescribe, at a time and place to be determined by the Board. A person shall not be registered if such person fails to meet the minimum grade requirements for examination specified by the Board. Failure to pass an examination shall not prohibit such person from being examined at subsequent times and places as specified by the ~~Board; and~~Board.

(7) Has paid a fee set by the Board not to exceed the cost of purchasing the examination and an administrative fee not to exceed one hundred fifty dollars ($150.00).

(b) The Board may issue a certificate to a person serving as a registered environmental health specialist intern without the person meeting the full requirements for experience of a registered environmental health specialist for a period not to exceed ~~three~~ two years from the date of initial registration as a registered environmental health specialist intern, provided, the person meets the educational requirements in G.S. 90A-53 and is in the field of environmental health practice."

SECTION 9.1.(b) This section becomes effective October 1, 2023.

EXTEND AUTHORIZATION TO ALIGN WITH FEDERAL LAW TO FACILITATE THE ADMINISTRATION OF COVID-19 VACCINATIONS, DIAGNOSTIC TESTS, OR OTHER TREATMENTS

SECTION 9.2.(a) Section 9G.7(e) of S.L. 2022-74 reads as rewritten:

"**SECTION 9G.7.(e)** This section is effective when it becomes law and expires on December 31, ~~2023.~~2024."

SECTION 9.2.(b) This section is effective when it becomes law.

CORRECT STATUTORY REFERENCE

SECTION 9.3.(a) G.S. 90-85.15B(a), as amended by Section 3(a) of S.L. 2023-15, reads as rewritten:

"**§ 90-85.15B. Immunizing pharmacists.**

(a) Except as provided in subsections ~~(b),~~ (a1), (b1), and (c) of this section, an immunizing pharmacist may only administer vaccinations or immunizations to persons at least 18 years of age pursuant to a specific prescription order."

SECTION 9.3.(b) This section is effective when it becomes law.

PART X. ALLOW OPIOID TREATMENT PROGRAM MEDICATION UNITS AND MOBILE UNITS

SECTION 10.1. G.S. 122C-3 reads as rewritten:

"**§ 122C-3. Definitions.**

The following definitions apply in this Chapter:

…

(14) Facility. – Any person at one ~~location~~ location, or in the case of an opioid treatment program facility licensed to operate an opioid treatment program medication unit, an opioid treatment program mobile unit, or both, any person at one or more locations, whose primary purpose is to provide services for the care, treatment, habilitation, or rehabilitation of individuals with mental illnesses or intellectual or other developmental disabilities or substance abusers, and includes all of the following:

…

i. An opioid treatment program facility licensed to operate an opioid treatment program medication unit, an opioid treatment program mobile unit, or both.

…

(23b) Mobile unit. – A motor vehicle that operates with more than three wheels in contact with the ground that may lawfully be used on the public streets, roads, or highways and from which opioid treatment program mobile unit services are provided at one or more locations.

…

(25a) Opioid treatment program. – A facility with a current and valid registration under 21 U.S.C. § 823(g)(1) that meets all of the following criteria:

a. Is engaged in dispensing and administering treatment medication approved by the Food and Drug Administration for the treatment of individuals with opioid use disorders.

b. Has been licensed as an opioid treatment program facility by the Division of Health Service Regulation.

(25b) Opioid treatment program medication unit. – A unit established as part of an opioid treatment program facility that meets all of the following criteria:

a. Operates at a geographically separate location from the opioid treatment program facility.

b. Is a site at which treatment medication approved by the Food and Drug Administration for the treatment of opioid use disorder is dispensed or administered and samples are collected for drug testing or analysis.

c. Is a site where intake or initial psychosocial and appropriate medical assessments may be conducted with a full physical examination to be completed or provided within 14 days of admission and the site provides appropriate privacy and adequate space for quality patient care, where treatment with medication approved by the Food and Drug Administration may be initiated after an appropriate medical assessment has been performed, and where other opioid treatment program services, such as counseling, may be provided directly, or when permissible, through the use of telehealth services and the site provides appropriate privacy and adequate space for quality patient care.

(25c) Opioid treatment program mobile unit. – A mobile unit established as a mobile component of an opioid treatment program facility that meets all of the following criteria:

a. Operates at one or more geographically separate, predetermined locations from the opioid treatment program facility.

b. Is a site at which treatment medication approved by the Food and Drug Administration for treatment of opioid use disorder is dispensed or administered and samples are collected for drug testing or analysis.

c. Is a site where intake or initial psychosocial and appropriate medical assessments may be conducted with a full physical examination to be completed or provided within 14 days of admission and the site provides appropriate privacy and adequate space for quality patient care, where treatment with medication approved by the Food and Drug Administration may be initiated after an appropriate medical assessment has been performed, and where other opioid treatment program services, such as counseling, may be provided directly or, when permissible, through the use of telehealth services and the site provides appropriate privacy and adequate space for quality patient care.

…."

SECTION 10.2. Article 2 of Chapter 122C of the General Statutes is amended by adding a new section to read:

"**§ 122C-35. Licensure of opioid treatment program medication units and opioid treatment program mobile units.**

(a) Any licensed opioid treatment program facility that intends to establish, maintain, or operate an opioid treatment program medication unit or opioid treatment program mobile unit shall apply to the Division of Health Service Regulation on forms prescribed by the Department for certified services provided from an opioid treatment program medication unit or opioid treatment program mobile unit to be added to its license. The Commission shall adopt rules establishing the requirements for obtaining such licensure, which shall include a requirement that each opioid treatment program medication unit and each opioid treatment program mobile unit seeking to operate in this State must demonstrate satisfactory proof to the Secretary that it has (i) obtained approval from the State Opioid Treatment Authority and (ii) registered with the Department's Drug Control Unit and the federal Drug Enforcement Agency.

(b) An opioid treatment program facility shall not submit a license application to the Division of Health Service Regulation to provide certified services at an opioid treatment program facility medication unit or opioid treatment program mobile unit prior to receiving approval from the State Opioid Treatment Authority or prior to receiving confirmation of registration with the Department's Drug Control Unit and the federal Drug Enforcement Agency.

(c) The Department may issue a license to an opioid treatment program facility to provide certified services at an opioid treatment program medication unit or an opioid treatment program mobile unit if the Secretary finds that the program is in compliance with all rules adopted by the Commission regarding opioid treatment programs. The Secretary may approve or deny an application for a license to provide certified services based upon consideration of all of the following criteria:

(1) The applicant's capacity, qualifications, and experience with regard to providing treatment and operating an opioid treatment program medication unit in compliance with applicable federal and State laws, regulations, and accepted clinical standards of practice.

(2) Any history of adverse regulatory actions involving the applicant in North Carolina or another state.

(3) Any history of suspension or revocation of, or other adverse regulatory action against, any professional licenses or narcotic licenses of persons proposed to be employed in the opioid treatment program medication unit or opioid treatment program mobile unit, in North Carolina or in another state, or any adverse regulatory action against the license of the opioid treatment program facility within the 12-month period preceding the application for licensure.

(4) Any additional criteria or standards established in rules adopted by the Commission regarding opioid treatment programs.

(d) An opioid treatment program facility shall not establish, maintain, or operate an opioid treatment program medication unit or opioid treatment program mobile unit without a current license from the Secretary that includes and covers that specific medication unit or mobile unit and without first obtaining certification from the Substance Abuse and Mental Health Services Administration.

(e) An opioid treatment program mobile unit or opioid treatment program medication unit added to an opioid treatment program facility license shall be deemed part of the opioid treatment program facility license and may be subject to inspections the Department deems necessary to validate compliance with the requirements set forth in this section, applicable rules adopted by the Commission, and all applicable federal laws and regulations, including, without limitation, Substance Abuse and Mental Health Services Administration regulations in Parts 8 and 21 of Title 42 of the Code of Federal Regulations governing opioid treatment programs, and federal Drug Enforcement Agency regulations in Parts 1300, 1301, and 1304 of Title 21 of the Code of Federal Regulations, including 21 C.F.R. § 1301.13(e), governing controlled substances, dispensers of controlled substances, mobile narcotic treatment programs, and federal Drug Enforcement Agency restraints. Substantial failure to comply with the requirements of this section, applicable rules adopted by the Commission, and applicable federal laws and regulations may result in an adverse action on a license under G.S. 122C-24 and administrative penalties under G.S. 122C-24.1. Any required services not provided in an opioid treatment program mobile unit or opioid treatment program medication unit must be conducted at the opioid treatment program facility, including medical, counseling, vocational, educational, and other assessment and treatment services.

(f) Each license issued under this section to an opioid treatment program facility to provide certified services at an opioid treatment program mobile unit or an opioid treatment program medication unit shall expire on December 31 of the year for which it was issued and shall be renewed annually by filing with the Division of Health Service Regulation on or after December 1 an application for license renewal on forms prescribed by the Department, accompanied by the required fee. License renewal shall be contingent upon (i) the applicant providing all information required by the Secretary for renewal and (ii) continued compliance with this Article and any applicable rules adopted by the Commission regarding opioid treatment programs. The Department shall charge an opioid treatment program facility a nonrefundable annual license fee plus a nonrefundable annual per-unit fee of two hundred sixty-five dollars ($265.00) for each opioid treatment program medication unit or opioid treatment program mobile unit.

(g) The opioid treatment program facility is responsible for ensuring that opioid treatment program medication units and opioid treatment program mobile medication units adhere to all State and federal requirements for opioid treatment programs.

(h) Notwithstanding G.S. 122C-25(a), an opioid treatment program facility with no previous violations of State or federal requirements for opioid treatment programs may be subject to inspection once every other year, excluding any complaint investigation. An opioid treatment program facility with either an opioid treatment program medication unit or an opioid treatment program mobile unit may be subject to annual inspections.

(i) The Commission shall adopt emergency, temporary, or permanent rules for the licensure, inspection, and operation of opioid treatment program medication units and opioid treatment program mobile units, including rules concerning any of the following:

(1) Compliance with all applicable Substance Abuse and Mental Health Services Administration and federal Drug Enforcement Agency regulations governing opioid treatment program mobile units and opioid treatment program medication units.

(2) Identification of the location of opioid treatment program medication units and opioid treatment program mobile units.

(3) Schedules for the days and hours of operation to meet client needs.
(4) Maintenance and location of records.
(5) Requisite clinical staff and staffing ratios to meet immediate client needs at each opioid treatment program medication unit or opioid treatment program mobile unit, including client needs for nursing, counseling, and medical care.
(6) Emergency staffing requirements to ensure service delivery.
(7) Criteria for policies and procedures for a clinical and individualized assessment of individuals to receive services at an opioid treatment medication unit or opioid treatment mobile unit that consider medical and clinical appropriateness and accessibility to individuals served.
(8) Number of clients allowed per opioid treatment program medication unit and opioid treatment program mobile unit, based on staffing ratios.
(9) Criteria to ensure the opioid treatment program facility is providing the required counseling to individuals receiving services at an opioid treatment program medication unit or opioid treatment program mobile unit.
(10) Criteria for the opioid treatment program facility to ensure that individuals receiving services at an opioid treatment program medication unit or opioid treatment program mobile unit receive medical interventions when necessary."

SECTION 10.3. The Commission for Mental Health, Developmental Disabilities, and Substance Use Services shall adopt, pursuant to G.S. 150B-21.1A, emergency rules for the implementation of G.S. 122C-35, enacted by Section 10.2 of this act, without prior notice or hearing or upon any abbreviated notice or hearing that the agency finds practical because adherence to the notice and hearing requirements would be contrary to the public interest and that the immediate adoption of the rule is required by a serious and unforeseen threat to the public health or safety. The Commission for Mental Health, Developmental Disabilities, and Substance Use Services is further authorized to adopt temporary or permanent rules as described in G.S. 122C-35(i), enacted by Section 10.2 of this act.

SECTION 10.4. Section 10.3 of this act is effective when it becomes law. Section 10.1 and Section 10.2 of this act become effective on the effective date of the emergency rules adopted by the Commission for Mental Health, Developmental Disabilities, and Substance Use Services in accordance with Section 10.3 of this act. The Secretary of the Department of Health and Human Services shall notify the Revisor of Statutes of the effective date of the emergency rules adopted by the Commission for Mental Health, Developmental Disabilities, and Substance Use Services.

PART XI. ADD GABAPENTIN TO CONTROLLED SUBSTANCE REPORTING SYSTEM

SECTION 11.1. G.S. 90-113.73(b) reads as rewritten:

"(b) The Commission shall adopt rules requiring dispensers to report the following information. The Commission may modify these requirements as necessary to carry out the purposes of this Article. The dispenser shall report:

(1) The dispenser's DEA ~~number.~~number for prescriptions of controlled substances, and for prescriptions of gabapentin, whether the dispenser has a DEA number.
(2) The name of the patient for whom the controlled substance is being dispensed, and the patient's:
    a. Full address, including city, state, and zip code.
    b. Telephone number.
    c. Date of birth.
(3) The date the prescription was written.

(4) The date the prescription was filled.
(5) The prescription number.
(6) Whether the prescription is new or a refill.
(7) ~~Metric~~ The metric quantity of the dispensed drug.
(8) ~~Estimated~~ The estimated days of supply of dispensed drug, if provided to the dispenser.
(9) The National Drug Code of dispensed drug.
(10) ~~Prescriber's DEA number.~~The prescriber's DEA number for prescriptions of controlled substances, and for prescriptions of gabapentin, if the prescriber has a DEA number and the number is known by the dispenser.
(10a) ~~Prescriber's~~ The presciber's national provider identification number, for any prescriber that has a national provider identification number. A pharmacy shall not be subject to a civil penalty under subsection (e) of this section for failure to report the prescriber's national provider identification number when it is not received by the pharmacy.
(11) ~~Method~~ The method of payment for the prescription."

SECTION 11.2. G.S. 90-113.73(c) reads as rewritten:

"(c) A dispenser shall not be required to report instances in which a controlled ~~substance~~ substance, or gabapentin, is provided directly to the ultimate user and the quantity provided does not exceed a 48-hour supply."

SECTION 11.2A. G.S. 90-113.73 is amended by adding a new subsection to read:

"(c1) A dispenser shall not be required to report gabapentin to the controlled substances reporting system when gabapentin is a component of a compounded prescription that is dispensed in dosages of 100 milligrams or less."

SECTION 11.3. G.S. 90-113.73(f) reads as rewritten:

"(f) For purposes of this section, a "dispenser" includes a person licensed to practice veterinary medicine pursuant to Article 11 of Chapter 90 of the General Statutes when that person dispenses any Schedule II through V controlled ~~substances.~~ substance or gabapentin. Notwithstanding subsection (b) of this section, the Commission shall adopt rules requiring the information to be reported by a person licensed to practice veterinary medicine pursuant to Article 11 of Chapter 90 of the General Statutes."

SECTION 11.4. Section 11.1, Section 11.2, and Section 11.2A of this act become effective March 1, 2024. Section 11.3 of this act becomes effective March 1, 2025.

PART XII. REQUIRE ELECTRONIC PRESCRIBING OF CODEINE COUGH SYRUP

SECTION 12.1. G.S. 90-106 reads as rewritten:

"**§ 90-106. Prescriptions and labeling.**

…

(a1) Electronic Prescription Required; Exceptions. – Unless otherwise exempted by this subsection, a practitioner shall electronically prescribe all targeted controlled ~~substances.~~ substances and all controlled substances included in G.S. 90-93(a)(1)a. This subsection does not apply to any product that is sold at retail without a prescription by a pharmacist under G.S. 90-93(b) through (d). This subsection does not apply to prescriptions for targeted controlled substances or any controlled substances included in G.S. 90-93(a)(1)a. issued by any of the following:

(1) A practitioner, other than a pharmacist, who dispenses directly to an ultimate user.
(2) A practitioner who orders a controlled substance to be administered in a hospital, nursing home, hospice facility, outpatient dialysis facility, or residential care facility, as defined in G.S. 14-32.2(i).

(3) A practitioner who experiences temporary technological or electrical failure or other extenuating circumstance that prevents the prescription from being transmitted electronically. The practitioner, however, shall document the reason for this exception in the patient's medical record.

(4) A practitioner who writes a prescription to be dispensed by a pharmacy located on federal property. The practitioner, however, shall document the reason for this exception in the patient's medical record.

(5) A person licensed to practice veterinary medicine pursuant to Article 11 of this Chapter. A person licensed to practice veterinary medicine pursuant to Article 11 of this Chapter may continue to prescribe targeted controlled substances from valid written, oral, or facsimile prescriptions that are otherwise consistent with applicable laws.

(a2) Verification by Dispenser Not Required. – A dispenser is not required to verify that a practitioner properly falls under one of the exceptions specified in subsection (a1) of this section prior to dispensing a targeted controlled ~~substance.~~ substance or a controlled substance included in G.S. 90-93(a)(1)a. A dispenser may continue to dispense targeted controlled substances and controlled substances included in G.S. 90-93(a)(1)a. from valid written, oral, or facsimile prescriptions that are otherwise consistent with applicable laws.

…."

SECTION 12.2. This section becomes effective January 1, 2024.

PART XIII. OVER-THE-COUNTER OPIOID ANTAGONIST TREATMENT

SECTION 13.1. G.S. 90-12.7 reads as rewritten:

"**§ 90-12.7. Treatment of overdose with opioid antagonist; immunity.**

(a) As used in this section, "opioid antagonist" means naloxone hydrochloride that is approved by the federal Food and Drug Administration for the treatment of a drug overdose.

(b) The following individuals may prescribe an opioid antagonist in the manner prescribed by this subsection:

(1) A practitioner acting in good faith and exercising reasonable care may directly or by standing order prescribe an opioid antagonist to (i) a person at risk of experiencing an opiate-related overdose or (ii) a family member, friend, or other person in a position to assist a person at risk of experiencing an opiate-related overdose. As an indicator of good faith, the practitioner, prior to prescribing an opioid under this subsection, may require receipt of a written communication that provides a factual basis for a reasonable conclusion as to either of the following:

a. The person seeking the opioid antagonist is at risk of experiencing an opiate-related overdose.

b. The person other than the person who is at risk of experiencing an opiate-related overdose, and who is seeking the opioid antagonist, is in relation to the person at risk of experiencing an opiate-related overdose:

1. A family member, friend, or other person.

2. In the position to assist a person at risk of experiencing an opiate-related overdose.

(2) The State Health Director or a designee may prescribe an opioid antagonist pursuant to subdivision (1) of this subsection by means of a statewide standing order.

(3) A practitioner acting in good faith and exercising reasonable care may directly or by standing order prescribe an opioid antagonist to any governmental or nongovernmental organization, including a local health department, a law

enforcement agency, or an organization that promotes scientifically proven ways of mitigating health risks associated with substance use disorders and other high-risk behaviors, for the purpose of distributing, through its agents, the opioid antagonist to (i) a person at risk of experiencing an opiate-related overdose or (ii) a family member, friend, or other person in a position to assist a person at risk of experiencing an opiate-related overdose.

(c) A pharmacist may dispense an opioid antagonist to a person or organization pursuant to a prescription issued in accordance with subsection (b) of this section. For purposes of this section, the term "pharmacist" is as defined in G.S. 90-85.3.

(c1) A governmental or nongovernmental organization, including a local health department, a law enforcement agency, or an organization that promotes scientifically proven ways of mitigating health risks associated with substance use disorders and other high-risk behaviors may, through its agents, distribute an opioid antagonist obtained pursuant to a prescription issued in accordance with subdivision (3) of subsection (b) of this section or obtained over-the-counter to (i) a person at risk of experiencing an opiate-related overdose or (ii) a family member, friend, or other person in a position to assist a person at risk of experiencing an opiate-related overdose. An organization, through its agents, shall include with any distribution of an opioid antagonist pursuant to this subsection basic instruction and information on how to administer the opioid antagonist.

(d) A person who receives an opioid antagonist that was prescribed pursuant to subsection (b) of this section or distributed pursuant to subsection (c1) of this section or obtained over-the-counter may administer an opioid antagonist to another person if (i) the person has a good faith belief that the other person is experiencing a drug-related overdose and (ii) the person exercises reasonable care in administering the drug to the other person. Evidence of the use of reasonable care in administering the drug shall include the receipt of basic instruction and information on how to administer the opioid antagonist.

(e) All of the following individuals are immune from any civil or criminal liability for actions authorized by this section:

(1) Any practitioner who prescribes an opioid antagonist pursuant to subsection (b) of this section.

(2) Any pharmacist who dispenses an opioid antagonist pursuant to subsection (c) of this section.

(3) Any person who administers an opioid antagonist pursuant to subsection (d) of this section.

(4) The State Health Director acting pursuant to subsection (b) of this section.

(5) Any organization, or agent of the organization, that distributes an opioid antagonist pursuant to subsection (c1) of this section."

SECTION 13.2. This section is effective when it becomes law.

PART XIII-A. PARENTAL LEAVE TECHNICAL CORRECTIONS

SECTION 13A.1.(a) G.S. 126-8.6, as enacted by S.L. 2023-14, reads as rewritten:

"**§ 126-8.6. Paid parental leave.**

…

(b) Paid Parental Leave. – The State Human Resources Commission shall adopt rules and policies to provide that a permanent, probationary, or time-limited full-time State employee may take the following paid parental leave:

(1) Up to eight weeks of paid leave after giving birth to a child; or

(2) Up to four weeks of paid leave after any other qualifying event.

(c) Part-Time Employees. – The State Human Resources Commission shall adopt rules and policies to provide that a permanent, probationary, or time-limited part-time State employee may take a prorated amount of paid leave after giving birth, not to exceed ~~four~~ eight weeks, or

paid leave after any other qualifying event, not to exceed ~~two~~ four weeks, in addition to any other leave available to the employee.

(c1) The State Human Resources Commission shall adopt rules and policies providing for a period of minimum service before an employee becomes eligible for parental leave, the maximum number of uses of paid parental leave within a 12-month period, and how much leave is to be provided in the event of miscarriage or the death of a child during birth.

…."

SECTION 13A.1.(b) G.S. 126-5(c19), as enacted by S.L. 2023-14, reads as rewritten:

"(c19) ~~The provisions of G.S. 126-8.6 shall apply to all exempt and nonexempt State employees in the executive branch; to public school employees; and to community college employees.~~ Notwithstanding any other provision of this Chapter, G.S. 126-8.6 applies to all State employees, public school employees, and community college employees. G.S. 126-8.6 does not apply to employees described in subdivisions (2) and (3) of subsection (c1) of G.S. 126-5. The legislative and judicial branches shall adopt parental leave policies."

SECTION 13A.1.(c) G.S. 115C-336.1, as amended by S.L. 2023-14, reads as rewritten:

"**§ 115C-336.1. Parental leave.**

(a) In addition to paid parental leave authorized by G.S. 126-8.6, a school employee may use annual leave or leave without pay to care for a newborn child or for a child placed with the employee for adoption or foster care. A school employee may also use up to 30 days of sick leave to care for a child placed with the employee for adoption. The leave may be for consecutive workdays during the first 12 months after the date of birth or placement of the child, unless the school employee and the local board of education agree otherwise.

(b) To the extent funds are made available for this purpose, the Department of Public Instruction shall administer funds to public school units for the payment of substitute teachers for any public school unit teacher using paid parental leave as provided in G.S. 126-8.6."

SECTION 13A.1.(d) G.S. 115C-218.90(a) is amended by adding a new subdivision to read:

"(6) A board of directors may provide paid parental leave consistent with the requirements of G.S. 126-8.6. If the board provides paid parental leave, it shall be eligible to receive funds as provided in G.S. 115C-336.1(b)."

SECTION 13A.1.(e) G.S. 115C-238.68 is amended by adding a new subdivision to read:

"(8) Paid parental leave. – Teachers employed by the board of directors shall be eligible for paid parental leave as provided in G.S. 126-8.6. The board of directors shall be eligible to receive funds as provided in G.S. 115C-336.1(b)."

SECTION 13A.1.(f) G.S. 116-239.10 is amended by adding a new subdivision to read:

"(9) Paid parental leave. – Teachers employed by the board of the constituent institution shall be eligible for paid parental leave as provided in G.S. 126-8.6. The constituent institution shall be eligible to receive funds as provided in G.S. 115C-336.1(b)."

SECTION 13A.1.(g) Section 5.1(e) of S.L. 2023-14 reads as rewritten:

"**SECTION 5.1.(e)** There is appropriated from the General Fund to the Department of Public Instruction the sum of ten million dollars ($10,000,000) in recurring funds for the 2023-2024 fiscal year and the sum of ten million dollars ($10,000,000) in recurring funds for the 2024-2025 fiscal year to ~~fund paid parental leave authorized by this section.~~provide substitute teachers in accordance with G.S. 115C-336.1(b)."

SECTION 13A.1.(h) This section becomes effective July 1, 2023, and applies to requests for paid parental leave related to births occurring on or after that date.

PART XIII-B. IN-PERSON CONSULTATION

SECTION 13B.1.(a) G.S. 90-21.83A, as enacted by S.L. 2023-14, reads as rewritten:

"**§ 90-21.83A. Informed consent to medical abortion.**

…

(b) Except in the case of a medical emergency, consent to a medical abortion is voluntary and informed only if all of the following conditions are satisfied:

…

(2) The consent form shall include, at a minimum, all of the following:

…

k. The location of the hospital that offers obstetrical or gynecological care located within 30 miles of the location where the medical abortion is performed or induced and at which the physician performing or inducing the medical abortion has clinical privileges. If the physician who will perform the medical abortion has no local hospital admitting privileges, that information shall be communicated.

If the physician or qualified professional does not know the information required in sub-subdivision a., j., or k. of this subdivision, the woman shall be advised that this information will be directly available from the physician who is to perform the medical abortion. However, the fact that the physician or qualified professional does not know the information required in sub-subdivision a., j., or k. shall not restart the 72-hour period. The information required by this subdivision shall be provided in English and in each language that is the primary language of at least two percent (2%) of the State's population. The information shall be provided orally in person, by the physician or qualified professional, in which case the required information may be based on facts supplied by the woman to the physician and whatever other relevant information is reasonably available. The information required by this subdivision shall not be provided by a tape recording but shall be provided during ~~a consultation in which the physician is able to ask questions of the patient and the patient is able to ask questions of the physician.~~ an in-person consultation conducted by a qualified professional or a qualified physician. A physician must be available to ask and answer questions within the statutory time frame upon request of the patient or the qualified professional. If, in the medical judgment of the physician, a physical examination, tests, or the availability of other information to the physician subsequently indicates a revision of the information previously supplied to the patient, then that revised information may be communicated to the patient at any time before the performance of the medical abortion. Nothing in this section may be construed to preclude provision of required information in a language understood by the patient through a translator.

…."

SECTION 13B.1.(b) This section becomes effective July 1, 2023.

PART XIV. TECHNICAL AND CONFORMING CHANGES TO S.L. 2023-14

SECTION 14.1.(a) G.S. 14-23.7 reads as rewritten:

"**§ 14-23.7. Exceptions.**

Nothing in this Article shall be construed to permit the prosecution under this Article of any of the following:

(1) Acts which cause the death of an unborn child if those acts were lawful, pursuant to the provisions of ~~G.S. 14-45.1.~~Article 1I of Chapter 90 of the General Statutes.

(2) Acts which are committed pursuant to usual and customary standards of medical practice during diagnostic testing or therapeutic treatment.

(3) Acts committed by a pregnant woman with respect to her own unborn child, including, but not limited to, acts which result in miscarriage or stillbirth by the woman. The following definitions shall apply in this section:

a. Miscarriage. – The interruption of the normal development of an unborn child, other than by a live birth, and which is not an induced abortion permitted under ~~G.S. 14-45.1,~~ Article 1I of Chapter 90 of the General Statutes, resulting in the complete expulsion or extraction from a pregnant woman of the unborn child.

b. Stillbirth. – The death of an unborn child prior to the complete expulsion or extraction from a woman, irrespective of the duration of pregnancy and which is not an induced abortion permitted under ~~G.S. 14-45.1.~~Article 1I of Chapter 90 of the General Statutes."

SECTION 14.1.(b) G.S. 90-21.81A, as enacted by S.L. 2023-14, reads as rewritten:

"**§ 90-21.81A. Abortion.**

(a) Abortion. – It shall be unlawful after the twelfth week of a woman's pregnancy to ~~advise, procure, or cause~~ procure or cause a miscarriage or ~~abortion.~~abortion in the State of North Carolina.

…."

SECTION 14.1.(c) G.S. 90-21.81B, as enacted by S.L. 2023-14, reads as rewritten:

"**§ 90-21.81B. When abortion is lawful.**

Notwithstanding any of the provisions of G.S. 14-44 and G.S. 14-45, and subject to the provisions of this Article, it shall not be unlawful to ~~advise, procure, or cause~~ procure or cause a miscarriage or an abortion in the State of North Carolina in the following circumstances:

…."

SECTION 14.1.(d) G.S. 90-21.82(b), as amended by S.L. 2023-14, reads as rewritten:

"(b) Except in the case of a medical emergency, consent to a surgical abortion is voluntary and informed only if all of the following conditions are satisfied:

…

(1a) The consent form shall include, at a minimum, all of the following:

a. The name of the physician who will perform the surgical abortion to ensure the safety of the procedure and prompt medical attention to any complications that may ~~arise.~~ arise, specific information for the physician's hospital admitting privileges, and whether the physician accepts the pregnant woman's insurance. The physician performing a surgical abortion shall be physically present during the performance of the entire abortion procedure.

…."

SECTION 14.1.(e) G.S. 90-21.83A(b), as enacted by S.L. 2023-14, reads as rewritten:

"(b) Except in the case of a medical emergency, consent to a medical abortion is voluntary and informed only if all of the following conditions are satisfied:

…

(2) The consent form shall include, at a minimum, all of the following:

a. The name of the physician who will prescribe, dispense, or otherwise provide the abortion-inducing drugs to ensure the safety of the

procedure and prompt medical attention to any complications that may ~~arise.~~ arise, specific information for the physician's hospital admitting privileges, and whether the physician accepts the pregnant woman's insurance. The physician prescribing, dispensing, or otherwise providing any drug or chemical for the purpose of inducing an abortion shall be physically present in the same room as the woman when the first drug or chemical is administered to the woman.

…."

SECTION 14.1.(f) G.S. 90-21.83B, as enacted by S.L. 2023-14, reads as rewritten:

"**§ 90-21.83B. Distribution of abortion-inducing drugs and duties of physician.**

(a) A physician prescribing, administering, or dispensing an abortion-inducing drug must examine the woman in person and, prior to providing an abortion-inducing drug, shall do all of the following:

…

(6) Verify ~~that~~ the probable gestational age of the unborn ~~child is no more than 70 days.~~child.

(7) Document in the woman's medical chart the probable ~~gestation~~ gestational age and existence of an intrauterine ~~location of the~~ pregnancy, and whether the woman received treatment for an Rh negative condition or any other diagnostic tests.

…."

SECTION 14.1.(g) G.S. 90-21.83C, as enacted by S.L. 2023-14, is repealed.

SECTION 14.1.(h) G.S. 90-21.85(a) reads as rewritten:

"(a) Notwithstanding ~~G.S. 14-45.1,~~ G.S. 90-21.81B, except in the case of a medical emergency, in order for the woman to make an informed decision, at least four hours before a woman having any part of an abortion performed or induced, and before the administration of any anesthesia or medication in preparation for the abortion on the woman, the physician who is to perform the abortion, or qualified technician working in conjunction with the physician, shall do each of the following:

…."

SECTION 14.1.(i) G.S. 131E-269 reads as rewritten:

"**§ 131E-269. Authorization to charge fee for certification of facilities suitable to perform abortions.**

The Department of Health and Human Services shall charge each hospital or clinic certified by the Department as a facility suitable for the performance of abortions, as authorized under ~~G.S. 14-45.1,~~ G.S. 90-21.81C, a nonrefundable annual certification fee in the amount of seven hundred dollars ($700.00)."

SECTION 14.1.(j) G.S. 90-21.93, as enacted by S.L. 2023-14, reads as rewritten:

"**§ 90-21.93. Reporting requirements.**

(a) Report. – After a surgical or medical abortion is performed, the physician or health care provider that conducted the surgical or medical abortion shall complete and transmit a report to the Department in compliance with the requirements of this section. The report shall be completed by either the hospital, clinic, or health care provider in which the surgical or medical abortion was completed and signed by the physician who dispensed, administered, prescribed, or otherwise provided the abortion-inducing drug or performed the procedure or treatment to the woman. Any physician or health care provider shall make reasonable efforts to include all of the required information in this section in the report without violating the privacy of the woman. The report shall be transmitted to the Department within 15 days after either the (i) date of the follow-up appointment following a medical abortion, (ii) date of the last patient encounter for treatment directly related to a surgical abortion, or (iii) end of the month in which the last scheduled appointment occurred, whichever is later. A report completed under this section for a

minor shall be sent to the Department and the Division of Social Services within ~~three~~ 30 days of the surgical or medical abortion.

…."

SECTION 14.1.(k) This section becomes effective July 1, 2023.

PART XV. EFFECTIVE DATE

SECTION 15.1. Except as otherwise provided, this act is effective when it becomes law.

In the General Assembly read three times and ratified this the 27th day of June, 2023.

s/ Phil Berger
President Pro Tempore of the Senate

s/ Sarah Stevens
Presiding Officer of the House of Representatives

s/ Roy Cooper
Governor

Approved 2:51 p.m. this 29th day of June, 2023

10A NCAC 13B .3801 is readopted with changes 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.~~ as required in Paragraph (e) of this Rule.

(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)~~(2) planning for and the evaluation of the delivery of nursing care ~~delivery~~ system;

~~(4)~~(3) establishment of a mechanism to validate qualifications, knowledge, and skills of nursing personnel;

~~(5)~~(4) provision of orientation and educational opportunities related to expected nursing ~~performance,~~ performance and maintenance of records pertaining thereto;

~~(6)~~(5) implementation of a system for performance evaluation;

~~(7)~~(6) 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)~~(7) 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)~~(8) 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; 143B-165;*
Eff. January 1, ~~1996.~~ 1996;
Readopted Eff. August 1, 2023.

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

10A NCAC 13B .3903 PRESERVATION OF MEDICAL RECORDS

(a) The manager of the medical records service shall maintain medical ~~records,~~ records that were created when the patient was an adult, whether original, computer media, or ~~microfilm,~~ digital archived 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.~~ that were created when the patient was a minor, whether original, computer media, or digital archived, until the patient's 30th birthday. If a minor patient is readmitted as an adult, the manager of the medical records shall maintain medical records according to Paragraph (a) of this Rule.

(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.~~ date or according to Paragraph (b) of this Rule if the patient was a minor.

~~(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~~ digital archiving of medical records. ~~Microfilming~~ Digital archiving 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~~ digital archived medical records shall not be destroyed until the medical records department has had an opportunity to review the ~~processed film~~ digital record 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 the Health Insurance Portability and Accountability Act (HIPAA) ~~regulations~~ found in 42 CFR 482, which is incorporated by reference including subsequent amendments and editions, shall have access to medical records. This regulation may be obtained free of charge at https://www.govinfo.gov/help/cfr. 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~~ shall remain the property of the hospital, 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; 143B-165;*
Eff. January 1, 1996;
Amended Eff. July 1, ~~2009.~~ 2009;

Readopted Eff. August 1, 2023.

10A NCAC 13B .4103 is readopted with changes 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; 143B-165;*
Eff. January 1, ~~1996.~~ 1996;
Readopted Eff. August 1, 2023.

10A NCAC 13B .4104 is readopted with changes 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); 143B-165;*
RRC objection due to lack of statutory authority Eff. July 13, 1995;
Eff. January 1, ~~1996.~~ 1996;
Readopted Eff. August 1, 2023.

10A NCAC 13B .4106 is readopted with changes 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; 143B-165;*
Eff. January 1, ~~1996.~~ 1996;
Readopted Eff. August 1, 2023.

10A NCAC 13B .4305 is readopted with changes 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 neonates who are large for gestational ~~age neonates.~~ age.

(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~~ 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~~ or approximately 32 and less than 36 completed weeks of gestational ~~age)~~ 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~~ 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; 143B-165;*
Eff. January 1, 1996;
Temporary Amendment Eff. March 15, 2002;
Amended Eff. April 1, ~~2003.~~ 2003;
Readopted Eff. August 1, 2023.

10A NCAC 13B .4603 is readopted with changes 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; 143B-165;*
Eff. January 1, ~~1996.~~ 1996;
Readopted Eff. August 1, 2023.

10A NCAC 13B .4801 is readopted with changes 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; 143B-165;*
RRC objection due to lack of statutory authority and ambiguity Eff. July 13, 1995;
Eff. January 1, ~~1996.~~ 1996;
Readopted Eff. August 1, 2023.

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)~~(c) 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)~~(d) 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; 143B-165;*
Eff. January 1, ~~1996.~~ 1996;
Readopted Eff. August 1, 2023.

10A NCAC 13B .5102 is readopted with changes 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; 143B-165;*
Eff. January 1, ~~1996.~~ 1996;
Readopted Eff August 1, 2023.

10A NCAC 13B .5105 is readopted with changes 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; 143B-165;*
Eff. January 1, ~~1996.~~ 1996;
Readopted Eff. August 1, 2023.

10A NCAC 13B .5406 is readopted with changes 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 of care have been reached, or a determination by the interdisciplinary care team has been made that care in a less intensive setting ~~would be appropriate,~~ to return to the setting from which was admitted, or that further progress is unlikely, the patient shall be discharged to ~~an appropriate setting.~~ another inpatient or residential health care facility that can address the patient's needs including skilled nursing homes, assisted living facilities, nursing homes, or other hospitals. 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~~ community-based services to include, but not limited to, home health services, hospice or palliative care, respiratory services, rehabilitation services to include occupational therapy, physical therapy, and speech therapy, end stage renal disease, nutritional, medical equipment and supplies, transportation services, meal services, and household services such as housekeeping 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; 143B-165;*
Eff. March 1, ~~1996.~~ 1996;
Readopted Eff. August 1, 2023.

10A NCAC 13B .5408 is readopted with changes 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;~~ the needs of the patient;

(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)~~(4) 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)~~(5) 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; 143B-165;*
RRC Objection due to lack of statutory authority Eff. January 18, 1996;
Eff. May 1, ~~1996.~~ 1996;
Readopted Eff. August 1, 2023.

10A NCAC 13B .5411 is repealed through readoption with changes 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; 143B-165;*
Eff. March 1, ~~1996.~~ 1996;
Repealed Eff. August 1, 2023.

Burgos, Alexander N

Subject: FW: SL2023-65

From: Pfeiffer, Nadine <nadine.pfeiffer@dhhs.nc.gov>
Sent: Friday, June 30, 2023 11:37 AM
To: Liebman, Brian R <brian.liebman@oah.nc.gov>
Cc: Burgos, Alexander N <alexander.burgos@oah.nc.gov>; Hill, Greta D <greta.hill@dhhs.nc.gov>; Conley, Azzie <azzie.conley@dhhs.nc.gov>
Subject: RE: SL2023-65

HI Brian,
Thank you for letting me know what is needed for the July 20th meeting for these hospital rules. There should be no problem getting them to you prior to July 10th and that will include the revision to rule .4805 that has the outstanding objection to lack of clarity.

Nadine Pfeiffer
Rules Review Manager
Division of Health Service Regulation
NC Department of Health and Human Services

Office: 919-855-3811
Fax: 919-733-2757
nadine.pfeiffer@dhhs.nc.gov

809 Ruggles Drive, Edgerton Building
2701 Mail Service Center
Raleigh, NC 27699-2701

Burgos, Alexander N

From: Liebman, Brian R
Sent: Friday, June 30, 2023 11:28 AM
To: Pfeiffer, Nadine
Cc: Burgos, Alexander N
Subject: RE: SL2023-65

Hi Nadine,

I saw that the bill was signed. I'm glad it means we can wrap up these rules.

Looking back at the rules, there were two separate ground for objection.

First, was the overarching objection on authority that applied to all the rules. I think the new authority conferred on MCC by SL2023-65 satisfies that objection. You'll need to revise all the rules to add 143B-165 to the history notes, and I think you're good to go on that front.

Second, was the objection for lack of clarity to Rule .4805. There, the issue related to the amount of experience you're requiring for the physician appointed to the radiation safety committee. The rule merely states that the physician must be "experienced" in the handling of isotopes and their therapeutic use. The language would equally encompass someone who has spent a career handling isotopes as well as someone who took a 2 day course. The rule needs to specify some level of experience for the sake of clarity.

So, as long as we can get .4805 hammered out, I think there's no reason we can't get this all wrapped up at the July meeting. I am anticipating taking some time off the week of July 10. Given the minor changes necessary, do you think you can get me revised versions of the Rules before then?

Brian

Brian Liebman
Counsel to the North Carolina Rules Review Commission
Office of Administrative Hearings
(984)236-1948
brian.liebman@oah.nc.gov

From: Pfeiffer, Nadine <nadine.pfeiffer@dhhs.nc.gov>
Sent: Friday, June 30, 2023 8:33 AM
To: Liebman, Brian R <brian.liebman@oah.nc.gov>
Subject: SL2023-65

Good Morning, Brian,
Guess what? H190 was signed into law yesterday as SL2023-65! So that means the revisions to G.S. 143B-165 (the MCC statute) have been completed and are effective 6/29/23 and we can now clear up the follow up matter for the Hospital readoption rules. This has been a long time coming and I apologize for the long delay.

I assume the rules can be taken to the July 20th RRC meeting, correct? If so, please let me know what you need for the meeting and when do you need them by. I believe I had sent you many months ago the rules that were revised to satisfy

the other objections that were in addition to the lack of statutory authority objections, but I have no problem sending the whole set of rules to you again, and of course the effective date would need to reflect August 1, 2023.

Thank you.

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Rules Review Manager
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nadine.pfeiffer@dhhs.nc.gov

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Burgos, Alexander N

Subject: FW: 10A NCAC 13B - Follow Up

From: Liebman, Brian R <brian.liebman@oah.nc.gov>
Sent: Monday, May 15, 2023 1:49 PM
To: Pfeiffer, Nadine <nadine.pfeiffer@dhhs.nc.gov>
Cc: Burgos, Alexander N <alexander.burgos@oah.nc.gov>
Subject: RE: 10A NCAC 13B - Follow Up

OK. Thanks for letting me know.

Best,
Brian

Brian Liebman
Counsel to the North Carolina Rules Review Commission
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brian.liebman@oah.nc.gov

From: Pfeiffer, Nadine <nadine.pfeiffer@dhhs.nc.gov>
Sent: Monday, May 15, 2023 1:48 PM
To: Liebman, Brian R <brian.liebman@oah.nc.gov>
Cc: Burgos, Alexander N <alexander.burgos@oah.nc.gov>
Subject: RE: 10A NCAC 13B - Follow Up

Hi Brian,
Still waiting on the bill. Unfortunately, making a change to a statute does not appear to be done quickly.

Nadine Pfeiffer
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From: Liebman, Brian R <brian.liebman@oah.nc.gov>
Sent: Monday, May 15, 2023 1:33 PM

To: Pfeiffer, Nadine <nadine.pfeiffer@dhhs.nc.gov>
Cc: Burgos, Alexander N <alexander.burgos@oah.nc.gov>
Subject: 10A NCAC 13B - Follow Up

Hi Nadine,

I'm just checking in with you on the status of the hospital licensure rules we have on follow up. Any updates on the legislative fix that I can give the Commission?

Thanks!
Brian

Brian Liebman
Counsel to the North Carolina Rules Review Commission
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Burgos, Alexander N

Subject: FW: RRC Agenda Follow-up Rules - 10A NCAC 13B

From: Liebman, Brian R <brian.liebman@oah.nc.gov>
Sent: Wednesday, February 15, 2023 3:34 PM
To: Pfeiffer, Nadine <nadine.pfeiffer@dhhs.nc.gov>
Cc: Burgos, Alexander N <alexander.burgos@oah.nc.gov>
Subject: RE: RRC Agenda Follow-up Rules - 10A NCAC 13B

OK, thanks for letting me know. Have a great rest of your week!

Brian

Brian Liebman
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From: Pfeiffer, Nadine <nadine.pfeiffer@dhhs.nc.gov>
Sent: Wednesday, February 15, 2023 3:33 PM
To: Liebman, Brian R <brian.liebman@oah.nc.gov>
Subject: RE: RRC Agenda Follow-up Rules - 10A NCAC 13B

Hi Brian,
No updates yet, sorry. As soon as we have something we'll let you know.

Nadine Pfeiffer
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From: Liebman, Brian R <brian.liebman@oah.nc.gov>
Sent: Wednesday, February 15, 2023 3:16 PM
To: Pfeiffer, Nadine <nadine.pfeiffer@dhhs.nc.gov>

Cc: Burgos, Alexander N <alexander.burgos@oah.nc.gov>
Subject: RE: RRC Agenda Follow-up Rules - 10A NCAC 13B

Hi Nadine,

Just checking with you about the status of these rules before tomorrow's meeting. Any updates I can give RRC?

Thanks!
Brian

Brian Liebman
Counsel to the North Carolina Rules Review Commission
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Burgos, Alexander N

Subject: FW: Tomorrow's RRC meeting

From: Liebman, Brian R <brian.liebman@oah.nc.gov>
Sent: Wednesday, November 16, 2022 2:07 PM
To: Pfeiffer, Nadine <nadine.pfeiffer@dhhs.nc.gov>
Cc: Burgos, Alexander N <alexander.burgos@oah.nc.gov>
Subject: RE: Tomorrow's RRC meeting

Great, thanks for the update Nadine!

Brian Liebman
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Burgos, Alexander N

From: Pfeiffer, Nadine
Sent: Wednesday, November 16, 2022 1:24 PM
To: Liebman, Brian R
Cc: Burgos, Alexander N
Subject: Tomorrow's RRC meeting

Hi Brian,
Just to let you know agency staff for the follow up rules from the MCC rules in 10A NCAC 13B will be attending the meeting tomorrow via WebEx. From what you are planning on telling the Commission, it seems unlikely for the Commission to have questions for us; however, if they do, we will be available online to answer if needed.

Thank you.

Nadine Pfeiffer
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Burgos, Alexander N

Subject: FW: MCC follow up rules for Thursday's RRC meeting

From: Pfeiffer, Nadine <nadine.pfeiffer@dhhs.nc.gov>
Sent: Wednesday, November 16, 2022 8:47 AM
To: Liebman, Brian R <brian.liebman@oah.nc.gov>
Cc: Burgos, Alexander N <alexander.burgos@oah.nc.gov>
Subject: RE: MCC follow up rules for Thursday's RRC meeting

Good Morning, Brian,
Thank you for your email. I will let our team know that the additional objections to rules 13B .4801 & .4805 will be recommended as being satisfied. We were aiming to get those resolved so we could focus on the overarching statutory authority objection for the upcoming General Assembly session. Thank you in advance for letting the RRC of those rules at tomorrow's meeting.

Yes, we are both on the same page in understanding that the overarching statutory authority objection remains outstanding for those rules until we obtain the statutory change we are pursuing. We do not request the rules to be returned to us. I will keep you abreast of our progress with the statute change.

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Burgos, Alexander N

Subject: FW: MCC follow up rules for Thursday's RRC meeting

From: Liebman, Brian R <brian.liebman@oah.nc.gov>
Sent: Tuesday, November 15, 2022 6:11 PM
To: Pfeiffer, Nadine <nadine.pfeiffer@dhhs.nc.gov>
Cc: Burgos, Alexander N <alexander.burgos@oah.nc.gov>
Subject: RE: MCC follow up rules for Thursday's RRC meeting

Hi Nadine,

I sincerely apologize, the day has really gotten away from me as several unexpected issues have come up. I did look at the revised language .4801 and .4805, and I agree that the 1995 objection to .4801 has been satisfied, and that the secondary objection for ambiguity to .4805 has been satisfied. I will let the Commission know that at the meeting this week.

However, as I understand it, the overarching statutory authority objection remains outstanding until you obtain the statutory change you're pursuing. Thus, I don't think anything changes on that overarching objection, and all the rules currently under review will remain under review unless you request that they be returned.

Thanks,
Brian

Brian Liebman
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Burgos, Alexander N

From: Pfeiffer, Nadine
Sent: Tuesday, November 15, 2022 10:41 AM
To: Liebman, Brian R
Cc: Burgos, Alexander N
Subject: RE: MCC follow up rules for Thursday's RRC meeting

Brian,
I was getting worried because its getting down to the wire. I'll wait for your email today. Thank you.

Nadine Pfeiffer
Rules Review Manager
Division of Health Service Regulation
NC Department of Health and Human Services

Office: 919-855-3811
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From: Liebman, Brian R <brian.liebman@oah.nc.gov>
Sent: Tuesday, November 15, 2022 10:38 AM
To: Pfeiffer, Nadine <nadine.pfeiffer@dhhs.nc.gov>
Subject: RE: MCC follow up rules for Thursday's RRC meeting

Hi Nadine,

Yes, sorry, things have gotten a bit hectic. Will get back to you on those today.

Brian

Brian Liebman
Counsel to the North Carolina Rules Review Commission
Office of Administrative Hearings
(984)236-1948
brian.liebman@oah.nc.gov

From: Pfeiffer, Nadine <nadine.pfeiffer@dhhs.nc.gov>
Sent: Tuesday, November 15, 2022 10:37 AM
To: Liebman, Brian R <brian.liebman@oah.nc.gov>
Cc: Burgos, Alexander N <alexander.burgos@oah.nc.gov>
Subject: MCC follow up rules for Thursday's RRC meeting

Hi Brian,
Just touching base since the RRC meeting is in 2 days. I hadn't heard back from you on the rules and email I sent you on 11/7/22 for the follow-up matter rules from the Medical Care Commission in 10A NCAC 13B. Is there any feedback you can give me?

Thank you.

Nadine Pfeiffer
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Burgos, Alexander N

Subject: FW: RRC Agenda Follow-up Rules - 10A NCAC 13B

From: Pfeiffer, Nadine <nadine.pfeiffer@dhhs.nc.gov>
Sent: Monday, November 7, 2022 10:15 AM
To: Liebman, Brian R <brian.liebman@oah.nc.gov>
Cc: Burgos, Alexander N <alexander.burgos@oah.nc.gov>; Randolph, Kimberly <krandolph@ncdoj.gov>; Conley, Azzie <azzie.conley@dhhs.nc.gov>; Hill, Greta D <greta.hill@dhhs.nc.gov>; Hunt, Eric R <ehunt@NCDOJ.GOV>
Subject: RE: RRC Agenda Follow-up Rules - 10A NCAC 13B

Thanks Brian. I also didn't say that no other changes were done to the rules I sent along since the last time you saw them, but didn't point out specifically, but I thought you would figure that out. 😊

Nadine Pfeiffer
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Burgos, Alexander N

Subject: FW: RRC Agenda Follow-up Rules - 10A NCAC 13B

From: Liebman, Brian R <brian.liebman@oah.nc.gov>
Sent: Monday, November 7, 2022 10:12 AM
To: Pfeiffer, Nadine <nadine.pfeiffer@dhhs.nc.gov>
Cc: Burgos, Alexander N <alexander.burgos@oah.nc.gov>; Randolph, Kimberly <krandolph@ncdoj.gov>; Conley, Azzie <azzie.conley@dhhs.nc.gov>; Hill, Greta D <greta.hill@dhhs.nc.gov>; Hunt, Eric R <ehunt@NCDOJ.GOV>
Subject: RE: RRC Agenda Follow-up Rules - 10A NCAC 13B

Thanks, Nadine. I'll take a look and get back to you.

Brian Liebman
Counsel to the North Carolina Rules Review Commission
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(984)236-1948
brian.liebman@oah.nc.gov

Burgos, Alexander N

From: Pfeiffer, Nadine
Sent: Monday, November 7, 2022 9:37 AM
To: Liebman, Brian R
Cc: Burgos, Alexander N; Randolph, Kimberly; Conley, Azzie; Hill, Greta D; Hunt, Eric R
Subject: RRC Agenda Follow-up Rules - 10A NCAC 13B
Attachments: 10A NCAC 13B .3801.docx; 10A NCAC 13B .3903.docx; 10A NCAC 13B .4103.docx; 10A NCAC 13B .4104.docx; 10A NCAC 13B .4106.docx; 10A NCAC 13B .4305.docx; 10A NCAC 13B .4603.docx; 10A NCAC 13B .4801.docx; 10A NCAC 13B .4805.docx; 10A NCAC 13B .5102.docx; 10A NCAC 13B .5105.docx; 10A NCAC 13B .5406.docx; 10A NCAC 13B .5408.docx; 10A NCAC 13B .5411.docx

Follow Up Flag: Follow up
Flag Status: Flagged

Hi Brian,
This email is in response to G.S. 150B-21-12. The Medical Care Commission (MCC) met on November 4, 2022 to discuss the objections of the Rules Review Commission (RRC) for rules 10A NCAC 13B .3801, .3903, .4103, .4104, .4106, .4305, .4603, .4801, .4805, .5102, .5105, .5406, .5408, and .5411. The MCC approved a revision to Rule 10A NCAC 13B .4801 to satisfy the outstanding 1995 statutory objection. The MCC also approved a revision to Rule 10A NCAC 13B .4805 to satisfy the objection to ambiguity.

I am attaching all the rules for this rule package for your convenience for the November 17, 2002 RRC meeting. Please see attached Rule 10A NCAC 13B .4801 with the removal of text in lines 7 & 8 and Rule 10A NCAC 13B .4805 with the removal of text in lines 10-13.

As for the outstanding objection by the RRC for lack of statutory authority for all the rules, the MCC through the DHHS will be seeking a statute change in the next session of the General Assembly therefore no changes were made to the rules' history notes or effective dates at this time.

Please let me know if you have any questions.

Nadine Pfeiffer
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10A NCAC 13B .3801 is readopted with changes 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.~~ as required in Paragraph (e) of this Rule.

(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)~~(2) planning for and the evaluation of the delivery of nursing care ~~delivery~~ system;

~~(4)~~(3) establishment of a mechanism to validate qualifications, knowledge, and skills of nursing personnel;

~~(5)~~(4) provision of orientation and educational opportunities related to expected nursing ~~performance,~~ performance and maintenance of records pertaining thereto;

~~(6)~~(5) implementation of a system for performance evaluation;

~~(7)~~(6) 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)~~(7) 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)~~(8) 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. September 1, 2022.

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

10A NCAC 13B .3903 PRESERVATION OF MEDICAL RECORDS

(a) The manager of the medical records service shall maintain medical ~~records,~~ records that were created when the patient was an adult, whether original, computer media, or ~~microfilm,~~ digital archived 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.~~ that were created when the patient was a minor, whether original, computer media, or digital archived, until the patient's 30th birthday. If a minor patient is readmitted as an adult, the manager of the medical records shall maintain medical records according to Paragraph (a) of this Rule.

(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.~~ date or according to Paragraph (b) of this Rule if the patient was a minor.

~~(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~~ digital archiving of medical records. ~~Microfilming~~ Digital archiving 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~~ digital archived medical records shall not be destroyed until the medical records department has had an opportunity to review the ~~processed film~~ digital record 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 the Health Insurance Portability and Accountability Act (HIPAA) ~~regulations~~ found in 42 CFR 482, which is incorporated by reference including subsequent amendments and editions, shall have access to medical records. This regulation may be obtained free of charge at https://www.govinfo.gov/help/cfr. 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~~ shall remain the property of the hospital, 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. September 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 with changes 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 neonates who are large for gestational ~~age neonates.~~ age.

(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~~ 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~~ or approximately 32 and less than 36 completed weeks of gestational ~~age)~~ 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~~ 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. September 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 with changes 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 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)~~(c) 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)~~(d) 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.

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 with changes 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 of care have been reached, or a determination by the interdisciplinary care team has been made that care in a less intensive setting ~~would be appropriate,~~ to return to the setting from which was admitted, or that further progress is unlikely, the patient shall be discharged to ~~an appropriate setting.~~ another inpatient or residential health care facility that can address the patient's needs including skilled nursing homes, assisted living facilities, nursing homes, or other hospitals. 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~~ community-based services to include, but not limited to, home health services, hospice or palliative care, respiratory services, rehabilitation services to include occupational therapy, physical therapy, and speech therapy, end stage renal disease, nutritional, medical equipment and supplies, transportation services, meal services, and household services such as housekeeping 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. September 1, 2022.

10A NCAC 13B .5408 is readopted with changes 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;~~ the needs of the patient;

(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)~~(4) 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)~~(5) 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.

Burgos, Alexander N

Subject: FW: 10A NCAC 13B Objection Letter

From: Pfeiffer, Nadine <nadine.pfeiffer@dhhs.nc.gov>
Sent: Tuesday, August 23, 2022 8:35 AM
To: Liebman, Brian R <brian.liebman@oah.nc.gov>
Cc: Randolph, Kimberly <krandolph@ncdoj.gov>; Burgos, Alexander N <alexander.burgos@oah.nc.gov>
Subject: RE: 10A NCAC 13B Objection Letter

Thank you for the clarification on the rule with 1995 outstanding objection, Brian.

Nadine Pfeiffer
Rules Review Manager
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Raleigh, NC 27699-2701

Burgos, Alexander N

Subject: FW: 10A NCAC 13B Objection Letter

From: Liebman, Brian R <brian.liebman@oah.nc.gov>
Sent: Monday, August 22, 2022 5:06 PM
To: Pfeiffer, Nadine <nadine.pfeiffer@dhhs.nc.gov>
Cc: Randolph, Kimberly <krandolph@ncdoj.gov>; Burgos, Alexander N <alexander.burgos@oah.nc.gov>
Subject: RE: 10A NCAC 13B Objection Letter

Hi Nadine,

Thanks for letting me know your timetable. I'll keep an eye out for MCC's response for the November meeting then.

I believe the Rule to which the 1995 objection remains applicable is .4801.

Thanks,
Brian

Brian Liebman
Counsel to the North Carolina Rules Review Commission
Office of Administrative Hearings
(984)236-1948
brian.liebman@oah.nc.gov

From: Pfeiffer, Nadine <nadine.pfeiffer@dhhs.nc.gov>
Sent: Monday, August 22, 2022 2:34 PM
To: Liebman, Brian R <brian.liebman@oah.nc.gov>
Cc: Randolph, Kimberly <krandolph@ncdoj.gov>; Burgos, Alexander N <alexander.burgos@oah.nc.gov>
Subject: RE: 10A NCAC 13B Objection Letter

Thank you, Brian. We will take these objections before our next regularly scheduled Medical Care Commission meeting on November 4th. Within 10 days of that meeting, we will send you the MCC's response to this action by the RRC.

One question for clarification please. The staff opinion stated all the rules were objected to due to lack of statutory authority and gave the reasons for the objection. However at the RRC meeting on Thursday, you told the Commission that of these rules there were 2 rules that had additional statutory objections from 1995, one of which had been satisfied with the submitted rewritten rules and one objection that was still outstanding. Please tell me which rule that 1995 objection still remains.

Thank you.

Nadine Pfeiffer
Rules Review Manager
Division of Health Service Regulation
NC Department of Health and Human Services

Office: 919-855-3811
Fax: 919-733-2757
nadine.pfeiffer@dhhs.nc.gov

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2701 Mail Service Center
Raleigh, NC 27699-2701

From: Liebman, Brian R <brian.liebman@oah.nc.gov>
Sent: Monday, August 22, 2022 11:05 AM
To: Pfeiffer, Nadine <nadine.pfeiffer@dhhs.nc.gov>
Cc: Randolph, Kimberly <krandolph@ncdoj.gov>; Burgos, Alexander N <alexander.burgos@oah.nc.gov>
Subject: 10A NCAC 13B Objection Letter

Good morning,

Attached, please find a letter regarding the RRC's objection to the above captioned rules considered at last week's meeting.

Please do not hesitate to contact me with any questions or concerns.

Thanks,
Brian

Brian Liebman
Counsel to the North Carolina Rules Review Commission
Office of Administrative Hearings
(984)236-1948
brian.liebman@oah.nc.gov

Burgos, Alexander N

From: Pfeiffer, Nadine
Sent: Monday, August 22, 2022 2:34 PM
To: Liebman, Brian R
Cc: Randolph, Kimberly; Burgos, Alexander N
Subject: RE: 10A NCAC 13B Objection Letter

Thank you, Brian. We will take these objections before our next regularly scheduled Medical Care Commission meeting on November 4th. Within 10 days of that meeting, we will send you the MCC's response to this action by the RRC.

One question for clarification please. The staff opinion stated all the rules were objected to due to lack of statutory authority and gave the reasons for the objection. However at the RRC meeting on Thursday, you told the Commission that of these rules there were 2 rules that had additional statutory objections from 1995, one of which had been satisfied with the submitted rewritten rules and one objection that was still outstanding. Please tell me which rule that 1995 objection still remains.

Thank you.

Nadine Pfeiffer
Rules Review Manager
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NC Department of Health and Human Services

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Fax: 919-733-2757
nadine.pfeiffer@dhhs.nc.gov

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2701 Mail Service Center
Raleigh, NC 27699-2701

From: Liebman, Brian R <brian.liebman@oah.nc.gov>
Sent: Monday, August 22, 2022 11:05 AM
To: Pfeiffer, Nadine <nadine.pfeiffer@dhhs.nc.gov>
Cc: Randolph, Kimberly <krandolph@ncdoj.gov>; Burgos, Alexander N <alexander.burgos@oah.nc.gov>
Subject: 10A NCAC 13B Objection Letter

Good morning,

Attached, please find a letter regarding the RRC's objection to the above captioned rules considered at last week's meeting.

Please do not hesitate to contact me with any questions or concerns.

Thanks,
Brian

Brian Liebman
Counsel to the North Carolina Rules Review Commission
Office of Administrative Hearings

(984)236-1948
brian.liebman@oah.nc.gov

Burgos, Alexander N

From: Liebman, Brian R
Sent: Monday, August 22, 2022 11:05 AM
To: Pfeiffer, Nadine
Cc: Randolph, Kimberly; Burgos, Alexander N
Subject: 10A NCAC 13B Objection Letter
Attachments: 08.2022 MCC Objection Letter.pdf

Good morning,

Attached, please find a letter regarding the RRC's objection to the above captioned rules considered at last week's meeting.

Please do not hesitate to contact me with any questions or concerns.

Thanks,
Brian

Brian Liebman
Counsel to the North Carolina Rules Review Commission
Office of Administrative Hearings
(984)236-1948
brian.liebman@oah.nc.gov

Burgos, Alexander N

From: Pfeiffer, Nadine
Sent: Friday, August 12, 2022 3:39 PM
To: Liebman, Brian R
Cc: Conley, Azzie; Randolph, Kimberly; Hill, Greta D; Burgos, Alexander N
Subject: RE: RE: Submission of Permanent Rule Technical Changes - 10A NCAC 13B

Brian,
Received. Disheartened. Will send to Dana.

Nadine Pfeiffer
Rules Review Manager
Division of Health Service Regulation
NC Department of Health and Human Services

Office: 919-855-3811
Fax: 919-733-2757
nadine.pfeiffer@dhhs.nc.gov

809 Ruggles Drive, Edgerton Building
2701 Mail Service Center
Raleigh, NC 27699-2701

From: Liebman, Brian R <brian.liebman@oah.nc.gov>
Sent: Friday, August 12, 2022 3:18 PM
To: Pfeiffer, Nadine <nadine.pfeiffer@dhhs.nc.gov>
Cc: Conley, Azzie <azzie.conley@dhhs.nc.gov>; Randolph, Kimberly <krandolph@ncdoj.gov>; Hill, Greta D <greta.hill@dhhs.nc.gov>; Burgos, Alexander N <alexander.burgos@oah.nc.gov>
Subject: RE: RE: Submission of Permanent Rule Technical Changes - 10A NCAC 13B

Hi all,

Thanks for submitting these revised Rules. I think these Rules are as clear as they can be, and I don't have any further requests. I have issued a separate staff opinion on Rule .4805, as I believe the Rule remains ambiguous, given that it does not specify what amount of experience is required to satisfy (c)(1). It is attached here.

While I'm not recommending approval, you'll need to send the final version of all of your rules to Dana for filing. I think I have all the final versions, but given that we've gone through 3 versions, I want to make sure. Please just copy me on your submission.

Thanks and have a great weekend,
Brian

Brian Liebman
Counsel to the North Carolina Rules Review Commission
Office of Administrative Hearings
(984)236-1948
brian.liebman@oah.nc.gov

From: Pfeiffer, Nadine <nadine.pfeiffer@dhhs.nc.gov>
Sent: Thursday, August 11, 2022 12:56 PM
To: Liebman, Brian R <brian.liebman@oah.nc.gov>
Cc: Conley, Azzie <azzie.conley@dhhs.nc.gov>; Randolph, Kimberly <krandolph@ncdoj.gov>; Hill, Greta D <greta.hill@dhhs.nc.gov>
Subject: RE: Submission of Permanent Rule Technical Changes - 10A NCAC 13B

Hi Brian,
In response to your additional questions for the MCC rules at 10A NCAC 13B emailed to us on 8/9/22, please see the following revised attached rules: 10A NCAC 13B .3801, .3903, .4805, and .5406. Also attached is a document containing your additional questions and our responses in light blue font.

Thanks!

Nadine Pfeiffer
Rules Review Manager
Division of Health Service Regulation
NC Department of Health and Human Services

Office: 919-855-3811
Fax: 919-733-2757
nadine.pfeiffer@dhhs.nc.gov

809 Ruggles Drive, Edgerton Building
2701 Mail Service Center
Raleigh, NC 27699-2701

Burgos, Alexander N

Subject: FW: [External] Permission to speak at the RRC meeting

From: Randolph, Kimberly <Krandolph@ncdoj.gov>
Sent: Friday, August 12, 2022 12:12 PM
To: Liebman, Brian R <brian.liebman@oah.nc.gov>
Cc: Pfeiffer, Nadine <nadine.pfeiffer@dhhs.nc.gov>; Burgos, Alexander N <alexander.burgos@oah.nc.gov>
Subject: Re: [External] Permission to speak at the RRC meeting

Thanks Brian.

Sent from my iPhone

Burgos, Alexander N

Subject: FW: [External] Permission to speak at the RRC meeting

---

From: Liebman, Brian R <brian.liebman@oah.nc.gov>
Sent: Friday, August 12, 2022 9:46 AM
To: Pfeiffer, Nadine <nadine.pfeiffer@dhhs.nc.gov>; Randolph, Kimberly <krandolph@ncdoj.gov>
Cc: Burgos, Alexander N <alexander.burgos@oah.nc.gov>
Subject: RE: [External] Permission to speak at the RRC meeting

Hi Nadine,

If y'all just want to attend, I think that's fine, and there's no deadline on that. Only caveat to that is I think this may be a well-attended meeting, so you might need to sit in the overflow room if it's too crowded.

Thanks,
Brian

Brian Liebman
Counsel to the North Carolina Rules Review Commission
Office of Administrative Hearings
(984)236-1948
brian.liebman@oah.nc.gov

Burgos, Alexander N

From: Pfeiffer, Nadine
Sent: Thursday, August 11, 2022 5:16 PM
To: Liebman, Brian R; Randolph, Kimberly
Cc: Burgos, Alexander N
Subject: RE: [External] Permission to speak at the RRC meeting

Also, Brian, I know you all like to keep the attendees down to 2/agency but will make accommodations for others if needed. Besides Kim and Dr. Meier attending, I would also like to attend the meeting in person that day. I will confirm if Azzie Conley, Section Chief for the Acute and Home Care Licensure and Certification Section would like to attend in person. Is there a deadline for letting you know this?

Nadine Pfeiffer
Rules Review Manager
Division of Health Service Regulation
NC Department of Health and Human Services

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Fax: 919-733-2757
nadine.pfeiffer@dhhs.nc.gov

809 Ruggles Drive, Edgerton Building
2701 Mail Service Center
Raleigh, NC 27699-2701

From: Liebman, Brian R <brian.liebman@oah.nc.gov>
Sent: Thursday, August 11, 2022 5:12 PM
To: Randolph, Kimberly <krandolph@ncdoj.gov>
Cc: Pfeiffer, Nadine <nadine.pfeiffer@dhhs.nc.gov>; Burgos, Alexander N <alexander.burgos@oah.nc.gov>
Subject: RE: [External] Permission to speak at the RRC meeting

Hi Kim,

Thanks for letting me know. I will let the Commission know to expect you both.

Have a great day,
Brian

Brian Liebman
Counsel to the North Carolina Rules Review Commission
Office of Administrative Hearings
(984)236-1948
brian.liebman@oah.nc.gov

From: Randolph, Kimberly <Krandolph@ncdoj.gov>
Sent: Thursday, August 11, 2022 4:30 PM

To: Liebman, Brian R <brian.liebman@oah.nc.gov>
Cc: Pfeiffer, Nadine <nadine.pfeiffer@dhhs.nc.gov>
Subject: [External] Permission to speak at the RRC meeting

Hey Brian,

I hope you are well!

I would like to request permission to speak at the RRC meeting regarding the readoption of the hospital rules next week for the following:

Kim Randolph – Assistant Attorney General, DOJ
Dr. John Meier – Chair, Medical Care Commission

Please let me know if you need anything additional. Thank you.

Kim Randolph
Assistant Attorney General
Health Service Section
(919) 716-0270 - Direct
(919) 716-6756 - Fax
krandolph@ncdoj.gov
P.O. Box 629 Raleigh, NC 27602-0629
ncdoj.gov

Burgos, Alexander N

Subject: FW: Submission of Permanent Rule Technical Changes - 10A NCAC 13B

From: Pfeiffer, Nadine <nadine.pfeiffer@dhhs.nc.gov>
Sent: Wednesday, August 10, 2022 9:57 AM
To: Liebman, Brian R <brian.liebman@oah.nc.gov>
Cc: Randolph, Kimberly <krandolph@ncdoj.gov>; Conley, Azzie <azzie.conley@dhhs.nc.gov>; Burgos, Alexander N <alexander.burgos@oah.nc.gov>
Subject: RE: Submission of Permanent Rule Technical Changes - 10A NCAC 13B

Brian,
Email received. We will have answers to your questions by your deadline.

Nadine Pfeiffer
Rules Review Manager
Division of Health Service Regulation
NC Department of Health and Human Services

Office: 919-855-3811
Fax: 919-733-2757
nadine.pfeiffer@dhhs.nc.gov

809 Ruggles Drive, Edgerton Building
2701 Mail Service Center
Raleigh, NC 27699-2701

Burgos, Alexander N

Subject: FW: Submission of Permanent Rule Technical Changes - 10A NCAC 13B

From: Liebman, Brian R <brian.liebman@oah.nc.gov>
Sent: Tuesday, August 9, 2022 12:35 PM
To: Pfeiffer, Nadine <nadine.pfeiffer@dhhs.nc.gov>
Cc: Randolph, Kimberly <krandolph@ncdoj.gov>; Conley, Azzie <azzie.conley@dhhs.nc.gov>; Burgos, Alexander N <alexander.burgos@oah.nc.gov>
Subject: RE: Submission of Permanent Rule Technical Changes - 10A NCAC 13B

Good morning,

I have a few further questions regarding these rules. I'm copying my original change request and the agency response below, and then adding my follow up in red.

Rule .3801

In (c), line 11, what "required functions" are you referring to? ***The state licensed and Medicare certified, accreditation organizations, and regulated providers are knowledgeable of the regulations and daily operations which define the various functions warranting the development and implementation of policies and procedures for patient care.***

This really isn't responsive to my question. The rule requires the nurse executive to establish policies and procedures to "accomplish required functions" but does not state what they are.

In (d), who is evaluating the quality and efficiency of nursing services? Under what framework? ***The state licensed and Medicare certified, accreditation organizations, and regulated providers are knowledgeable of the regulations and daily operations. Hospitals define parameters for staffing related to patient care acuity and needs to ensure the delivery of safe and quality care. Staffing is patient care directed.***

Again, this really isn't responsive. If you're having a meeting to "evaluate the quality and efficacy of nursing services" it seems obvious that someone or some group has to actually make the evaluation. I assume that same person/group would make changes thereafter based on the evaluation. The rule doesn't identify that person/group.

In (e)(2), would it change the meaning to say "…standards, ~~and~~ policies, and procedures…." Moreover, how is this different from what is required in (b)? ***To amend the statement and delete "and" does not alter the intent of the regulation.***

Thank you for answering the first part of the question and making the change. I'm still curious what you think about the second part – is the requirement in (b) different than what is being required in (e)(2)?

Rule .3903

In (b), at what time must the patient be a minor for this provision to apply? At the time of treatment, or at discharge? ***The patient is defined as a minor during the inpatient and / or outpatient hospitalization. The age is determined on admission, during the course of the hospitalization, and point of discharge or disposition.***

I don't understand the response. For instance, if someone is a minor when admitted, but attains majority while hospitalized, how are the records characterized, and under which provision do they fall?

Moreover, if someone who was treated as a minor is readmitted later as an adult, but before age 30, do the medical records from the period of minority fall then fall under (a), rather than (b)?

Correct. Records for the stage of life defined as minor fall under (b)

I believe this is contradictory. I'm asking if a person's minor medical records become part of their adult records if the person is readmitted as an adult, but before the age of 30, thus requiring them to be preserved for another 11 years. My main point for asking these questions is to point out, at least in my mind, that there seems to be ambiguity in how medical records are classified and thus preserved when a patient has been admitted as both a minor and as an adult.

Rule .4305

In (a)(3), please remove the parenthetical and incorporate the material into the body of the Rule. ***Suggestion made in rule.*** *Also, I do not understand the contents of the parenthetical. Can you clarify which infants you're referring to?* ***Level III neonates are fragile or ill infants with a gestational age of 32 weeks to 36 weeks.***

I still am a little confused by the new language, and with this response. The new language in the Rule says (with changes redacted for clarity):

> 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 text of the rule indicates that Level III neonates are healthy AND high risk, OR small, OR between 32-36 weeks, OR sick AND requiring intermediate care. Your response indicates that they are "fragile" (which I assume captures high risk and small) OR ill AND between 32 and 36 weeks. Can you clarify what the intent is here?

Rule .4801

In (c), G.S. 150B-21.6 requires that the agency "must specify in the rule both where copies of the material can be obtained and the cost on the date the rule is adopted of a copy of the material." Obviously, these rules are available online and at no cost, but please add a hyperlink and state that they are available at no cost. **Prior RRC staff counsel directed agencies to not use "and editions" in rule when referring by reference to other rules in the Code. Likewise, agencies were directed by RRC staff attorneys that it was not necessary to write in the rules the cost and where to find another rule referenced in the Code because the rule was already in the Code and online, the referenced rule was also in the Code and online, therefore that person would be able to find the referenced rule without cost online. Please advise on any change to this prior direction from RRC staff counsel.**

I suppose if you're referring to other provisions of the NCAC this is fine. No change necessary then.

Rule .4805

In (c), is the Medical Care Commission requiring these safety inspections or are these already required by Radiation Protection? In other words, is this necessary or are you repeating something that is already required? ***The rule is essential to promoting safe practices and standards in the delivery of radiation services.***

I don't think this is quite responsive to my question, which was whether the Rule is repeating a requirement that appears elsewhere in the Code.

In (c), lines 8-9, do you mean that the Division shall make available copies of the report to the public? Or that the Division shall be the entity to review the report?

The Division is responsible for identifying areas of noncompliance and writing the report for corrective action. Also, the Division is responsible for disclosing reports to the public.

The text of the Rule states:

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.

As written, this is unclear. It sounds like the Division conducts an inspection, then someone, presumably Division staff, prepares a report, and then the report is available for review "by the Division." It is not clear from the text of the Rule that the Division is responsible for drafting the report, and the Rule says nothing about making the report public. Under what circumstances is the report made public? Is it posted on the Division's website? Is it available on request pursuant to Ch. 132 as a public record?

In (d)(1), please define "experienced." ***The state licensed Medicare certified regulated providers are knowledgeable of the regulations and daily operations. Experienced is hospital specific and defined by the hospital's medical staff bylaws and includes a combination of educations, and hands on exposure or skill over a specific period.***

Based on this answer, I will have to recommend objection to this rule on the basis of ambiguity. You're requiring a hospital to maintain a committee, stating who shall be on the committee, and setting a qualification for that role, but not defining the qualification and leaving it up to the hospital.

Rule .5406

In (a), line 6, what "established goals" are you referring to? ***Goals of care.***
This is not clear from the text. Consider revising for clarity.

Again in (a), line 6, who makes this determination? The attending physician? A utilization review board? The patient? ***The state licensed Medicare certified regulated providers are knowledgeable of the regulations and processes for assessing and implementing care to meet the needs of patients with an overarching goal of improvement to returning to an independent state of health with the least parameters of assistance. The team and decision-making are a comprehensive team approach addressing the needs of the rehab patient. The attending physician or physiatrist direct the comprehensive rehab program. This is an inclusive process of a multi-disciplinary team of health care providers which may include OT, PT, SLP, mental health professionals, psychologist, psychiatrist, etc.***
It isn't clear from the text of the rule who makes these determinations, and thus who bears the burden of complying with the Rule because the Rule is written in the passive tense. Please consider revising in the active tense.

In (a), line 7, what is an "appropriate setting"? ***Appropriate care setting is a place considered discharge appropriate to meet the needs of the reference patient. The overall goal to promote stabilization and improvement in the patient's condition.***
Again, this is not clear from the text of the Rule. Please clarify.

In (a), line 10, what are "referral sources"? ***Referral sources include persons, inpatient and / or outpatient dwellings to promote a smooth transition from the hospital setting to the home or other dwelling.***
Again, this is not clear from the text. Is this term defined elsewhere?

If you could, I'd appreciate responses by the end of the day on Friday.

Thanks,
Brian

Brian Liebman
Counsel to the North Carolina Rules Review Commission

Burgos, Alexander N

Subject: FW: Submission of Permanent Rule Technical Changes - 10A NCAC 13B

From: Pfeiffer, Nadine <nadine.pfeiffer@dhhs.nc.gov>
Sent: Wednesday, August 10, 2022 9:22 AM
To: Liebman, Brian R <brian.liebman@oah.nc.gov>; Burgos, Alexander N <alexander.burgos@oah.nc.gov>
Cc: Randolph, Kimberly <krandolph@ncdoj.gov>; Conley, Azzie <azzie.conley@dhhs.nc.gov>
Subject: RE: Submission of Permanent Rule Technical Changes - 10A NCAC 13B

Brian,
Received. Thank you.

Nadine Pfeiffer
Rules Review Manager
Division of Health Service Regulation
NC Department of Health and Human Services

Office: 919-855-3811
Fax: 919-733-2757
nadine.pfeiffer@dhhs.nc.gov

809 Ruggles Drive, Edgerton Building
2701 Mail Service Center
Raleigh, NC 27699-2701

Office of Administrative Hearings
(984)236-1948
brian.liebman@oah.nc.gov

From: Pfeiffer, Nadine <nadine.pfeiffer@dhhs.nc.gov>
Sent: Wednesday, July 27, 2022 8:58 AM
To: Rules, Oah <oah.rules@oah.nc.gov>
Cc: Liebman, Brian R <brian.liebman@oah.nc.gov>; Randolph, Kimberly <krandolph@ncdoj.gov>; Conley, Azzie <azzie.conley@dhhs.nc.gov>
Subject: Submission of Permanent Rule Technical Changes - 10A NCAC 13B

We have been notified of the technical changes requested by Mr. Brian Liebman on June 3, 2022 pursuant to G.S. 150B-21.10 for the following rules: 10A NCAC 13B .3801, .3903, .4103, .4104, .4106, .4305, .4603, .4801, .4805, .5102, .5406, and .5408. In preparation for the August 18, 2022 RRC meeting, attached to this email you will find the amended text for rules 10A NCAC 13B .3801, .3903, .4305, .4805, and .5408 as requested in the Request for Technical Change document received, as well as the Agency's responses to the concerns raised in the "Request for Changes" document as seen in bold black font on the document. In addition, to accompany the Agency's responses to the "Request for Changes" attached is an additional document titled "Response to RRC Staff Attorney for Hospital Rules 7-25-22" that addresses the statutory authority concerns and staff opinion issued by Mr. Liebman on June 7, 2022 for these rules.

Should you have any questions regarding the attachments, please feel free to contact me. ***Please note, I will be on annual leave August 3 through August 9.

Thank you,

Nadine Pfeiffer
Rules Review Manager
Division of Health Service Regulation
NC Department of Health and Human Services

Office: 919-855-3811
Fax: 919-733-2757
nadine.pfeiffer@dhhs.nc.gov

809 Ruggles Drive, Edgerton Building
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Raleigh, NC 27699-2701

Burgos, Alexander N

Subject: FW: Submission of Permanent Rule Technical Changes - 10A NCAC 13B
Attachments: 2022.06 - MCC - 13B Staff Opinion 2.0.doc

From: Liebman, Brian R <brian.liebman@oah.nc.gov>
Sent: Friday, August 5, 2022 3:18 PM
To: Pfeiffer, Nadine <nadine.pfeiffer@dhhs.nc.gov>; Burgos, Alexander N <alexander.burgos@oah.nc.gov>
Cc: Randolph, Kimberly <krandolph@ncdoj.gov>; Conley, Azzie <azzie.conley@dhhs.nc.gov>
Subject: RE: Submission of Permanent Rule Technical Changes - 10A NCAC 13B

Hi Nadine,

Attached, please find my revised staff opinion with respect to statutory authority for all rules in this package. Please also be aware that I anticipate issuing several other staff opinions for individual rules early next week.

Thanks,
Brian

Brian Liebman
Counsel to the North Carolina Rules Review Commission
Office of Administrative Hearings
(984)236-1948
brian.liebman@oah.nc.gov

Burgos, Alexander N

Subject: FW: Submission of Permanent Rule Technical Changes - 10A NCAC 13B

From: Pfeiffer, Nadine <nadine.pfeiffer@dhhs.nc.gov>
Sent: Wednesday, July 27, 2022 10:48 AM
To: Liebman, Brian R <brian.liebman@oah.nc.gov>; Burgos, Alexander N <alexander.burgos@oah.nc.gov>
Cc: Randolph, Kimberly <krandolph@ncdoj.gov>; Conley, Azzie <azzie.conley@dhhs.nc.gov>
Subject: RE: Submission of Permanent Rule Technical Changes - 10A NCAC 13B

Thank you.

Nadine Pfeiffer
Rules Review Manager
Division of Health Service Regulation
NC Department of Health and Human Services

Office: 919-855-3811
Fax: 919-733-2757
nadine.pfeiffer@dhhs.nc.gov

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2701 Mail Service Center
Raleigh, NC 27699-2701

From: Liebman, Brian R <brian.liebman@oah.nc.gov>
Sent: Wednesday, July 27, 2022 10:43 AM
To: Pfeiffer, Nadine <nadine.pfeiffer@dhhs.nc.gov>; Burgos, Alexander N <alexander.burgos@oah.nc.gov>
Cc: Randolph, Kimberly <krandolph@ncdoj.gov>; Conley, Azzie <azzie.conley@dhhs.nc.gov>
Subject: RE: Submission of Permanent Rule Technical Changes - 10A NCAC 13B

Hi Nadine,

Thank you. I will review this and get back to you soon. If I don't speak with you prior to your vacation, I hope you have a great week!

Brian

Brian Liebman
Counsel to the North Carolina Rules Review Commission
Office of Administrative Hearings
(984)236-1948
brian.liebman@oah.nc.gov

From: Pfeiffer, Nadine <nadine.pfeiffer@dhhs.nc.gov>
Sent: Wednesday, July 27, 2022 8:58 AM

To: Rules, Oah <oah.rules@oah.nc.gov>
Cc: Liebman, Brian R <brian.liebman@oah.nc.gov>; Randolph, Kimberly <krandolph@ncdoj.gov>; Conley, Azzie <azzie.conley@dhhs.nc.gov>
Subject: Submission of Permanent Rule Technical Changes - 10A NCAC 13B

We have been notified of the technical changes requested by Mr. Brian Liebman on June 3, 2022 pursuant to G.S. 150B-21.10 for the following rules: 10A NCAC 13B .3801, .3903, .4103, .4104, .4106, .4305, .4603, .4801, .4805, .5102, .5406, and .5408. In preparation for the August 18, 2022 RRC meeting, attached to this email you will find the amended text for rules 10A NCAC 13B .3801, .3903, .4305, .4805, and .5408 as requested in the Request for Technical Change document received, as well as the Agency's responses to the concerns raised in the "Request for Changes" document as seen in bold black font on the document. In addition, to accompany the Agency's responses to the "Request for Changes" attached is an additional document titled "Response to RRC Staff Attorney for Hospital Rules 7-25-22" that addresses the statutory authority concerns and staff opinion issued by Mr. Liebman on June 7, 2022 for these rules.

Should you have any questions regarding the attachments, please feel free to contact me. ***Please note, I will be on annual leave August 3 through August 9.

Thank you,

Nadine Pfeiffer
Rules Review Manager
Division of Health Service Regulation
NC Department of Health and Human Services

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809 Ruggles Drive, Edgerton Building
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REQUEST FOR CHANGES PURSUANT TO G.S. 150B-21.10

AGENCY: North Carolina Medical Care Commission

RULE CITATION: 10A NCAC 13B .3801

DEADLINE FOR RECEIPT: Friday, June 10, 2022.

***PLEASE NOTE:* This request may extend to several pages. Please be sure you have reached the end of the document.**

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may email the reviewing attorney to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following changes be made:

In (a), line 6, what is a "centralized organizational structure" and what is a "decentralized organizational structure?" Is your regulated public familiar with these terms? ***The state licensed and Medicare certified, accreditation organizations, and regulated providers are knowledgeable of the regulations and daily operations and familiar with the terms, "centralized organizational structure" and "decentralized organizational structure. The organizational structures are hospital specific references in the use of the centralized or decentralized structure.***

In (a), generally, R. .3001 defines "nurse executive" as a "registered nurse who is the director of nursing services or a representative of decentralized nursing management staff." Given that definition, does a nurse executive have different duties between a centralized or decentralized organizational structure? ***Yes. This depends on the structure of the centralized or decentralized organization. The traditional Nurse Executive duties are often split between roles or delegated down which they still have oversight of nurse responsibilities. The Nurse Executive is still at the top of the organizational chart in both structures and responsible for nursing. In a decentralized organizational structure, there is a shared governance where the Nurse Executive delegates and empowers nursing staff at various levels in the decision-making process. In summary, one Nurse Executive should have the overall responsibility for nursing services. The hospital should have policies, procedures, o-charts, and position descriptions that define the overall delivery of nursing services. The difference resolves around the manner duties are carried out in a centralized as opposed to decentralized system. O-charts vary from hospital to hospital. We rely on the O-chart and position descriptions.***

In (c), line 11, what "required functions" are you referring to? ***The state licensed and Medicare certified, accreditation organizations, and regulated providers are knowledgeable of the regulations and daily operations which define the***

Brian Liebman
Commission Counsel
Date submitted to agency: June 3, 2022

various functions warranting the development and implementation of policies and procedures for patient care.

In (d), who is evaluating the quality and efficiency of nursing services? Under what framework? ***The state licensed and Medicare certified, accreditation organizations, and regulated providers are knowledgeable of the regulations and daily operations. Hospitals define parameters for staffing related to patient care acuity and needs to ensure the delivery of safe and quality care. Staffing is patient care directed.***

In (e)(2), would it change the meaning to say "…standards, ~~and~~ policies, and procedures…." Moreover, how is this different from what is required in (b)? ***To amend the statement and delete "and" does not alter the intent of the regulation.***

In (e)(3), is not repetitive to say "the ***delivery*** *of nursing care* ***delivery*** *system"?* ***Yes. There is no concern deleting the second "delivery" as recommended.***

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

Brian Liebman
Commission Counsel
Date submitted to agency: June 3, 2022

REQUEST FOR CHANGES PURSUANT TO G.S. 150B-21.10

AGENCY: North Carolina Medical Care Commission

RULE CITATION: 10A NCAC 13B .3903

DEADLINE FOR RECEIPT: Friday, June 10, 2022.

***PLEASE NOTE:* This request may extend to several pages. Please be sure you have reached the end of the document.**

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may email the reviewing attorney to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following changes be made:

In (a), line 4, should it state "the manager of the medical records service…."? **Suggestion made in rule**

In (b), at what time must the patient be a minor for this provision to apply? At the time of treatment, or at discharge? ***The patient is defined as a minor during the inpatient and / or outpatient hospitalization. The age is determined on admission, during the course of the hospitalization, and point of discharge or disposition.***

I assume that if someone is discharged, and then subsequently readmitted, the 11-year clock re-starts, correct? ***Correct.***

Moreover, if someone who was treated as a minor is readmitted later as an adult, but before age 30, do the medical records from the period of minority fall then fall under (a), rather than (b)? ***Correct. Records for the stage of life defined as minor fall under (b)***

In (f), lines 20-21, I'm a little confused by the construction here. Is it personnel authorized by (1) State laws, (2) HIPAA, and (3) regulations (which I assume are federal regulations, per our usual construction of that term), or personnel authorized by (1) State laws and (2) HIPAA regulations (which I imagine would be part of the CFR)? If the latter, I think a reference to the precise portions of the CFR would be appropriate here. ***Only personnel authorized by State laws and Health Insurance Portability and Accountability Act (HIPPA) regulations shall have access to medical records. Added 42 CFR 482 to rule text with refer by reference language, where to access regulation and cost.***

Where is your statutory authority for (g)? ***Please refer to additional document submitted titled "Response to RRC Staff Attorney for Hospital Rules 7-25-22"***

Brian Liebman
Commission Counsel
Date submitted to agency: June 3, 2022

In (g), line 24, what is the facility "jurisdiction"? What are the bounds here? ***(g), line 24 revised for clarity. Medical records are the property of the hospital, ~~they shall not be removed from the facility jurisdiction~~ and shall remain the property of the hospital, except through a court order.***

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

Brian Liebman
Commission Counsel
Date submitted to agency: June 3, 2022

REQUEST FOR CHANGES PURSUANT TO G.S. 150B-21.10

AGENCY: North Carolina Medical Care Commission

RULE CITATION: 10A NCAC 13B .4103

DEADLINE FOR RECEIPT: Friday, June 10, 2022.

***PLEASE NOTE:* This request may extend to several pages. Please be sure you have reached the end of the document.**

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may email the reviewing attorney to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following changes be made:

What are you relying upon for authority for (a)? Which statute are you implementing? 131E-79 only grants rulemaking authority for rules "necessary to implement this Article. ***Please refer to additional document submitted titled "Response to RRC Staff Attorney for Hospital Rules 7-25-22"***
"

For (b) and (c), what are you relying upon as your authority to require certain hospital equipment? I see you have this authority over ambulances in Article 7. Where is your authority over equipment at facilities? ***Please refer to additional document submitted titled "Response to RRC Staff Attorney for Hospital Rules 7-25-22"***

In (b), line 8, what does "emergency services under the rules of this Section" refer to? What limit are you trying to set? ***The licensed hospital's governing body and medical staff define the emergency services to be provided within the capability and scope of acute care services provided to meet the needs of the community. Hospitals have the option of advertising services as a dedicated emergency department or providing emergency services per their definitions. All must have the capability to render services to a pregnant patient and / or deliver babies.***

In (c), I take it you are still governing "facilities," correct? ***Yes***

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

Brian Liebman
Commission Counsel
Date submitted to agency: June 3, 2022

REQUEST FOR CHANGES PURSUANT TO G.S. 150B-21.10

AGENCY: North Carolina Medical Care Commission

RULE CITATION: 10A NCAC 13B .4104

DEADLINE FOR RECEIPT: Friday, June 10, 2022.

PLEASE NOTE: ***This request may extend to several pages. Please be sure you have reached the end of the document.***

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may email the reviewing attorney to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following changes be made:

> *Where is your statutory authority for Paragraphs (a), (c), and (d)?* ***Please refer to additional document submitted titled "Response to RRC Staff Attorney for Hospital Rules 7-25-22"***

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

Brian Liebman
Commission Counsel
Date submitted to agency: June 3, 2022

REQUEST FOR CHANGES PURSUANT TO G.S. 150B-21.10

AGENCY: North Carolina Medical Care Commission

RULE CITATION: 10A NCAC 13B .4104

DEADLINE FOR RECEIPT: Friday, June 10, 2022.

PLEASE NOTE: ***This request may extend to several pages. Please be sure you have reached the end of the document.***

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may email the reviewing attorney to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following changes be made:

> *Where is your statutory authority for Paragraphs (a), (c), and (d)?* ***Duplicate comment, this rule was addressed on previous page by RRC counsel.***

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

Brian Liebman
Commission Counsel
Date submitted to agency: June 3, 2022

REQUEST FOR CHANGES PURSUANT TO G.S. 150B-21.10

AGENCY: North Carolina Medical Care Commission

RULE CITATION: 10A NCAC 13B .4106

DEADLINE FOR RECEIPT: Friday, June 10, 2022.

PLEASE NOTE: ***This request may extend to several pages. Please be sure you have reached the end of the document.***

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may email the reviewing attorney to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following changes be made:

> *Where is your statutory authority for this Rule?* ***Please refer to additional document submitted titled "Response to RRC Staff Attorney for Hospital Rules 7-25-22"***

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

Brian Liebman
Commission Counsel
Date submitted to agency: June 3, 2022

REQUEST FOR CHANGES PURSUANT TO G.S. 150B-21.10

AGENCY: North Carolina Medical Care Commission

RULE CITATION: 10A NCAC 13B .4305

DEADLINE FOR RECEIPT: Friday, June 10, 2022.

***PLEASE NOTE:* This request may extend to several pages. Please be sure you have reached the end of the document.**

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may email the reviewing attorney to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following changes be made:

Where is your statutory authority for this Rule? ***Please refer to additional document submitted titled "Response to RRC Staff Attorney for Hospital Rules 7-25-22"***

In (a)(1), line 7, consider "infants who are small for gestational age or neonates who are large for gestational age ~~neonates~~" if this is what you mean. ***Replaced wording as suggested.***

In (a)(2), line 9, capitalize "Level" to remain consistent with the rest of the Rule. ***Suggestion made in rule***

In (a)(3), please remove the parenthetical and incorporate the material into the body of the Rule. ***Suggestion made in rule.*** *Also, I do not understand the contents of the parenthetical. Can you clarify which infants you're referring to?* ***Level III neonates are fragile or ill infants with a gestational age of 32 weeks to 36 weeks.***

In (a)(4), line 18, add the oxford comma following "unstable." ***Suggestion made in rule***

In (a)(4), line 19, what does "approximately under 32 weeks" mean? ***Replaced with neonates ~~approximately~~ under 32 weeks of gestational age***

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

Brian Liebman
Commission Counsel
Date submitted to agency: June 3, 2022

REQUEST FOR CHANGES PURSUANT TO G.S. 150B-21.10

AGENCY: North Carolina Medical Care Commission

RULE CITATION: 10A NCAC 13B .4603

DEADLINE FOR RECEIPT: Friday, June 10, 2022.

PLEASE NOTE: ***This request may extend to several pages. Please be sure you have reached the end of the document.***

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may email the reviewing attorney to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following changes be made:

> *Where is your statutory authority for this Rule?* ***Please refer to additional document submitted titled "Response to RRC Staff Attorney for Hospital Rules 7-25-22"***

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

Brian Liebman
Commission Counsel
Date submitted to agency: June 3, 2022

REQUEST FOR CHANGES PURSUANT TO G.S. 150B-21.10

AGENCY: North Carolina Medical Care Commission

RULE CITATION: 10A NCAC 13B .4801

DEADLINE FOR RECEIPT: Friday, June 10, 2022.

***PLEASE NOTE:* This request may extend to several pages. Please be sure you have reached the end of the document.**

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may email the reviewing attorney to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following changes be made:

Where is your statutory authority for this Rule? ***Please refer to additional document submitted titled "Response to RRC Staff Attorney for Hospital Rules 7-25-22"***

In (c), G.S. 150B-21.6 requires that the agency "must specify in the rule both where copies of the material can be obtained and the cost on the date the rule is adopted of a copy of the material." Obviously, these rules are available online and at no cost, but please add a hyperlink and state that they are available at no cost. **Prior RRC staff counsel directed agencies to not use "and editions" in rule when referring by reference to other rules in the Code. Likewise, agencies were directed by RRC staff attorneys that it was not necessary to write in the rules the cost and where to find another rule referenced in the Code because the rule was already in the Code and online, the referenced rule was also in the Code and online, therefore that person would be able to find the referenced rule without cost online. Please advise on any change to this prior direction from RRC staff counsel.**

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

Brian Liebman
Commission Counsel
Date submitted to agency: June 3, 2022

REQUEST FOR CHANGES PURSUANT TO G.S. 150B-21.10

AGENCY: North Carolina Medical Care Commission

RULE CITATION: 10A NCAC 13B .4805

DEADLINE FOR RECEIPT: Friday, June 10, 2022.

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The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may email the reviewing attorney to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following changes be made:

Where is your statutory authority for this Rule? ***Please refer to additional document submitted titled "Response to RRC Staff Attorney for Hospital Rules 7-25-22"***

In (b), line 6, please define or delete "proper". ***Suggestion made in rule for deletion.***

In (c), is the Medical Care Commission requiring these safety inspections or are these already required by Radiation Protection? In other words, is this necessary or are you repeating something that is already required? ***The rule is essential to promoting safe practices and standards in the delivery of radiation services.***

In (c), lines 8-9, do you mean that the Division shall make available copies of the report to the public? Or that the Division shall be the entity to review the report?
The Division is responsible for identifying areas of noncompliance and writing the report for corrective action. Also, the Division is responsible for disclosing reports to the public.

In (d)(1), please define "experienced." ***The state licensed Medicare certified regulated providers are knowledgeable of the regulations and daily operations. Experienced is hospital specific and defined by the hospital's medical staff bylaws and includes a combination of educations, and hands on exposure or skill over a specific period.***

In (e), G.S. 150B-21.6 requires that the agency "must specify in the rule both where copies of the material can be obtained and the cost on the date the rule is adopted of a copy of the material." Obviously, these rules are available online and at no cost, but please add a hyperlink and state that they are available at no cost. **Prior RRC staff counsel directed agencies and page 21 of the Rules Style Guide state "*If incorporating material by reference that will affect a set of rules, please do note the agency only needs to incorporate the material using this method one time. The agency does not have to repeatedly incorporate the same material***

within the same rule or set of rules." **The rules in 10A NCAC 15 are already incorporated by reference in Rule 13B .4801. Please advise on any change to this prior direction from RRC staff counsel and the Rules Style Guide.**

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

Brian Liebman
Commission Counsel
Date submitted to agency: June 3, 2022

REQUEST FOR CHANGES PURSUANT TO G.S. 150B-21.10

AGENCY: North Carolina Medical Care Commission

RULE CITATION: 10A NCAC 13B .5102

DEADLINE FOR RECEIPT: Friday, June 10, 2022.

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The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may email the reviewing attorney to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following changes be made:

> *Where is your statutory authority for this Rule?* ***Please refer to additional document submitted titled "Response to RRC Staff Attorney for Hospital Rules 7-25-22"***

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

Brian Liebman
Commission Counsel
Date submitted to agency: June 3, 2022

REQUEST FOR CHANGES PURSUANT TO G.S. 150B-21.10

AGENCY: North Carolina Medical Care Commission

RULE CITATION: 10A NCAC 13B .5105

DEADLINE FOR RECEIPT: Friday, June 10, 2022.

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The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may email the reviewing attorney to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following changes be made:

> *Where is your statutory authority for this Rule?* ***Please refer to additional document submitted titled "Response to RRC Staff Attorney for Hospital Rules 7-25-22"***

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

Brian Liebman
Commission Counsel
Date submitted to agency: June 3, 2022

REQUEST FOR CHANGES PURSUANT TO G.S. 150B-21.10

AGENCY: North Carolina Medical Care Commission

RULE CITATION: 10A NCAC 13B .5406

DEADLINE FOR RECEIPT: Friday, June 10, 2022.

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The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may email the reviewing attorney to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following changes be made:

Where is your statutory authority for this Rule? ***Please refer to additional document submitted titled "Response to RRC Staff Attorney for Hospital Rules 7-25-22"***

In (a), line 6, what "established goals" are you referring to? ***Goals of care.***

Again in (a), line 6, who makes this determination? The attending physician? A utilization review board? The patient? ***The state licensed Medicare certified regulated providers are knowledgeable of the regulations and processes for assessing and implementing care to meet the needs of patients with an overarching goal of improvement to returning to an independent state of health with the least parameters of assistance. The team and decision-making are a comprehensive team approach addressing the needs of the rehab patient. The attending physician or physiatrist direct the comprehensive rehab program. This is an inclusive process of a multi-disciplinary team of health care providers which may include OT, PT, SLP, mental health professionals, psychologist, psychiatrist, etc.***

In (a), line 7, what is an "appropriate setting"? ***Appropriate care setting is a place considered discharge appropriate to meet the needs of the reference patient. The overall goal to promote stabilization and improvement in the patient's condition.***

In (a), line 10, what are "referral sources"? ***Referral sources include persons, inpatient and / or outpatient dwellings to promote a smooth transition from the hospital setting to the home or other dwelling.***

Brian Liebman
Commission Counsel
Date submitted to agency: June 3, 2022

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

Brian Liebman
Commission Counsel
Date submitted to agency: June 3, 2022

REQUEST FOR CHANGES PURSUANT TO G.S. 150B-21.10

AGENCY: North Carolina Medical Care Commission

RULE CITATION: 10A NCAC 13B .5408

DEADLINE FOR RECEIPT: Friday, June 10, 2022.

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The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may email the reviewing attorney to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following changes be made:

Where is your statutory authority for this Rule? ***Please refer to additional document submitted titled "Response to RRC Staff Attorney for Hospital Rules 7-25-22"***

More specifically, where is your statutory authority to set supervision requirements, with the exception of physicians supervising care as provided in 131E-76(3)? Is this already governed by occupational licensing boards? ***Removed Subparagraph (a)(4), and text in new Subparagraph (a)(5).***

Where is your authority to set staff qualification requirements? ***Please refer to additional document submitted titled "Response to RRC Staff Attorney for Hospital Rules 7-25-22"***

What does (b) require? How is this measured? How do you determine whether the requirements in (b) have been met? ***The state licensed Medicare certified regulated providers are knowledgeable of the regulations and processes for assessing, implementing, and ongoing evaluation of a comprehensive plan of care to meet the needs of the patient centered and directed goals. The multi-disciplinary team is responsible for an ongoing assessment and evaluation of the rehab patient to obtain goals. Examples of rehab measures may include but are not limited to ability to button clothing without assistance, ability to walk with a cane as opposed to a walker, or the ability to increase steps.***

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

Brian Liebman
Commission Counsel
Date submitted to agency: June 3, 2022

Agency Response to
Hospital Rules Statutory Authority Opinion
by Brian Lieberman

The Medical Care Commission ("MCC") was created by the General Assembly in 1973. Pursuant to N.C. Gen. Stat. § 143B-165:

> (6) The Commission 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.

N.C. Gen. Stat. § 143B-165(6)***(emphasis added).***

Chapter 131, Article 13A, the Hospital Licensing Act (Attachment A) was repealed and replaced with Chapter 131E, Article 5, the Hospital Licensure Act. The North Carolina General Statutes Annotated for Chapter 131 (Attachment B) includes as *Cross References* "[a]s to health care facilities and services, see now Chapter 131E." Although, the reference to Article 13A was not changed in N.C. Gen. Stat. § 143B-165(6), the General Assembly did not remove the duty of the MCC to promulgate standards for hospital. The Hospital Licensing Act and the Hospital Licensure Act are in reference to facilities that provide medical and nursing care to two or more individuals in excess of 24 hours. Both are in reference to the same type of facility, a hospital. *See* N.C. Gen. Stat. § 131E-76(3).

The purpose of Article 5 of Chapter 131E, the Hospital Licensure Act (the "Hospital Licensure Act") is 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***." *See* N.C. Gen. Stat. § 131E-75 (***emphasis added***).

Article 5.

Hospital Licensure Act.

Part 1. Article Title and Definitions.

§ 131E-75. Title; purpose.

(a) This Article shall be known as the "Hospital Licensure Act."

(b) The purpose of this article is 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.

N.C. Gen. Stat. § 131E-75.

The Hospital Licensure Act requires and expressly authorizes the MCC to promulgate rules necessary to carry out the Article. Pursuant to N.C. Gen. Stat. § 131E-79(a) & (b), the Commission is mandated to promulgate rules to carry out the Article and the North Carolina Department of

Health and Human Services ("Department" or "Agency") is then charged with enforcing these rules, including the rules that establish basic standards of safe care for patients. *See* N.C. Gen. Stat. §§ 131E-75(b) and -79(a) & (b).

> **§ 131E-79. Rules and enforcement.**
> (a) The Commission shall promulgate rules necessary to implement this Article.
> (b) The Department shall enforce this Article and the rules of the Commission.

N.C. Gen. Stat. § 131E-79.

The Department is charged with the responsibility of determining if an initial license should be issued to a hospital and determining if the license should be renewed on an annual basis. *See* N.C. Gen. Stat. § 131E-77(a) & (d).

> **§ 131E-77. Licensure requirement.**
> (a) No person or governmental unit shall establish or operate a hospital in this state without a license. An infirmary is not required to obtain a license under this Part.
> (b) The Commission shall prescribe by rule that any licensee or prospective applicant seeking to make specified types of alteration or addition to its facilities or to construct new facilities shall submit plans and specifications before commencement to the Department for preliminary inspection and approval or recommendations with respect to compliance with the applicable rules under this Part.
> (c) An applicant for licensing under this Part shall provide information related to as requested by the Department. The required information shall be submitted by the applicant on forms provided by the Department and established by rule.
> (d) Upon receipt of an application for a license, the Department shall issue a license if it finds that the applicant complies with the provisions of this Article and the rules of the Commission. The Department ***shall renew*** each license in accordance with the rules of the Commission…

N.C. Gen. Stat. § 131E-77(a) & (d)***(emphasis added).***

In issuing and renewing licenses, the Department is required to assess if a hospital is meeting the "requirements which promote public health, safety and welfare to provide for the development, establishment and enforcement of basic standards for the care and treatment of patients" including "information related to hospital operations as requested by the Department." *See* N.C. Gen. Stat. §§ 131E-75(b) and -77(d).

The licensing of a hospital encompasses ongoing regulation beyond that of the initial license. *See* N.C. Gen. Stat. § 131E-77(a). After the Department issues an initial license, the Department has "the authority to deny, suspend, revoke, annul, withdraw, recall, cancel, or amend a license…" after issuance. *See* N.C. Gen. Stat. § 131E-78(a). The Department inspects the hospital to validate continuing compliance with providing the basic standards of care and treatment of patients. *See* N.C. Gen. Stat. § 131E-80(a) & (d). To aid in this process, the Department has the

authority to inspect hospital records involving admission, discharge, medication, and treatment. *See* N.C. Gen. Stat. § 131E-80(d). When the hospital is in compliance with this Part and the rules, the Department issues a renewal license. N.C. Gen. Stat. § 131E-77(d).

Therefore, the regulated hospitals must be informed of the operational standards related to the health, safety, and basic standards of care and treatment of the patients, that the Department will survey during complaint and compliance inspections, to maintain its license and avoid adverse action on the license. *See* N.C. Gen. Stat. § 131E-80(d). For example, Rule 10A NCAC 13B .4103 outlines exactly what the Department will be reviewing for facilities providing emergency services to ensure all patients receive fair, timely, and consistent treatment, including medical direction, in an emergency.

In turn, the Department must establish, through rules, the operational minimum standards related to the health, safety and basic standards of care and treatment of patients it will use during complaint and compliance inspections, in order for regulated hospitals to ensure compliance. For example, when a patient goes to the hospital for imaging services, they have some assurance that the employee is qualified, supervised by a physician, the equipment is safe, and the radiation exposure is handled appropriately. *See* Rule 10 NCAC 13B .4805. In both examples, Rules 10A NCAC 13B .4103 and 10A NCAC 13B .4805, the Agency has set the standard, informed the hospitals of the standards and will conduct inspections for compliance according to the standards in order to protect the public's health, safety, and welfare.

The Supreme Court has said, since early times, that to require proficiency and skill in the business mentioned is, an exercise of the police power "for the protection of the public against incompetents and impostors." *State. v. Call,* 121 N.C. 643, 28 S.E. 517 (1897). It is upon the same principles "that the Legislature has required a license of physicians, surgeons, osteopaths, chiropractors, chiropodists, dentists, opticians, barbers, and others[.]" *Roach v Durham*, 204 N.C. 587, 591, 169 S.E. 149, 151 (1993) (citations and quotation marks omitted). The Legislature has determined that the same is true for hospitals. The MCC is responsible for developing the hospital rules for licensing and safety standards similar to the other agencies created by the General Assembly for the various other licenses issued in North Carolina. *Igram v. N.C. State Bd. Of Plumbing, Heating and Fire Sprinkler, Contrs.*, 269 N.C. App. 476, 839 S.E.2d 74 (2020).

The requirement for express authority does not equate to a requirement for the Legislature to specify, subject by subject, each area of rule promulgation to an agency. The General Assembly has not specifically enumerated every area of rule promulgation with any of the agencies creating rules for licensing. Instead, the General Assembly expressly authorizes the agencies to promulgate rules.

The Dental Examiners, for example, have authority to create rules to govern the practice of dentistry in N.C. Gen. Stat. § 90-48. Based on this authority, Rules 21 NCAC 16P .0101-.0105 is used to regulate communications concerning dental services and advertising which are not specified topics for rules addressed in the Article. Similarly, Rule 21 NCAC 16T .010 requires a record retention period of 10 years even though the Legislature did not specifically instruct the Dental Examiners to set a period for record retention.

The Board of Chiropractic Examiners has authority to create rules necessary to carry out and enforce the provisions of the Chapter 90, Article 8. *See* N.C. Gen. Stat. § 90-142. This express authority has resulted in the creation of rules such as 21 NCAC 10 .0208 Acupuncture and 21 NCAC 10 .0305 Prepaid Treatment Plans. The words "acupuncture" and "prepaid treatment plans" are not in Chapter 90, Article 8; instead, the Legislature gave express authority for creation of these rules for protection of the public under the practice of medicine and allied occupations.

The same is true here; the Legislature gave express authority for the creation of rules for protection of the public in hospitals and medical facilities. A hospital license is a representation to the public that the hospital will adhere to basic standards for the care and treatment of patients established by the MCC and enforced by the Department, which promote public health, safety, and welfare. *See* N.C. Gen. Stat. §§ 131E-75(b) and -79(a) & (b). A renewed license is a representation to the public that the hospital continues to adhere to the basic standards for the care and treatment of patients that promote public health, safety, and welfare. *Id.*

The hospital rules listed below are necessary for the protection of the health, safety, and welfare of patients in hospitals in North Carolina and provide minimum standards for the care and treatment of patients. The MCC respectfully requests the Rules Review Commission find that these rules are within the authority delegated to the MCC by the General Assembly.

10A NCAC 13B .3801	Nurse Executive
10A NCAC 13B .3903	Preservation of Medical Records
10A NCAC 13B .4103	Provision of Emergency Services
10A NCAC 13B .4104	Medical Director
10A NCAC 13B .4106	Policies and Procedures
10A NCAC 13B .4305	Organization of Neonatal Services
10A NCAC 13B .4603	Surgical and Anesthesia Staff
10A NCAC 13B .4801	Organization
10A NCAC 13B .4805	Safety
10A NCAC 13B .5102	Policies and Procedures
10A NCAC 13B .5105	Sterile Supply Services
10A NCAC 13B .5406	Discharge Criteria For Inpatient Rehabilitation Facilities or Units
10A NCAC 13B .5408	Comprehensive Inpatient Rehabilitation Program Staffing Requirements
10A NCAC 13B .5411	Repealed

A

THE NORTH CAROLINA MEDICAL CARE COMMISSION

CHAPTER 131. GENERAL STATUTES OF NORTH CAROLINA

ARTICLE 13A

HOSPITAL LICENSING ACT

Sec. 131-126.1. *Definitions.*—As used in this article. (a) "Hospital" means an institution devoted primarily to the rendering of medical, surgical, obstetrical, or nursing care, which maintains and operates facilities for the diagnosis, treatment or care of two or more nonrelated individuals suffering for illness, injury or deformity, or where obstetrical or other medical or nursing care is rendered over a period exceeding twenty-four hours.

The term "hospital" for clarification purposes, includes, but not by way of limitation, an institution that receives patients and renders for them diagnostic, medical, surgical and nursing care; and "hospital" means also an allied institution that provides for patients diagnostic, medical, surgical and nursing care in branches of medicine such as obstetric, pediatric, orthopedic, and eye, ear, nose and throat and cardiac services, and in the diagnosis and treatment of mental and neurological ailments, and in the diagnosis and treatment and care of chronic diseases and transmissible diseases.

The term "hospital" as used in this article does not apply to a welfare institution, the primary purpose of which is to provide domiciliary and/or custodial care to its residents, and it does not apply to an infirmary which such institution may maintain to provide medical and nursing care for its residents.

Further to distinguish a "hospital" from a "welfare institution," as the term is used in this article, the latter means orphanages; penal and correctional institutions; home for the county or city poor, aged, and infirm; nursing homes for the mentally and physically infirm; homes for the aged; and convalescent and rest homes; and homes for pregnant women who require public assistance and/or custodial care or obstetrical and nursing care in such home, or nursing care prior to or subsequent to delivery in a "hospital."

(b) "Person" means any individual, firm, partnership, corporation, company, association, or joint stock association; and includes any trustee, receiver, assignee or other similar representative thereof.

(c) "Governmental unit" means the state, or any county, municipal or other political subdivision or any department, division, board or other agency of any of the foregoing.

(d) "Commission" means the North Carolina Medical Care Commission as established by chapter 1096 of the Session Laws of 1945, as amended, and as the same may be hereafter amended.

Sec. 131-126.2 *Purpose.*—The purpose of this article is to provide for the development, establishment and enforcement of basic standards (1) for the care and treatment of individuals in hospitals and (2) for the construction, maintenance and operation of such hospitals, which, in the light of existing knowledge, will ensure safe and adequate treatment of such individuals in hospitals, provided, that nothing in this article shall be construed as repealing any of the provisions of article 27 of chapter 130 of the General Statutes of North Carolina.

Sec. 131-126.3. *Licensure.*—After July 1st, 1947, no person or governmental unit, acting severally or jointly with any other person or governmental unit shall establish, conduct or maintain a hospital in this state without a license. None of the provisions of Chapter 104C of the General Statutes shall apply to X-ray facilities in or as a part of any hospital or medical facility which is, or will upon its completion become, subject to the provisions of law relating to the licensing thereof by the North Carolina Medical Care Commission pursuant to this Article.

Sec. 131-126.4. *Application for license.*—Licenses shall be obtained from the Commission. Applications shall be upon such forms and shall contain such information as the said Commission may reasonably require, which may include affirmative evidence of ability to comply with such reasonable standards, rules and regulations as may be lawfully prescribed hereunder.

Sec. 131-126.5. *Issuance and renewal of license.*—Upon receipt of an application for license, the Commission shall issue a license if it finds that the applicant and hospital facilities comply with the provisions of this article and the regulations of the said Commission. Each such license, unless sooner suspended or revoked, shall be renewable annually without charge upon filing of the license, and approval by the Commission, of an annual report upon such uniform dates and containing such information in such form as the Commission shall prescribe by regulation. Each license shall be issued only for the premises and persons or governmental units named in the application and shall not be transferable or assignable except with the written approval of the Commission. Licenses shall be posted in a conspicuous place on the licensed premises as prescribed by regulation of the said Commission.

Sec. 131-126.6. *Denial or revocation of license; hearings and review.*—The Commission shall have the authority to deny, suspend or revoke a license in any case where it finds that there has been a substantial failure to comply with the provisions of this article or the rules, regulations or minimum standards promulgated under this article.

Such denial, suspension, or revocation shall be effected by mailing to the applicant or licensee by registered mail, or by personal service of, a notice setting forth the particular reasons for such action. Such denial, suspension, or revocation shall become effective thirty days after the mailing or

B

General Statutes of North Carolina

ANNOTATED

2021 EDITION

CHAPTER 131.
PUBLIC HOSPITALS.

§§ 131-1 through 131-188: Repealed by Session Laws 1983, c. 775, s. 1.

Cross References.

As to health care facilities and services, see now Chapter 131E.

Editor's Note.

Session Laws 1983, c. 775, s. 3, provides: "Sec. 3. Notwithstanding the foregoing, any unit of government, or units of government acting jointly, that as of December 31, 1983, is operating a hospital or hospitals pursuant to Articles 2 or 2A of Chapter 131 of the General Statutes may continue to operate pursuant to the provisions of those Articles as they existed on December 31, 1983, to the extent that those Articles are inconsistent with this Chapter. However, a unit of government that has been operating a hospital pursuant to those Articles may choose to continue operations under the provisions of one of the Parts of Article 2 of this Chapter by adopting an appropriate resolution and by satisfying all other requirements of the relevant Part of Article 2 of this Chapter."

Session Laws 1989, c. 283, effective June 12, 1989, amends G.S. 131-7. Session Laws 1989, c. 283, ss. 1 and 2 provide:

"Section 1. G.S. 131-7, as it applies to hospitals continuing to operate under Article 2, Chapter 131 of the North Carolina General Statutes pursuant to Section 3, Chapter 775 of the 1983 Session Laws, is amended by rewriting the first sentence to read: 'Should a majority of the qualified voters upon the question be in favor of establishing such county, township, or town hospital, the governing body shall proceed at once to appoint seven trustees chosen from the citizens at large with reference to their fitness for such office, all residents of the county, township or town, who shall constitute a board of trustees for such public hospital.'

"Sec. 2. G.S. 131-7 is amended by deleting the phrase 'No practicing physician may serve as a trustee.', and substituting 'One practicing physician may serve as a trustee'."

Session Laws 1999-377, s. 1, effective August 4, 1999, amends G.S. 131-4 as it applies to hospitals continuing to operate under Article 2, Chapter 131 of the North Carolina General Statutes pursuant to Section 3, Chapter 775 of the 1983 Session Laws, by adding a new subdivision to read:

"(4) Extension of Tax Levy. Prior to or following the expiration of the tax levy specified in subdivision (3) of this section, a new petition may be presented to the governing body of any county in which a township is located, signed by 200 resident freeholders of such township asking that an annual tax continue to be levied for the maintenance, operation, and improvement of the public hospital, after the expiration of the tax levy specified in subdivision (3). The procedure for submitting the petition and holding an election on the issue of continuing the tax levy shall be the same as the procedure for the petition and election for establishment of the initial tax levy, provided that the requirement that 150 of the 200 petitioners not be residents of the city, town, or village where the hospital is to be located shall not apply. The tax to be levied under such new election shall not exceed one twenty-fifth of one cent (1/25 of 1 cent) on the dollar ($1.00) for a period of time not exceeding 30 years and shall be for the issue of county or township bonds to provide funds for the maintenance and improvement of the public hospital."

Session Laws 1999-377, s. 2, amends G.S. 131-5 by adding a sentence providing that the procedure for submission of the issue of continuation of the tax levy is to be the same as set forth previously in G.S. 131-5, so long as the tax is not to exceed one twenty-fifth of one cent on the dollar, and by providing the statement to be used on ballots when the issue is submitted.

Session Laws 1999-377, s. 3, provides that all hospitals which continue to operate under Article 2 of Chapter 131, of the General Statutes pursuant to Section 3 of Chapter 775 of the 1983 Session Laws, shall, in addition to the powers granted in that article have the powers set forth in G.S. 131E-7(a)(1), (3), (5), (6), 131E-7(b), 131E-7(c), 131E-7.1, 131E-11, 131E-23(1), (2), (5), (6), (7), (8), (10), (11), (12), (13), (14), (15), (16), (17), (18), (19), (23), (24), (25), (26), (27), (28), (30), (31), (32), (33), (34), 131E-26, and 131E-27.

Session Laws 1999-377, s. 4, provides that any hospital continuing to operate under Article 2 of Chapter 131, pursuant to Section 3 of Chapter 775 of the 1983 Session Laws, shall be considered a "public hospital" within the meaning of G.S. 159-39 and a "unit of local government" within the meaning of G.S. 160A-20.

Session Laws 2018-81, s. 2(a), (b), provides: "(a) All hospitals that continue to operate under Article 2 of Chapter 131 of the General Statutes pursuant to Section 3 of Chapter 775 of the 1983 Session Laws may, in addition to the powers and authorities set forth in said Article

2 of Chapter 131 of the General Statutes, exercise each of the powers, authorities, and exemptions set forth in the following provisions of Chapter 131E of the General Statutes, singly or in combination:

"(1) G.S. 131E-7(a)(1), (3), (5), and (6).
"(2) G.S. 131E-7(b).
"(3) G.S. 131E-7(c).
"(4) G.S. 131E-7(f).
"(5) G.S. 131E-7.1.
"(6) G.S. 131E-8.
"(7) G.S. 131E-10.
"(8) G.S. 131E-11.
"(9) G.S. 131E-13.
"(10) G.S. 131E-14.1.
"(11) G.S. 131E-23(a)(1) through (38).
"(12) G.S. 131E-23(b).
"(13) G.S. 131E-23(d).
"(14) G.S. 131E-26.
"(15) G.S. 131E-27.
"(16) G.S. 131E-32.
"(17) G.S. 131E-47.1.

"(b) This act amends and adds to the powers and authorities previously conveyed by Section 3 of S.L. 1999-377 to hospitals that continue to operate under Article 2 of Chapter 131 of the General Statutes. This act is not intended to alter or amend the remaining provisions of S.L. 1999-377."

10A NCAC 13B .3801 is readopted with changes 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~~ standards, 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. September 1, 2022.

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

10A NCAC 13B .3903 PRESERVATION OF MEDICAL RECORDS

(a) The manager of the 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.~~ date or according to Paragraph (b) of this Rule if the patient was a minor.

~~(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~~ digital archiving of medical records. ~~Microfilming~~ Digital archiving 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~~ digital archived medical records shall not be destroyed until the medical records department has had an opportunity to review the ~~processed film~~ digital record 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 the Health Insurance Portability and Accountability Act (HIPAA) ~~regulations~~ found in 42 CFR 482, which is incorporated by reference including subsequent amendments and editions, shall have access to medical records. This regulation may be obtained free of charge at https://www.govinfo.gov/help/cfr. 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~~ shall remain the property of the hospital, 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. September 1, 2022.

10A NCAC 13B .4305 is readopted with changes 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 neonates who are large for gestational ~~age neonates.~~ age.

(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~~ 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~~ or approximately 32 and less than 36 completed weeks of gestational ~~age)~~ 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~~ 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. September 1, 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 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.

10A NCAC 13B .5408 is readopted with changes 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;~~ the needs of the patient;

(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)~~(4) 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)~~(5) 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.

Burgos, Alexander N

Subject: FW: Technical changes - MCC 10A NCAC 13B rules

From: Liebman, Brian R <brian.liebman@oah.nc.gov>
Sent: Thursday, July 7, 2022 10:38 AM
To: Pfeiffer, Nadine <nadine.pfeiffer@dhhs.nc.gov>
Cc: Burgos, Alexander N <alexander.burgos@oah.nc.gov>
Subject: RE: Technical changes - MCC 10A NCAC 13B rules

Nadine,

First, I think we both forgot to copy Alex on this correspondence, so I am adding him here so he can post this chain on our website.

Continuing to August is fine, and I will let the Commission know that MCC is a no action item for this month's meeting.

As for the due date, I'll expect your responses by close of business on 8/2. If you don't think you'll be able to make that deadline, then let me know, and we'll adjust from there.

Thanks,
Brian

Brian Liebman
Counsel to the North Carolina Rules Review Commission
Office of Administrative Hearings
(984)236-1948
brian.liebman@oah.nc.gov

From: Pfeiffer, Nadine <nadine.pfeiffer@dhhs.nc.gov>
Sent: Thursday, July 7, 2022 10:34 AM
To: Liebman, Brian R <brian.liebman@oah.nc.gov>
Subject: RE: Technical changes - MCC 10A NCAC 13B rules

Thank you Brian. Yes, we do want to continue this matter to the August RRC meeting.

Also, thank you for the deadline date and time for sending you responses for the August meeting. Just for your planning purposes, I am on vacation August 3-9 and will be out of state. With that in mind, we will shoot for sending you our revisions/responses before I am on leave.

Nadine Pfeiffer
Rules Review Manager
Division of Health Service Regulation
NC Department of Health and Human Services

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From: Liebman, Brian R <brian.liebman@oah.nc.gov>
Sent: Thursday, July 7, 2022 9:30 AM
To: Pfeiffer, Nadine <nadine.pfeiffer@dhhs.nc.gov>
Subject: RE: Technical changes - MCC 10A NCAC 13B rules

Hi Nadine,

Yes, I received your email on Tuesday. I apparently did not hit send on this email yesterday morning. I'm sorry about that.

Pursuant to G.S. 150B-21.13, when RRC extends the period for review, as it did at the June 2022 meeting, RRC must approve or object to the rules "[w]ithin 70 days after extending the period for review." So, to answer your questions:

a) No, you do not need to request a second extension. If you want to go to the August meeting, I will let RRC know at this month's meeting, and we'll simply put you back on the agenda for August.
b) Yes, this is the only extension that RRC can grant, as the statutory language requires RRC to approve or object within 70 days.
c) With respect to a timetable for August, given the potential complexity, I would want your revisions/responses back with sufficient lead time for me to review and respond or amend my staff opinion. The August meeting is scheduled for Thursday, 8/18, so let's set that deadline for 9 AM on Monday, 8/8. That way, if we should have a busy month, I'll have time to devote to reviewing your responses.

Thanks,
Brian

Brian Liebman
Counsel to the North Carolina Rules Review Commission
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From: Pfeiffer, Nadine <nadine.pfeiffer@dhhs.nc.gov>
Sent: Thursday, July 7, 2022 9:07 AM
To: Liebman, Brian R <brian.liebman@oah.nc.gov>
Subject: FW: Technical changes - MCC 10A NCAC 13B rules

Good Morning Brian,
Just checking that you received this email I sent to you on Tuesday since I have not heard back from you. I have issues with sending email to someone else and was hoping this wasn't also happening with emails to you.

Nadine Pfeiffer

Rules Review Manager
Division of Health Service Regulation
NC Department of Health and Human Services

Office: 919-855-3811
Fax: 919-733-2757
nadine.pfeiffer@dhhs.nc.gov

809 Ruggles Drive, Edgerton Building
2701 Mail Service Center
Raleigh, NC 27699-2701

From: Pfeiffer, Nadine
Sent: Tuesday, July 5, 2022 4:37 PM
To: Liebman, Brian R <brian.liebman@oah.nc.gov>
Subject: Technical changes - MCC 10A NCAC 13B rules

Hi Brian,
Because I have not experienced this situation before, I have a couple questions regarding the technical change request for the Medical Care Commission rules in 10A NCAC 13B originally sent to me on June 3, 2022:

a) We received one approval from the RRC to extend the period of review for these rules following the June meeting. If we need additional time to work on the concerns identified in the technical change request, do we submit a second request for the July meeting?
b) If a) is correct, am I correct that this is the last extension and the rules will put on the agenda for the August meeting for consideration by the RRC?
c) If the period of review is extended to the August RRC meeting for these rules, what is the last day you will accept revised rules and responses to the technical change concerns?

Thank you.

Nadine Pfeiffer
Rules Review Manager
Division of Health Service Regulation
NC Department of Health and Human Services

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nadine.pfeiffer@dhhs.nc.gov

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Raleigh, NC 27699-2701

Burgos, Alexander N

Subject: FW: NC Medical Care Commission Request for Changes - June 2022 RRC

From: Snyder, Ashley B <ashley.snyder@oah.nc.gov>
Sent: Wednesday, June 15, 2022 12:23 PM
To: Pfeiffer, Nadine <nadine.pfeiffer@dhhs.nc.gov>
Cc: Liebman, Brian R <brian.liebman@oah.nc.gov>; Burgos, Alexander N <alexander.burgos@oah.nc.gov>
Subject: RE: NC Medical Care Commission Request for Changes - June 2022 RRC

Thank you, Nadine. It looks like Alex was not copied on the email chain. I have added him here so he will see this and post.

Ashley Snyder
Codifier of Rules
Office of Administrative Hearings
(984) 236-1941

From: Pfeiffer, Nadine <nadine.pfeiffer@dhhs.nc.gov>
Sent: Wednesday, June 15, 2022 11:54 AM
To: Snyder, Ashley B <ashley.snyder@oah.nc.gov>
Subject: FW: NC Medical Care Commission Request for Changes - June 2022 RRC

These emails have not been posted on your website for agency communication.

Nadine Pfeiffer
Rules Review Manager
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NC Department of Health and Human Services

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Fax: 919-733-2757
nadine.pfeiffer@dhhs.nc.gov

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Raleigh, NC 27699-2701

From: Pfeiffer, Nadine
Sent: Monday, June 6, 2022 7:39 AM
To: Liebman, Brian R <brian.liebman@oah.nc.gov>
Subject: RE: NC Medical Care Commission Request for Changes - June 2022 RRC

Good Morning Brian,
Yes, I did receive your email on Friday after I had left the office for the weekend and I am just able to respond to it now. I will communicate your concerns with legal and other relevant Division staff. Due to the unusually short due date timeframe requested by your agency of five business days, we hope to be in a position to respond accordingly.

Nadine Pfeiffer

Rules Review Manager
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nadine.pfeiffer@dhhs.nc.gov

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From: Liebman, Brian R <brian.liebman@oah.nc.gov>
Sent: Saturday, June 4, 2022 11:27 AM
To: Pfeiffer, Nadine <nadine.pfeiffer@dhhs.nc.gov>
Subject: RE: NC Medical Care Commission Request for Changes - June 2022 RRC

Hi Nadine,

Just wanted to confirm you received these? I know it was late on Friday, and I do apologize for not getting these to you sooner, it's been yet another heavy month for us here.

As always, let me know if you have any questions or concerns.

Brian

Brian Liebman
Counsel to the North Carolina Rules Review Commission
Office of Administrative Hearings
(984)236-1948
brian.liebman@oah.nc.gov

From: Liebman, Brian R
Sent: Friday, June 3, 2022 6:18 PM
To: Pfeiffer, Nadine <nadine.pfeiffer@dhhs.nc.gov>
Cc: Burgos, Alexander N <alexander.burgos@oah.nc.gov>
Subject: NC Medical Care Commission Request for Changes - June 2022 RRC

Hi Nadine,

I'm the attorney who reviewed the Rules submitted by the Board for the June 2022 RRC meeting. The RRC will formally review these Rules at its meeting on Thursday, June 16, 2022, at 9:00 a.m. The meeting will be a hybrid of in-person and WebEx attendance, and an evite should be sent to you as we get closer to the meeting. If there are any other representatives from your agency who will want to attend virtually, let me know prior to the meeting, and we will get evites out to them as well.

Please submit the revised Rules to me via email, no later than 5 p.m. on Friday, June 10, 2022. You'll note I had statutory authority questions for all rules contained in this packet. If you want to discuss, I'm available at your convenience next week.

In the meantime, do not hesitate to reach out via email with any questions or concerns.

Thanks,

Brian

Brian Liebman
Counsel to the North Carolina Rules Review Commission
Office of Administrative Hearings
(984)236-1948
brian.liebman@oah.nc.gov

Burgos, Alexander N

From: Liebman, Brian R
Sent: Friday, June 10, 2022 1:53 PM
To: Pfeiffer, Nadine
Cc: Burgos, Alexander N
Subject: RE: Historical documents for Hospital rules

Thank you, Nadine. I'll review these and see if there are any other rules subject to objection that we need to work on.

Brian Liebman
Counsel to the North Carolina Rules Review Commission
Office of Administrative Hearings
(984)236-1948
brian.liebman@oah.nc.gov

From: Pfeiffer, Nadine <nadine.pfeiffer@dhhs.nc.gov>
Sent: Thursday, June 9, 2022 2:56 PM
To: Liebman, Brian R <brian.liebman@oah.nc.gov>
Subject: Historical documents for Hospital rules

Hi Brian,
As a follow-up to this afternoon's conference call, please see the attached documents I received from the prior Codifier on the rule filings for the hospital permanent rules prior to the rules becoming effective January 1, 1996. These documents include the RRC objections and RRC meeting minutes. Please note, the rules were recodified in 2003. Prior to recodification, the hospital rules Subchapter was 10 NCAC 13C but the rule numbers were the same as they are today.

I also have 3 documents (RRC rules-objections 7-95, RRC rules-objections2 7-95, & RRC rules-objections3 7-95) that look like it was all the rules that were submitted to RRC that became effective 1/1/96. From review of this document, it seems as the rules Joe DeLuca, staff attorney, did not object to are just the rules with maybe some highlights on them and the ones with an objection have the objection following the text of the rule.

Nadine Pfeiffer
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Raleigh, NC 27699-2701

Burgos, Alexander N

Subject: FW: Request to extend the period of review - 10A NCAC 13B rules

---

From: Liebman, Brian R <brian.liebman@oah.nc.gov>
Sent: Friday, June 10, 2022 11:00 AM
To: Pfeiffer, Nadine <nadine.pfeiffer@dhhs.nc.gov>
Cc: Burgos, Alexander N <alexander.burgos@oah.nc.gov>
Subject: RE: Request to extend the period of review - 10A NCAC 13B rules

Hi Nadine,

Thanks for sending me the request. I will recommend that RRC grant your request for an extension at next week's meeting.

Brian

Brian Liebman
Counsel to the North Carolina Rules Review Commission
Office of Administrative Hearings
(984)236-1948
brian.liebman@oah.nc.gov

From: Pfeiffer, Nadine <nadine.pfeiffer@dhhs.nc.gov>
Sent: Friday, June 10, 2022 10:26 AM
To: Liebman, Brian R <brian.liebman@oah.nc.gov>
Subject: Request to extend the period of review - 10A NCAC 13B rules

Brian,
On behalf of the N.C. Medical Care Commission, this is a request to extend the period of review for the hospital rules in 10A NCAC 13B to the July 21, 2022 Rules Review Commission meeting to address technical change requests issued by you on June 2, 2022. It is not unlikely the N.C. Medical Care Commission will need to seek a second extension of time; however, we work as quickly as possible to address the technical change concerns. Please let me know if this extension is approved.

Thank you.

Nadine Pfeiffer
Rules Review Manager
Division of Health Service Regulation
NC Department of Health and Human Services

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nadine.pfeiffer@dhhs.nc.gov

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Raleigh, NC 27699-2701

Burgos, Alexander N

Subject: FW: [External] Hospital Rules

From: Randolph, Kimberly <Krandolph@ncdoj.gov>
Sent: Wednesday, June 8, 2022 11:19 AM
To: Liebman, Brian R <brian.liebman@oah.nc.gov>
Cc: Pfeiffer, Nadine <nadine.pfeiffer@dhhs.nc.gov>; Burgon, Bethany A <bburgon@ncdoj.gov>; Burgos, Alexander N <alexander.burgos@oah.nc.gov>
Subject: Re: [External] Hospital Rules

Thanks Brian. I will send out a conf call number.

Sent from my iPhone

Burgos, Alexander N

Subject: FW: [External] Hospital Rules

From: Liebman, Brian R <brian.liebman@oah.nc.gov>
Sent: Wednesday, June 8, 2022 10:27 AM
To: Randolph, Kimberly <krandolph@ncdoj.gov>
Cc: Pfeiffer, Nadine <nadine.pfeiffer@dhhs.nc.gov>; Burgon, Bethany A <bburgon@ncdoj.gov>; Burgos, Alexander N <alexander.burgos@oah.nc.gov>
Subject: RE: [External] Hospital Rules

Hi Kim,

Thanks for the information. I'll take a look at 143B-165 and let you know my thoughts. As for the meeting, 1:00 tomorrow would be great. Look forward to speaking with you all.

Thanks,
Brian

Brian Liebman
Counsel to the North Carolina Rules Review Commission
Office of Administrative Hearings
(984)236-1948
brian.liebman@oah.nc.gov

Burgos, Alexander N

Subject: FW: [External] Hospital Rules

From: Randolph, Kimberly <Krandolph@ncdoj.gov>
Sent: Wednesday, June 8, 2022 8:10 AM
To: Liebman, Brian R <brian.liebman@oah.nc.gov>
Cc: Pfeiffer, Nadine <nadine.pfeiffer@dhhs.nc.gov>; Burgon, Bethany A <bburgon@ncdoj.gov>; Burgos, Alexander N <alexander.burgos@oah.nc.gov>
Subject: RE: [External] Hospital Rules

Hi Brian,

Just FYI - I was able to confirm that Article 5, in N.C. Gen. Stat. § 131E, did replace Article 13A when it was repealed, even though that reference has not been updated in N.C. Gen. Stat. § 143B-165(6).

Additionally, I just noticed I inadvertently proposed 10 for a call tomorrow when I intended to propose 1:00, since you indicated you preferred the afternoon. We are available at 1:00 tomorrow if that works for you. I will be happy to set up a conference call number for tomorrow at 1:00, if that time works. Thanks!

Kim Randolph
Assistant Attorney General
(919) 716-0270 Direct

Burgos, Alexander N

Subject: FW: [External] Hospital Rules

From: Randolph, Kimberly <Krandolph@ncdoj.gov>
Sent: Tuesday, June 7, 2022 2:21 PM
To: Liebman, Brian R <brian.liebman@oah.nc.gov>
Cc: Pfeiffer, Nadine <nadine.pfeiffer@dhhs.nc.gov>; Burgon, Bethany A <bburgon@ncdoj.gov>; Burgos, Alexander N <alexander.burgos@oah.nc.gov>
Subject: RE: [External] Hospital Rules

Hi Brian,

That you for your quick response! After we looked at these again, we noticed that N.C. Gen. Stat. § 143B-165 was not listed. We believe we need to add that to our history note. When reading N.C. Gen. Stat. § 143B-165, in conjunction with N.C. Gen. Stat. § 131E-75(b) and the specific authority of N.C. Gen. Stat. § 131E-79, will that provide the authority you are looking for these rules? Will be glad to hear your thoughts.

Would 10 on Thursday work for a call? Thanks again!

Kim Randolph
Assistant Attorney General
(919) 716-0270 Direct

Counsel to the North Carolina Rules Review Commission
Office of Administrative Hearings
(984)236-1948
brian.liebman@oah.nc.gov

Burgos, Alexander N

From: Liebman, Brian R
Sent: Tuesday, June 7, 2022 12:48 PM
To: Randolph, Kimberly
Cc: Pfeiffer, Nadine; Burgon, Bethany A; Burgos, Alexander N
Subject: RE: [External] Hospital Rules
Attachments: 2022.06 - MCC - 13B Staff Opinion.doc

Hi Kim,

I hope you are well also! Thanks for reaching out.

I have received the pre-review responses you sent to Ashley, and I have had an opportunity to review them today. It appears to me that these statutory authority issues were raised during the pre-review, and the agency's position is that the policy statute within Article 5—G.S. 131E-75(b)—provides sufficient statutory authority for each of these rules. Unfortunately, I do not believe that this statute, in light of the entirety of the Hospital Licensure Act, is sufficient authority to adopt the Rules currently before RRC. As such, I am issuing the attached staff opinion recommending that RRC object to these rules for lack of statutory authority, with the caveat that it may be revised or withdrawn depending on further argument MCC may make in response to my request for changes, or further review on my part.

While I can't meet on Wednesday, I can definitely speak with you on Thursday. I'd prefer the afternoon, but I can do anytime after 9:30 a.m. I look forward to speaking with you.

Thanks,
Brian

Brian Liebman
Counsel to the North Carolina Rules Review Commission
Office of Administrative Hearings
(984)236-1948
brian.liebman@oah.nc.gov

From: Randolph, Kimberly <Krandolph@ncdoj.gov>
Sent: Tuesday, June 7, 2022 12:07 PM
To: Liebman, Brian R <brian.liebman@oah.nc.gov>
Cc: Pfeiffer, Nadine <nadine.pfeiffer@dhhs.nc.gov>; Burgon, Bethany A <bburgon@ncdoj.gov>
Subject: [External] Hospital Rules
Importance: High

Hey Brian,

Hope you are well.

I understand you received our 8-2-2021 response to pre-review comments today. Will you please let me know if you need any additional information in response to your comments, after you have had a chance to review our response?

If you need additional information, can we set up a time to talk on Wed at 9:00 or 2:00 or anytime Thursday? Thank you.

Kim Randolph
Assistant Attorney General
Health Service Section
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(919) 716-6756 - Fax
krandolph@ncdoj.gov
P.O. Box 629 Raleigh, NC 27602-0629
ncdoj.gov

Please note messages to or from this address may be public records.

Burgos, Alexander N

Subject: FW: Pre-review comments response - 10A NCAC 13B Phase 4 readoption rules

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From: Snyder, Ashley B
Sent: Tuesday, June 7, 2022 10:38 AM
To: Pfeiffer, Nadine <nadine.pfeiffer@dhhs.nc.gov>
Subject: RE: Pre-review comments response - 10A NCAC 13B Phase 4 readoption rules

Thank you, Nadine. I am not sure if Amber or Amanda provided a copy of your responses to Brian, though I do know they left folders of pre-review materials. I provided him a copy of what you just sent.

Ashley Snyder
Codifier of Rules
Office of Administrative Hearings
(984) 236-1941

From: Pfeiffer, Nadine <nadine.pfeiffer@dhhs.nc.gov>
Sent: Tuesday, June 7, 2022 10:14 AM
To: Snyder, Ashley B <ashley.snyder@oah.nc.gov>
Subject: FW: Pre-review comments response - 10A NCAC 13B Phase 4 readoption rules

Hi Ashley,
Thank you for taking the time to look through your files for the pre-review comments on our 13B rules. We take all the pre-review comments we receive extremely seriously and we do make changes to our rules accordingly and also send responses back to your office so the staff attorneys will have them when they review the permanent rules. When we received your pre-review comments, we discussed the statutory authority concerns with attorneys at DOJ and made revisions to the history notes based on their counsel to us. I sent our pre-review responses to Amanda and Amber on 8/2/21 that included explanations for the concerns asked in your pre-review. (see email below). I sent this to the two of them because you had already been named Codifier and no longer was in the staff attorney role. I know both of these ladies are no longer employed by your agency; however, was this document forwarded to Brian for his consideration when he reviewed our rules?

Nadine Pfeiffer
Rules Review Manager
Division of Health Service Regulation
NC Department of Health and Human Services

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Fax: 919-733-2757
nadine.pfeiffer@dhhs.nc.gov

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From: Pfeiffer, Nadine
Sent: Monday, August 2, 2021 4:48 PM

To: Reeder, Amanda J <amanda.reeder@oah.nc.gov>; May, Amber Cronk <amber.may@oah.nc.gov>
Subject: Pre-review comments response - 10A NCAC 13B Phase 4 readoption rules

Hello!
You can't get enough of me today, can you? We got a pre-review back that Ashley did on our Phase 4 Hospital rules in 10A NCAC 13B on 6/16/21. One of you lucky ladies will most likely get these when we file for permanent rule for the June '22 meeting (or maybe you will pawn them off to one of your new staff whenever they get hired), but in any case, here are our responses to the pre-review comments for those rules.

Nadine Pfeiffer
Rules Review Manager
Division of Health Service Regulation
NC Department of Health and Human Services

Find a vaccine location, get questions answered and more at YourSpotYourShot.nc.gov.

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nadine.pfeiffer@dhhs.nc.gov

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Burgos, Alexander N

From: Snyder, Ashley B
Sent: Tuesday, June 7, 2022 9:41 AM
To: Pfeiffer, Nadine
Cc: Burgos, Alexander N
Subject: RE: Reviewed rules for June meeting
Attachments: 10A NCAC 13B - ABS.docx

Nadine,

I was curious if I missed something in the pre-review so I pulled my notes. See attached. I asked numerous questions about significant statutory authority concerns in the pre-review. Brian's change requests line up with the same questions raised in the pre-review. These questions should come as no surprise.

Ashley Snyder
Codifier of Rules
Office of Administrative Hearings
(984) 236-1941

From: Pfeiffer, Nadine <nadine.pfeiffer@dhhs.nc.gov>
Sent: Monday, June 6, 2022 8:10 AM
To: Snyder, Ashley B <ashley.snyder@oah.nc.gov>
Subject: RE: Reviewed rules for June meeting

Good Morning Ashley,
Thank you for getting back with me. Yes, I did receive the technical changes from Brian, however they were received after business hours on Friday (like 6:18pm) and I had left for the day. You are correct, I as the rule coordinator cannot answer any of the technical change questions the staff attorneys pose. Those are handled by the subject matter experts in our Sections that implement the rules. What I do when I get the technical changes is send the document over to them to answer and then I make all the rule changes they want made (I automatically do any "easy" things like changing a word here and there or punctuation changes etc). My folks have no idea how to make changes to the rule text after the NOT is filed so it is easier if I just do it for them, so yes, all of this takes time and a lot of back and forth. I am glad you impressed upon your staff the time it does take agencies to accomplish all of this and the amount of people that are sometimes involved. Thank you!

As for the technical changes I received late Friday evening for the hospital rules, I am disappointed that for 12 of the 14 (1 was a repeal) rules there were questions on the statutory authority for those rules after we had sent those rules for a pre-review and you were the attorney who sent us back the comments on the pre-review and this was not mentioned for all these rules. It would have been nice to know in advance of these issues, which to me, could be a game stopper. Also, to give us a five business day deadline to get the changes back to your agency, instead of the usual 10 business days, when we have to involve DOJ at this point, feels punitive. Our staff subject matter experts have other duties besides rulemaking. They are oftentimes in the field conducting health and safety surveys of facilities for the residents of NC. It is not as easy as one would think to get the answers needed to the technical changes in the typical 10 business days, and now we are asked to do it in five. Yes, I am aware we could ask to extend the period of review for these rules and other rules in the future if we cannot make the deadline for submission of technical changes; however, there will be some rules like CON rules that this will not be possible since the rules will have to become effective the 1st day of the month after the RRC meeting or it will affect the applicants for CONs.

I am truly sorry that there was a large amount of rule filings for this month, but there will be many months like that and have been in the past. Just like for us rulemaking coordinators. When agencies have met the permanent rule submission deadline or submitted earlier than the deadline, I do not feel it is a fair practice to place a shortened technical change submission deadline on agencies because of OAH's workload. Please give this some thought.

Thank you.

Nadine Pfeiffer
Rules Review Manager
Division of Health Service Regulation
NC Department of Health and Human Services

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nadine.pfeiffer@dhhs.nc.gov

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From: Snyder, Ashley B <ashley.snyder@oah.nc.gov>
Sent: Saturday, June 4, 2022 7:57 AM
To: Pfeiffer, Nadine <nadine.pfeiffer@dhhs.nc.gov>
Subject: RE: Reviewed rules for June meeting

Good morning, Nadine,

We do have these rules and they are assigned to Brian. As a former rulemaking coordinator, I understand your concern and frustration. It can be difficult to turnaround tech change requests in a short timeline. I actually took a minute to explain that to our staff attorneys on Thursday – rulemaking coordinators often have to take drafts to other staffers, their boss, etc. so they need time to respond to the changes and circulate them within their agency.

From our point of view, please understand we have had heavy filings months in a row resulting in a high volume of rules for the staff attorneys to review this month in addition to numerous follow-up matters. I can assure you our staff attorneys have been working overtime to complete their review as quickly as possible. We are also working on hiring our 4th staff attorney position. I will reach out to Brian and ask him to give you an update.

Thank you for contacting me about this. I always appreciate feedback.

Ashley Snyder
Codifier of Rules
Office of Administrative Hearings
(984) 236-1941

From: Pfeiffer, Nadine <nadine.pfeiffer@dhhs.nc.gov>
Sent: Friday, June 3, 2022 4:26 PM
To: Snyder, Ashley B <ashley.snyder@oah.nc.gov>
Subject: Reviewed rules for June meeting

Hi Ashley,
I am just checking to see that you all did receive my Submission for Permanent Rule from the Medical Care Commission for 14 readoption rules for 10A NCAC 13B. I submitted the rules on May 16, 2022 and did not get a bounce back from my

email. I have not received any correspondence from your agency on these rules, not an acknowledgement of the receipt, nor any technical change requests. This is highly unusual. In all the years I have worked on rules, there has never been this long of delay in receiving any type of communication from OAH. Typically I would have gotten technical change requests by the beginning of this week at the latest, since they are due to your office next Friday. Have you all received them? I am getting quite worried.

Thank you.

Nadine Pfeiffer
Rules Review Manager
Division of Health Service Regulation
NC Department of Health and Human Services

Office: 919-855-3811
Fax: 919-733-2757
nadine.pfeiffer@dhhs.nc.gov

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Medical Care Commission – 10A NCAC 13B

Pre-Review

Ashley Snyder

General Notes:

- As a reminder, pre-reviews are conducted voluntarily by RRC staff counsel. Staff counsel may still issue technical corrections or staff opinions upon filing the rules for review by the Rules Review Commission.
- I see you cited G.S. 131E-70 for all of these rules. That is a grant of general rulemaking authority to implement G.S. 131E, Article 5. That statute does not grant authority for anything the agency wants to do, for example, implementation of requirements not mentioned in G.S. 131E, Article 5. You will see questions about this in multiple rules. Please think about what statute you are implementing. What language in 131E, Article 5 are you relying upon for the rule? RRC has historically interpreted statutory authority narrowly. Please keep this in mind as you review.

.3801:

- What authority are you relying upon for this Rule? I see you have cited 131E-79, which provides authority to "promulgate rules necessary to implement this Article," but which statute or statutes within this Article are you implementing? G.S. 131E-77(c) allows you to require the provision of information related to hospital operations. Where is your authority to govern operations instead of just request information related to operations?
- In (a), what is a "centralized organizational structure" and what is a "decentralized organizational structure?" Is your regulated public familiar with these terms?
- Do nurse executives work in centralized organizational structures? Please review the definition of "nurse executive" in 13B .3001.
- In (b), please add a comma after "policies."
- In (c), what "required functions" are you referring to?
- In (d), please delete the commas after "meetings" and "days."
- In (d), is it up to the facility to determine how nursing staff evaluates nursing services?
- Is (e)(2) the same as (b)? Is there some overlap with (e)(9) as well? If so, please avoid repetition.
- In (e)(5), please delete the comma.

.3903:

- Are you relying upon 131E-80(d) as your authority? If so, please add that statute to your history note.

- What are you relying upon as statutory authority for (d)?
- In (g), please capitalize "State" if you are only referring to North Carolina.
- In (g), consider adding "(HIPPA)" after the name of the Act.
- In (h), what is considered an "authorized purpose?" What is not? How is this determination made?
- Why is G.S. 90-21.20B listed in your history note? Does that statute grant authority to the Medical Care Commission? I do not think it does.

.4103:

- What are you relying upon for authority for (a)? Which statute are you implementing? 131E-79 only grants rulemaking authority for rules "necessary to implement this Article."
- If you keep (a), please delete or define "appropriate." For example, which medical screening policies are appropriate vs. not appropriate? What does this Rule require?
- For (b) and (c), what are you relying upon as your authority to require certain hospital equipment? I see you have this authority over ambulances in Article 7. Where is your authority over equipment at facilities?
- In (c), I take it you are still governing "facilities," correct?
- In (c), if the rules 10A NCAC 13P were promulgated by the Medical Care Commission, you do not need to incorporate them by reference because they are your rules! Simply refer to them. Incorporation lets your regulated public know "We're enforcing this other document now and making it part of our rules." You're already enforcing 13P, so a cross-reference is all you need.

.4104:

- Where is your statutory authority for Paragraphs (a), (c), and (d)?
- For Paragraph (b), are you relying upon 131E-85? If so, please add that to your history note.

.4106:

- Where is your statutory authority for this Rule?
- In (11), please capitalize "State" if you are only referring to North Carolina.

.4305:

- Where is your statutory authority for this Rule?
- In (a)(1), consider "This may include infants who are small…"

.4603:

- To the extent this Rule governs hospital privileges, please add 131E-85 to your history note. Does that statute provide authority for this entire Rule? For example, what authority are you relying upon for (b)(5)?
- Is (b) the list of processes required in (a)? If so, please make that clear. Consider combining (a) and (b) so you just have one paragraph followed by a list.
- In (b)(2), please delete or define "qualified physician" and "immediately."
- In (b)(4), delete or define "qualified." Are you just requiring a registered nurse or are you requiring additional qualifications?

.4801:

- Does this Rule govern hospital privileges as well? If so, please add 131E-85 to your history note. If not, what is your statutory authority for this Rule?
- In (a), please change "must" to "shall."
- In (b), what are you getting at here? Is it that radio-therapy services shall be conducted under supervision of a radiologist or other experienced physician as described in (a)? If so, consider: "Radio-therapy shall be considered an imaging service" or "Radio-therapy is a type of imaging service."
- In (c), define "qualified personnel."

.4805:

- Why is (a) necessary? It repeats .4801(a).
- Why is (b) necessary? It repeats .4801(c).
- For (c), is the Medical Care Commission requiring these safety inspections or are these already required by Radiation Protection? In other words, is this necessary or are you repeating something that is already required?
- In (d), do you need to say "but is not limited to?" Does it make the rule clearer to retain this language or is "shall include" sufficient?
- In (d)(1), define "experienced." What experience is required?
- Where is your statutory authority for this Rule?

.5102 and .5105:

- Where is your statutory authority for these Rules?

.5406:

- Where is your statutory authority for this Rule? Are you relying upon G.S. 131E-80(d) or 131E-90?

- In (a), what "established goals" are you referring to?
- At line 6, a determination by who? Does this refer to the two physicians mentioned in 131E-90? Please clarify.

.5408:

- Overall, what are you relying upon for authority? What statute or statutes are you implementing?
- Throughout this Rule, where is your statutory authority to set supervision requirements, with the exception of physicians supervising care as provided in 131E-76(3)? Is this already governed by occupational licensing boards?
- What are you requiring in (a)(1)? Are you requiring a rehabilitation nurse as defined in .5401?
- Where is your authority to set staff qualification requirements?
- What does (b) require? How is this measured? How do you determine whether the requirements in (b) have been met?

.5411:

- What are you relying upon for authority for Paragraph (a)?
- In (b), please delete "the rules outlined in" and simply refer to "Sections .6000 and .6100." "Section" refers to an entire division of rules - .0100, .0200, etc. Here you have a reference to a section and an individual rule, .6105. I think you intended to refer to all of .6100, but please confirm.

Burgos, Alexander N

From: Liebman, Brian R
Sent: Friday, June 3, 2022 6:18 PM
To: Pfeiffer, Nadine
Cc: Burgos, Alexander N
Subject: NC Medical Care Commission Request for Changes - June 2022 RRC
Attachments: 06.2022 - Medical Care Commission 13B Request for Changes.docx

Hi Nadine,

I'm the attorney who reviewed the Rules submitted by the Board for the June 2022 RRC meeting. The RRC will formally review these Rules at its meeting on Thursday, June 16, 2022, at 9:00 a.m. The meeting will be a hybrid of in-person and WebEx attendance, and an evite should be sent to you as we get closer to the meeting. If there are any other representatives from your agency who will want to attend virtually, let me know prior to the meeting, and we will get evites out to them as well.

Please submit the revised Rules to me via email, no later than 5 p.m. on Friday, June 10, 2022. You'll note I had statutory authority questions for all rules contained in this packet. If you want to discuss, I'm available at your convenience next week.

In the meantime, do not hesitate to reach out via email with any questions or concerns.

Thanks,

Brian

Brian Liebman
Counsel to the North Carolina Rules Review Commission
Office of Administrative Hearings
(984)236-1948
brian.liebman@oah.nc.gov

Medical Care Commission – 10A NCAC 13B

Pre-Review

Ashley Snyder

General Notes:

- As a reminder, pre-reviews are conducted voluntarily by RRC staff counsel. Staff counsel may still issue technical corrections or staff opinions upon filing the rules for review by the Rules Review Commission.
- I see you cited G.S. 131E-70 for all of these rules. That is a grant of general rulemaking authority to implement G.S. 131E, Article 5. That statute does not grant authority for anything the agency wants to do, for example, implementation of requirements not mentioned in G.S. 131E, Article 5. You will see questions about this in multiple rules. Please think about what statute you are implementing. What language in 131E, Article 5 are you relying upon for the rule? **G.S. 131E-75(b)** RRC has historically interpreted statutory authority narrowly. Please keep this in mind as you review.

.3801:

- What authority are you relying upon for this Rule? **G.S. 131E-75(b)** I see you have cited 131E-79, which provides authority to "promulgate rules necessary to implement this Article," but which statute or statutes within this Article are you implementing? **G.S. 131E-75(b)** G.S. 131E-77(c) allows you to require the provision of information related to hospital operations. Where is your authority to govern operations instead of just request information related to operations? **G.S. 131E-75(b)**
- In (a), what is a "centralized organizational structure" and what is a "decentralized organizational structure?" Is your regulated public familiar with these terms? **The state licensed and Medicare certified, accreditation organizations, and regulated providers are knowledgeable of the regulations and daily operations and familiar with the terms**, **"centralized organizational structure" and "decentralized organizational structure. The organizational structures are hospital specific references the use of the centralized or decentralized structure.**
- Do nurse executives work in centralized organizational structures? **Yes.** Please review the definition of "nurse executive" in 13B .3001. **The definition of nurse executive expanded as common nomenclature as hospitals transitioned to centralized organizational structures.**
- In (b), please add a comma after "policies." **Done**
- In (c), what "required functions" are you referring to? **The state licensed and Medicare certified, accreditation organizations, and regulated providers are knowledgeable of the regulations and daily operations which define the various functions warranting the development and implementation of policies and procedures for patient care.**

- In (d), please delete the commas after "meetings" and "days." **Done**
- In (d), is it up to the facility to determine how nursing staff evaluates nursing services? **Yes. The state licensed and Medicare certified, accreditation organizations, and regulated providers are knowledgeable of the regulations and daily operations. Hospitals define parameters for staffing related to patient care acuity and needs to ensure the delivery of safe and quality care. Staffing is patient care directed.**
- Is (e)(2) the same as (b)? **No** Is there some overlap with (e)(9) as well? **Yes. Staffing is correlated to the policies and procedure implemented to direct the delivery of the patient care.** If so, please avoid repetition.
- In (e)(5), please delete the comma. **Done**

.3903:

- Are you relying upon 131E-80(d) as your authority? **G.S. 131E-75(b)** If so, please add that statute to your history note. **Done**
- What are you relying upon as statutory authority for (d)? **G.S. 131E-75(b)**
- In (g), please capitalize "State" if you are only referring to North Carolina. **Done**
- In (g), consider adding "(HIPPA)" after the name of the Act. **Done**
- In (h), what is considered an "authorized purpose?" What is not? How is this determination made? **The state licensed and Medicare certified regulated providers are knowledgeable of the regulations and daily operations on the disclosure of medical records in accordance with HIPAA regulations. Hospitals must have defined policies and procedures for implementation that clearly defines those authorized and not authorized. Pursuant to Medicare regulations § 482.24(b)(3) …. Information from or copies of medical records may be released only to authorized individuals, and the hospital must ensure that unauthorized individuals cannot gain access to or alter patient records. Additional examples of authorized purposes include court orders, subpoenas, continuation of medical care, case reviews. Individuals have the right to access their personal medical records at any time and disclose as they deem appropriate.**
- Why is G.S. 90-21.20B listed in your history note? Does that statute grant authority to the Medical Care Commission? I do not think it does. **G.S. 90-21.20B removed.**

.4103:

- What are you relying upon for authority for (a)? **G.S.131E-75(b)** Which statute are you implementing? **G.S.131E-75(b)** 131E-79 only grants rulemaking authority for rules "necessary to implement this Article."
- If you keep (a), please delete or define "appropriate." For example, which medical screening policies are appropriate vs. not appropriate? What does this Rule require? **"appropriate" deleted**
- For (b) and (c), what are you relying upon as your authority to require certain hospital equipment? **Article 5 Hospital Licensure Act § 131E-75. Title: purpose This is the**

basic for safe care to 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. I see you have this authority over ambulances in Article 7. Where is your authority over equipment at facilities? **The definition of hospital under Article 5 131E-76 includes the provision of diagnostic and therapeutic care. This article covers our ability to ensure safe equipment. The provision of safe care includes assurances equipment is safe and operational.**

- In (c), I take it you are still governing "facilities," correct? **Yes**
- In (c), if the rules 10A NCAC 13P were promulgated by the Medical Care Commission, you do not need to incorporate them by reference because they are your rules! Simply refer to them. Incorporation lets your regulated public know "We're enforcing this other document now and making it part of our rules." You're already enforcing 13P, so a cross-reference is all you need. **Cross reference done.**

.4104:

- Where is your statutory authority for Paragraphs (a), (c), and (d)? **G.S. 131E-75(b) The agency has no statutory authority for regulating the qualifications of the director of emergency services.**
- For Paragraph (b), are you relying upon 131E-85? If so, please add that to your history note. **131E-85(a) added to history note.**

.4106:

- Where is your statutory authority for this Rule? **G.S.131E-75(b)**
- In (11), please capitalize "State" if you are only referring to North Carolina. **Done**

.4305:

- Where is your statutory authority for this Rule? **G.S.131E-75(b)**
- In (a)(1), consider "This may include infants who are small…" **Replaced with "include infants who are small"**

.4603:

- To the extent this Rule governs hospital privileges, please add 131E-85 to your history note. **Done** Does that statute provide authority for this entire Rule? For example, what authority are you relying upon for (b)(5)? **G.S. 131e-75(b)**

- Is (b) the list of processes required in (a)? If so, please make that clear. Consider combining (a) and (b) so you just have one paragraph followed by a list. **Done**
- In (b)(2), please delete or define "qualified physician" and "immediately." **Done**
- In (b)(4), delete or define "qualified." Are you just requiring a registered nurse or are you requiring additional qualifications? **Done**

.4801:

- Does this Rule govern hospital privileges as well? If so, please add 131E-85 to your history note. If not, what is your statutory authority for this Rule? **G.S.131E-75(b)**
- In (a), please change "must" to "shall." **Done**
- In (b), what are you getting at here? Is it that radio-therapy services shall be conducted under supervision of a radiologist or other experienced physician as described in (a)? If so, consider: "Radio-therapy shall be considered an imaging service" or "Radio-therapy is a type of imaging service." **Replaced with "Radio-therapy is a type of imaging service."**
- In (c), define "qualified personnel." **"Qualified" deleted**

.4805:

- Why is (a) necessary? It repeats .4801(a). **The state licensed Medicare certified regulated providers are knowledgeable of the regulations and daily operations. Although, the regulation may seem duplicative, .4801 lays out the organizational structure. The organizational structures are hospital specific. The intent of the regulation is to ensure a designated person is assigned the responsibility of ensuring the use of safe equipment and ongoing preventative maintenance. The regulation is essential.**
- Why is (b) necessary? It repeats .4801(c). **The state licensed Medicare certified regulated providers are knowledgeable of the regulations and daily operations. The intent of the regulations is to ensure systems are in place for individual staff safety. The regulation is essential to promote safety. It is noted, the monitoring of staff safety is often overlooked.**
- For (c), is the Medical Care Commission requiring these safety inspections or are these already required by Radiation Protection? In other words, is this necessary or are you repeating something that is already required?
- In (d), do you need to say "but is not limited to?" **No** Does it make the rule clearer to retain this language or is "shall include" sufficient? **Shall include is sufficient. Remove "but is not limited to" and replace with…The committee shall include:**

- In (d)(1), define "experienced." What experience is required? **The state licensed Medicare certified regulated providers are knowledgeable of the regulations and daily operations. Experienced is hospital specific and defined by the hospital's**

medical staff bylaws and includes a combination of educations, and hands on exposure or skill over a specific period.

- Where is your statutory authority for this Rule? **131E-75(b)**

.5102 and .5105:

- Where is your statutory authority for these Rules? **131E-75(b)**

.5406:

- Where is your statutory authority for this Rule? Are you relying upon G.S. 131E-80(d) or 131E-90? **G.S.131E-75(b)**
- In (a), what "established goals" are you referring to? **Goals of care.**
- At line 6, a determination by who? Does this refer to the two physicians mentioned in 131E-90? Please clarify. **Yes. The state licensed Medicare certified regulated providers are knowledgeable of the regulations and processes for assessing and implementing care to meet the needs of patients with an overarching goal of improvement to returning to an independent state of health with the least parameters of assistance. The team and decision-making are a comprehensive team approach addressing the needs of the rehab patient. The attending physician or physiatrist direct the comprehensive rehab program. This is an inclusive process of a multi-disciplinary team of health care providers which may include OT, PT, SLP, mental health professionals, psychologist, psychiatrist, etc.**

.5408:

- Overall, what are you relying upon for authority? What statute or statutes are you implementing? **G.S.131E-75(b)**
- Throughout this Rule, where is your statutory authority to set supervision requirements, with the exception of physicians supervising care as provided in 131E-76(3)? Is this already governed by occupational licensing boards? **G.S. 131E-75(b)**
- What are you requiring in (a)(1)? Are you requiring a rehabilitation nurse as defined in .5401? **Yes**
  Where is your authority to set staff qualification requirements? **The agency has no statutory authority to set staff qualification requirements.**
- What does (b) require? How is this measured? How do you determine whether the requirements in (b) have been met? **The state licensed Medicare certified regulated providers are knowledgeable of the regulations and processes for assessing, implementing, and ongoing evaluation of a comprehensive plan of care to meet the needs of the patient centered and directed goals. The multi-disciplinary team is responsible for an ongoing assessment and evaluation of the rehab patient to obtain**

goals. Examples of rehab measures may include but are not limited to ability to button clothing without assistance, ability to walk with a cane as opposed to a walker, or the ability to increase steps.

.5411:

- What are you relying upon for authority for Paragraph (a)?
- In (b), please delete "the rules outlined in" and simply refer to "Sections .6000 and .6100." "Section" refers to an entire division of rules - .0100, .0200, etc. Here you have a reference to a section and an individual rule, .6105. I think you intended to refer to all of .6100, but please confirm. **.5411 Repealed**