STATE OF NORTH CAROLINA
DEPARTMENT OF HEALTH AND HUMAN SERVICES

MEDICAL CARE COMMISSION PLANNING MEETING
DIVISION OF HEALTH SERVICE REGULATION
809 RUGGLES DRIVE
RALEIGH, NORTH CAROLINA 27603
CONFERENCE ROOM #026A – EDGERTON BUILDING
or
VIDEO CONFERENCE (LINK: Join Microsoft Teams Meeting)
or
DIAL-IN (1-984-204-1487 / Passcode: 249668659#)

THURSDAY, NOVEMBER 12, 2020
3:00 P.M.

AGENDA

I. **Meeting Opens and Comments**……..……..……..…….……..…..Dr. John Meier

II. **Public Meeting Statement**…….....Dr. John Meier

This meeting of the Medical Care Commission is open to the public but is not a public hearing. Therefore, any discussion will be limited to members of the Commission and staff unless questions are specifically directed by the Commission to someone in the audience.

III. **Ethics Statement**……...…Dr. John Meier

The State Government Ethics Act requires members to act in the best interest of the public and adhere to the ethical standards and rules of conduct in the State Government Ethics Act, including the duty to continually monitor, evaluate, and manage personal, financial, and professional affairs to ensure the absence of conflicts of interest.

IV. **Old Business** (Discuss Rules, fiscal note, and comments submitted)

A. Rules for Adoption

1. Ambulatory Surgical Center Rules……..…...……Nadine Pfeiffer & Azzie Conley

Readoption of four rules following Periodic Review and the amendment of two rules

- Rules: 10A NCAC 13C.0202, 0203, 0301, 0501, 0702, and .0902
  (See Exhibits C thru C/1)

2. Hospice Licensing Rules……..……...……..Nadine Pfeiffer and Cindy Deporter

Readoption of five rules following Periodic Review

- Rules: 10A NCAC 13K .0102, .0401, .0604, .0701, and .1104
  (See Exhibits C/2 thru C/4)

3. Licensing of Nursing Home Rules…….…..…..……Nadine Pfeiffer and Beverly Speroff

Amendment of two rules and repeal of one rule for ventilator assisted care

- Rules: 10A NCAC 13D .2001, .2506, and .3003
  (See Exhibits C/5 thru C/6)

V. New Business (Discuss Rules & Fiscal Note)

A. Rule for Initiating Rulemaking Approval

1. Emergency Medical Services and Trauma Rules……..…….Nadine Pfeiffer & Tom Mitchell

Amendment of twenty-two rules for education and credentialing.

- Rules: 10A NCAC 13P .0101, .0102, .0222, .0501, .0502, .0504, .0507, .0508, .0510, .0512, .0601, .0602, .0904, .0905, .1101, .1401, .1403, .1404, .1405, .1505, .1507, and .1511 **(See Exhibits D thru D/2)**

B. Adult Care Home/Family Care Rules…….……...……...…….Nadine Pfeiffer and Megan Lamphere

2. Readoption of four rules following Periodic Review and amendment of one rule – Phase 2

- Rules: 10A NCAC 13F .0403, .0406; 10A NCAC 13G .0402, .0403, and .0405
  (See Exhibits D/3 thru D/5)

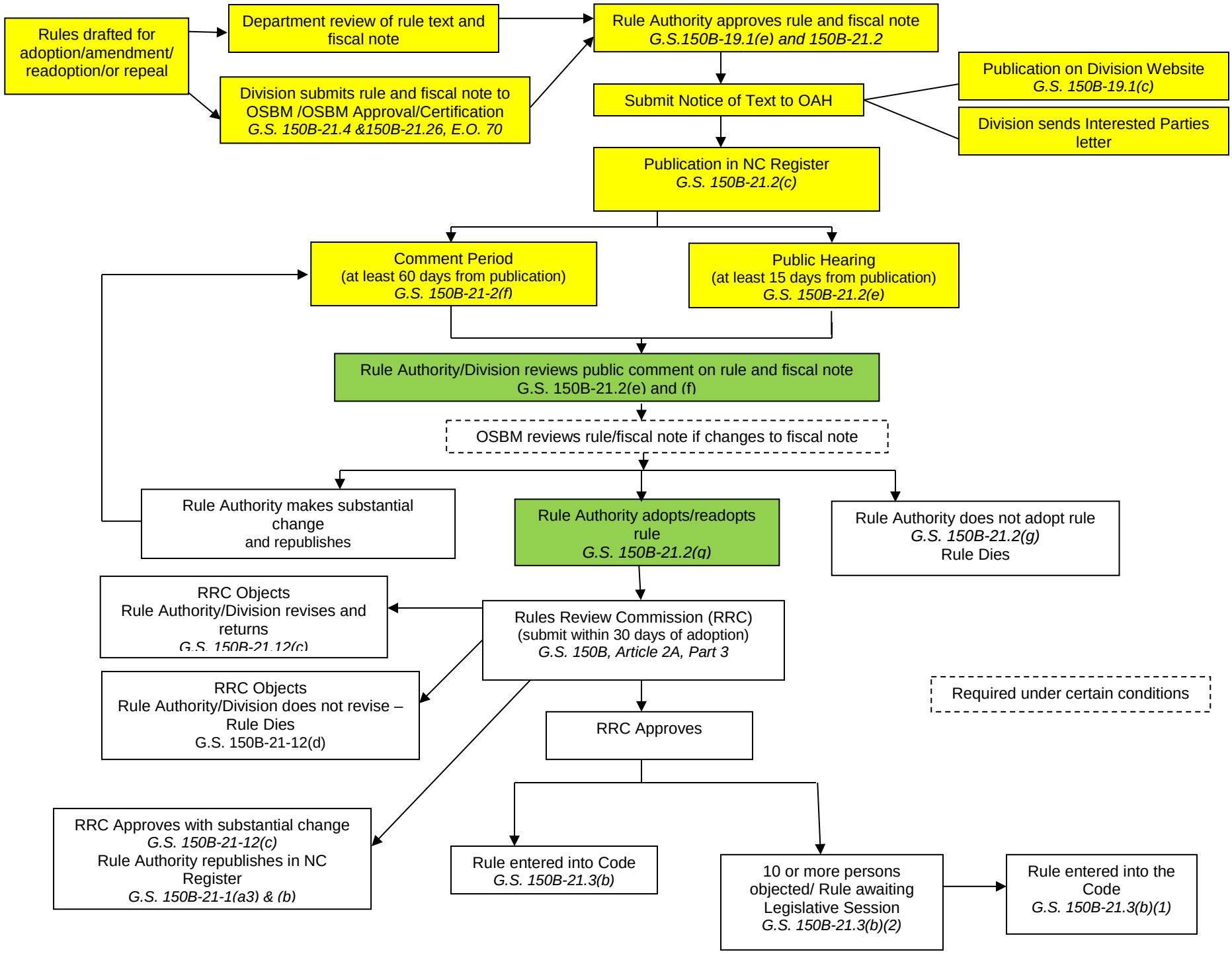
VI. Compliance Policy Update……..……..……..……Geary W. Knapp

Discuss proposed new compliance policy and feedback from current program participants.
(See Exhibit E)

VII. Meeting Adjournment – The Agenda is to be referred to the Friday, November 13, 2020 meeting without any action being taken.

Process for Medical Care Commission to Adopt/Readopt Rule

Exhibit C



10A NCAC 13C .0202 is readopted as published in 34:24 NCR 2375-2377 as follows:

10A NCAC 13C .0202 REQUIREMENTS FOR ISSUANCE OF LICENSE

(a) Upon application for a license from a facility never before licensed, a representative of the Department shall make an inspection of that facility. Every building, institution, or establishment ~~for which a license~~ that has been issued a license shall be inspected for compliance with the rules found in this Subchapter. An ambulatory surgery facility shall be deemed to meet licensure requirements if the ambulatory surgery facility is accredited by The Joint ~~Commission (formerly known as "JCAHO"),~~ Commission, AAAHC or AAAASF. Accreditation ~~does~~ shall not exempt a facility from statutory or rule requirements for licensure nor ~~does~~ shall it prohibit the Department from conducting inspections as provided in this Rule to determine compliance with all requirements.

(b) If the applicant has been issued a Certificate of Need and is found to be in compliance with the Rules found in this Subchapter, then the Department shall issue a license to expire on December 31 of each year.

(c) The Department shall be notified at the time of:

(1) any change of the owner or operator;

(2) any change of location;

(3) any change as to a lease; and

(4) any transfer, assignment, or other disposition or change of ownership or control of 20 percent or more of the capital stock or voting rights thereunder of a corporation that is the operator or owner of an ambulatory surgical facility, or any transfer, assignment, or other disposition of the stock or voting rights thereunder of such corporation that results in the ownership or control of more than 20 percent of the stock or voting rights thereunder of such corporation by any person.

A new application shall be submitted to the Department in the event of such a change or changes.

(d) The Department shall not grant a license until the plans and specifications that are stated in Section .1400 of this Subchapter, covering the construction of new buildings, additions, or material alterations to existing buildings are approved by the Department.

(e) The facility design and construction shall be in accordance with the licensure rules for ambulatory surgical facilities found in this Subchapter, the North Carolina State Building Code, and local municipal codes.

(f) Submission of Plans.

(1) ~~Before construction is begun, schematic plans and specifications and final plans and specifications covering construction of the new buildings, alterations, renovations, or additions to existing buildings shall be submitted to the Division for approval.~~ When construction or remodeling of a facility is planned, one copy of construction documents and specifications shall be submitted by the owner or owner's appointed representative to the Department for review and approval. As a preliminary step to avoid last minute difficulty with construction documents approval, schematic design drawings and design development drawings may be submitted for approval prior to the required submission of construction documents.

(2) ~~The Division shall review the plans and notify the licensee that said buildings, alterations, additions, or changes are approved or disapproved. If plans are disapproved the Division shall give the applicant notice of deficiencies identified by the Division.~~ Approval of construction documents and specifications shall be obtained from the Department prior to licensure. Approval of construction documents and specifications shall expire one year after the date of approval unless a building permit for the construction has been obtained prior to the expiration date of the approval of construction documents and specifications.

(3) The plans shall include a plot plan showing the size and shape of the entire site and the location of all existing and proposed facilities.

~~(4) Plans shall be submitted in duplicate. The Division shall distribute a copy to the Department of Insurance for review of the North Carolina State Building Code requirements if required by the North Carolina State Building Code which is hereby incorporated by reference, including all subsequent amendments. Copies of the Code may be accessed electronically free of charge at: http://www.ecodes.biz/ecodes_support/Free_Resources/2012NorthCarolina/12NorthCarolina_main.html.~~

(g) To qualify for licensure or license renewal, each facility shall provide to the Division, with its application, an attestation statement in a form provided by the Division verifying compliance with the requirements defined in Rule .0301(d) of this Subchapter.

History Note: *Authority G.S. 131E-91; 131E-147; 131E-149; ~~S.L. 2013-382, s. 13.1;~~*
Eff. October 14, 1978;
Amended Eff. April 1, 2003;
Temporary Amendment Eff. May 1, 2014;
Amended Eff. November 1, ~~2014.~~ 2014;
Readopted Eff. January 1, 2021.

10A NCAC 13C .0203 is amended as published in 34:24 NCR 2375-2377 as follows:

10A NCAC 13C .0203 SUSPENSION OR REVOCATION: AMBULATORY SURGICAL FACILITY

(a) The license may be suspended or revoked at any time for noncompliance with the ~~regulations~~ rules of the Department.

(b) Suspension or revocation of the license shall be covered by the rules regarding contested cases as found in ~~10 NCAC 3B .0200.~~ G.S. 150B-23.

(c) Notwithstanding ~~Subsection~~ Paragraph (a) and (b) of this Rule, the Department may summarily suspend the license pursuant to ~~General Statute~~ G.S. 150B-3(c).

History Note: *Authority G.S. 131E-148; 131E-149; 143B-165; 150B-3(c); 150B-23;*
Eff. October 14, 1978;
Amended Eff. November 1, 1989;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 23, ~~2017.~~ 2017;
Amended Eff. January 1, 2021.

10A NCAC 13C .0301 is readopted as published in 34:24 NCR 2375-2377 as follows:

SECTION .0300 – GOVERNING AUTHORITY MANAGEMENT

10A NCAC 13C .0301 GOVERNING AUTHORITY

(a) The facility's governing authority shall adopt bylaws or other operating policies and procedures to assure that:

(1) a named individual is identified who is responsible for the overall operation and maintenance of the facility. The governing authority shall have methods in place for the oversight of the individual's performance;

(2) ~~at least~~ annual meetings of the governing authority ~~are~~ shall be conducted if the governing authority consists of two or more individuals. Minutes shall be maintained of such meetings;

(3) a policy and procedure manual is created that is designed to ensure professional and safe care for the patients. The manual shall be reviewed annually and revised ~~when necessary.~~ in accordance with facility policy. The manual shall include provisions for administration and use of the facility, compliance, personnel quality assurance, procurement of outside services and consultations, patient care ~~policies~~ policies, and services offered; and

(4) annual reviews and evaluations of the facility's policies, management, and operation are conducted.

(b) When services such as dietary, laundry, or therapy services are purchased from others, the governing authority shall be responsible ~~to assure~~ for assuring the supplier meets the same local and ~~state~~ State standards the facility would have to meet if it were providing those services ~~itself~~ using its own staff.

(c) The governing authority shall provide for the selection and appointment of the professional staff and the granting of clinical privileges and shall be responsible for the professional conduct of these persons.

(d) The governing authority shall establish written policies and procedures to assure billing and collection practices in accordance with G.S. 131E-91. These policies and procedures shall include:

(1) a financial assistance policy as defined in G.S. 131E-214.14(b)(3);

(2) how a patient may obtain an estimate of the charges for the statewide 20 most common outpatient imaging procedures and 20 most common outpatient surgical procedures based on the primary Current Procedure Terminology Code (CPT). The policy shall require that the information be provided to the patient in writing, either electronically or by mail, within three business days;

(3) how a patient or patient's representative may dispute a bill;

(4) issuance of a refund within 45 days of the patient receiving notice of the overpayment when a patient has overpaid the amount due to the facility;

(5) providing written notification to the patient or patient's representative, ~~at least~~ 30 days prior to submitting a delinquent bill to a collections agency;

(6) providing the patient or patient's representative with the facility's charity care and financial assistance policies, if the facility is required to file a Schedule H, federal form 990;

(7) the requirement that a collections agency, entity, or other assignee obtain written consent from the facility prior to initiating litigation against the patient or patient's representative;

(8) a policy for handling debts arising from the provision of care by the ambulatory surgical facility involving the doctrine of necessaries, in accordance with G.S. 131E-91(d)(5); and

(9) a policy for handling debts arising from the provision of care by the ambulatory surgical facility to a minor, in accordance with G.S. 131E-91(d)(6).

History Note: *Authority G.S. 131E-91; 131E-147.1; 131E-149; 131E-214.13(f); 131E-214.14; ~~S.L. 2013-382, s. 10.1; S.L. 2013-382, s. 13.1;~~*
Eff. October 14, 1978;
Amended Eff. November 1, 1989; November 1, 1985; December 24, 1979;
Temporary Amendment Eff. May 1, 2014;
Amended Eff. November 1, ~~2014.~~ 2014;
Readopted Eff. January 1, 2021.

10A NCAC 13C .0501 is readopted as published in 34:24 NCR 2375-2377 as follows:

SECTION .0500 - ANESTHESIA SERVICES

10A NCAC 13C .0501 PROVIDING ANESTHESIA SERVICES

Only a physician, ~~dentist~~ dentist, or qualified anesthetist or qualified anesthesiologist as defined in Rule .0103 of this Subchapter, shall administer anesthetic ~~agents (general and regional).~~ agents. Podiatrists shall administer only local anesthesia. The governing authority shall establish written policies and procedures concerning the provision of anesthesia services, including the designation of those persons authorized to administer ~~anesthetics.~~ anesthetics in accordance with State law.

History Note: *Authority G.S. 131E-149;*
Eff. October 14, ~~1978.~~ 1978;
Readopted Eff. January 1, 2021.

10A NCAC 13C .0702 is amended as published in 34:24 NCR 2375-2377 as follows:

10A NCAC 13C .0702 REGULATIONS FOR PERFORMED SERVICES

Radiation protection shall be provided in accordance with the rules and regulations adopted by the Radiation Protection Commission found in ~~10 NCAC 3G, and the recommendations of the National Council on Radiation Protection and Measurements.~~ 10A NCAC 15. Records shall be kept of at least annual checks and calibration of all ionizing radiation therapy equipment used in the facility.

History Note: *Authority G.S. 131E-149;*
Eff. October 14, 1978;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 23, ~~2017.~~ 2017;
Amended Eff. January 1, 2021.

10A NCAC 13C .0902 is readopted as published in 34:24 NCR 2375-2377 as follows:

10A NCAC 13C .0902 NURSING PERSONNEL

(a) ~~An adequate number of licensed~~ Licensed and ancillary nursing personnel shall be on duty to assure that staffing levels meet the ~~total~~ nursing needs of patients ~~based on the number of patients~~ in the facility and their individual nursing care needs.

(b) At least one registered nurse shall be in the facility during the hours ~~it is in~~ of operation. Nursing personnel shall be assigned to duties consistent with their training and experience.

History Note: *Authority G.S. 131E-149;*
Eff. October 14, ~~1978.~~ 1978;
Readopted Eff. January 1, 2021.

10A NCAC 13K .0102 is readopted as published in 34:24 NCR 2380-2383 as follows:

10A NCAC 13K .0102 DEFINITIONS

In addition to the definitions set forth in G.S. ~~131E-201~~ 131E-201, the following definitions shall apply throughout this ~~Subchapter following:~~ Subchapter:

(1) "Agency" means a licensed hospice as defined in ~~Article 10~~ G.S. 131E-201(3).

~~(2) "Attending Physician" means the physician licensed to practice medicine in North Carolina who is identified by the patient at the time of hospice admission as having the most significant role in the determination and delivery of medical care for the patient.~~

~~(3)~~(2) "Care Plan" means the proposed method developed in writing by the interdisciplinary care team through which the hospice seeks to provide services ~~which~~ that meet the patient's and family's medical, ~~psychosocial~~ psychosocial, and spiritual needs.

~~(4)~~(3) "Clergy Member" means an individual who has received a degree ~~from an~~ from a theological school and has fulfilled ~~appropriate~~ denominational seminary requirements; or an individual who, by ordination or authorization from the individual's denomination, has been approved to function in a pastoral capacity. Each hospice shall designate a clergy member responsible for coordinating spiritual care to hospice patients and families.

~~(5)~~(4) "Coordinator of Patient Family Volunteers" means an individual on the hospice ~~staff~~ team who coordinates and supervises the activities of all patient family volunteers.

~~(6)~~(5) "Dietary Counseling" means counseling given by a licensed ~~dietitian~~ dietitian, licensed dietitian/nutritionist, or licensed nutritionist as defined in ~~G.S. 90-357.~~ G.S. 90-352.

~~(7)~~(6) "Director" means the person having administrative responsibility for the operation of the hospice.

(7) "Division" means the Division of Health Service Regulation of the North Carolina Department of Health and Human Services.

(8) "Governing Body" means the group of persons responsible for overseeing ~~the~~ operations of the hospice, ~~specifically for~~ including the development and monitoring of policies and procedures related to all aspects of the operations of the hospice program. The governing body ensures that all services provided are consistent with accepted standards of hospice practice.

(9) "Hospice" means a coordinated program of services as defined in G.S. ~~131E-176(13a).~~ 131E-201.

(10) "Hospice Caregiver" means an individual on the hospice ~~staff~~ team who has completed hospice caregiver training as defined in ~~10A NCAC 13K~~ Rule .0402 of this Subchapter and is assigned to a hospice residential facility or hospice inpatient unit.

(11) "Hospice Inpatient Facility or Hospice Inpatient Unit" means ~~a licensed facility~~ as defined in ~~G.S. 131E-201(3).~~ G.S.131E-201(3a).

(12) "Hospice Residential Facility" means as defined in ~~G.S. 131E-201(5) is a facility licensed to provide hospice care to hospice patients as defined in G.S. 131E-201(4) and their families in a group residential setting.~~ G.S. 131E-201(5a).

(13) "Hospice ~~Staff"~~ Team" means ~~members of the interdisciplinary team~~ as defined in ~~G.S. 131E-201(7), nurse aides, administrative and support personnel and patient family volunteers.~~ G.S. 131E-201(6).

(14) "Informed Consent" means the agreement to receive hospice care made by the patient and family ~~which~~ that specifies in writing the type of care and services to be provided. The informed consent form shall be signed by the patient prior to service. If the patient's medical condition is such that a signature cannot be obtained, a signature shall be obtained from the individual having legal guardianship, applicable durable or health care power of attorney, or the family member or individual assuming the responsibility of primary caregiver.

~~(15) "Inpatient Beds" means beds licensed as such by the Department of Health and Human Services for use by hospice patients, for medical management of symptoms or for respite care.~~

~~(16)~~(15) "Interdisciplinary Team" means ~~a group of hospice staff~~ as defined in ~~G.S. 131E-201(7).~~ G.S. 131E-201(6).

~~(17)~~(16) "Licensed Practical Nurse" means ~~a nurse holding a valid current license as required by G.S. 90, Article 9A.~~ as defined in G.S. 90-171.30 or G.S. 171.32.

~~(18)~~(17) "Medical Director" means a physician licensed to practice medicine in North Carolina who directs the medical aspects of the hospice's patient care program.

(18) "Nurse Practitioner" means as defined in G.S. 90-18.2(a).

(19) "Nurse Aide" means an individual who is authorized to provide nursing care under the supervision of a licensed nurse, has completed a training and competency evaluation program or competency evaluation program and is listed on the Nurse Aide Registry, at the Division of Health Service Regulation. If the nurse aide performs Nurse Aide II tasks, ~~he or she~~ the nurse aide ~~must~~ shall also meet the requirements established by the N.C. Board of Nursing as defined in 21 NCAC 36 ~~.0405.~~ .0405, incorporated by reference including subsequent amendments and editions. This Rule may be accessed at http://reports.oah.state.nc.us/ncac.asp at no charge.

~~(20) "Occupational Therapist" means a person duly licensed as such, holding a current license as required by G.S. 90-270.29.~~

~~(21)~~(20) "Patient and Family Care Coordinator" means a registered nurse designated by the hospice to coordinate the provision of hospice services for each patient and family.

~~(22)~~(21) "Patient Family Volunteer" means an individual who has received orientation and training as defined in Rule .0402 of this Subchapter, and provides volunteer services to a patient and the patient's family in the patient's home or in a hospice inpatient facility or hospice inpatient unit, or a hospice residential facility.

~~(23)~~(22) "Pharmacist" means ~~an individual licensed to practice pharmacy in North Carolina as required in G.S. 90-85(15).~~ as defined in G.S. 90-85.3.

~~(24) "Physical Therapist" means an individual holding a valid current license as required by G.S. 90, Article 18B.~~

~~(25)~~(23) "Physician" means ~~an individual licensed to practice medicine in North Carolina.~~ as defined in G.S. 90-9.1 or G.S. 90-9.2.

~~(26)~~(24) "Premises" means the location or licensed site ~~from which~~ where the agency provides hospice services or maintains patient service records or advertises itself as a hospice agency.

~~(27)~~(25) "Primary Caregiver" means the family member or other person who assumes the overall responsibility for the care of the patient in the patient's home.

~~(28)~~(26) "Registered Nurse" means ~~a nurse holding a valid current license as required by G.S. 90, Article 9A.~~ as defined in G.S. 90-171.30 or G.S. 90-171.32.

~~(29)~~(27) "Respite Care" means care provided to a patient for temporary relief to family members or others caring for the patient at home.

~~(30) "Social Worker" means an individual who performs social work and holds a bachelor's or advanced degree in social work from a school accredited by the Council of Social Work Education or a bachelor's or an advanced degree in psychology, counseling or psychiatric nursing.~~

~~(31) "Speech and Language Pathologist" means an individual holding a valid current license as required by G.S. 90, Article 22.~~

~~(32)~~(28) "Spiritual Caregiver" means an individual authorized by the patient and family to provide for their spiritual ~~direction.~~ needs.

History Note: *Authority G.S. 131E-202;*
Eff. November 1, 1984;
Amended Eff. February 1, 1996; February 1, 1995; June 1, 1991; November 1, ~~1989.~~ 1989;
Readopted Eff. January 1, 2021.

10A NCAC 13K .0401 is readopted as published in 34:24 NCR 2380-2383 as follows:

SECTION .0400 - PERSONNEL

10A NCAC 13K .0401 PERSONNEL

(a) Written policies shall be established and implemented by the agency regarding infection control and exposure to communicable diseases consistent with the rules set forth in 10A NCAC ~~41A.~~ 41A, which is incorporated by reference, including subsequent amendments and editions. These policies and procedures shall include provisions for compliance with 29 CFR 1910 ~~(Occupational~~ Occupational Safety and Health ~~Standards)~~ Standards, which is incorporated by reference including subsequent ~~amendments.~~ amendments and editions. ~~Emphasis shall be placed on compliance with~~ These editions shall include 29 CFR 1910.1030 ~~(Airborne and Bloodborne Pathogens).~~ Bloodborne Pathogens. Copies of Title 29 Part 1910 can be ~~purchased from the Superintendent of Documents, U.S. Government Printing Office, P.O. Box 371954, Pittsburgh, PA 15250-7954 or by calling Washington, D.C. (202) 512-1800. The cost is twenty-one dollars ($21.00) and may be purchased with a credit card.~~ obtained online at no charge at https://www.osha.gov/pls/oshaweb/owadisp.show_document?p_id=10051&p_table=STANDARDS.

(b) Hands-on care employees ~~must~~ shall have a baseline ~~skin~~ test for tuberculosis. Individuals who test positive ~~must~~ shall demonstrate non-infectious status prior to assignment in a patient's home. Individuals who have previously tested positive to the tuberculosis ~~skin~~ test shall obtain a baseline and subsequent annual verification that they are free of tuberculosis symptoms. The verification shall be obtained from the local health department, a private ~~physician~~ physician, or health nurse employed by the agency. The ~~Tuberculosis Control~~ Communicable Disease Branch of the North Carolina Department of Health and Human Services, Division of Public Health, ~~1902~~ 1905 Mail Service Center, Raleigh, NC ~~27699-1902~~ 27699-1905 will ~~provide,~~ provide free of charge guidelines for conducting and verification utilizing ~~and~~ Form ~~DEHNR~~ DHHS 3405 (Record of Tuberculosis Screening). Employees identified by agency risk assessment to be at risk for exposure ~~are required to~~ shall be subsequently tested ~~at intervals prescribed by OSHA standards.~~ in accordance with Centers for Disease Control (CDC) guidelines, which is incorporated by reference with subsequent amendments and editions. A copy of the CDC guidelines can be obtained online at no charge at https://search.cdc.gov/search/?query=TB+testing+intervals&sitelimit=&utf8=%E2%9C%93&affiliate=cdc-main.

~~(b)~~(c) Written policies shall be established and implemented ~~which~~ by the agency that include personnel record content, orientation, patient family volunteer training, and in-service education. Records on the subject of in-service education and attendance shall be maintained by the agency and retained for ~~at least~~ one year.

~~(c)~~(d) Job descriptions for every position, including volunteers involved in direct patient/family services, shall be established ~~in writing which~~ by the agency and shall include the position's qualifications and specific responsibilities. ~~Individuals~~ Hospice team member(s) shall be assigned only to duties ~~for which~~ that they are trained and competent to ~~perform and when applicable for which they are properly licensed.~~ perform, or licensed to perform.

~~(d)~~(e) Personnel records shall be established and maintained for ~~all~~ hospice ~~staff,~~ team, both paid and direct patient/family services volunteers. These records shall be maintained ~~at least~~ for one year after ~~termination from~~

~~agency employment.~~ employment or volunteer service ends. When ~~requested,~~ requested by the State surveyors, the records shall be available on the agency premises for inspection by the Department. The records shall include:

(1) an application or resume ~~which~~ that lists education, ~~training~~ training, and previous employment that can be verified, including job title;

(2) a job description with record of acknowledgment by the ~~staff;~~ team member(s);

(3) reference checks or verification of previous employment;

(4) records of tuberculosis annual screening for ~~those employees for whom the test is necessary as described in Paragraph (a) of this Rule;~~ hands-on care team;

(5) documentation of Hepatitis B immunization or declination for hands on care ~~staff;~~ team;

(6) ~~airborne and~~ bloodborne pathogen training for ~~hands on~~ hands-on care ~~staff,~~ team, including annual updates, in compliance with 29 CFR 1910 and in accordance with the agency's exposure control plan;

(7) performance evaluations according to agency ~~policy and~~ policy, or at least annually;

(8) verification of ~~staff credentials as applicable;~~ team member(s) credentials;

(9) records of the verification of competencies by agency supervisory personnel of ~~all~~ skills required of hospice services personnel to carry out patient care ~~tasks to which the staff is assigned.~~ tasks. The method of verification shall be defined in agency policy.

History Note: *Authority G.S. 131E-202;*
Eff. November 1, 1984;
Amended Eff. February 1, 1996; November 1, ~~1989~~ 1989;
Readopted Eff. January 1, 2021.

10A NCAC 13K .0604 is readopted as published in 34:24 NCR 2380-2383 as follows:

10A NCAC 13K .0604 PATIENT'S RIGHTS AND RESPONSIBILITIES

(a) A hospice agency shall provide each patient with a written notice of the patient's rights and responsibilities in advance of furnishing care to the patient or during the initial evaluation visit before the initiation of services. The agency ~~must~~ shall maintain documentation showing that each patient has received a copy of ~~his~~ their rights and ~~responsibilities.~~ responsibilities as defined in G.S. 131E-144.3.

~~(b) The notice shall include at a minimum the patient's right to:~~

~~(1) be informed and participate in the patient's plan of care;~~

~~(2) voice grievances about the patient's care and not be subjected to discrimination or reprisal for doing so;~~

~~(3) confidentiality of the patient's records;~~

~~(4) be informed of the patient's liability for payment for services;~~

~~(5) be informed of the process for acceptance and continuance of service and eligibility determination;~~

~~(6) accept or refuse services;~~

~~(7) be informed of the agency's on-call service;~~

~~(8) be advised of the agency's procedures for discharge; and~~

~~(9) be informed of supervisory accessibility and availability~~

~~(c)~~(b) A hospice agency shall provide ~~all~~ patients with a business hours telephone number for information, ~~questions~~ questions, or complaints about services provided by the agency. The agency shall also provide the Division of Health Service Regulation's complaints ~~number and the Department of Health and Human Services Careline number.~~ intake telephone numbers: within N.C. (800) 624-3004; outside of N.C. (919) 855-4500. The Division of Health Service Regulation shall investigate all allegations of non-compliance with the ~~rules.~~ rules of this Subchapter.

~~(d)~~(c) A hospice agency shall initiate an investigation within ~~72 hours~~ 72 hours of complaints made by a patient or his or her family. Documentation of both the existence of the complaint and the resolution of the complaint shall be maintained by the ~~agency.~~ agency, at a minimum of one-year, in accordance with hospice agency policy and procedures.

History Note: *Authority G.S. 131E-202;*
Eff. February 1, ~~1996.~~ 1996;
Readopted Eff. January 1, 2021.

10A NCAC 13K .0701 is readopted as published in 34:24 NCR 2380-2383 as follows:

SECTION .0700 - PATIENT/FAMILY CARE PLAN

10A NCAC 13K .0701 CARE PLAN

(a) The ~~hospice~~ agency shall develop and implement policies and procedures ~~which~~ that ensure ~~that~~ a written care plan is developed and maintained for each patient and family. The plan shall be established by the interdisciplinary ~~care~~ team in accordance with the orders of the attending physician and be based on the ~~complete~~ assessment of the patient's and family's medical, ~~psychosocial~~ psychosocial, and spiritual needs. The patient and family care coordinator shall have the primary responsibility for assuring the implementation of the patient's care plan. The care plan shall include the following:

(1) the patient's diagnosis and prognosis;

(2) the identification of problems or needs and the establishment of ~~appropriate goals;~~ goals that are appropriate for the patient;

(3) the types and frequency of services required to meet the goals; and

(4) the identification of personnel and disciplines responsible for each service.

(b) The care plan shall be reviewed by ~~appropriate~~ the interdisciplinary ~~care~~ team members and updated ~~at least once~~ monthly. The interdisciplinary ~~care~~ team and other ~~appropriate~~ personnel shall meet at ~~least once~~ a minimum every ~~two weeks~~ 15 days for the purpose of care plan review and staff support. Minutes shall be kept of these meetings that include the date, names of those in ~~attendance~~ attendance, and the names of the patients discussed. Additionally, entries shall be recorded in the medical records of those patients whose care plans are reviewed.

History Note: *Authority G.S. 131E-202;*
Eff. November 1, 1984;
Amended Eff. February 1, 1996; November 1, ~~1989.~~ 1989;
Readopted Eff. January 1, 2021.

10A NCAC 13K .1104 is readopted as published in 34:24 NCR 2380-2383 as follows:

10A NCAC 13K .1104 DIETARY SERVICES

(a) The hospice shall develop and maintain written policies and procedures for dietary services.

(b) Dietary services shall be provided directly or ~~may be provided~~ through written agreement with a food service company. The written agreement, ~~if applicable,~~ shall meet the provisions of Rule .0505 of this Subchapter.

(c) The hospice shall assure that residents' favorite foods are included in their diets whenever possible.

(d) The food service shall be planned and staffed to serve three balanced meals at regular intervals or at a variety of times depending upon the needs of the residents. No more than 14 hours shall elapse between a substantial evening meal and breakfast.

(e) The hospice shall appoint a staff member trained or experienced in food management to:

(1) plan menus to meet the nutritional needs of the ~~residents.~~ residents; and

(2) supervise meal preparation and service.

(f) Therapeutic diets shall be prescribed by the physician and planned by a registered dietitian.

(g) Between-meal snacks of nourishing quality shall be offered and be available on a ~~24 hour~~ 24-hour basis.

(h) The procurement, ~~storage~~ storage, and refrigeration of food, refuse ~~handling~~ handling, and pest control shall comply with ~~the most current sanitation rules~~ 15A NCAC 18A which are hereby incorporated by reference, including subsequent amendments and editions promulgated by the ~~Division of Environmental~~ Commission for Public Health. These rules may be accessed at http://reports.oah.state.nc.us/ncac.asp free of charge.

History Note: *Authority G.S. 131E-202;*
Eff. June 1, ~~1991.~~ 1996;
Readopted Eff. January 1, 2021.

Fiscal Impact Analysis
Readoption Rules without Substantial Economic Impact

Agency Proposing Rule Change
North Carolina Medical Care Commission

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

Title of Rules Changes and Statutory Citation

Rule Readoptions:
10A NCAC 13K .0102 Definitions
10A NCAC 13K .0401 Personnel
10A NCAC 13K .0604 Patient's Rights and Responsibilities
10A NCAC 13K .0701 Patient/Family Care Plan
10A NCAC 13K .1104 Dietary Services

*See Appendix for rule text

Statutory Authority
G.S. 131E-202

Background and Purpose
The Medical Care Commission is proposing to update Hospice licensure rules that, in some cases, have not been updated in 24 years. There are 209 licensed Hospice Agencies in North Carolina. The amendments will update practices and language to current industry standards, address previous Rules Review Commission objections, and implement technical changes for clarification. Changes will also allow reference to the General Statute.

Under authority of G.S. 150B-21-3A, Periodic review and expiration of existing rules, the Medical Care Commission, Rules Review Commission and the Joint Legislative Administrative Procedure Oversight Committee approved the Subchapter report with classifications for the rules located at 10A NCAC 13K Rules Hospice Licensing Rules: on August 10, 2018, October 18, 2018, and December 22, 2018 respectively. A total of five (5) rules were determined necessary with substantive public interest and therefore subject to readoption as new rules. The rule readoptions presented in this fiscal analysis will be for the Hospice Rules readoptions required by G.S. 150B-21.3.A.A Hospice stakeholder group was put together to assist in the rule readoption by providing expertise and providing input on Hospice processes, current standards of practice, and to ensure Hospices have an opportunity to provide input as we move forward with the readoption process.

Rules Summary and Anticipated Fiscal Impact

Rule 13K .0102 – Definitions
The agency is proposing to readopt this rule with substantive changes. This rule lists definitions that apply throughout the Subchapter and is being changed to update definitions, delete definitions that are no longer used in the Subchapter, to relocate definitions to other existing rules, and to reference definitions in the General Statute. Generally, the definitions in the statute are the same as those used in the rule. There are several minor differences that are noted in the General Statute definitions, but those minor differences do not materially change the scope of the definition and are not any more stringent than the definitions in the current rule; therefore, the agency does not expect these changes to have any fiscal impact. The definitions in the General Statute will always prevail. Six definitions are not utilized in the Subchapter and were deleted.

Rule 13K.0401 - Personnel:
The agency is proposing to readopt this rule with substantive changes. The rule was last amended in 1996. This rule changes in parts (a) and (c)-(e) include technical and grammatical corrections to outdated language and nomenclature. Substantive changes in part (b) update the reference for TB testing guidelines for at-risk employees. These changes have no economic impact as TB testing following the new CDC guidelines is already required by the existing public health rule 10A NCAC 13J .1003 for staff working in health care and going into individuals' homes to provide care. Furthermore, the TB testing costs under the new CDC guidelines are not significantly different than testing under the previous OSHA guidelines.

Rule 13K .0604 - Patients Rights and Responsibilities:
The agency is proposing to readopt this rule with substantive changes. The rule was last updated in 1996. It had outdated language and references to out dated patients' rights. These changes provide that clarity and updated information by referencing the patients' rights requirements in the General Statutes. The requirements in statute are already independently enforceable; these conforming rule amendments are simply technical corrections for clarity with no fiscal impact.

Rule 13K .0701 - Care Plan and Rule 13K 1104 - Dietary Services
The agency is proposing to readopt these rules without substantive changes other than correcting grammar and removing ambiguous words. These rules have not been updated since 1996.

10A NCAC 13K .0102 is proposed for readoption with substantive changes as follows:

10A NCAC 13K .0102 DEFINITIONS

In addition to the definitions set forth in G.S. ~~131E-201~~ 131E-201, the following definitions shall apply throughout this ~~Subchapter following:~~ Subchapter:

(1) "Agency" means a licensed hospice as defined in ~~Article 10~~ G.S. 131E-201(3).

~~(2) "Attending Physician" means the physician licensed to practice medicine in North Carolina who is identified by the patient at the time of hospice admission as having the most significant role in the determination and delivery of medical care for the patient.~~

~~(3)~~(2) "Care Plan" means the proposed method developed in writing by the interdisciplinary care team through which the hospice seeks to provide services ~~which~~ that meet the patient's and family's medical, ~~psychosocial~~ psychosocial, and spiritual needs.

~~(4)~~(3) "Clergy Member" means an individual who has received a degree ~~from an~~ from a theological school and has fulfilled ~~appropriate~~ denominational seminary requirements; or an individual who, by ordination or authorization from the individual's denomination, has been approved to function in a pastoral capacity. Each hospice shall designate a clergy member responsible for coordinating spiritual care to hospice patients and families.

~~(5)~~(4) "Coordinator of Patient Family Volunteers" means an individual on the hospice ~~staff~~ team who coordinates and supervises the activities of all patient family volunteers.

~~(6)~~(5) "Dietary Counseling" means counseling given by a licensed ~~dietitian~~ dietitian, licensed dietitian/nutritionist, or licensed nutritionist as defined in ~~G.S. 90-357.~~ G.S. 90-352.

~~(7)~~(6) "Director" means the person having administrative responsibility for the operation of the hospice.

(7) "Division" means the Division of Health Service Regulation of the North Carolina Department of Health and Human Services.

(8) "Governing Body" means the group of persons responsible for overseeing ~~the~~ operations of the hospice, ~~specifically for~~ including the development and monitoring of policies and procedures related to all aspects of the operations of the hospice program. The governing body ensures that all services provided are consistent with accepted standards of hospice practice.

(9) "Hospice" means a coordinated program of services as defined in G.S. ~~131E-176(13a).~~ 131E-201.

(10) "Hospice Caregiver" means an individual on the hospice ~~staff~~ team who has completed hospice caregiver training as defined in ~~10A NCAC 13K~~ Rule .0402 of this Subchapter and is assigned to a hospice residential facility or hospice inpatient unit.

(11) "Hospice Inpatient Facility or Hospice Inpatient Unit" means ~~a licensed facility~~ as defined in ~~G.S. 131E-201(3).~~ G.S.131E-201(3a).

(12) "Hospice Residential Facility" means as defined in ~~G.S. 131E-201(5) is a facility licensed to provide hospice care to hospice patients as defined in G.S. 131E-201(4) and their families in a group residential setting.~~ G.S. 131E-201(5a).

(13) "Hospice ~~Staff"~~ Team" means ~~members of the interdisciplinary team~~ as defined in ~~G.S. 131E-201(7), nurse aides, administrative and support personnel and patient family volunteers.~~ G.S. 131E-201(6).

(14) "Informed Consent" means the agreement to receive hospice care made by the patient and family ~~which~~ that specifies in writing the type of care and services to be provided. The informed consent form shall be signed by the patient prior to service. If the patient's medical condition is such that a signature cannot be obtained, a signature shall be obtained from the individual having legal guardianship, applicable durable or health care power of attorney, or the family member or individual assuming the responsibility of primary caregiver.

~~(15) "Inpatient Beds" means beds licensed as such by the Department of Health and Human Services for use by hospice patients, for medical management of symptoms or for respite care.~~

~~(16)~~(15) "Interdisciplinary Team" means ~~a group of hospice staff~~ as defined in ~~G.S. 131E-201(7).~~ G.S. 131E-201(6).

~~(17)~~(16) "Licensed Practical Nurse" means ~~a nurse holding a valid current license as required by G.S. 90, Article 9A.~~ as defined in G.S. 90-171.30 or G.S. 171.32.

~~(18)~~(17) "Medical Director" means a physician licensed to practice medicine in North Carolina who directs the medical aspects of the hospice's patient care program.

(18) "Nurse Practitioner" means as defined in G.S. 90-18.2(a).

~~(19)~~(19) "Nurse Aide" means an individual who is authorized to provide nursing care under the supervision of a licensed nurse, has completed a training and competency evaluation program or competency evaluation program and is listed on the Nurse Aide Registry, at the Division of Health Service Regulation. If the nurse aide performs Nurse Aide II tasks, ~~he or she~~ the nurse aide ~~must~~ shall also meet the requirements established by the N.C. Board of Nursing as defined in 21 NCAC 36 ~~.0405.~~ .0405, incorporated by reference including subsequent amendments and editions. This rule may be accessed at http://reports.oah.state.nc.us/ncac.asp at no charge.

~~(20) "Occupational Therapist" means a person duly licensed as such, holding a current license as required by G.S. 90-270.29.~~

~~(21)~~(20) "Patient and Family Care Coordinator" means a registered nurse designated by the hospice to coordinate the provision of hospice services for each patient and family.

~~(22)~~(21) "Patient Family Volunteer" means an individual who has received orientation and training as defined in Rule .0402 of this Subchapter, and provides volunteer services to a patient and the patient's family in the patient's home or in a hospice inpatient facility or hospice inpatient unit, or a hospice residential facility.

~~(23)~~(22) "Pharmacist" means ~~an individual licensed to practice pharmacy in North Carolina as required in G.S. 90-85(15).~~ as defined in G.S. 90-85.3.

~~(24) "Physical Therapist" means an individual holding a valid current license as required by G.S. 90, Article 18B.~~

~~(25)~~(23) "Physician" means ~~an individual licensed to practice medicine in North Carolina.~~ as defined in G.S. 90-9.1 or G.S. 90-9.2.

~~(26)~~(24) "Premises" means the location or licensed site ~~from which~~ where the agency provides hospice services or maintains patient service records or advertises itself as a hospice agency.

~~(27)~~(25) "Primary Caregiver" means the family member or other person who assumes the overall responsibility for the care of the patient in the patient's home.

~~(28)~~(26) "Registered Nurse" means ~~a nurse holding a valid current license as required by G.S. 90, Article 9A.~~ as defined in G.S. 90-171.30 or G.S. 90-171.32.

~~(29)~~(27) "Respite Care" means care provided to a patient for temporary relief to family members or others caring for the patient at home.

~~(30) "Social Worker" means an individual who performs social work and holds a bachelor's or advanced degree in social work from a school accredited by the Council of Social Work Education or a bachelor's or an advanced degree in psychology, counseling or psychiatric nursing.~~

~~(31) "Speech and Language Pathologist" means an individual holding a valid current license as required by G.S. 90, Article 22.~~

~~(32)~~(28) "Spiritual Caregiver" means an individual authorized by the patient and family to provide for their spiritual ~~direction.~~ needs.

History Note: *Authority G.S. 131E-202;*
Eff. November 1, 1984;
Amended Eff. February 1, 1996; February 1, 1995; June 1, 1991; November 1, ~~1989.~~ 1989;
Readopted Eff. January 1, 2021.

10A NCAC 13K .0401 is proposed for readoption with substantive changes as follows:

SECTION .0400 - PERSONNEL

10A NCAC 13K .0401 PERSONNEL

(a) Written policies shall be established and implemented by the agency regarding infection control and exposure to communicable diseases consistent with the rules set forth in 10A NCAC ~~41A.~~ 41A, which is incorporated by reference, including subsequent amendments and editions. These policies and procedures shall include provisions for compliance

with 29 CFR 1910 ~~(Occupational~~ Occupational Safety and Health ~~Standards)~~ Standards, which is incorporated by reference including subsequent ~~amendments.~~ amendments and editions. ~~Emphasis shall be placed on compliance with~~ These editions shall include 29 CFR 1910.1030 ~~(Airborne and Bloodborne Pathogens).~~ Bloodborne Pathogens. Copies of Title 29 Part 1910 can be ~~purchased from the Superintendent of Documents, U.S. Government Printing Office, P.O. Box 371954, Pittsburgh, PA 15250-7954 or by calling Washington, D.C. (202) 512-1800. The cost is twenty-one dollars ($21.00) and may be purchased with a credit card.~~ obtained online at no charge at https://www.osha.gov/pls/oshaweb/owadisp.show_document?p_id=10051&p_table=STANDARDS.

(b) Hands-on care employees ~~must~~ shall have a baseline ~~skin~~ test for tuberculosis. Individuals who test positive ~~must~~ shall demonstrate non-infectious status prior to assignment in a patient's home. Individuals who have previously tested positive to the tuberculosis ~~skin~~ test shall obtain a baseline and subsequent annual verification that they are free of tuberculosis symptoms. The verification shall be obtained from the local health department, a private ~~physician~~ physician, or health nurse employed by the agency. The ~~Tuberculosis Control~~ Communicable Disease Branch of the North Carolina Department of Health and Human Services, Division of Public Health, ~~1902~~ 1905 Mail Service Center, Raleigh, NC ~~27699-1902~~ 27699-1905 will ~~provide,~~ provide free of charge guidelines for conducting and verification utilizing ~~and~~ Form ~~DEHNR~~ DHHS 3405 (Record of Tuberculosis Screening). Employees identified by agency risk assessment to be at risk for exposure ~~are required to~~ shall be subsequently tested ~~at intervals prescribed by OSHA standards.~~ in accordance with Centers for Disease Control (CDC) guidelines, which is incorporated by reference with subsequent amendments and editions. A copy of the CDC guidelines can be obtained online at no charge at https://search.cdc.gov/search/?query=TB+testing+intervals&sitelimit=&utf8=%E2%9C%93&affiliate=cdc-main.

~~(b)~~(c) Written policies shall be established and implemented ~~which~~ by the agency that include personnel record content, orientation, patient family volunteer training, and in-service education. Records on the subject of in-service education and attendance shall be maintained by the agency and retained for ~~at least~~ one year.

~~(c)~~(d) Job descriptions for every position, including volunteers involved in direct patient/family services, shall be established ~~in writing which~~ by the agency and shall include the position's qualifications and specific responsibilities. ~~Individuals~~ Hospice team member(s) shall be assigned only to duties ~~for which~~ that they are trained and competent to ~~perform and when applicable for which they are properly licensed.~~ perform, or licensed to perform.

~~(d)~~(e) Personnel records shall be established and maintained for ~~all~~ hospice ~~staff,~~ team, both paid and direct patient/family services volunteers. These records shall be maintained ~~at least~~ for one year after ~~termination from agency employment.~~ employment or volunteer service ends. When ~~requested,~~ requested by the State surveyors, the records shall be available on the agency premises for inspection by the Department. The records shall include:

(1) an application or resume ~~which~~ that lists education, ~~training~~ training, and previous employment that can be verified, including job title;

(2) a job description with record of acknowledgment by the ~~staff;~~ team member(s);

(3) reference checks or verification of previous employment;

(4) records of tuberculosis annual screening for ~~those employees for whom the test is necessary as described in Paragraph (a) of this Rule;~~ hands-on care team;

(5) documentation of Hepatitis B immunization or declination for hands on care ~~staff;~~ team;

(6) ~~airborne and~~ bloodborne pathogen training for ~~hands-on~~ hands-on care ~~staff,~~ team, including annual updates, in compliance with 29 CFR 1910 and in accordance with the agency's exposure control plan;

(7) performance evaluations according to agency ~~policy and~~ policy, or at least annually;

(8) verification of ~~staff credentials as applicable;~~ team member(s) credentials;

(9) records of the verification of competencies by agency supervisory personnel of ~~all~~ skills required of hospice services personnel to carry out patient care ~~tasks to which the staff is assigned.~~ tasks. The method of verification shall be defined in agency policy.

History Note: *Authority G.S. 131E-202;*
Eff. November 1, 1984;
Amended Eff. February 1, 1996; November 1, ~~1989~~ 1989;
Readopted Eff. January 1, 2021.

10A NCAC 13K .0604 is proposed for readoption with substantive changes as follows:

10A NCAC 13K .0604 PATIENT'S RIGHTS AND RESPONSIBILITIES

(a) A hospice agency shall provide each patient with a written notice of the patient's rights and responsibilities in advance of furnishing care to the patient or during the initial evaluation visit before the initiation of services. The agency ~~must~~ shall maintain documentation showing that each patient has received a copy of ~~his~~ their rights and ~~responsibilities.~~ responsibilities as defined in G.S. 131E-144.3.

~~(b) The notice shall include at a minimum the patient's right to:~~

~~(1) be informed and participate in the patient's plan of care;~~

~~(2) voice grievances about the patient's care and not be subjected to discrimination or reprisal for doing so;~~

~~(3) confidentiality of the patient's records;~~

~~(4) be informed of the patient's liability for payment for services;~~

~~(5) be informed of the process for acceptance and continuance of service and eligibility determination;~~

~~(6) accept or refuse services;~~

~~(7) be informed of the agency's on-call service;~~

~~(8) be advised of the agency's procedures for discharge; and~~

~~(9) be informed of supervisory accessibility and availability~~

~~(c)~~(b) A hospice agency shall provide ~~all~~ patients with a business hours telephone number for information, ~~questions~~ questions, or complaints about services provided by the agency. The agency shall also provide the Division of Health Service Regulation's complaints ~~number and the Department of Health and Human Services Careline number.~~ intake

telephone numbers: within N.C. (800) 624-3004; outside of N.C. (919) 855-4500. The Division of Health Service Regulation shall investigate all allegations of non-compliance with the ~~rules.~~ rules of this Subchapter.

~~(d)~~(c) A hospice agency shall initiate an investigation within ~~72 hours~~ 72 hours of complaints made by a patient or his or her family. Documentation of both the existence of the complaint and the resolution of the complaint shall be maintained by the ~~agency.~~ agency, at a minimum of one-year, in accordance with hospice agency policy and procedures.

History Note: *Authority G.S. 131E-202;*
Eff. February 1, ~~1996.~~ 1996;
Readopted Eff. January 1, 2021.

10A NCAC 13K .0701 is proposed for readoption without substantive changes as follows:

SECTION .0700 - PATIENT/FAMILY CARE PLAN

10A NCAC 13K .0701 CARE PLAN

(a) The ~~hospice~~ agency shall develop and implement policies and procedures ~~which~~ that ensure ~~that~~ a written care plan is developed and maintained for each patient and family. The plan shall be established by the interdisciplinary ~~care~~ team in accordance with the orders of the attending physician and be based on the ~~complete~~ assessment of the patient's and family's medical, ~~psychosocial~~ psychosocial, and spiritual needs. The patient and family care coordinator shall have the primary responsibility for assuring the implementation of the patient's care plan. The care plan shall include the following:

(1) the patient's diagnosis and prognosis;

(2) the identification of problems or needs and the establishment of ~~appropriate goals;~~ goals that are appropriate for the patient;

(3) the types and frequency of services required to meet the goals; and

(4) the identification of personnel and disciplines responsible for each service.

(b) The care plan shall be reviewed by ~~appropriate~~ the interdisciplinary ~~care~~ team members and updated ~~at least once~~ monthly. The interdisciplinary ~~care~~ team and other ~~appropriate~~ personnel shall meet at ~~least once~~ a minimum every ~~two weeks~~ 15 days for the purpose of care plan review and staff support. Minutes shall be kept of these meetings that include the date, names of those in ~~attendance~~ attendance, and the names of the patients discussed. Additionally, entries shall be recorded in the medical records of those patients whose care plans are reviewed.

History Note: *Authority G.S. 131E-202;*
Eff. November 1, 1984;

Amended Eff. February 1, 1996; November 1, ~~1989.~~ 1989;
Readopted Eff. January 1, 2021.

10A NCAC 13K .1104 is proposed for readoption without substantive changes as follows:

10A NCAC 13K .1104 DIETARY SERVICES

(a) The hospice shall develop and maintain written policies and procedures for dietary services.

(b) Dietary services shall be provided directly or ~~may be provided~~ through written agreement with a food service company. The written agreement, ~~if applicable,~~ shall meet the provisions of Rule .0505 of this Subchapter.

(c) The hospice shall assure that residents' favorite foods are included in their diets whenever possible.

(d) The food service shall be planned and staffed to serve three balanced meals at regular intervals or at a variety of times depending upon the needs of the residents. No more than 14 hours shall elapse between a substantial evening meal and breakfast.

(e) The hospice shall appoint a staff member trained or experienced in food management to:

(1) plan menus to meet the nutritional needs of the ~~residents.~~ residents; and

(2) supervise meal preparation and service.

(f) Therapeutic diets shall be prescribed by the physician and planned by a registered dietitian.

(g) Between-meal snacks of nourishing quality shall be offered and be available on a ~~24-hour~~ 24-hour basis.

(h) The procurement, ~~storage~~ storage, and refrigeration of food, refuse ~~handling~~ handling, and pest control shall comply with ~~the most current sanitation rules~~ 15A NCAC 18A which are hereby incorporated by reference, including subsequent amendments and editions promulgated by the ~~Division of Environmental~~ Commission for Public Health. These rules may be accessed at http://reports.oah.state.nc.us/ncac.asp free of charge.

History Note: *Authority G.S. 131E-202;*
Eff. June 1, ~~1991.~~ 1996;
Readopted Eff. January 1, 2021.

Exhibit C/4

Hospice Licensing Rules Readoption
10A NCAC 13K .0102, .0401, .0604, .0701, and .1104 – Public Comments
Comment Period 6/15/20 – 8/14/20

Introduction:

Three individuals submitted comments during the public comment period on the readoption of rules 10A NCAC 13K .0102, .0401, .0604, .0701, and .1104. Of these comments, two people made statements during the public hearing conducted on July 29, 2020. These comments were submitted by representatives from The Carolinas Center for Hospice and End of Life Care, Teleios Collaborative Healthcare, and The Joint Commission. A summary of all comments received on these rules is below:

1) Listing of Comments Received and Agency's Consideration of Comments for Readoption Rule 13K .0102 – Definitions:

Commenter	Comment Summary
The Carolinas Center for Hospice and End of Life Care (public hearing)	Worked a long time on the rules and had a lot of challenges. DHSR was very understanding and cooperative in working on removal of the social work definition. Questions whether removing this social worker definition will defer to the Medicare Hospice Rules in ensuring the appropriate staff is in that roll.

Agency Response to Comments Above:

The term social worker was not previously used in the NC Rules and Regulations governing the licensure of hospice agencies and supported deleting the term from definitions under 10A NCAC 13K .0102(30). The CMS Medicare regulations define qualifications of the social worker in Medicare certified hospice agencies. Medicare certified hospice agencies will be expected to be in compliance with the Medicare regulations.

2) Listing of Comments Received and Agency's Consideration of General Comments:

Commenter	Comment Summary
1) Teleios Collaborative Network (public hearing)	Thanked the DHSR team for the work on these rules and their work with stakeholders in addressing concerns on the rules. However, concerns about other rules in the Subchapter they had issues with were not addressed as these were the only rules proposed for change. Questioned if there was a way to submit concerns or if they had to wait until the next round to make rule changes.
2) The Joint Commission (TJC)	Supports our efforts to revise and update the Hospice minimum standards. Requests consideration to allow reliance on TJC accreditation for licensure renewal inspections for hospice licensees. 31 states rely on TJC home care services accreditation for licensure determination and it has proven effective in maintaining oversight while managing resources. Reliance on accreditation in lieu of license renewal inspections allows the Dept. to redirect

Commenter	Comment Summary
	their resources to essential activities such as initial licensure surveys and complaint investigations. TJC maintains open communication with the state for periodic status updates and informs them of adverse accreditation decisions. TJC provides a comprehensive evaluation of a facility's compliance with evidenced-based, continuously updated standards that are performance focused and organized around functions, developed by experts in the field. Organizations undergo an on-site survey by a TJC team at least every three yrs. to earn and maintain accreditation.

Agency Response to Comments Above:

1) **DHSR Comments: DHSR welcomes comments and recommendations to amend rules to promote the delivery of quality care and less burdensome on providers. There is no defined schedule for amendments or proposals to the rules. The stakeholder is welcome to submit a petition for rulemaking to the Medical Care Commission in accordance with G.S. 150 B and this process was shared with the stakeholder during the public hearing.**

2) **The DHSR annual licensure renewal process for licensed hospice agencies is a paper process that collects data for the development of the annual Medical Facilities Plan as opposed to an onsite state licensure survey. TJC quality of care survey process is not state specific and does not capture the data required to address and meet the needs of health care in North Carolina.**

10A NCAC 13D .2001 is amended as published in 34:24 NCR 2377-2380 as follows:

SECTION .2000 – GENERAL INFORMATION

10A NCAC 13D .2001 DEFINITIONS

In addition to the definitions set forth in 131E-101, the ~~The~~ following definitions ~~will~~ shall apply throughout this Subchapter:

(1) "Abuse" means the willful infliction of injury, unreasonable confinement, intimidation or punishment with resulting physical harm, pain, or mental anguish.

(2) "Accident" means an unplanned event resulting in the injury or wounding, no matter how slight, of a patient or other individual.

(3) "Addition" means an extension or increase in floor area or height of a building.

(4) "Administrator" as defined in G.S. 90-276(4).

(5) "Alteration" means any construction or renovation to an existing structure other than repair, maintenance, or addition.

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

(7) "Capacity" means the maximum number of patient or resident beds for which the facility is licensed to maintain at any given time.

(8) "Combination facility" means a combination home as defined in G.S. 131E-101.

(9) "Comprehensive, inpatient rehabilitation program" means a program for the treatment of persons with functional limitations or chronic disabling conditions who have the potential to achieve a significant improvement in activities of daily living, including bathing, dressing, grooming, transferring, eating, and using speech, language, or other communication systems. A comprehensive, inpatient rehabilitation program utilizes a coordinated and integrated, interdisciplinary approach, directed by a physician, to assess patient needs and to provide treatment and evaluation of physical, psychosocial, and cognitive deficits.

(10) "Department" means the North Carolina Department of Health and Human Services.

(11) "Director of nursing" means a registered nurse who has authority and ~~direct~~ responsibility for all nursing services and nursing care.

(12) "Discharge" means a physical relocation of a patient to another health care setting, the discharge of a patient to his or her home, or the relocation of a patient from a nursing bed to an adult care home bed, or from an adult care home bed to a nursing bed.

(13) "Existing facility" means a facility currently licensed, a proposed facility, a proposed addition to a licensed facility, or a proposed remodeled licensed facility that will be built according to design development drawings and specifications approved by the Department for compliance with the standards established in Sections .3100, .3200, and .3400 of this Subchapter, to the effective date of this Rule.

(14) "Facility" means a nursing facility or combination facility as defined in this Rule.

(15) "Incident" means any accident, event, or occurrence that is unplanned, or unusual, and has ~~actually~~ caused harm to a patient, or has the potential for harm.

(16) "Inpatient rehabilitation facility or unit" means a free-standing facility or a unit (unit pertains to contiguous dedicated beds and spaces) within an existing licensed health service facility approved in accordance with G.S. 131E, Article 9 to establish inpatient, rehabilitation beds and to provide a comprehensive, inpatient rehabilitation program.

(17) "Interdisciplinary" means an integrated process involving representatives from disciplines of the health care team.

(18) "Licensee" means the person, firm, partnership, association, corporation, or organization to whom a license to operate the facility has been issued. The licensee is the legal entity that is responsible for the operation of the business.

(19) "Medication error rate" means the measure of discrepancies between medication that was ordered for a patient by the health care provider and medication that is ~~actually~~ administered to the patient. The medication error rate is calculated by dividing the number of errors observed by the surveyor by the opportunities for error, multiplied times 100.

(20) "Misappropriation of property" means the deliberate misplacement, exploitation, or wrongful, temporary or permanent use of a patient's belongings or money without the patient's consent.

(21) "Neglect" means a failure to provide goods and services necessary to avoid physical harm, mental anguish, or mental illness.

(22) "New facility" means a proposed facility, a proposed addition to an existing facility, or a proposed remodeled portion of an existing facility that will be built according to design development drawings and specifications approved by the Department for compliance with the standards established in Sections .3100, .3200, and .3400 of this Subchapter after the effective date of this Rule.

(23) "Nurse Aide" means a person who is listed on the N.C. Nurse Aide Registry and provides nursing or nursing-related services to patients in a nursing home. A nurse aide is not a licensed health professional. Nursing homes that participate in Medicare or Medicaid shall comply with 42 CFR Part 483.75(e), which is incorporated by reference, including subsequent amendments. The Code of Federal Regulations may be accessed at ~~http://www.access.gpo.gov/nara/cfr/waisidx_08/42cfr483_08.~~ https://www.ecfr.gov.

(24) "Nursing facility" means a nursing home as defined in G.S. 131E-101.

(25) "Patient" means any person admitted for nursing care.

(26) "Remodeling" means alterations, renovations, rehabilitation work, repairs to structural systems, and replacement of building systems at a nursing or combination facility.

(27) "Repair" means reconstruction or renewal of any part of an existing building for the purpose of its maintenance.

(28) "Resident" means any person admitted for care to an adult care home part of a combination ~~facility as defined in G.S. 131E-101.~~ facility.

(29) "Respite care" means services provided for a patient on a temporary basis, not to exceed 30 days.

(30) "Surveyor" means ~~an authorized~~ a representative of the Department who inspects nursing facilities and combination facilities to determine compliance with ~~rules~~ rules, laws, and regulations as set forth in G.S. 131E-117; Subchapters 13D and 13F of this Chapter; and 42 CFR Part 483, Requirements for States and Long Term Care Facilities.

~~(31) "Ventilator dependence" means a physiological dependency by a patient on the use of a ventilator for more than eight hours a day.~~

~~(32)~~(31) "Violation" means a failure to comply with ~~the regulations, standards, and requirements~~ rules, laws, and regulations as set forth in G.S. 131E-117 and 131D–21; Subchapters 13D and 13F of this Chapter; or 42 CFR Part 483, Requirements for States and Long Term Care Facilities, that ~~directly~~ relates to a patient's or resident's health, safety, or welfare, or ~~which~~ that creates a ~~substantial~~ risk that death, or ~~serious~~ physical harm ~~will~~ may occur.

History Note: *Authority G.S. 131E-104;*
RRC objection due to lack of statutory authority Eff. July 13, 1995;
Eff. January 1, 1996;
Readopted Eff. July 1, ~~2016.~~ 2016;
Amended Eff. January 1, 2021.

10A NCAC 13D .2506 is repealed as published in 34:24 NCR 2377-2380 as follows:

10A NCAC 13D .2506 PHYSICIAN SERVICES FOR VENTILATOR DEPENDENT PATIENTS

History Note: *Authority G.S. 131E-104;*
RRC objection due to lack of statutory authority and ambiguity Eff. July 13, 1995;
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. March 22, ~~2015.~~ 2015;
Repealed Eff. January 1, 2021.

10A NCAC 13D .3003 is amended as published in 34:24 NCR 2377-2380 as follows:

10A NCAC 13D .3003 VENTILATOR ~~DEPENDENCE~~ ASSISTED CARE

(a) ~~The general requirements in this Subchapter shall apply when applicable. In addition, facilities having patients requiring the use of ventilators for more than eight hours a day shall meet the following requirements:~~ For the purpose of this Rule, ventilator assisted individuals, means as defined in 42 CFR Part 483.25(i), F695, herein incorporated by reference including subsequent amendments and editions. Copies of the Code of Federal Regulations, Title 42, Public Health, Part 482-End, 2019 may be accessed free of charge online at https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_pp_guidelines_ltcf.pdf.

(b) Facilities having patients who are ventilator assisted individuals shall:

(1) ~~The facility shall be located within 30 minutes of an acute care facility.~~ administer respiratory care in accordance with 42 CFR Part 483.25(i), F695;

(2) ~~Respiratory therapy shall be provided and supervised by a respiratory therapist currently registered by the National Board for Respiratory Care.~~ administer respiratory care in accordance with the scope of practice for respiratory therapists defined in G.S. 90-648; and ~~The respiratory therapist shall:~~

~~(a) make, as a minimum, weekly on site assessments of each patient receiving ventilator support with corresponding progress notes;~~

~~(b) be on call 24 hours daily; and~~

~~(c) assist the pulmonologist and nursing staff in establishing ventilator policies and procedures, including emergency policies and procedures.~~

(3) ~~Direct nursing care staffing shall be in accordance with Rule .3005 of this Section.~~ provide pulmonary services from a physician who has training in pulmonary medicine according to The American Board of Internal Medicine. The physician shall be responsible for respiratory services and shall:

(A) establish with the respiratory therapist and nursing staff, ventilator policies and procedures, including emergency procedures;

(B) assess each ventilator assisted patient's status at least monthly with corresponding progress notes;

(C) respond to emergency communications 24-hours a day; and

(D) participate in individual care planning.

(c) Direct care nursing personnel staffing ratios established in Rule .2303 of this Subchapter shall not be applied to nursing services for patients who are ventilator assisted at life support settings. The minimum direct care nursing staff shall be 5.5 hours per patient day, allocated on a per shift basis as the facility chooses; however, in no event shall the direct care nursing staff fall below a registered nurse and a nurse aide I at any time during a 24-hour period.

History Note: *Authority G.S. 131E-104;*
RRC objection due to lack of statutory authority Eff. July 13, 1995;

Eff. January 1, 1996;

Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. March 22, ~~2015.~~ 2015;

Amended Eff. January 1, 2021.

Fiscal Impact Analysis of

Nursing Home Ventilator Rules Permanent Rule Amendments

Agency Proposing Rule Change
North Carolina Medical Care Commission

Contact Persons
Beverly Speroff, Assistant Chief, Nursing Home Licensure & Certification Section – (919) 855-4555
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Impact Summary

State Government: Yes
Local Government: No Impact
Private Business: Yes
Patients: Yes
Substantial Impact: None

Title of Rules
10A NCAC 13D .2001 Definitions (Amend)
10A NCAC 13D .2506 Physician Services for Ventilator Dependent Patients (Repeal)
10A NCAC 13D .3003 Ventilator ~~Dependence~~ Assisted Care (Amend)

*See proposed text of these rules in Appendix

Statutory Authority
G.S. 131E-104

Summary

North Carolina does not have enough beds distributed across the state to meet the need for patients requiring life supporting ventilator care. To address this issue, the N.C. Medical Care Commission is proposing to amend the Rules for the Licensing of Nursing Homes in 10A NCAC 13D for ventilator assisted care. The proposed rules expand the definition of ventilator assisted care according to patient needs and remove location requirements based on proximity to an acute care facility. The changes also require administration of respiratory care in accordance with federal guidance (F695) for individuals with this type of care need.

The agency expects these rule amendments to reduce regulatory barriers associated with proximity to an acute care facility and adherence to the current definition for ventilator dependence for providers and encourage more availability of ventilator assisted care services in Nursing Homes, benefiting patients and their families. Nursing Homes serving Medicare and/or Medicaid-eligible individuals must already adhere to the federal requirements for administering ventilator assisted care. If these facilities choose to expand respiratory care services due to the rule amendments, we can assume their expected revenue gains would equal or exceed the cost of compliance. The smaller number of private pay-only nursing homes are not expected to pursue this service and so the changes to the respiratory care requirements will have no impact. Finally, DHSR will incur staff time costs of approximately $2,025 per case for application and construction review.

Background, Problem, and Description of the Rule Revisions

Background

North Carolina has three nursing homes in the state that provide ventilator beds. These homes are in Guilford, Forsyth and Alexander counties. These locations are in the central and western portions of the state. The combined bed capacity is 90 beds. In past years, two additional nursing homes located in Wake and Washington counties provided 19 more ventilator beds. These two nursing homes closed in 2012 and 2014. The Nursing Home Licensure & Certification Section has had hospital discharge planners seeking placement for residents requiring life supporting ventilator care and NC did not having any bed availability close to families in eastern North Carolina.

Historically, nursing homes have expressed an interest in providing life-supporting mechanical ventilation beds and then withdrew interest. The reasons associated with not following through with licensure included difficulty securing a contract with a pulmonologist, staffing requirements, decision to focus on existing care for residents and lack of clarity on the definition of life supporting versus non-life supporting care. As of late, we have had a new interest in licensing ventilator beds with more inquiries about the rules.

Problem

There is an identified need for more ventilator assisted care beds in nursing homes as currently, access to care for these residents is limited with there being only three Nursing Homes in the state providing residents ventilator assisted care. By adopting the requirements in the Code of Federal Regulations (CFR) in the proposed rule amendments, confusion will be eliminated between the differences in the standards between the State licensure rules and the CFR. The requirements of the CFR currently apply to all providers who participate in Medicare and/or Medicaid. Aligning the requirements in the proposed rule amendments with the federal requirements is expected to reduce regulatory barriers associated with proximity to an acute care facility and adherence to the current definition for ventilator dependence for providers and encourage more availability of ventilator assisted care service in Nursing Homes. The requirements will be more up-to-date and relevant, in addition to being backed by research.

Description of the Rule Revisions

The proposed rule amendments include technical changes to clarify definitions, and the deletion of the definition of ventilator dependence in rule 10A NCAC 13D .2001 because the definition is being redefined in Rule 10A NCAC 13D .3003 with a refer by reference to the CFR. The rules added the requirement for administration of respiratory care with a reference to the CFR. Reference to the location of a facility was deleted. The lack of statutory authority for respiratory therapists has been eliminated by including a reference to statute G.S. 90-648, regarding The North Carolina Respiratory Care Board. The requirements in Rule 10A NCAC 13D .2506 for physician services for ventilator dependent patients was repealed. The lack of statutory authority in Rule 10A NCAC 13D .2506 was addressed with new language and a reference to The American Board of Internal Medicine. The duties of the physician are the same as they were described in Rule 10A NCAC 13D .2506. The requirements for direct care nursing personnel staffing ratios have been incorporated into one rule from Rule 10A NCAC 13D .3005. There is no change in the staffing ratios.

The current definition in rule 10A NCAC 13D .2001 is “Ventilator dependence means a physiological dependency by a patient on the use of a ventilator for more than eight hours a day.” This definition was effective in 1996 and had not been updated. The definition is not supported by reference or current practice.

42 CFR Part §483.25(i), Respiratory Care, was issued on 11/22/17 and became effective on 11/28/17. The regulation included intent, definitions, guidance to surveyors, sections on care policies, staffing and personnel, monitoring and documentation of respiratory services/response, modalities/respiratory therapy/care/services, coughing/deep breathing/therapeutic percussion/vibration and bronchopulmonary drainage, respiratory medication versus aerosols, generators, oxygen therapy, obstructive sleep apnea, respiratory services for mechanical ventilation with tracheostomy/tracheotomy care and care plan for mechanical ventilation/tracheostomy care. The federal

definition is **"Mechanical Ventilation"** that may be defined as a life support system designed to replace or support normal ventilatory lung function and a **"Ventilator Assisted Individual (VAI)"** requires mechanical aid for breathing to augment or replace spontaneous ventilatory efforts to achieve medical stability or maintain life.

The federal regulation also includes other relevant definitions such as ***"Noninvasive ventilation (NIV)"*** *refers to the administration of ventilatory support without using an invasive artificial airway (endotracheal tube or tracheostomy tube).* These clarifying respiratory care definitions are helpful to providers, surveyors and the public so that everyone understands the difference between treatments that are life supporting care versus other specialized respiratory treatments.

Differences in existing Nursing Home rules and the federal regulation

Topic	**NH Rule** 10A NCAC 13D .2001, .2506 & .3003	**Federal Regulation** 42 CFR Part 483.25(i), F695
Definition	Outdated 1996 8 hours/day	Up-to-date 2017 clarifying definitions, supported by research Life-supporting mechanical ventilation
Physician Services	Lacked Statutory authority	yield to state laws and scope of practice
Location of Nursing Home	30 min from acute care facility	Not mentioned
Respiratory Therapist (RT)	Lacked Statutory authority	Have sufficient numbers of trained, competent, qualified staff, consistent with State practice acts/laws*;*
RT frequency of assessment	RT weekly onsite assessment with progress notes	based on current professional standards of practice
Policies & Procedures	Establish ventilator and emergency P&P	Extensive, but not all inclusive, list of P&P needed to care for residents
Staffing	Direct Nursing Care 5.5 hrs./ppd	Have sufficient numbers of trained, competent, qualified staff, consistent with State practice acts/laws*;*
Guidance to Surveyors	None	Guidance provided such as Respiratory Services for Mechanical Ventilation with Tracheostomy/Tracheotomy Care
Examples of Deficient Practice Severity	None	Severity guidance

Impact

Nursing Homes

428 nursing home providers participate in M/M and 9 nursing home providers in the state do not participate in M/M. Any nursing home provider that chooses to provide care to patients requiring mechanical ventilation at life support settings will be impacted with costs outlined below. If M/M facilities choose to expand respiratory care services due to the rule amendments, we can assume their expected revenue gains would equal or exceed the cost of compliance. There would be no newer or higher costs to a M/M provider because those providers must comply with the CFR. Similar costs would exist for a non-M/M provider who chose to develop this new service. However, the agency does not expect private pay-only providers to pursue this service based on feedback received from stakeholders representing this group.

Costs associated with providing ventilator services:

- Services from a physician trained in pulmonary medicine $130/hour
- Services from a respiratory therapist $33.00/hour ($305,000 per year)
- DHSR Construction Plan Review Cost $500.00
- Facility architect, if needed $38.00/hour
- Costs associated with getting room/unit ventilator ready (electrical & gas)
- Cost of the ventilator and associated equipment & parts ($5000 + per unit)
- Cost of respiratory supplies ($8000/month according to one NH with an 18-bed unit)
- Liquid oxygen refills $4000/month according to one NH with an 18-bed unit)
- Inspection Fee $1000/year
- Preventative Maintenance $2600/month for each machine according to one NH with an 18-bed unit
- Costs associated with 5.5 direct care staff per patient day

Benefits to Providers

The current rules limit the use of ventilator care to life-saving situations. The proposed rules expand the definition to allow ventilator care in more settings. Providers are no longer bound by the definition of ventilator dependence meaning physiological dependence by a patient on the use of a ventilator for more than eight hours a day. Providers have the benefit of an array of respiratory definitions that clear the path for care modalities that meet a variety of patient needs. Furthermore, providers no longer need to be concerned with the proximity of the nursing home to a hospital. Together, these changes are intended to reduce regulatory barriers to providers interested in providing this service.

Patient

Currently, patients who need life-saving ventilator care can only receive it in three locations in North Carolina. The existing providers are in Greensboro, Winston Salem and Taylorsville. Families from the eastern part of North Carolina must travel two to four hours to visit their loved ones. The proposed rules eliminate a nursing home's proximity to an acute care facility and make it easier for a rural facility to provide this service.

State

We would anticipate an increase of approximately one application a year once the definition is consistent with the federal requirement. An increase of one application a year due to the proposed rule amendments would not have an immediate and significant financial impact on DHSR. DHSR's Nursing Home Section would require approximately 3 hours of time to review contracts and policies and procedures by a FCCII ($36.05 per hour) per application. DHSR's Construction Section would require approximately 16 hours of plan reviews from both an Architect and Engineer ($38.46 & $36.05 per hour, respectively) per application. Further, DHSR's Construction Section would conduct an annual 2 to 4-hour inspection at the facility ($20.19 per hour), per application. The total cost to DHSR per application is estimated at $2025.00.

Appendix: Source of the Cost Estimates

Cost Estimate	Source
physician trained in pulmonary medicine $130/hour	https://www.salary.com/research/salary/benchmark/pulmonary-physician-hourly-wages accessed 3/8/2020
Services from a respiratory therapist $33.00/hour or $305,000 per year	NH Provider with a vent unit
DHSR Construction Plan Review Cost $500.00	DHSR Construction Section Chief
Facility architect, if needed $38.00/hour	https://www.salary.com/research/salary/listing/architect-salary accessed 3/8/2020
Costs associated with getting room/unit ventilator ready (electrical & gas)	NH Provider with a vent unit
Cost of the ventilator and associated equipment & parts ($5000 + per unit)	NH Provider with a vent unit
Cost of respiratory supplies ($8000/month)	NH Provider with a vent unit
Liquid oxygen refills $4000/month	NH Provider with a vent unit
Inspection Fee $1000/year	NH Provider with a vent unit
Preventative Maintenance $2600/month	NH Provider with a vent unit
Costs associated with 5.5 direct care staff per patient day (already in the rule)	
DHSR FCC II contract, P&P & application review (salary + benefits according OSHR's compensation calculator) and assuming 2080 hours/year (40-hour work week) $53.82 x 3 hours = $161.00	DHSR Budget Office
DHSR Architect plan review/application (salary + benefits according OSHR's compensation calculator) and assuming 2080 hours/year (40-hour work week) $57.22 x 16 hours = $915.00	DHSR Budget Office
DHSR Engineer plan review/application (salary + benefits according OSHR's compensation calculator) and assuming 2080 hours/year (40-hour work week) $53.81 x 16 hours = $860.96	DHSR Budget Office
Annual 4-hour inspection at $20.19/hour/application	DHSR Construction Section
Total Cost to DHSR/application $2018.19	DHSR

10A NCAC 13D .2001 is proposed for amendment as follows:

SECTION .2000 – GENERAL INFORMATION

10A NCAC 13D .2001 DEFINITIONS

In addition to the definitions set forth in 131E-101, the ~~The~~ following definitions ~~will~~ shall apply throughout this Subchapter:

(1) "Abuse" means the willful infliction of injury, unreasonable confinement, intimidation or punishment with resulting physical harm, pain, or mental anguish.

(2) "Accident" means an unplanned event resulting in the injury or wounding, no matter how slight, of a patient or other individual.

(3) "Addition" means an extension or increase in floor area or height of a building.

(4) "Administrator" as defined in G.S. 90-276(4).

(5) "Alteration" means any construction or renovation to an existing structure other than repair, maintenance, or addition.

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

(7) "Capacity" means the maximum number of patient or resident beds for which the facility is licensed to maintain at any given time.

(8) "Combination facility" means a combination home as defined in G.S. 131E-101.

(9) "Comprehensive, inpatient rehabilitation program" means a program for the treatment of persons with functional limitations or chronic disabling conditions who have the potential to achieve a significant improvement in activities of daily living, including bathing, dressing, grooming, transferring, eating, and using speech, language, or other communication systems. A comprehensive, inpatient rehabilitation program utilizes a coordinated and integrated, interdisciplinary approach, directed by a physician, to assess patient needs and to provide treatment and evaluation of physical, psychosocial, and cognitive deficits.

(10) "Department" means the North Carolina Department of Health and Human Services.

(11) "Director of nursing" means a registered nurse who has authority and ~~direct~~ responsibility for all nursing services and nursing care.

(12) "Discharge" means a physical relocation of a patient to another health care setting, the discharge of a patient to his or her home, or the relocation of a patient from a nursing bed to an adult care home bed, or from an adult care home bed to a nursing bed.

(13) "Existing facility" means a facility currently licensed, a proposed facility, a proposed addition to a licensed facility, or a proposed remodeled licensed facility that will be built according to design development drawings and specifications approved by the Department for compliance with the standards established in Sections .3100, .3200, and .3400 of this Subchapter, to the effective date of this Rule.

(14) "Facility" means a nursing facility or combination facility as defined in this Rule.

(15) "Incident" means any accident, event, or occurrence that is unplanned, or unusual, and has ~~actually~~ caused harm to a patient, or has the potential for harm.

(16) "Inpatient rehabilitation facility or unit" means a free-standing facility or a unit (unit pertains to contiguous dedicated beds and spaces) within an existing licensed health service facility approved in accordance with G.S. 131E, Article 9 to establish inpatient, rehabilitation beds and to provide a comprehensive, inpatient rehabilitation program.

(17) "Interdisciplinary" means an integrated process involving representatives from disciplines of the health care team.

(18) "Licensee" means the person, firm, partnership, association, corporation, or organization to whom a license to operate the facility has been issued. The licensee is the legal entity that is responsible for the operation of the business.

(19) "Medication error rate" means the measure of discrepancies between medication that was ordered for a patient by the health care provider and medication that is ~~actually~~ administered to the patient. The medication error rate is calculated by dividing the number of errors observed by the surveyor by the opportunities for error, multiplied times 100.

(20) "Misappropriation of property" means the deliberate misplacement, exploitation, or wrongful, temporary or permanent use of a patient's belongings or money without the patient's consent.

(21) "Neglect" means a failure to provide goods and services necessary to avoid physical harm, mental anguish, or mental illness.

(22) "New facility" means a proposed facility, a proposed addition to an existing facility, or a proposed remodeled portion of an existing facility that will be built according to design development drawings and specifications approved by the Department for compliance with the standards established in Sections .3100, .3200, and .3400 of this Subchapter after the effective date of this Rule.

(23) "Nurse Aide" means a person who is listed on the N.C. Nurse Aide Registry and provides nursing or nursing-related services to patients in a nursing home. A nurse aide is not a licensed health professional. Nursing homes that participate in Medicare or Medicaid shall comply with 42 CFR Part 483.75(e), which is incorporated by reference, including subsequent amendments. The Code of Federal Regulations may be accessed at ~~http://www.access.gpo.gov/nara/cfr/waisidx_08/42cfr483_08.~~ *https://www.ecfr.gov.*

(24) "Nursing facility" means a nursing home as defined in G.S. 131E-101.

(25) "Patient" means any person admitted for nursing care.

(26) "Remodeling" means alterations, renovations, rehabilitation work, repairs to structural systems, and replacement of building systems at a nursing or combination facility.

(27) "Repair" means reconstruction or renewal of any part of an existing building for the purpose of its maintenance.

(28) "Resident" means any person admitted for care to an adult care home part of a combination ~~facility as defined in G.S. 131E-101.~~ facility.

(29) "Respite care" means services provided for a patient on a temporary basis, not to exceed 30 days.

(30) "Surveyor" means ~~an authorized~~ a representative of the Department who inspects nursing facilities and combination facilities to determine compliance with ~~rules~~ rules, laws, and regulations as set forth in G.S. 131E-117; Subchapters 13D and 13F of this Chapter; and 42 CFR Part 483, Requirements for States and Long Term Care Facilities.

~~(31) "Ventilator dependence" means a physiological dependency by a patient on the use of a ventilator for more than eight hours a day.~~

~~(32)~~(31) "Violation" means a failure to comply with ~~the regulations, standards, and requirements~~ rules, laws, and regulations as set forth in G.S. 131E-117 and 131D–21; Subchapters 13D and 13F of this Chapter; or 42 CFR Part 483, Requirements for States and Long Term Care Facilities, that ~~directly~~ relates to a patient's or resident's health, safety, or welfare, or ~~which~~ that creates a ~~substantial~~ risk that death, or ~~serious~~ physical harm ~~will~~ may occur.

History Note: *Authority G.S. 131E-104;*
RRC objection due to lack of statutory authority Eff. July 13, 1995;
Eff. January 1, 1996;
Readopted Eff. July 1, ~~2016.~~ 2016;
Amended Eff. January 1, 2021.

10A NCAC 13D .2506 is proposed for repeal as follows:

10A NCAC 13D .2506 PHYSICIAN SERVICES FOR VENTILATOR DEPENDENT PATIENTS

History Note: *Authority G.S. 131E-104;*
RRC objection due to lack of statutory authority and ambiguity Eff. July 13, 1995;
Eff. January 1, 1996;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. March 22, ~~2015.~~ 2015;
Repealed Eff. January 1, 2021.

10A NCAC 13D .3003 is proposed for amendment as follows:

10A NCAC 13D .3003 VENTILATOR ~~DEPENDENCE~~ ASSISTED CARE

(a) ~~The general requirements in this Subchapter shall apply when applicable. In addition, facilities having patients requiring the use of ventilators for more than eight hours a day shall meet the following requirements:~~ For the purpose of this Rule, ventilator assisted individuals, means as defined in 42 CFR Part 483.25(i), F695, herein incorporated by reference including subsequent amendments and editions. Copies of the Code of Federal Regulations, Title 42, Public Health, Part 482-End, 2019 may be accessed free of charge online at https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_pp_guidelines_ltcf.pdf.

(b) Facilities having patients who are ventilator assisted individuals shall:

(1) ~~The facility shall be located within 30 minutes of an acute care facility.~~ administer respiratory care in accordance with 42 CFR Part 483.25(i), F695;

(2) ~~Respiratory therapy shall be provided and supervised by a respiratory therapist currently registered by the National Board for Respiratory Care.~~ administer respiratory care in accordance with the scope of practice for respiratory therapists defined in G.S. 90-648; and ~~The respiratory therapist shall:~~

~~(a) make, as a minimum, weekly on site assessments of each patient receiving ventilator support with corresponding progress notes;~~

~~(b) be on call 24 hours daily; and~~

~~(c) assist the pulmonologist and nursing staff in establishing ventilator policies and procedures, including emergency policies and procedures.~~

(3) ~~Direct nursing care staffing shall be in accordance with Rule .3005 of this Section.~~ provide pulmonary services from a physician who has training in pulmonary medicine according to The American Board of Internal Medicine. The physician shall be responsible for respiratory services and shall:

(A) establish with the respiratory therapist and nursing staff, ventilator policies and procedures, including emergency procedures;

(B) assess each ventilator assisted patient's status at least monthly with corresponding progress notes;

(C) respond to emergency communications 24-hours a day; and

(D) participate in individual care planning.

(c) Direct care nursing personnel staffing ratios established in Rule .2303 of this Subchapter shall not be applied to nursing services for patients who are ventilator assisted at life support settings. The minimum direct care nursing staff shall be 5.5 hours per patient day, allocated on a per shift basis as the facility chooses; however, in no event shall the direct care nursing staff fall below a registered nurse and a nurse aide I at any time during a 24-hour period.

History Note: *Authority G.S. 131E-104;*
RRC objection due to lack of statutory authority Eff. July 13, 1995;

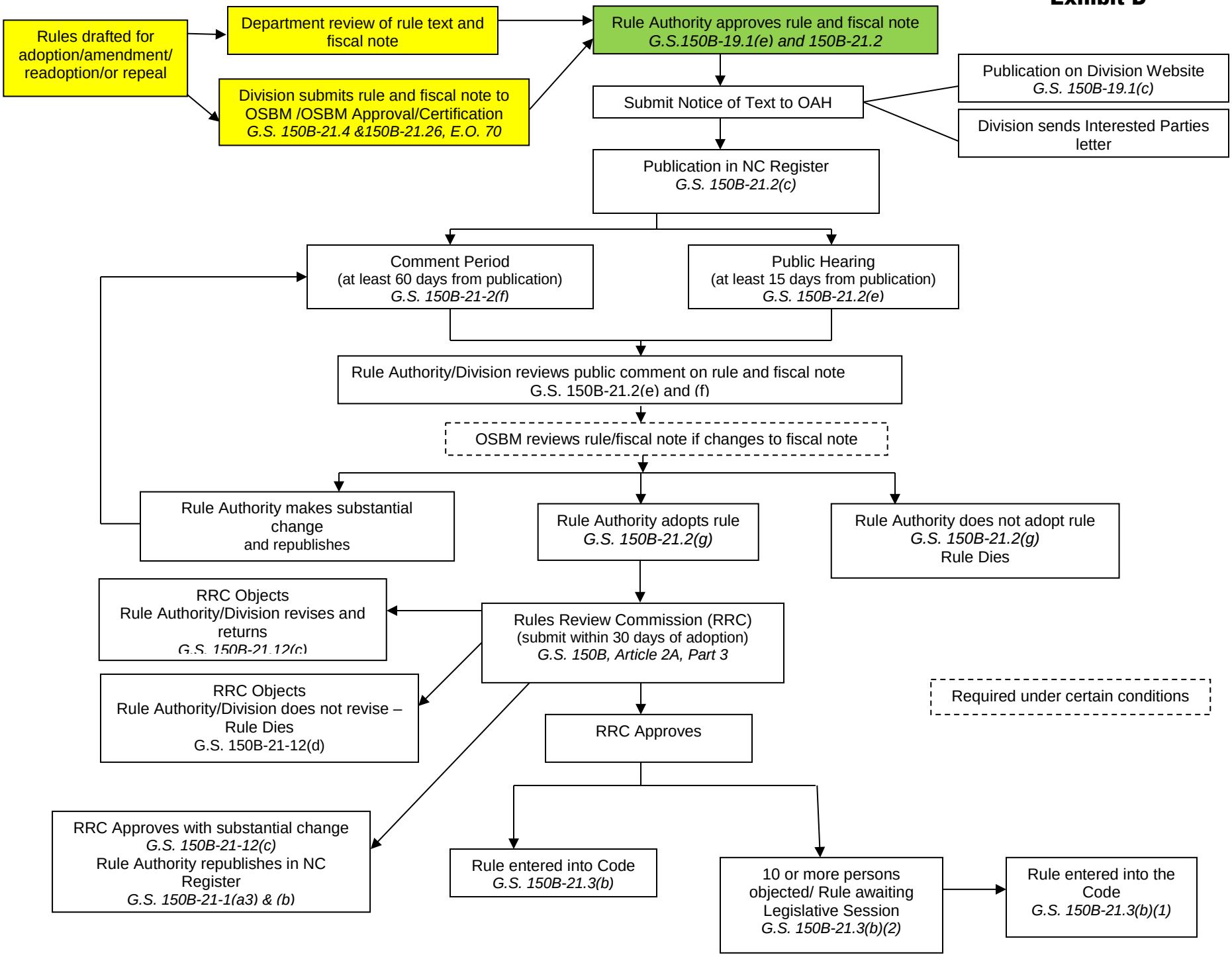
Eff. January 1, 1996;

Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. March 22, ~~2015.~~ 2015;

Amended Eff. January 1, 2021.

Process for Medical Care Commission to Initiate Rulemaking

Exhibit D



10A NCAC 13P .0101 is proposed for amendment as follows:

10A NCAC 13P .0101 ABBREVIATIONS

As used in this Subchapter, the following abbreviations mean:

(1) ACS: American College of Surgeons;

(2) AEMT: Advanced Emergency Medical Technician;

(3) AHA: American Heart Association;

(4) ASTM: American Society for Testing and Materials;

(5) CAAHEP: Commission on Accreditation of Allied Health Education Programs;

(6) CPR: Cardiopulmonary Resuscitation;

(7) ED: Emergency Department;

(8) EMD: Emergency Medical Dispatcher;

(9) EMR: Emergency Medical Responder;

(10) EMS: Emergency Medical Services;

(11) EMS-NP: EMS Nurse Practitioner;

(12) EMS-PA: EMS Physician Assistant;

(13) EMT: Emergency Medical Technician;

(14) FAA: Federal Aviation Administration;

~~(15) FAR: Federal Aviation Regulation;~~

~~(16)~~(15) FCC: Federal Communications Commission;

~~(17) GCS: Glasgow Coma Scale;~~

~~(18)~~(16) ICD: International Classification of Diseases;

~~(19)~~(17) ISS: Injury Severity Score;

~~(20) ICU: Intensive Care Unit;~~

~~(21) IV: Intravenous;~~

~~(22) LPN: Licensed Practical Nurse;~~

~~(23)~~(18) MICN: Mobile Intensive Care Nurse;

~~(24)~~(19) NHTSA: National Highway Traffic Safety Administration;

~~(25)~~(20) OEMS: Office of Emergency Medical Services;

~~(26)~~(21) OR: Operating Room;

~~(27)~~(22) PSAP: Public Safety Answering Point;

~~(28)~~(23) RAC: Regional Advisory Committee;

~~(29)~~(24) RFP: Request For Proposal;

~~(30) RN: Registered Nurse;~~

~~(31)~~(25) SCTP: Specialty Care Transport Program;

~~(32)~~(26) SMARTT: State Medical Asset and Resource Tracking Tool;

~~(33)~~(27) STEMI: ST Elevation Myocardial Infarction; and

~~(34)~~ ~~TR: Trauma Registrar;~~

~~(35)~~ ~~TPM: Trauma Program Manager; and~~

~~(36)~~(28) US DOT: United States Department of Transportation.

History Note: *Authority G.S. 143-508(b);*
Temporary Adoption Eff. January 1, 2002;
Eff. April 1, 2003;
Amended Eff. January 1, 2009; January 1, 2004;
Readopted Eff. January 1, ~~2017.~~ 2017;
Amended Eff. July 1, 2021.

10A NCAC 13P .0102 is proposed for amendment as follows:

10A NCAC 13P .0102 DEFINITIONS

In addition to the definitions in G.S. 131E-155, the following definitions apply throughout this Subchapter:

(1) "Affiliated EMS Provider" means the firm, corporation, agency, organization, or association identified with a specific county EMS system as a condition for EMS Provider Licensing as required by Rule .0204 of this Subchapter.

(2) "Affiliated Hospital" means a non-trauma center hospital that is owned by the Trauma Center or there is a contract or other agreement to allow for the acceptance or transfer of the Trauma Center's patient population to the non-trauma center hospital.

(3) "Affiliate" or "Affiliation" means a reciprocal agreement and association that includes active participation, collaboration, and involvement in a process or system between two or more parties.

(4) "Alternative Practice Setting" means a practice setting that utilizes credentialed EMS personnel that may not be affiliated with or under the oversight of an EMS System or EMS System Medical Director.

(5) "Air Medical Ambulance" means an aircraft configured and medically equipped to transport patients by air. The patient care compartment of air medical ambulances shall be staffed by medical crew members approved for the mission by the Medical Director.

(6) "Air Medical Program" means a SCTP or EMS System utilizing rotary-wing or fixed-wing aircraft configured and operated to transport patients.

(7) "Assistant Medical Director" means a physician, EMS-PA, or EMS-NP who assists the Medical Director with the medical aspects of the management of a practice setting utilizing credentialed EMS personnel or medical crew members.

(8) "Bypass" means a decision made by the patient care technician to transport a patient from the scene of an accident or medical emergency past a receiving facility for the purposes of accessing a facility with a higher level of care, or a hospital of its own volition reroutes a patient from the scene of an accident or medical emergency or referring hospital to a facility with a higher level of care.

(9) "Community Paramedicine" means an EMS System utilizing credentialed personnel who have received additional training as determined by the EMS system Medical Director to provide knowledge and skills for the community needs beyond the 911 emergency response and transport operating guidelines defined in the EMS system plan.

(10) "Contingencies" mean conditions placed on a designation that, if unmet, may result in the loss or amendment of a designation.

(11) "Convalescent Ambulance" means an ambulance used on a scheduled basis solely to transport patients having a known non-emergency medical condition. Convalescent ambulances shall not be used in place of any other category of ambulance defined in this Subchapter.

(12) "Deficiency" means the failure to meet essential criteria for a designation that can serve as the basis for a focused review or denial of a designation.

(13) "Department" means the North Carolina Department of Health and Human Services.

(14) "Diversion" means the hospital is unable to accept a patient due to a lack of staffing or resources.

(15) "Educational Medical Advisor" means the physician responsible for overseeing the medical aspects of approved EMS educational programs.

(16) "EMS Care" means all services provided within each EMS System by its affiliated EMS agencies and personnel that relate to the dispatch, response, treatment, and disposition of any patient.

(17) "EMS Educational Institution" means any agency credentialed by the OEMS to offer EMS educational programs.

(18) "EMS Non-Transporting Vehicle" means a motor vehicle operated by a licensed EMS provider dedicated and equipped to move medical equipment and EMS personnel functioning within the scope of practice of an AEMT or Paramedic to the scene of a request for assistance. EMS nontransporting vehicles shall not be used for the transportation of patients on the streets, highways, waterways, or airways of the state.

(19) "EMS Peer Review Committee" means a committee as defined in G.S. 131E-155(6b).

(20) "EMS Performance Improvement Self-Tracking and Assessment of Targeted Statistics" means one or more reports generated from the State EMS data system analyzing the EMS service delivery, personnel performance, and patient care provided by an EMS system and its associated EMS agencies and personnel. Each EMS Performance Improvement Self-Tracking and Assessment of Targeted Statistics focuses on a topic of care such as trauma, cardiac arrest, EMS response times, stroke, STEMI (heart attack), and pediatric care.

(21) "EMS Provider" means those entities defined in G.S. 131E-155(13a) that hold a current license issued by the Department pursuant to G.S. 131E-155.1.

(22) "EMS System" means a coordinated arrangement of local resources under the authority of the county government (including all agencies, personnel, equipment, and facilities) organized to respond to medical emergencies and integrated with other health care providers and networks including public health, community health monitoring activities, and special needs populations.

(23) "Essential Criteria" means those items that are the requirements for the respective level of trauma center designation (I, II, or III), as set forth in Rule .0901 of this Subchapter.

(24) "Focused Review" means an evaluation by the OEMS of corrective actions to remove contingencies that are a result of deficiencies following a site visit.

(25) "Ground Ambulance" means an ambulance used to transport patients with traumatic or medical conditions or patients for whom the need for specialty care, emergency, or non-emergency medical care is anticipated either at the patient location or during transport.

(26) "Hospital" means a licensed facility as defined in G.S. 131E-176 or an acute care in-patient diagnostic and treatment facility located within the State of North Carolina that is owned and operated by an agency of the United States government.

~~(27) "Immediately Available" means the physical presence of the health professional or the hospital resource within the trauma center to evaluate and care for the trauma patient.~~

~~(28)~~(27) "Inclusive Trauma System" means an organized, multi-disciplinary, evidence-based approach to provide quality care and to improve measurable outcomes for all defined injured patients. EMS, hospitals, other health systems, and clinicians shall participate in a structured manner through leadership, advocacy, injury prevention, education, clinical care, performance improvement, and research resulting in integrated trauma care.

~~(29)~~(28) "Infectious Disease Control Policy" means a written policy describing how the EMS system will protect and prevent its patients and EMS professionals from exposure and illness associated with contagions and infectious disease.

~~(30)~~(29) "Lead RAC Agency" means the agency (comprised of one or more Level I or II trauma centers) that provides staff support and serves as the coordinating entity for trauma planning.

~~(31)~~(30) "Level I Trauma Center" means a hospital that has the capability of providing guidance, research, and total care for every aspect of injury from prevention to rehabilitation.

~~(32)~~(31) "Level II Trauma Center" means a hospital that provides trauma care regardless of the severity of the injury, but may lack the comprehensive care as a Level I trauma center, and does not have trauma research as a primary objective.

~~(33)~~(32) "Level III Trauma Center" means a hospital that provides assessment, resuscitation, emergency operations, and stabilization, and arranges for hospital transfer as needed to a Level I or II trauma center.

~~(34) "Licensed Health Care Facility" means any health care facility or hospital licensed by the Department of Health and Human Services, Division of Health Service Regulation.~~

~~(35)~~(33) "Medical Crew Member" means EMS personnel or other health care professionals who are licensed or registered in North Carolina and are affiliated with a SCTP.

~~(36)~~(34) "Medical Director" means the physician responsible for the medical aspects of the management of a practice setting utilizing credentialed EMS personnel or medical crew members, or a Trauma Center.

~~(37)~~(35) "Medical Oversight" means the responsibility for the management and accountability of the medical care aspects of a practice setting utilizing credentialed EMS personnel or medical crew members. Medical Oversight includes physician direction of the initial education and continuing education of EMS personnel or medical crew members; development and monitoring of both operational and treatment protocols; evaluation of the medical care rendered by EMS personnel or medical crew members; participation in system or program evaluation; and directing, by two-way voice communications, the medical care rendered by the EMS personnel or medical crew members.

~~(38)~~(36) "Mobile Integrated Healthcare" means utilizing credentialed personnel who have received additional training as determined by the Alternative Practice Setting medical director to provide knowledge and skills for the healthcare provider program needs.

~~(39) "Off-line Medical Control" means medical supervision provided through the EMS System Medical Director or SCTP Medical Director who is responsible for the day-to-day medical care provided by EMS personnel. This includes EMS personnel education, protocol development, quality management, peer review activities, and EMS administrative responsibilities related to assurance of quality medical care.~~

~~(40)~~(37) "Office of Emergency Medical Services" means a section of the Division of Health Service Regulation of the North Carolina Department of Health and Human Services located at 1201 Umstead Drive, Raleigh, North Carolina 27603.

~~(41)~~(38) "On-line Medical Control" means the medical supervision or oversight provided to EMS personnel through direct communication in-person, via radio, cellular phone, or other communication device during the time the patient is under the care of an EMS professional.

~~(42)~~(39) "Operational Protocols" means the administrative policies and procedures of an EMS System or that provide guidance for the day-to-day operation of the system.

~~(43) "Participating Hospital" means a hospital that supplements care within a larger trauma system by the initial evaluation and assessment of injured patients for transfer to a designated trauma center if needed.~~

~~(44)~~(40) "Physician" means a medical or osteopathic doctor licensed by the North Carolina Medical Board to practice medicine in the state of North Carolina.

~~(45)~~(41) "Regional Advisory Committee" means a committee comprised of a lead RAC agency and a group representing trauma care providers and the community, for the purpose of regional planning, establishing, and maintaining a coordinated trauma system.

~~(46)~~(42) "Request for Proposal" means a State document that must be completed by each hospital seeking initial or renewal trauma center designation.

~~(47)~~(43) "Significant Failure to Comply" means a degree of non-compliance determined by the OEMS during compliance monitoring to exceed the ability of the local EMS System to correct, warranting enforcement action pursuant to Section .1500 of this Subchapter.

~~(48)~~(44) "State Medical Asset and Resource Tracking Tool" means the Internet web-based program used by the OEMS both in its daily operations and during times of disaster to identify, record, and monitor EMS, hospital, health care, and sheltering resources statewide, including facilities, personnel, vehicles, equipment, and pharmaceutical and supply caches.

~~(49)~~(45) "Specialty Care Transport Program" means a program designed and operated for the transportation of a patient by ground or air requiring specialized interventions, monitoring, and staffing by a paramedic who has received additional training as determined by the program Medical Director

beyond the minimum training prescribed by the OEMS, or by one or more other healthcare professional(s) qualified for the provision of specialized care based on the patient's condition.

~~(50)~~(46) "Specialty Care Transport Program Continuing Education Coordinator" means a ~~Level I~~ Level II EMS Instructor within a SCTP who is responsible for the coordination of EMS continuing education programs for EMS personnel within the program.

~~(51)~~(47) "Stretcher" means any wheeled or portable device capable of transporting a person in a recumbent position and may only be used in an ambulance vehicle permitted by the Department.

~~(52)~~(48) "Stroke" means an acute cerebrovascular hemorrhage or occlusion resulting in a neurologic deficit.

~~(53)~~(49) "System Continuing Education Coordinator" means the ~~Level I~~ Level II EMS Instructor designated by the local EMS System who is responsible for the coordination of EMS continuing education programs.

~~(54)~~(50) “System Data" means all information required for daily electronic submission to the OEMS by all EMS Systems using the EMS data set, data dictionary, and file format as specified in "North Carolina College of Emergency Physicians: Standards for Medical Oversight and Data Collection," incorporated herein by reference including subsequent amendments and editions. This document is available from the OEMS, 2707 Mail Service Center, Raleigh, North Carolina 27699- 2707, at no cost and online at www.ncems.org at no cost.

~~(55)~~(51) "Trauma Center" means a hospital designated by the State of North Carolina and distinguished by its ability to manage, on a 24-hour basis, the severely injured patient or those at risk for severe injury.

~~(56) "Trauma Center Criteria" means essential criteria to define Level I, II, or III trauma centers.~~

~~(57) "Trauma Center Designation" means a process of approval in which a hospital voluntarily seeks to have its trauma care capabilities and performance evaluated by experienced on-site reviewers.~~

~~(58) "Trauma Diversion" means a trauma center of its own volition declines to accept an acutely injured patient due to a lack of staffing or resources.~~

~~(59) "Trauma Guidelines" mean standards for practice in a variety of situations within the trauma system.~~

~~(60) "Trauma Minimum Data Set" means the basic data required of all hospitals for submission to the Trauma Registry.~~

~~(61)~~(52) "Trauma Patient" means any patient with an ICD-CM discharge diagnosis as defined in the "North Carolina Trauma Registry Data Dictionary," incorporated herein by reference, including subsequent amendments and editions. This document is available from the OEMS, 2707 Mail Service Center, Raleigh, North Carolina 27699-2707, at no cost and online at https://info.ncdhhs.gov/dhsr/EMS/trauma/traumaregistry.html at no cost.

~~(62)~~(53) "Trauma Program" means an administrative entity that includes the trauma service and coordinates other trauma-related activities. It shall also include the trauma Medical Director, trauma program manager/trauma coordinator, and trauma registrar. This program's reporting structure shall give it

the ability to interact with at least equal authority with other departments in the hospital providing patient care.

~~(63)~~(54) "Trauma Registry" means a disease-specific data collection composed of a file of uniform data elements that describe the injury event, demographics, pre-hospital information, diagnosis, care, outcomes, and costs of treatment for injured patients collected and electronically submitted as defined by the OEMS. The elements of the Trauma Registry can be accessed at https://info.ncdhhs.gov/dhsr/EMS/trauma/traumaregistry.html at no cost.

~~(64)~~(55) "Treatment Protocols" means a document approved by the Medical Directors of the local EMS System, Specialty Care Transport Program, Alternative Practice Setting, or Trauma Center and the OEMS specifying the diagnostic procedures, treatment procedures, medication administration, and patient-care-related policies that shall be completed by EMS personnel or medical crew members based upon the assessment of a patient.

~~(65)~~(56) "Triage" means the assessment and categorization of a patient to determine the level of EMS and healthcare facility based care required.

~~(66)~~(57) "Water Ambulance" means a watercraft specifically configured and medically equipped to transport patients.

History Note: *Authority G.S. 131E-155(6b); 131E-162; 143-508(b), 143-508(d)(1); 143-508(d)(2); 143-508(d)(3); 143-508(d)(4); 143-508(d)(5); 143-508(d)(6); 143-508(d)(7); 143-508(d)(8); 143-508(d)(13); 143-518(a)(5);*
Temporary Adoption Eff. January 1, 2002;
Eff. April 1, 2003;
Amended Eff. March 3, 2009 pursuant to E.O. 9, Beverly Perdue, March 3, 2009;
Pursuant to G.S. 150B-21.3(c), a bill was not ratified by the General Assembly to disapprove this rule;
Readopted Eff. January 1, 2017;
Amended Eff. July 1, 2021; September 1, 2019; July 1, 2018.

10A NCAC 13P .0222 is proposed for amendment as follows:

10A NCAC 13P .0222 TRANSPORT OF STRETCHER BOUND PATIENTS

(a) Any person transported on a stretcher as defined in Rule .0102 of this Subchapter meets the definition of patient as defined in G.S. 131E-155(16).

(b) Stretchers may only be utilized for patient transport in an ambulance permitted by the OEMS in accordance with G.S. 131E-156 and Rule .0211 of this Section.

(c) The Medical Care Commission exempts wheeled chair devices used solely for the transportation of mobility impaired persons seated in an upright position in non-permitted vehicles from the definition of stretcher.

History Note: *Authority G.S. 131E-156; 131E-157; 143-508(d)(8);*
Eff. January 1, 2017;
Amended Eff. July 1, 2021; July 1, 2018.

10A NCAC 13P .0501 is proposed for amendment as follows:

10A NCAC 13P .0501 EDUCATIONAL PROGRAMS

(a) EMS educational programs that qualify credentialed EMS personnel to perform within their scope of practice shall be offered by an EMS educational institution as set forth in Section .0600 of this Subchapter, or by an EMS educational institution in another state where the education and credentialing requirements have been approved for legal recognition by the Department pursuant to G.S. 131E-159 as determined using the professional judgment of OEMS staff following comparison of out-of-state standards with the program standards set forth in this Rule.

(b) Educational programs approved to qualify EMS personnel for credentialing shall meet the educational content of the "US DOT NHTSA National EMS Education Standards," which is hereby incorporated by reference, including subsequent amendments and editions. This document is available online at no cost at www.ems.gov/education.html.

(c) Educational programs approved to qualify EMS personnel for AEMT and Paramedic credentialing shall meet the requirements of Paragraph (b) of this Rule and possess verification of accreditation or a valid letter of review from the Commission on Accreditation of Allied Health Education Programs (CAAHEP) or other accrediting agency determined using the professional judgment of OEMS staff following a comparison of standards.

~~(c)~~ (d) Educational programs approved to qualify EMD personnel for credentialing shall conform with the "ASTM ~~F1258 – 95(2006):~~ F1258 – 95(2014): Standard Practice for Emergency Medical ~~"Dispatch"~~ Dispatch" incorporated by reference including subsequent amendments and editions. This document is available from ASTM International, 100 Barr Harbor Drive, PO Box C700, West Conshohocken, PA, 19428-2959 USA, at a cost of forty eight dollars ~~($40.00)~~ ($48.00) per copy.

~~(d)~~ (e) Instructional methodology courses approved to qualify Level I EMS instructors shall conform with the "US DOT NHTSA 2002 National Guidelines for Educating EMS Instructors" incorporated by reference including subsequent amendments and additions. This document is available online at no cost at www.ems.gov/education.html.

~~(e)~~ (f) Continuing educational programs approved by the OEMS to qualify EMS personnel for renewal of credentials shall be approved by demonstrating the ability to assess cognitive competency in the skills and medications for the level of application as defined by the North Carolina Medical Board pursuant to G.S. 143-514.

~~(f)~~ (g) Refresher courses shall comply with the requirements defined in Rule .0513 of this Section.

History Note: *Authority G.S. 143-508(d)(3); 143-508(d)(4); 143-514;*
Temporary Adoption Eff. January 1, 2002;
Eff. January 1, 2004;
Amended Eff. January 1, 2009;
Readoption Eff. January 1, ~~2017.~~ 2017;
Amended Eff. July 1, 2021.

10A NCAC 13P .0502 is proposed for amendment as follows:

10A NCAC 13P .0502 INITIAL CREDENTIALING REQUIREMENTS FOR EMR, EMT, AEMT, PARAMEDIC, AND EMD

(a) In order to be credentialed by the OEMS as an EMR, EMT, AEMT, or Paramedic, individuals shall:

(1) ~~be~~ Be at least 18 years of age. An examination may be taken at age 17; however, the EMS credential shall not be issued until the applicant has reached the age of 18.

(2) ~~complete~~ Complete an approved educational program as set forth in Rule ~~.0501(b)~~ .0501 of this Section for their level of application.

(3) ~~complete~~ Complete a scope of practice performance evaluation that uses performance measures based on the cognitive, psychomotor, and affective educational objectives set forth in Rule ~~.0501(b)~~ .0501 of this Section and that is consistent with their level of application, and approved by the OEMS. This scope of practice evaluation shall be completed no more than one year prior to examination. This evaluation shall be conducted by a Level I or Level II EMS Instructor credentialed at or above the level of application or under the direction of the primary credentialed EMS instructor or educational medical advisor for the approved educational program.

(4) ~~within~~ Within 90 days from their course graded date as reflected in the OEMS credentialing database, complete a written examination administered by the OEMS. If the applicant fails to register and complete a written examination within the ~~90-day~~ 90-day period, the applicant shall obtain a letter of authorization to continue eligibility for testing from his or her EMS Educational Institution's program coordinator to qualify for an extension of the ~~90-day~~ 90-day requirement set forth in this Paragraph. If the EMS Educational Institution's program coordinator declines to provide a letter of authorization, the applicant shall be disqualified from completing the credentialing process. Following a review of the applicant's specific circumstances, OEMS staff will determine, based on professional judgment, if the applicant qualifies for EMS credentialing eligibility. The OEMS shall notify the applicant in writing within 10 business days of the decision.

(A) a maximum of three attempts within ~~nine~~ six months shall be allowed.

~~(B) if the individual fails to pass a written examination, the individual may continue eligibility for examination for an additional three attempts within the following nine months by submitting to the OEMS evidence the individual repeated a course specific scope of practice evaluation as set forth in Subparagraph (a)(3) of this Rule, and evidence of completion of a refresher course as set forth in Rule .0513 of this Section for the level of application; or~~

~~(C)~~(B) if unable to pass the written examination requirement after ~~six attempts~~ three attempts, ~~within an 18 period following course grading date as reflected in the OEMS credentialing database,~~ the educational program shall become invalid and the individual may only

become eligible for credentialing by repeating the requirements set forth in Rule .0501 of this Section.

(5) ~~submit~~ Submit to a criminal background history check as set forth in Rule .0511 of this Section.

(6) ~~submit~~ Submit evidence of completion of all court conditions resulting from any misdemeanor or felony conviction(s).

(b) An individual seeking credentialing as an EMR, EMT, ~~AEMT~~ AEMT, or Paramedic may qualify for initial credentialing under the legal recognition option set forth in G.S. 131E-159(c).

(1) Individuals possessing a credential for less than two years being used for the level of application shall complete a written examination administered by the OEMS as set forth in this Rule.

(2) Individuals seeking credentialing as an AEMT or Paramedic shall submit documentation that the credential being used for application is from a CAAHEP Accredited program.

(c) In order to be credentialed by the OEMS as an EMD, individuals shall:

(1) be at least 18 years of age;

(2) complete the educational requirements set forth in Rule ~~.0501(c)~~ .0501 of this Section;

(3) complete, within one year prior to application, an AHA CPR course or a course determined by the OEMS to be equivalent to the AHA CPR course, including infant, child, and adult CPR;

(4) submit to a criminal background history check as defined in Rule .0511 of this Section;

(5) submit evidence of completion of all court conditions resulting from any misdemeanor or felony conviction(s); and

(6) possess an EMD nationally recognized credential pursuant to G.S. 131E-159(d).

(d) Pursuant to G.S. 131E-159(h), the Department shall not issue an EMS credential for any person listed on the Department of Public Safety, Sex Offender and Public Protection Registry, or who was convicted of an offense that would have required registration if committed at a time when registration would have been required by law.

History Note: *Authority G.S. 131E-159(a); 131E-159(b); 131E-159(g); 131E-159(h); 143-508(d)(3); 143B-952;*
Temporary Adoption Eff. January 1, 2002;
Eff. February 1, 2004;
Amended Eff. January 1, 2009;
Readopted Eff. January 1, ~~2017.~~ 2017;
Amended Eff. July 1, 2021.

10A NCAC 13P .0504 is proposed for amendment as follows:

10A NCAC 13P .0504 RENEWAL OF CREDENTIALS FOR EMR, EMT, AEMT, PARAMEDIC, AND EMD

(a) EMR, EMT, AEMT, and Paramedic applicants shall renew credentials by meeting the following criteria:

(1) presenting documentation to the OEMS or an approved EMS educational institution or program as set forth in Rule .0601 or .0602 of this Subchapter that they have completed an approved educational program as described in Rule ~~.0501(e) or (f)~~ .0501 of this Section;

(2) submit to a criminal background history check as set forth in Rule .0511 of this Section;

(3) submit evidence of completion of all court conditions resulting from applicable misdemeanor or felony conviction(s); and

(4) be a resident of North Carolina or affiliated with an EMS provider approved by the Department.

(b) An individual may renew credentials by presenting documentation to the OEMS that he or she holds a valid EMS credential for his or her level of application issued by the National Registry of Emergency Medical Technicians or by another state where the education and credentialing requirements have been determined by OEMS staff in their professional judgment to be equivalent to the educations and credentialing requirements set forth in this Section.

(c) EMD applicants shall renew credentials by presenting documentation to the OEMS that he or she holds a valid EMD credential issued by a national credentialing agency using the education criteria set forth in Rule ~~.0501(c)~~ .0501 of this Section.

(d) Upon request, an EMS professional may renew at a lower credentialing level by meeting the requirements defined in Paragraph (a) of this Rule. To restore the credential held at the higher level, the individual shall meet the requirements set forth in Rule .0512 of this Section.

(e) EMS credentials may not be renewed through a local credentialed institution or program more than 90 days prior to the date of expiration.

(f) Pursuant to G.S. 150B-3(a), if an applicant makes a timely and sufficient application for renewal, the EMS credential shall not expire until a decision on the credential is made by the Department. If the application is denied, the credential shall remain effective until the last day for applying for judicial review of the Department's order.

(g) Pursuant to G.S. 131E-159(h), the Department shall not renew the EMS credential for any person listed on the North Carolina Department of Public Safety, Sex Offender and Public Protection Registry, or who was convicted of an offense that would have required registration at a time when registration would have been required by law.

History Note: *Authority G.S. 131E-159(a); 131E-159(g); 131E-159(h); 143-508(d)(3); 143B-952; 150B-3(a);*
Temporary Adoption Eff. January 1, 2002;
Eff. February 1, 2004;
Amended Eff. January 1, 2009;
Readopted Eff. January 1, ~~2017.~~ 2017;
Amended Eff. July 1, 2021.

10A NCAC 13P .0507 is proposed for amendment as follows:

10A NCAC 13P .0507 INITIAL CREDENTIALING REQUIREMENTS FOR LEVEL I EMS INSTRUCTORS

(a) Applicants for credentialing as a Level I EMS Instructor shall:

(1) be currently credentialed by the OEMS as an EMT, AEMT, or Paramedic;

(2) have completed post-secondary level education equal to or exceeding a minimum of an Associate Degree from an institution accredited by an approved agency listed on the U.S. Department of Education website, www.ed.gov:

(A) The Department shall accept degrees from programs accredited by the Accreditation Commission for Education in Nursing (ACEN) and the Commission on Accreditation of Allied Health Education Programs.

(B) Additional degrees may be accepted based on the professional judgment of OEMS staff following a comparison of standards;

~~(2)~~(3) have three years experience at the scope of practice for the level of application;

~~(3)~~(4) within one year prior to application, complete an in-person evaluation that demonstrates the applicant's ability to provide didactic and clinical instruction based on the cognitive, psychomotor, and affective educational objectives in Rule ~~.0501(b)~~ .0501 of this Section consistent with their level of application and approved by the OEMS:

(A) for a credential to teach at the EMT level, this evaluation shall be conducted under the direction of a Level II EMS Instructor credentialed at or above the level of application; and

(B) for a credential to teach at the AEMT or Paramedic level, this evaluation shall be conducted under the direction of the educational medical advisor, or a Level II EMS Instructor credentialed at or above the level of application and designated by the educational medical advisor;

~~(4)~~(5) have 100 hours of teaching experience at or above the level of application in an approved EMS educational program or a program determined by OEMS staff in their professional judgment equivalent to an EMS education program;

~~(5)~~(6) complete an educational program as described in Rule ~~.0501(d)~~ .0501 of this Section; and

~~(6)~~(7) within one year prior to application, attend an OEMS Instructor workshop sponsored by the OEMS. A listing of scheduled OEMS Instructor workshops is available from the OEMS at ~~www.ncems.org; and~~ https://info.ncdhhs.gov/dhsr/ems.

~~(7) have a high school diploma or General Education Development certificate.~~

(b) An individual seeking credentialing for Level I EMS Instructor may qualify for initial credentialing under the legal recognition option defined in G.S. 131E-159(c).

(c) The credential of a Level I EMS Instructor shall be valid for four years, or less pursuant to G.S. ~~131E-159(c)~~ 131E-159(c), unless any of the following occurs:

(1) the OEMS imposes an administrative action against the instructor credential; or

(2) the instructor fails to maintain a current EMT, AEMT, or Paramedic credential at the highest level that the instructor is approved to teach.

(d) Pursuant to the provisions of G.S. 131E-159(h), the Department shall not issue an EMS credential for any person listed on the Department of Public Safety, Sex Offender and Public Protection Registry, or who was convicted of an offense that would have required registration if committed at a time when registration would have been required by law.

History Note: *Authority G.S. 131E-159; 143-508(d)(3);*
Temporary Adoption Eff. January 1, 2002;
Eff. February 1, 2004;
Amended Eff. January 1, 2009;
Readopted Eff. January 1, 2017;
Amended Eff. July 1, 2021; September 1, 2019.

10A NCAC 13P .0508 is proposed for amendment as follows:

10A NCAC 13P .0508 INITIAL CREDENTIALING REQUIREMENTS FOR LEVEL II EMS INSTRUCTORS

(a) Applicants for credentialing as a Level II EMS Instructor shall:

(1) be currently credentialed by the OEMS as an EMT, AEMT, or Paramedic;

(2) be currently credentialed by the OEMS as a Level I Instructor at the EMT, AEMT, or Paramedic level;

~~(2)~~(3) have completed post-secondary level education equal to or exceeding ~~an Associate Degree;~~ a Bachelor's Degree from an institution accredited by an approved agency listed on the U.S. Department of Education website, www.ed.gov:

(A) The Department shall accept degrees from programs accredited by the Accreditation Commission for Education in Nursing (ACEN) and the Commission on Accreditation of Allied Health Education Programs.

(B) Additional degrees may be accepted based on the professional judgment of OEMS staff following a comparison of standards;

~~(3)~~(4) within one year prior to application, complete an in-person evaluation that demonstrates the applicant's ability to provide didactic and clinical instruction based on the cognitive, psychomotor, and affective educational objectives in Rule ~~.0501(b)~~ .0501 of this Section consistent with their level of application and approved by the OEMS:

(A) for a credential to teach at the EMT level, this evaluation shall be conducted under the direction of a Level II EMS Instructor credentialed at or above the level of application; and

(B) for a credential to teach at the AEMT or Paramedic level, this evaluation shall be conducted under the direction of the educational medical advisor, or a Level II EMS Instructor credentialed at or above the level of application and designated by the educational medical advisor;

~~(4)~~(5) ~~have two~~ a minimum two concurrent years teaching experience as a Level I EMS Instructor at or above the level of ~~application~~ application, or as a Level II EMS Instructor at a lesser credential level applying for a higher level in an approved EMS educational ~~program~~ program, or teaching experience determined by OEMS staff in their professional judgment to be equivalent to an EMS Level I education program;

~~(5)~~(6) complete the "EMS Education Administration Course conducted by a North Carolina Community College or the National Association of EMS Educators Level II Instructor ~~Course;~~ Course that is valid for the duration of the active Level II Instructor credential; and

~~(6)~~(7) within one year prior to application, attend an OEMS Instructor workshop sponsored by the OEMS. A listing of scheduled OEMS Instructor workshops is available from the OEMS at ~~www.ncems.org.~~ https://info.ncdhhs.gov/dhsr/ems.

(b) An individual seeking credentialing for Level II EMS Instructor may qualify for initial credentialing under the legal recognition option defined in G.S. 131E-159(c).

(c) The credential of a Level II EMS Instructor is valid for four years, or less pursuant to ~~G.S. 131E-159(c)~~ 131E-159(c), unless any of the following occurs:

(1) the OEMS imposes an administrative action against the instructor credential; or

(2) the instructor fails to maintain a current EMT, AEMT, or Paramedic credential at the highest level that the instructor is approved to teach.

(d) Pursuant to the provisions of G.S. 131E-159(h) the Department shall not issue an EMS credential for any person listed on the Department of Public Safety, Sex Offender and Public Protection Registry, or who was convicted of an offense that would have required registration if committed at a time when registration would have been required by law.

History Note: *Authority G.S. 131E-159; 143-508(d)(3);*
Temporary Adoption Eff. January 1, 2002;
Eff. February 1, 2004;
Amended Eff. January 1, 2009;
Readopted Eff. January 1, 2017;
Amended Eff. July 1, 2021; September 1, 2019.

10A NCAC 13P .0510 is proposed for amendment as follows:

10A NCAC 13P .0510 RENEWAL OF CREDENTIALS FOR LEVEL I AND LEVEL II EMS INSTRUCTORS

(a) Level I and Level II EMS Instructor applicants shall renew credentials by presenting documentation to the OEMS that they:

(1) are credentialed by the OEMS as an EMT, ~~AEMT~~ AEMT, or Paramedic;

(2) within one year prior to application, complete an evaluation that demonstrates the applicant's ability to provide didactic and clinical instruction based on the cognitive, psychomotor, and affective educational objectives in Rule ~~.0501(b)~~ .0501 of this Section consistent with their level of application and approved by the OEMS:

(A) to renew a credential to teach at the EMT level, this evaluation shall be conducted under the direction of a Level II EMS Instructor credentialed at or above the level of application; and

(B) to renew a credential to teach at the AEMT or Paramedic level, this evaluation shall be conducted under the direction of the educational medical advisor, or a Level II EMS Instructor credentialed at or above the level of application and designated by the educational medical advisor;

(3) completed 96 hours of EMS instruction at the level of ~~application; and~~ application. Individuals identified as EMS program coordinators or positions determined by OEMS staff in the professional judgment to the equivalent to an EMS program coordinator may provide up to 72 hours related to the institution's needs, with the remaining 24 hours in EMS instruction;

(4) completed 24 hours of educational professional development as defined by the educational institution that provides for:

(A) enrichment of knowledge;

(B) development or change of attitude in students; or

(C) acquisition or improvement of skills; and

(5) within one year prior to renewal application, attend an OEMS Instructor workshop sponsored by the OEMS.

(b) An individual may renew a Level I or Level II EMS Instructor credential under the legal recognition option defined in G.S. 131E-159(c).

(c) The credential of a Level I or Level II EMS Instructor is valid for four years, or less pursuant to G.S. 131E-159(c) unless any of the following occurs:

(1) the OEMS imposes an administrative action against the instructor credential; or

(2) the instructor fails to maintain a current EMT, AEMT, or Paramedic credential at the highest level that the instructor is approved to teach.

(d) Pursuant to the provisions of G.S. 131E-159(h), the Department shall not issue an EMS credential for any person listed on the Department of Public Safety, Sex Offender and Public Protection Registry, or who was convicted of an offense that would have required registration if committed at a time when registration would have been required by law.

History Note: *Authority G.S. 131E-159(a); 131E-159(b); 143-508(d)(3);*
Eff. February 1, 2004;
Amended Eff. February 1, 2009;
Readopted Eff. January 1, ~~2017.~~ 2017;
Amended Eff. July 1, 2021.

10A NCAC 13P .0512 is proposed for amendment as follows:

10A NCAC 13P .0512 REINSTATEMENT OF LAPSED EMS CREDENTIAL

(a) EMS personnel enrolled in an OEMS approved continuing education program as set forth in Rule .0601 of this Subchapter and ~~that~~ who was eligible for renewal of an EMS credential prior to expiration, may request the EMS educational institution submit documentation of the continuing education record to the OEMS. OEMS shall renew the EMS credential to be valid for four years from the previous expiration date.

(b) An individual with a lapsed North Carolina EMS credential is eligible for reinstatement through the legal recognition option defined in G.S. 131E-159(c) and Rule .0502 of this Section.

(c) EMR, EMT, AEMT, and Paramedic applicants for reinstatement of an EMS credential, lapsed up to ~~24~~ 12 months, shall:

(1) be ineligible for legal recognition pursuant to G.S. 131E-159(c);

(2) be a resident of North Carolina or affiliated with a North Carolina EMS Provider;

(3) at the time of application, present evidence that renewal education requirements were met prior to expiration or complete a refresher course at the level of application taken following expiration of the credential;

(4) ~~EMRs and EMTs shall~~ complete an OEMS administered written examination for the individual's level of credential application;

(5) undergo a criminal history check performed by the OEMS; and

(6) submit evidence of completion of all court conditions resulting from applicable misdemeanor or felony conviction(s).

~~(d) EMR and EMT applicants for reinstatement of an EMS credential, lapsed more than 24 months, must:~~

~~(1) be ineligible for legal recognition pursuant to G.S. 131E-159(c); and~~

~~(2) meet the provisions for initial credentialing set forth in Rule .0502 of this Section~~

~~(e) AEMT and Paramedic applicants for reinstatement of an EMS credential, lapsed between 24 and 48 months, shall:~~

~~(1) be ineligible for legal recognition pursuant to G.S. 131E-159(c);~~

~~(2) be a resident of North Carolina or affiliated with a North Carolina EMS Provider;~~

~~(3) present evidence of completion of a refresher course at the level of application taken following expiration of the credential;~~

~~(4) complete an OEMS administered written examination for the individuals level of credential application;~~

~~(5) undergo a criminal history check performed by the OEMS; and~~

~~(6) submit evidence of completion of all court conditions resulting from applicable misdemeanor or felony conviction(s).~~

~~(f)~~(d) ~~AEMT~~ EMR, EMT, AEMT, and Paramedic applicants for reinstatement of an EMS credential, lapsed more than ~~48~~ 12 months, shall:

(1) be ineligible for legal recognition pursuant to G.S. 131E-159(c); and

(2) meet the provisions for initial credentialing set forth in Rule .0502 of this Section.

(e) EMT, AEMT, and Paramedic applicants for reinstatement of an EMS Instructor Credential, lapsed up to 12 months, shall:

(1) be ineligible for legal recognition pursuant to G.S. 131E-159(c);

(2) be a resident of North Carolina or affiliated with a North Carolina EMS Provider; and

(3) at the time of application, present evidence that renewal requirements were met prior to expiration or within six months following the expiration of the Instructor credential.

(f) EMT, AEMT, and Paramedic applicants for reinstatement of an EMS Instructor credential, lapsed greater than 12 months, shall:

(1) be ineligible for legal recognition pursuant to G.S. 131E-159(c); and

(2) meet the requirements for initial Instructor credentialing set forth in Rules .0507 and .0508 of this Section. Degree requirements that were not applicable to EMS Instructors initially credentialed prior to April 1, 2021 shall be required for reinstatement of a lapsed credential.

(g) EMD applicants shall renew a lapsed credential by meeting the requirements for initial credentialing set forth in Rule .0502 of this Section.

(h) Pursuant to G.S. 131E-159(h), the Department shall not issue or renew an EMS credential for any person listed on the Department of Public Safety, Sex Offender and Public Protection Registry, or who was convicted of an offense that would have required registration if committed at a time when registration would have been required by law.

History Note: *Authority G.S. 131E-159; 143-508(d)(3); 143B-952;*
Eff. January 1, ~~2017.~~ 2017;
Amended Eff. July 1, 2021.

10A NCAC 13P .0601 is proposed for amendment as follows:

SECTION .0600 – EMS EDUCATIONAL INSTITUTIONS AND PROGRAMS

10A NCAC 13P .0601 CONTINUING EDUCATION EMS EDUCATIONAL ~~INSTITUTION~~ PROGRAM REQUIREMENTS

(a) Continuing Education EMS Educational ~~Institutions~~ Programs shall be credentialed by the OEMS to provide only EMS continuing ~~education programs.~~ education. An application for credentialing as an approved EMS continuing education ~~institution~~ program shall be submitted to the OEMS for review.

(b) Continuing Education EMS Educational ~~Institutions~~ Programs shall have:

(1) at least a Level I EMS Instructor as program coordinator and shall hold a Level I EMS Instructor credential at a level equal to or greater than the highest level of continuing education program offered in the EMS ~~System or~~ System, Specialty Care Transport ~~Program;~~ Program, or Agency;

(2) a continuing education program shall be consistent with the services offered by the EMS ~~System or~~ System, Specialty Care Transport ~~Program;~~ Program, or Agency;

(A) In an EMS System, the continuing education programs shall be reviewed and approved by the system continuing education coordinator and Medical Director; ~~and~~

(B) In a Specialty Care Transport Program, the continuing education program shall be reviewed and approved by Specialty Care Transport Program Continuing Education Coordinator and the Medical Director; and

(C) In an Agency not affiliated with an EMS System or Specialty Care Transport Program, the continuing education program shall be reviewed and approved by the Agency Program Medical Director;

(3) written educational policies and procedures to include each of the following;

(A) the delivery of educational programs in a manner where the content and material is delivered to the intended audience, with a limited potential for exploitation of such content and material;

(B) the record-keeping system of student attendance and performance;

(C) the selection and monitoring of EMS instructors; and

(D) student evaluations of faculty and the program's courses or components, and the frequency of the evaluations;

(4) access to instructional supplies and equipment necessary for students to complete educational programs as defined in Rule ~~.0501(b)~~ .0501 of this Subchapter;

(5) meet ~~at a minimum,~~ the educational program requirements as defined in Rule ~~.0501(c)~~ .0501 of this Subchapter;

(6) Upon request, the approved EMS continuing education ~~institution~~ program shall provide records to the OEMS in order to verify compliance and student eligibility for credentialing; and

(7) ~~unless accredited in accordance with Rule .0605 of this Section,~~ approved education ~~institution~~ program credentials are valid for a period not to exceed four years.

(c) Program coordinators shall attend an OEMS Program Coordinator workshop annually. A listing of scheduled OEMS Program Coordinator Workshops is available at https://emspic.org.

~~(c)~~(d) Assisting physicians delegated by the EMS System Medical Director as authorized by Rule ~~.0403(b)~~ .0403 of this Subchapter or SCTP Medical Director as authorized by Rule ~~.0404(b)~~ .0404 of this Subchapter for provision of medical oversight of continuing education programs must meet the Education Medical Advisor criteria as defined in the "North Carolina College of Emergency Physicians: Standards for Medical Oversight."

History Note: *Authority G.S. 143-508(d)(4); 143-508(d)(13);*
Temporary Adoption Eff. January 1, 2002;
Eff. January 1, 2004;
Amended Eff. January 1, 2009;
Readopted Eff. January 1, ~~2017.~~ 2017;
Amended Eff. July 1, 2021.

10A NCAC 13P .0602 is proposed for amendment as follows:

10A NCAC 13P .0602 BASIC AND ADVANCED EMS EDUCATIONAL INSTITUTION REQUIREMENTS

(a) Basic and Advanced EMS Educational Institutions may offer educational programs for which they have been credentialed by the OEMS.

(1) EMS Educational Institutions shall complete a minimum of two initial courses for each educational program approved for the Educational Institution's credential approval period.

(2) EMS Educational Institutions that do not complete two initial courses for each educational program approved shall be subject to action as set forth in in Rule .1505 of this Subchapter.

(b) For initial courses, Basic EMS Educational Institutions shall meet all of the requirements for continuing EMS educational ~~institutions~~ programs defined in Rule .0601 of this Section and shall have:

(1) at least a Level I EMS Instructor as each lead course instructor for ~~EMR and EMT~~ all courses. The lead course instructor must be credentialed at a level equal to or higher than the course ~~offered;~~ and shall meet the lead instructor responsibilities under Standard III of the CAAHEP Standards and Guidelines for the Accreditation of Educational Programs in the Emergency Medical Services Professions. The lead instructor shall:

(A) perform duties assigned under the direction and delegation of the program director.

(B) assist in coordination of the didactic, lab, clinical, and field internship instruction.

(2) a lead EMS educational program coordinator. This individual ~~may be either~~ shall be a Level II EMS Instructor credentialed at or above the highest level of course offered by the ~~institution, or a combination of staff who cumulatively meet the requirements of the Level II EMS Instructor set forth in this Subparagraph. These individuals may share the responsibilities of the lead EMS educational coordinator. The details of this option shall be defined in the educational plan required in Subparagraph (b)(5) of this Rule;~~ institution, and:

(A) have EMS or related allied health education, training, and experience;

(B) be knowledgeable about methods of instruction, testing, and evaluation of students;

(C) have field experience in the delivery of pre-hospital emergency care;

(D) have academic training and preparation related to emergency medical services, at least equivalent to that of a paramedic; and

(E) be knowledgeable of current versions of the National EMS Scope of Practice and National EMS Education Standards as defined by USDOT NHTSA National EMS, evidenced-informed clinical practice, and incorporated by Rule .0501 of this Section;

(3) a lead EMS educational program coordinator responsible for the following:

(A) the administrative oversight, organization, and supervision of the program;

(B) the continuous quality review and improvement of the program;

(C) the long-range planning on ongoing development of the program;

(D) evaluating the effectiveness of the instruction, faculty, and overall program;

(E) the collaborative involvement with the Education Medical Advisor;

(F) the training and supervision of clinical and field internship preceptors; and

(G) the effectiveness and quality of fulfillment of responsibilities delegated to another qualified individual;

~~(3)~~(4) written educational policies and procedures that include:

(A) the written educational policies and procedures set forth in Rule ~~.0601(b)(4)~~ .0601 of this Section;

(B) the delivery of cognitive and psychomotor examinations in a manner that will protect and limit the potential for exploitation of such content and material;

(C) the exam item validation process utilized for the development of validated cognitive examinations;

(D) the selection and monitoring of all in-state and out-of-state clinical education and field internship sites;

(E) the selection and monitoring of all educational institutionally approved clinical education and field internship preceptors;

(F) utilization of EMS preceptors providing feedback to the student and EMS program;

(G) the evaluation of preceptors by their students, including the frequency of evaluations;

(H) the evaluation of the clinical education and field internship sites by their students, including the frequency of evaluations; and

(I) completion of an annual evaluation of the program to identify any correctable deficiencies;

~~(4)~~(5) an Educational Medical Advisor that meets the criteria as defined in the "North Carolina College of Emergency Physicians: Standards for Medical Oversight and Data ~~Collection;" and~~ Collection" who is responsible for the following;

(A) medical oversight of the program;

(B) collaboration to provide appropriate and updated educational content for the program curriculum;

(C) establishing minimum requirements for program completion;

(D) oversight of student evaluation, monitoring, and remediation as needed;

(E) ensuring entry level competence;

(F) ensuring interaction of physician and students; and

~~(5)~~(6) written educational policies and procedures describing the delivery of educational programs, the record-keeping system detailing student attendance and performance, and the selection and monitoring of EMS instructors.

(c) For initial courses, Advanced Educational Institutions shall meet all requirements ~~defined~~ set forth in Paragraph (b) of this ~~Rule, and have a Level II EMS Instructor as lead instructor for AEMT and Paramedic initial courses. The lead instructor shall be credentialed at a level equal to or higher than the course offered.~~ Rule, standard III of the

CAAHEP Standards and Guidelines for the Accreditation of Educational Programs in the Emergency Medical Services Professions shall apply, and;

(1) The faculty must be knowledgeable in course content and effective in teaching their assigned subjects, and capable through academic preparation, training, and experience to teach the courses or topics to which they are assigned.

(2) A faculty member to assist in teaching and clinical coordination in addition to the program coordinator.

(d) Basic and Advanced EMS Educational Institution credentials shall be valid for a period of four years, unless the institution is accredited in accordance with Rule .0605 of this Section.

History Note: *Authority G.S. 143-508(d)(4); 143-508(d)(13);*
Temporary Adoption Eff. January 1, 2002;
Eff. January 1, 2004;
Amended Eff. January 1, 2009;
Readopted Eff. January 1, ~~2017.~~ 2017;
Amended Eff. July 1, 2021.

10A NCAC 13P .0904 is proposed for amendment as follows:

10A NCAC 13P .0904 INITIAL DESIGNATION PROCESS

(a) For initial Trauma Center designation, the hospital shall request a consult visit by OEMS and the consult shall occur within one year prior to submission of the RFP.

(b) A hospital interested in pursuing Trauma Center designation shall submit a letter of intent 180 days prior to the submission of an RFP to the OEMS. The letter shall define the hospital's primary trauma catchment area. Simultaneously, Level I or II applicants shall also demonstrate the need for the Trauma Center designation by submitting one original and three copies of documents that include:

(1) the population to be served and the extent that the population is underserved for trauma care with the methodology used to reach this conclusion;

(2) geographic considerations, to include trauma primary and secondary catchment area and distance from other Trauma Centers; and

(3) ~~evidence~~ for Level 1 applicants, evidence the Trauma Center will admit at least 1200 trauma patients annually or show that its trauma service will be taking care of at least 240 trauma patients yearly with an ISS greater than or equal to ~~15 yearly.~~ 15. ~~These criteria shall be met without compromising the quality of care or cost effectiveness of any other designated Level I or II Trauma Center sharing all or part of its catchment area or by jeopardizing the existing Trauma Center's ability to meet this same 240 patient minimum.~~

(c) The hospital shall be participating in the State Trauma Registry as defined in Rule .0102 of this Subchapter, and submit data to the OEMS weekly a minimum of 12 months prior to application that includes all the Trauma Center's trauma patients as defined in Rule .0102 of this ~~Subchapter who are:~~ Subchapter.

~~(1) diverted to an affiliated hospital;~~

~~(2) admitted to the Trauma Center for greater than 24 hours from an ED or hospital;~~

~~(3) die in the ED;~~

~~(4) are DOA; or~~

~~(5) are transferred from the ED to the OR, ICU, or another hospital (including transfer to any affiliated hospital).~~

(d) ~~OEMS shall review the regional Trauma Registry data from both the applicant and the existing trauma center(s), and ascertain the applicant's ability to satisfy the justification of need information required in Paragraph (b) of this Rule.~~ The OEMS shall notify the applicant's primary RAC of the ~~application and provide the regional data submitted by the applicant in Paragraph (b) of this Rule for review and comment.~~ application. ~~The~~ The applicant's primary RAC shall be given 30 days to submit written comments to the OEMS.

~~(e) OEMS shall notify the respective Board of County Commissioners in the applicant's primary catchment area of the request for initial designation to allow for comment during the same 30 day comment period.~~

~~(f)~~(e) OEMS shall notify the hospital in writing of its decision to allow submission of an RFP. ~~If approved, the RAC and Board of County Commissioners in the applicant's primary catchment area shall also be notified by the OEMS that an RFP will be submitted.~~

~~(g)~~(f) Once the hospital is notified that an RFP will be accepted, the hospital shall complete and submit an electronic copy of the completed RFP ~~with signatures~~ to the OEMS at least 45 days prior to the proposed site visit date.

~~(h)~~(g) The RFP shall demonstrate that the hospital meets the standards for the designation level applied for as found in Rule .0901 of this Section.

~~(i)~~(h) If OEMS does not recommend a site visit based upon failure to comply with Rule .0901 of this Section, the OEMS shall send the written reasons to the hospital within 30 days of the decision. The hospital may reapply for designation within six months following the submission of an updated RFP. If the hospital fails to respond within six months, the hospital shall reapply following the process outlined in Paragraphs (a) through ~~(h)~~ (g) of this Rule.

~~(j) If after review of the RFP, the OEMS recommends the hospital for a site visit, the OEMS shall notify the hospital within 30 days and the site visit shall be conducted within six months of the recommendation. The hospital and the OEMS shall agree on the date of the site visit.~~

~~(k)~~(i) Except for OEMS representatives, any in-state reviewer for a Level I or II visit shall be from outside the local or adjacent RAC, unless mutually agreed upon by the OEMS and the trauma center seeking designation where the hospital is located. The composition of a Level I or II state site survey team shall be as follows:

(1) one out-of-state trauma surgeon who is a Fellow of the ACS, experienced as a site surveyor, who shall be the primary reviewer;

(2) one in-state emergency physician who currently works in a designated trauma center, is a member of the American College of Emergency Physicians or American Academy of Emergency Medicine, and is boarded in emergency medicine by the American Board of Emergency Medicine or the American Osteopathic Board of Emergency Medicine;

(3) one in-state trauma surgeon who is a member of the North Carolina Committee on Trauma;

(4) for Level I designation, one out-of-state trauma program manager with an equivalent license from another state;

(5) for Level II designation, one in-state program manager who is licensed to practice nursing in North Carolina in accordance with the Nursing Practice Act, Article 9A, Chapter 90 of the North Carolina General Statutes; and

(6) OEMS Staff.

~~(l)~~(j) All site team members for a Level III visit shall be from in-state, and, except for the OEMS representatives, shall be from outside the local or adjacent RAC where the hospital is located. The composition of a Level III state site survey team shall be as follows:

(1) one trauma surgeon who is a Fellow of the ACS, who is a member of the North Carolina Committee on Trauma and shall be the primary reviewer;

(2) one emergency physician who currently works in a designated trauma center, is a member of the North Carolina College of Emergency Physicians or American Academy of Emergency Medicine,

and is boarded in emergency medicine by the American Board of Emergency Medicine or the American Osteopathic Board of Emergency Medicine;

(3) one trauma program manager who is licensed to practice nursing in North Carolina in accordance with the Nursing Practice Act, Article 9A, Chapter 90 of the North Carolina General Statutes; and

(4) OEMS Staff.

~~(m)~~(k) On the day of the site visit, the hospital shall make available all requested patient medical charts.

~~(n)~~(l) The primary reviewer of the site review team shall give a verbal post-conference report representing a consensus of the site review team. The primary reviewer shall complete and submit to the OEMS a written consensus report within 30 days of the site visit.

~~(o)~~(m) The report of the site survey team and the staff recommendations shall be reviewed by the State Emergency Medical Services Advisory Council at its next regularly scheduled meeting following the site visit. Based upon the site visit report and the staff recommendation, the State Emergency Medical Services Advisory Council shall recommend to the OEMS that the request for Trauma Center designation be approved or denied.

~~(p)~~(n) All criteria defined in Rule .0901 of this Section shall be met for initial designation at the level requested.

~~(q)~~(o) Hospitals with a deficiency(ies) resulting from the site visit shall be given up to 12 months to demonstrate compliance. Satisfaction of deficiency(ies) may require an additional site visit. The need for an additional site visit shall be determined on a case-by-case basis based on the type of deficiency. If compliance is not demonstrated within the time period set by OEMS, the hospital shall submit a new application and updated RFP and follow the process outlined in Paragraphs (a) through ~~(h)~~ (g) of this Rule.

~~(r)~~(p) The final decision regarding Trauma Center designation shall be rendered by the OEMS.

~~(s)~~(q) The OEMS shall notify the hospital in writing of the State Emergency Medical Services Advisory Council's and OEMS' final recommendation within 30 days of the Advisory Council meeting.

~~(t)~~(r) If a trauma center changes its trauma program administrative structure such that the trauma service, trauma Medical Director, trauma program manager, or trauma registrar are relocated on the hospital's organizational chart at any time, it shall notify OEMS of this change in writing within 30 days of the occurrence.

~~(u)~~(s) Initial designation as a trauma center shall be valid for a period of three years.

History Note: *Authority G.S. 131E-162; 143-508(d)(2);*
Temporary Adoption Eff. January 1, 2002;
Eff. April 1, 2003;
Amended Eff. January 1, 2009;
Readopted Eff. January 1, 2017;
Amended Eff. July 1,2021; July 1, 2018.

10 NCAC 13P .0905 is proposed for amendment as follows:

10A NCAC 13P .0905 RENEWAL DESIGNATION PROCESS

(a) Hospitals may utilize one of two options to achieve Trauma Center renewal:

(1) undergo a site visit conducted by OEMS to obtain a four-year renewal designation; or

(2) undergo a verification visit by the ACS, in conjunction with the OEMS, to obtain a three-year renewal designation.

(b) For hospitals choosing Subparagraph (a)(1) of this Rule:

(1) prior to the end of the designation period, the OEMS shall forward to the hospital an RFP for completion. The hospital shall, within 10 business days of receipt of the RFP, define for OEMS the Trauma Center's trauma primary catchment area. Upon this notification, OEMS shall notify the respective Board of County Commissioners in the applicant's trauma primary catchment area of the request for renewal to allow 30 days for comment.

(2) hospitals shall complete and submit an electronic copy of the RFP to the OEMS and the specified site surveyors at least 30 days prior to the site visit. The RFP shall include information that supports compliance with the criteria contained in Rule .0901 of this Section as it relates to the Trauma Center's level of designation.

(3) all criteria defined in Rule .0901 of this Section, as it relates to the Trauma Center's level of designation, shall be met for renewal designation.

(4) a site visit shall be conducted within 120 days prior to the end of the designation period. The hospital and the OEMS shall agree on the date of the site visit.

(5) the composition of a Level I or II site survey team shall be the same as that specified in Rule.0904(k) of this Section.

(6) the composition of a Level III site survey team shall be the same as that specified in Rule .0904(l) of this Section.

(7) on the day of the site visit, the hospital shall make available all requested patient medical charts.

(8) the primary reviewer of the site review team shall give a verbal post-conference report representing a consensus of the site review team. The primary reviewer shall complete and submit to the OEMS a written consensus report within 30 days of the site visit.

(9) the report of the site survey team and a staff recommendation shall be reviewed by the NC Emergency Medical Services Advisory Council at its next regularly scheduled meeting following the site visit. Based upon the site visit report and the staff recommendation, the NC Emergency Medical Services Advisory Council shall recommend to the OEMS that the request for Trauma Center renewal be:

(A) approved;

(B) approved with a contingency(ies) due to a deficiency(ies) requiring a focused review;

(C) approved with a contingency(ies) not due to a deficiency(ies) requiring a consultative visit; or

(D) denied.

(10) hospitals with a deficiency(ies) shall have up to 10 business days prior to the NC Emergency Medical Services Advisory Council meeting to provide documentation to demonstrate compliance. If the hospital has a deficiency that cannot be corrected in this period prior to the NC Emergency Medical Services Advisory Council meeting, the ~~hospital,~~ hospital shall be given 12 months by the OEMS to demonstrate compliance and undergo a focused review that may require an additional site visit. The need for an additional site visit is on a case-by-case basis based on the type of deficiency. The hospital shall retain its Trauma Center designation during the focused review period. If compliance is demonstrated within the prescribed time period, the hospital shall be granted its designation for the four-year period from the previous designation's expiration date. If compliance is not demonstrated within the 12 month time period, the Trauma Center designation shall not be renewed. To become redesignated, the hospital shall submit an updated RFP and follow the initial applicant process outlined in Rule .0904 of this Section.

(11) the final decision regarding trauma center renewal shall be rendered by the OEMS.

(12) the OEMS shall notify the hospital in writing of the NC Emergency Medical Services Advisory Council's and OEMS' final recommendation within 30 days of the NC Emergency Medical Services Advisory Council meeting.

(13) hospitals with a deficiency(ies) shall submit an action plan to the OEMS to address the deficiency(ies) within 10 business days following receipt of the written final decision on the trauma recommendations.

(c) For hospitals choosing Subparagraph (a)(2) of this Rule:

(1) at least six months prior to the end of the Trauma Center's designation period, the trauma center shall notify the OEMS of its intent to undergo an ACS verification visit. It shall simultaneously define in writing to the OEMS its trauma primary catchment area. Trauma Centers choosing this option shall then comply with all the ACS' verification procedures, as well as any additional state criteria as defined in Rule .0901 of this Section, that apply to their level of designation.

(2) when completing the ACS' documentation for verification, the Trauma Center shall ensure access to the ACS on-line PRQ (pre-review questionnaire) to OEMS. The Trauma Center shall simultaneously complete any documents supplied by OEMS and forward these to the OEMS.

~~(3) the OEMS shall notify the Board of County Commissioners within the trauma center's trauma primary catchment area of the Trauma Center's request for renewal to allow 30 days for comments.~~

~~(4)~~(3) the Trauma Center shall make sure the site visit is scheduled to ensure that the ACS' final written report, accompanying medical record reviews and cover letter are received by OEMS at least 30 days prior to a regularly scheduled NC Emergency Medical Services Advisory Council meeting to

ensure that the Trauma Center's state designation period does not terminate without consideration by the NC Emergency Medical Services Advisory Council.

~~(5)~~(4) any in-state review for a hospital choosing Subparagraph (a)(2) of this Rule, except for the OEMS staff, shall be from outside the local or adjacent RAC in which the hospital is located.

~~(6)~~(5) the composition of a Level I, II, or III site survey team for hospitals choosing Subparagraph (a)(2) of this Rule shall be as follows:

(A) one out-of-state trauma surgeon who is a Fellow of the ACS, experienced as a site surveyor, who shall be the primary reviewer;

(B) one out-of-state emergency physician who works in a designated trauma center, is a member of the American College of Emergency Physicians or the American Academy of Emergency Medicine, and is boarded in emergency medicine by the American Board of Emergency Physicians or the American Osteopathic Board of Emergency Medicine;

(C) one out-of-state trauma program manager with an equivalent license from another state; and

(D) OEMS staff.

~~(7)~~(6) the date, time, and all proposed members of the site visit team shall be submitted to the OEMS for review at least 45 days prior to the site visit. The OEMS shall approve the site visit schedule if the schedule does not conflict with the ability of attendance by required OEMS staff. The OEMS shall approve the proposed site visit team members if the OEMS determines there is no conflict of interest, such as previous employment, by any site visit team member associated with the site visit.

~~(8)~~(7) all state Trauma Center criteria shall be met as defined in Rule .0901of this Section for renewal of state designation. ACS' verification is not required for state designation. ACS' verification does not ensure a state designation.

~~(9)~~(8) The ACS final written report and supporting documentation described in Subparagraph (c)(4) of this Rule shall be used to generate a report following the post conference meeting for presentation to the NC Emergency Medical Services Advisory Council for renewal designation.

~~(10)~~(11) the final written report issued by the ACS' verification review committee, the accompanying medical record reviews from which all identifiers shall be removed and cover letter shall be forwarded to OEMS within 10 business days of its receipt by the Trauma Center seeking renewal.

~~(11)~~(10) the OEMS shall present its summary of findings report to the NC Emergency Medical Services Advisory Council at its next regularly scheduled meeting. The NC Emergency Medical Services Advisory Council shall recommend to the Chief of the OEMS that the request for Trauma Center renewal be:

(A) approved;

(B) approved with a contingency(ies) due to a deficiency(ies) requiring a focused review;

(C) approved with a contingency(ies) not due to a deficiency(ies); or

(D) denied.

~~(12)~~(11) the OEMS shall send the hospital written notice of the NC Emergency Medical Services Advisory Council's and OEMS' final recommendation within 30 days of the NC Emergency Medical Services Advisory Council meeting.

~~(13)~~(12) the final decision regarding trauma center designation shall be rendered by the OEMS.

~~(14)~~(13) hospitals with contingencies as the result of a deficiency(ies), as determined by OEMS, shall have up to 10 business days prior to the NC Emergency Medical Services Advisory Council meeting to provide documentation to demonstrate compliance. If the hospital has a deficiency that cannot be corrected in this time period, the hospital, may undergo a focused review to be conducted by the OEMS whereby the Trauma Center shall be given 12 months by the OEMS to demonstrate compliance. Satisfaction of contingency(ies) may require an additional site visit. The need for an additional site visit is on a case-by-case basis based on the type of deficiency. The hospital shall retain its Trauma Center designation during the focused review period. If compliance is demonstrated within the prescribed time period, the hospital shall be granted its designation for the three-year period from the previous designation's expiration date. If compliance is not demonstrated within the 12 month time period, the Trauma Center designation shall not be renewed. To become redesignated, the hospital shall submit a new RFP and follow the initial applicant process outlined in Rule .0904 of this Section.

~~(15)~~(14) hospitals with a deficiency(ies) shall submit an action plan to the OEMS to address the deficiency(ies) within 10 business days following receipt of the written final decision on the trauma recommendations.

(d) If a Trauma Center currently using the ACS' verification process chooses not to renew using this process, it must notify the OEMS at least six months prior to the end of its state trauma center designation period of its intention to exercise the option in Subparagraph (a)(1) of this Rule. Upon notification, the OEMS shall extend the designation for one additional year to ensure consistency with hospitals using Subparagraph (a)(1) of this Rule.

History Note: *Authority G.S. 131E-162; 143-508(d)(2);*
Temporary Adoption Eff. January 1, 2002;
Eff. April 1, 2003;
Amended Eff. April 1, 2009; January 1, 2009; January 1, 2004;
Readoption Eff. January 1, ~~2017.~~ 2017;
Amended Eff. July 1, 2021.

10A NCAC 13P .1101 is proposed for amendment as follows:

10A NCAC 13P .1101 STATE TRAUMA SYSTEM

(a) The state trauma system shall consist of regional plans, policies, guidelines, and performance improvement initiatives by the RACs to create an Inclusive Trauma System monitored by the OEMS.

(b) Each hospital and EMS System shall affiliate as defined in Rule ~~.0102(3)~~ .0102 of this Subchapter and participate with the RAC that includes the Level I or II Trauma Center where the majority of trauma patient referrals and transports occur. Each hospital and EMS System shall submit to the OEMS upon request patient transfer patterns from data sources that support the choice of their primary RAC affiliation. Each RAC shall include at least one Level I or II Trauma Center.

~~(c) The OEMS shall notify each RAC of its hospital and EMS System membership annually.~~

~~(d)~~(c) Each ~~hospital and each EMS System~~ Lead RAC Coordinator shall update and submit ~~its~~ RAC affiliation ~~information~~ membership for hospitals and EMS Systems to the OEMS no later than July 1 of each year. Each hospital or EMS System shall submit written notification to the OEMS for any RAC affiliation change. RAC affiliation may ~~only~~ be changed ~~during this annual update and~~ only if supported by a change in the majority of transfer patterns to a Level I or Level II Trauma Center. Documentation of these new transfer patterns shall be included in the request to change affiliation. ~~If no change is made in RAC affiliation, written notification shall be required annually to the OEMS to maintain current RAC affiliation.~~

History Note: *Authority G.S. 131E-162;*
Temporary Adoption Eff. January 1, 2002;
Eff. April 1, 2003;
Amended Eff. January 1, 2009;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016;
Amended Eff. July 1, 2021; January 1, 2017.

10A NCAC13P .1401 is proposed for amendment as follows:

10A NCAC 13P .1401 CHEMICAL ADDICTION OR ABUSE ~~TREATMENT~~ RECOVERY PROGRAM REQUIREMENTS

(a) The OEMS shall provide a ~~treatment~~ monitoring program for aiding in the recovery ~~and rehabilitation~~ of EMS personnel subject to disciplinary action for being unable to perform as credentialed EMS personnel with reasonable skill and safety to patients and the public by reason of use of alcohol, drugs, chemicals, or any other type of material as set forth in Rule ~~.1507(b)(9)~~ .1507 of this Subchapter.

(b) This program requires:

(1) an initial assessment by a healthcare professional ~~specialized~~ specializing in chemical dependency approved by the ~~treatment~~ program;

(2) a treatment plan developed ~~by the healthcare professional described in Subparagraph (b)(1) of this Rule~~ by a healthcare professional specializing in chemical dependency for the individual using the findings of the initial ~~assessment;~~ assessment. The Department and individual will enter into a consent agreement based up on the treatment plan; and

~~(3) random body fluid screenings using a standardized methodology designed by OEMS program staff to ensure reliability in verifying compliance with program standards;~~

~~(4) the individual attend three self-help recovery meetings each week for the first year of participation, and two each week for the remainder of participation in the treatment program;~~

~~(5)~~(3) monitoring by OEMS program staff of the individual for compliance with the ~~treatment program;~~ consent agreement entered into by the Department and the individual entering the program.

~~(6) written progress reports, shall be made available for review by OEMS upon completion of the initial assessment of the treatment program, upon request by OEMS throughout the individual's participation in the treatment program, and upon completion of the treatment program. Written progress reports shall include:~~

~~(A) progress or response to treatment and when the individual is safe to return to practice;~~

~~(B) compliance with program criteria;~~

~~(C) a summary of established long-term program goals; and~~

~~(D) contain pertinent medical, laboratory, and psychiatric records with a focus on chemical dependency.~~

History Note: *Authority G.S. 131E-159(f); 143-508(b); 143-508(d)(10);*
Eff. October 1, 2010;
Readopted Eff. January 1, ~~2017.~~ 2017;
Amended Eff. July 1, 2021.

10A NCAC 13P .1403 is proposed for amendment as follows:

10A NCAC 13P .1403 CONDITIONS FOR RESTRICTED PRACTICE WITH LIMITED PRIVILEGES

(a) In order to assist in determining eligibility for an individual to return to restricted practice, ~~the OEMS shall create a standing Reinstatement Committee that shall consist of at least the following members:~~ completion of all requirements outlined in the individual's consent agreement with the Department as described in Rule .1401 of this Section shall be presented to the Chief of the OEMS.

~~(1) one physician licensed by the North Carolina Medical Board, representing EMS Systems, who shall serve as Chair of this committee;~~

~~(2) one counselor trained in chemical addiction or abuse therapy; and~~

~~(3) the OEMS staff member responsible for managing the treatment program as set forth in Rule.1401 of this Section.~~

(b) Individuals who have surrendered his or her EMS credential(s) as a condition of entry into the ~~treatment~~ recovery program, as required in Rule ~~.1402(4)~~ .1402 of this Section, shall be reviewed by the OEMS ~~Reinstatement Committee~~ Chief to determine if ~~a recommendation to the OEMS for~~ issuance of an encumbered EMS credential is warranted by the Department.

(c) In order to obtain an encumbered credential with limited privileges, an individual shall:

(1) be compliant for a minimum of 90 consecutive days with the treatment program described in Rule ~~.1401(b)~~ .1401 of this Section; and

(2) be recommended in writing for review by the individual's ~~treatment counselor;~~ recovery healthcare professional overseeing the treatment plan developed as described in Rule .1401 of this Section.

~~(3) be interviewed by the OEMS Reinstatement Committee; and~~

~~(4) be recommended in writing by the OEMS Reinstatement Committee for issuance of an encumbered EMS credential. The OEMS Reinstatement Committee shall detail in their recommendation all restrictions and limitations to the individual's practice privileges.~~

(d) The individual shall agree to sign a consent agreement with the OEMS that details the practice restrictions and privilege limitations of the encumbered EMS credential, and that contains the consequences of failure to abide by the terms of this agreement.

(e) The individual shall be issued the encumbered credential by the OEMS within 10 business days following execution of the consent agreement described in Paragraph (d) of this Rule.

(f) The encumbered EMS credential shall be valid for a period not to exceed four years.

History Note: *Authority G.S. 131E-159(f); 143-508(b); 143-508(d)(10);*
Eff. October 1, 2010;
Readopted Eff. January 1, ~~2017.~~ 2017;
Amended Eff. July 1, 2021.

10A NCAC 13P .1404 is proposed for amendment as follows:

10A NCAC 13P .1404 REINSTATEMENT OF AN UNENCUMBERED EMS CREDENTIAL

Reinstatement of an unencumbered EMS credential is ~~dependant~~ dependent upon the individual successfully completing all requirements of the ~~treatment program~~ consent agreement as ~~defined in~~ set forth in Rule .1401 of this Section.

History Note: *Authority G.S. 131E-159(f); 143-508(d)(10); 143-509(13);*
Eff. October 1, 2010;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, ~~2016.~~ 2016;
Amended Eff. July 1, 2021.

10A NCAC 13P .1405 is proposed for amendment as follows:

10A NCAC 13P .1405 FAILURE TO COMPLETE THE CHEMICAL ADDICTION OR ABUSE ~~TREATMENT~~ RECOVERY PROGRAM

Individuals who fail to complete the ~~treatment program~~ consent agreement established in Rule .1401 of this Section, upon review by the OEMS, are subject to revocation of their EMS credential.

History Note: *Authority G.S. 131E-159(f); 143-508(b); 143-508(d)(10);*
Eff. October 1, 2010;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016;
Amended Eff. July 1, 2021; January 1, 2017.

10A NCAC 13P .1505 is proposed for amendment as follows:

10A NCAC 13P .1505 EMS EDUCATIONAL INSTITUTIONS

(a) For the purpose of this Rule, "focused review" means an evaluation by the OEMS of an educational institution's corrective actions to remove contingencies that are a result of deficiencies identified in the initial or renewal application process.

(b) The Department shall deny the initial or renewal designation, without first allowing a focused review, of an EMS Educational Institution for any of the following reasons:

(1) significant failure to comply with the provisions of ~~Section .0600~~ Sections .0500 and .0600 of this Subchapter; or

(2) attempting to obtain an EMS Educational Institution designation through fraud or misrepresentation.

(c) When an EMS Educational Institution is required to have a focused review, it shall demonstrate compliance with the provisions of ~~Section .0600~~ Sections .0500 and .0600 of this Subchapter within ~~12~~ six months or less.

(d) The Department shall amend, suspend, or revoke an EMS Educational Institution designation at any time whenever the Department finds that the EMS Educational Institution has significant failure to comply, as defined in Rule .0102 of this Subchapter, with the provisions of Section .0600 of this Subchapter, and:

(1) it is not probable that the EMS Educational Institution can remedy the deficiencies within ~~12~~ six months or less as determined by OEMS staff based upon analysis of the educational institution's ability to take corrective measures to resolve the issue of non-compliance with Section .0600 of this Subchapter;

(2) although the EMS Educational Institution may be able to remedy the deficiencies, it is not probable that the EMS Educational Institution shall be able to remain in compliance with credentialing rules;

(3) failure to produce records upon request as required in Rule ~~.0601(b)(6)~~ .0601 of this Subchapter;

(4) the EMS Educational Institution failed to meet the requirements of a focused review within ~~12~~ six months, as set forth in Paragraph (c) of this Rule;

(5) the failure to comply endangered the health, safety, or welfare of patients cared for as part of an EMS educational program as determined by OEMS staff in their professional judgment based upon a complaint investigation, in consultation with the Department and Department of Justice, to verify the results of the investigations are sufficient to initiate enforcement action pursuant to G.S. 150B; or

(6) the EMS Educational Institution altered, destroyed, or attempted to destroy evidence needed for a complaint investigation.

(e) The Department shall give the EMS Educational Institution written notice of ~~revocation and denial.~~ action taken on the Institution designation. This notice shall be given personally or by certified mail and shall set forth:

(1) the factual allegations;

(2) the statutes or rules alleged to be violated; and

(3) notice of the EMS Educational Institution's right to a contested case hearing, set forth in Rule .1509 of this Section, on the revocation of the designation.

(f) Focused review is not a procedural prerequisite to the revocation of a designation as set forth in Rule .1509 of this Section.

(g) If determined by the educational institution that suspending its approval to offer EMS educational programs is necessary, the EMS Educational Institution may voluntarily surrender its credential without explanation by submitting a written request to the OEMS stating its intention. The voluntary surrender shall not affect the original expiration date of the EMS Educational Institution's designation. To reactivate the designation:

(1) the institution shall provide OEMS written documentation requesting reactivation; and

(2) the OEMS shall verify the educational institution is compliant with all credentialing requirements set forth in Section .0600 of this Subchapter prior to reactivation of the designation by the OEMS.

(h) If the institution fails to resolve the issues that resulted in a voluntary surrender, the Department shall revoke the EMS Educational Institution designation.

(i) In the event of a revocation or voluntary surrender, the Department shall provide written notification to all EMS Systems within the EMS Educational Institution's defined service area. The Department shall provide written notification to all EMS Systems within the EMS Educational Institution's defined service area when the voluntary surrender reactivates to full credential.

(j) When an accredited EMS Educational Institution as defined in Rule .0605 of this Subchapter has administrative action taken against its accreditation, the OEMS shall determine if the cause of action is sufficient for revocation of the EMS Educational Institution designation or imposing a focused review pursuant to Paragraphs (b) and (c) of this Rule is warranted.

History Note: *Authority G.S. 143-508(d)(4); 143-508(d)(10);*
Eff. January 1, 2013;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016;
Amended Eff. July 1, 2021; July 1, 2018; January 1, 2017.

10A NCAC 13P .1507 EMS PERSONNEL CREDENTIALS

(a) ~~An~~ Any EMS credential that has been forfeited under G.S. 15A-1331.1 may not be reinstated until the person has complied with the court's requirements, has petitioned the Department for reinstatement, has completed the disciplinary process, and has received Department reinstatement approval.

(b) The Department shall amend, deny, suspend, or revoke the credentials of EMS personnel for any of the following:

(1) significant failure to comply with the applicable performance and credentialing requirements as found in this Subchapter;

(2) making false statements or representations to the Department, or concealing information in connection with an application for credentials;

(3) making false statements or representations, concealing information, or failing to respond to inquiries from the Department during a complaint investigation;

(4) tampering with, or falsifying any record used in the process of obtaining an initial EMS credential, or in the renewal of an EMS credential;

(5) in any manner or using any medium, engaging in the stealing, manipulating, copying, reproducing, or reconstructing of any written EMS credentialing examination questions, or scenarios;

(6) cheating, or assisting others to cheat while preparing to take, or when taking a written EMS credentialing examination;

(7) altering an EMS credential, using an EMS credential that has been altered, or permitting or allowing another person to use his or her EMS credential for the purpose of alteration. "Altering" includes changing the name, expiration date, or any other information appearing on the EMS credential;

(8) unprofessional conduct, including a significant failure to comply with the rules relating to the function of credentialed EMS personnel contained in this Subchapter, or the performance of or attempt to perform a procedure that is detrimental to the health and safety of any person, or that is beyond the scope of practice of credentialed EMS personnel or EMS instructors;

(9) being unable to perform as credentialed EMS personnel with reasonable skill and safety to patients and the public by reason of illness that will compromise skill and safety, use of alcohol, drugs, chemicals, or any other type of material, or by reason of any physical impairment;

(10) conviction in any court of a crime involving moral turpitude, a conviction of a felony, a conviction requiring registering on a sex offender registry, or conviction of a crime involving the scope of practice of credentialed EMS personnel;

(11) by theft or false representations obtaining or attempting to obtain, money or anything of value from a ~~patient;~~ patient, EMS Agency, or educational institution;

(12) adjudication of mental incompetence;

(13) lack of competence to practice with a reasonable degree of skill and safety for patients, including a failure to perform a prescribed procedure, failure to perform a prescribed procedure competently, or performance of a procedure that is not within the scope of practice of credentialed EMS personnel or EMS instructors;

(14) performing as a credentialed EMS personnel in any EMS System in which the individual is not affiliated and authorized to function;

(15) performing or authorizing the performance of procedures, or administration of medications detrimental to a student or individual;

(16) delay or failure to respond when on-duty and dispatched to a call for EMS assistance;

(17) testing positive, whether for-cause or at random, through urine, blood, or breath sampling, for any substance, legal or illegal, that is likely to impair the physical or psychological ability of the credentialed EMS personnel to perform all required or expected functions while on duty;

(18) failure to comply with G.S. 143-518 regarding the use or disclosure of records or data associated with EMS Systems, Specialty Care Transport Programs, Alternative Practice Settings, or patients;

(19) refusing to consent to any criminal history check required by G.S. 131E-159;

(20) abandoning or neglecting a patient who is in need of care, without making arrangements for the continuation of such care;

(21) falsifying a patient's record or any controlled substance records;

(22) harassing, abusing, or intimidating a patient, student, bystander, or OEMS staff, either physically, verbally, or in writing;

(23) engaging in any activities of a sexual nature with a patient, including kissing, fondling, or touching while responsible for the care of that individual;

(24) any criminal arrests that involve charges that have been determined by the Department to indicate a necessity to seek action in order to further protect the public pending adjudication by a court;

(25) altering, destroying, or attempting to destroy evidence needed for a complaint investigation being conducted by the OEMS;

(26) significant failure to comply with a condition to the issuance of an encumbered EMS credential with limited and restricted practices for persons in the chemical addiction or abuse treatment program;

(27) unauthorized possession of lethal or non-lethal weapons, chemical irritants to include mace, pepper (oleoresin capsicum) spray and tear gas, or explosives while in the performance of providing emergency medical services;

(28) significant failure to comply to provide EMS care records to the licensed EMS provider for submission to the OEMS as required by Rule .0204 of this Subchapter;

(29) continuing to provide EMS care after local suspension of practice privileges by the local EMS System, Medical Director, or Alternative Practice Setting; ~~or~~

(30) representing or allowing others to represent that the credentialed EMS personnel has a credential that the credentialed EMS personnel does not in fact ~~have.~~ have;

(31) diversion of any medication requiring medical oversight for credentialed EMS personnel; or

(32) filing a knowingly false complaint against an individual, EMS Agency, or educational institution.

(c) Pursuant to the provisions of G.S. 131E-159(h), the OEMS shall not issue an EMS credential for any person listed on the North Carolina Department of Public Safety, Sex Offender and Public Protection Registry, or who was

convicted of an offense that would have required registration if committed at a time when the registration would have been required by law.

(d) Pursuant to the provisions of G.S. 50-13.12, upon notification by the court, the OEMS shall revoke an individual's EMS credential until the Department has been notified by the court that evidence has been obtained of compliance with a child support order. The provisions of G.S. 50-13.12 supersede the requirements of Paragraph (f) of this Rule.

(e) When a person who is credentialed to practice as an EMS professional is also credentialed in another jurisdiction and the other jurisdiction takes disciplinary action against the person, the Department shall summarily impose the same or lesser disciplinary action upon receipt of the other jurisdiction's action. The EMS professional may request a hearing before the EMS Disciplinary Committee. At the hearing the issues shall be limited to:

(1) whether the person against whom action was taken by the other jurisdiction and the Department are the same person;

(2) whether the conduct found by the other jurisdiction also violates the rules of the N.C. Medical Care Commission; and

(3) whether the sanction imposed by the other jurisdiction is lawful under North Carolina law.

(f) The OEMS shall provide written notification of the amendment, denial, suspension, or revocation. This notice shall be given personally or by certified mail, and shall set forth:

(1) the factual allegations;

(2) the statutes or rules alleged to have been violated; and

(3) notice of the individual's right to a contested hearing, set forth in Rule .1509 of this Section, on the revocation of the credential.

(g) The OEMS shall provide written notification to the EMS professional within five business days after information has been entered into the National Practitioner Data Bank and the Healthcare Integrity and Protection Integrity Data Bank.

(h) The EMS System Administrator, Primary Agency Contact, Medical Director, Educational Institution Program Coordinator, or Medical Advisor shall notify the OEMS of any violation listed in Paragraph (b) of this Rule.

History Note: *Authority G.S. 131E-159; 143-508(d)(10); 143-519;*
Eff. January 1, 2013;
Readopted Eff. January 1, ~~2017.~~ 2017;
Amended Eff. July 1, 2021.

10 NCAC 13P .1511 is proposed for amendment as follows:

10A NCAC 13P .1511 PROCEDURES FOR QUALIFYING FOR AN EMS CREDENTIAL FOLLOWING ENFORCEMENT ACTION

(a) Any individual who has been subject to ~~denial,~~ suspension, revocation, or amendment of an EMS credential shall submit in writing to the OEMS a request for review to determine eligibility for credentialing.

(b) Factors the Department shall consider when determining eligibility shall include:

(1) the reason for administrative action, including:

(A) criminal history;

(B) patient care;

(C) substance abuse; and

(D) failure to meet credentialing requirements;

(2) the length of time since the administrative action was taken; and

(3) any mitigating or aggravating factors relevant to obtaining a valid EMS credential.

(c) In order to be considered for eligibility, the individual shall:

(1) wait a minimum of 36 months following administrative action before seeking review; and

(2) undergo a criminal history background check. If the individual has been charged or convicted of a misdemeanor or felony in this or any other state or country within the previous 36 months, the 36 month waiting period shall begin from the date of the latest charge or conviction.

(d) If determined to be eligible, the Department shall grant authorization for the individual to begin the process for EMS credentialing as set forth in Rule .0502 of this Subchapter.

(e) Prior to enrollment in an EMS educational program, the individual shall disclose the prior administrative action taken against the individual's credential in writing to the EMS Educational Institution.

(f) An individual who has undergone administrative action against his or her EMS credential is not eligible for legal recognition as defined in G.S. 131E-159(d) or issuance of a temporary EMS credential as defined in G.S. 131E159(e).

(g) For a period of 10 years following restoration of the EMS credential, the individual shall disclose the prior administrative action taken against his or her credential to every EMS System, Medical Director, EMS Provider, and EMS Educational Institution where he or she is affiliated and provide a letter to the OEMS from each verifying disclosure.

(h) If the Department determines the individual is ineligible for EMS credentialing pursuant to this Rule, the Department shall provide in writing the reason(s) for denial and inform him or her of the procedures for contested case hearing as set forth in Rule .1509 of this Section.

History Note: *Authority G.S. 131E-159(g); 143-508(d)(3); 143-508(d)(10);*
Eff. January 1, ~~2017.~~ 2017;
Amended Eff. July 1, 2021.

DHHS Fiscal Note
Permanent Rule Amendment without Substantial Economic Impact

Agencies Proposing Rule Change
North Carolina Medical Care Commission

Contact Persons
Nadine Pfeiffer, DHSR Rule Making Manager – (919) 855-3811
Tom Mitchell, OEMS Chief – (919) 855-3935
Chuck Lewis, OEMS Assistant Chief – (919) 855-3935
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Table of Contents

Lists of Appendices
Appendix A: The EMS and Trauma Rules under revision 10A NCAC 13P.

Authorizing Statutes
The following statutes are cited in the statutory authority of the rules under revision by the MCC.

G.S. 131E-151	Definitions
G.S. 131E-155.1	EMS Provider License Required
G.S. 131E-158	Credentialed Personnel Required
G.S. 131E-159	Credentialing Requirements
G.S. 131E-160	Exemptions
G.S. 143-508	Department of HHS to establish program; rules and regulations of Medical Care Commission
G.S. 143-509	Powers and Duties of Secretary
G.S. 143-510	North Carolina Emergency Medical Services Advisory Council
G.S. 143-511	Powers and Duties of the Council
G.S. 143-519	Emergency Medical Services Disciplinary Committee.

Titles of Rule Changes and Related Statutory Citations affected by amendment to the General Statues of the State of North Carolina.

To support proposed revisions to the 10A NCAC 13P EMS and Trauma rules, the OEMS is recommending §131E-159 be changed to remove "without testing" for individuals seeking legal recognition. The rule being updated to reflect the proposed change to the statutory language directly related to this change is as follows:

10A NCAC 13P

Section .0500 – EMS Personnel

- .0502 - Initial Credentialing Requirements for EMR, EMT, AEMT, Paramedic, and EMD

Titles of Rule Changes Proposed for Amendment

The following rules reflect the changes needed to update obsolete or unnecessary standards, clarify ambiguous language, incorporate changes in healthcare delivery models, recognize new technologies, and to provide all regulated entities and the public the most efficient and effective structure for services regulated for emergency medical and trauma systems. The Medical Care Commission meeting for initial approval of the proposed rules is scheduled for November 13, 2020.

These rules are identified as follows:

10A NCAC 13P (*See proposed text of these rules as Appendix A)*

Section .0100 – Definitions

- .0101 – Abbreviations (Amend)
- .0102 – Definitions (Amend)

Section .0200 – EMS Systems

- .0222 – Transport of Stretcher Bound Patients (Amend)

Section .0500 – EMS Personnel

- .0501 – Educational Programs (Amend)
- .0502 – Initial Credentialing Requirements for EMR, EMT, AEMT, Paramedic, and EMD (Amend)
- .0504 – Renewal of Credentials for EMR, EMT, AEMT, Paramedic, and EMD (Amend)
- .0507 – Credentialing Requirements for Level I EMS Instructors (Amend)
- .0508 – Initial credentialing Requirements for Level II EMS Instructors (Amend)
- .0510 – Renewal of Credentials for Level I and II EMS Instructors (Amend)
- .0512 – Reinstatement of Lapsed EMS Credential (Amend)

Section .0600 – EMS Educational Institutions

- .0601 Continuing Education EMS Educational Institution Requirements (Amend)
- .0602 – Basic and Advanced EMS Educational Institution Requirements (Amend)

Section .0900 – Trauma Center Standards and Approval

- .0904 – Initial Designation Process (Amend)

- .0905 – Renewal Designation Process (Amend)

Section .1100 – Truama System Design
- .1101 – State Trauma System (Amend)

.1400 – Recovery and Rehabilitation of Chemically Dependent EMS Personnel
- .1401 – Chemical Addiction or Abuse Treatment Program Requirements (Amend)
- .1403 – Conditions for Restricted Practice with Limited Privileges (Amend)
- .1404 – Reinstatement of an Unencumbered EMS Credential (Ament)
- .1405 – Failure to Complete the Chemical Addiction or Abuse Treatment Program (Amend)

.1500 – Denial, Suspension, Amendment, or Revocation
- .1505 – EMS Educational Institutions (Amend)
- .1507 – EMS Personnel Credentials (Amend)
- .1511 – Procedures for Qualifying for an EMS Credential Following Enforcement Action (Amend)

Overview

Overall, these rule changes do not present substantial economic impact to the regulated community. The primary costs related to these rules are the upfront costs of accreditation and the recurring ongoing fee for accreditation, as well as staff time and mileage for the annual conference for continuing education workshop. While OEMS cannot quantify the benefits of the increase in the educational quality offered by requiring accreditation for these programs, we believe that there are several important benefits to the accreditation process. These include but are not limited to: reduced barriers to professional mobility for EMT/AEMT professionals, increased quality of educational programs resulting in better prepared EMT professionals, and the potential for expansion of paramedicine programs that lead to lower costs and increased diversion from emergency departments.

Titles of Rule Changes Proposed for Amendment

The following rules reflect the changes needed to update obsolete or unnecessary standards, clarify ambiguous language, incorporate changes in healthcare delivery models, recognize new technologies, and to provide all regulated entities and the public the most efficient and effective structure for services regulated for emergency medical and trauma systems.

Summary of Revisions and its Anticipated Impact

Rules .0101 – Abbreviations and **.0102 – Definitions** are being amended to address revisions throughout the rules.

Impact

No impact associated with these rules.

Rule .0222 - Transport of Stretcher Bound Patients is being amended to clarify the permitted vehicle exemption of persons transported in wheeled chair devices. Rule 10A NCAC 13P .0102 defines a "stretcher" as "any wheeled or portable device capable of transporting a person in a recumbent position and may only be used in an ambulance vehicle permitted by the Department."

Advancement in the design of "wheeled" chair mobility devices has changed significantly in recent years. Newer mobility chairs designed for transport may recline, up to 90 degrees or completely flat, and some allow reclining even further into Trendelenburg Position (feet are higher than the head by 15-30 degrees). A Position Statement shared by the OEMS stated "any mobility impaired person incapable of being transported seated in a wheelchair is considered "incapacitated or helpless such the need for some medical assistance might be needed," [G.S. 131E-155(16)]. Mobility impaired persons transported unattended in a position other than "upright" in a wheeled chair device poses a significant safety concern for the individual. The OEMS has received complaints from licensed ambulance providers questioning the compliance and safety of these transports by unlicensed wheel chair transportation services. Although such complaints are rare, the safety concerns are serious and investigated by OEMS staff promptly. Complaint resolution may include the agency ceasing such transports when notified, a formal "cease and desist" issued, or OEMS staff provides technical assistance to the transport service in order to obtain an EMS Provider License.

Impact

No cost impact associated with amending this rule.

Rule .0501 - Educational Programs is being amended to require educational programs for the AEMT and paramedic credentials to be accredited through either CAAHEP or another accrediting agency that OEMS deems comparable. The intent of this change is to strengthen academic EMS programs for Advanced Emergency Medical Technician and Paramedic credentialing. Community Colleges are intimately familiar with the importance of not only institutional accreditation but also program accreditation. The Commission on Accreditation of Allied Health Education Programs (CAAHEP) is the only nationally recognized accrediting agency for EMS education programs. Many other Community College healthcare programs are accredited, including but not limited to Cardiovascular Technology, Dental Hygiene, Medical Laboratory Technology, Pharmacy Technology, Radiography, Respiratory Therapy, and Surgical Technology.

Strengthening the academic programs for AEMT and Paramedic programs is important because EMS as a profession continues to evolve. Paramedics are not only functioning as prehospital technicians, but also expanding their role as part of a healthcare team. Community Paramedicine and Mobile Integrated Healthcare Programs are growing nationally. Paramedics are transitioning from a technician who transports patients and performs certain medical care to a clinician who can treat patients within their scope of practice while also providing transport services. Paramedics are interacting more in the community and health system, and do not just transport

patients to the emergency department but to the most appropriate facility for the patient. The Centers for Medicare and Medicaid Services (CMS) is allowing limited participation in a program for EMS agencies to be reimbursed for not just transport of a patient to the emergency department, but also transport to an alternate facility (such as a primary care provider or mental health facility), or to even treat in place as defined by local EMS protocols. The 2017 Community Paramedicine Pilot Programs Report to the Joint Legislative Oversight Committee on Health and Human Services provided opportunity for significant savings in preventative cost (readmissions), high utilizers of Emergency Departments, and mental health patients being transported directly to an appropriate mental health facility rather than an Emergency Department. Patients received appropriate care, follow up, improved outcomes, and improved long-term health stability. The report stated Community Paramedicine programs implemented statewide could avoid potential EMS and Emergency Department charges of $1,355,681 - $1,885, 326 to NC Medicaid.[1] Telehealth can provide better assessments and more appropriate clinical decisions in conjunction with a medical provider. EMS personnel may also have access to patient's comprehensive medical records. These are all concepts discussed in the National Highway Transportation and Safety Administration's (NHTSA) EMS Agenda 2050.

Accredited EMS Programs are vital to the institutions providing eligibility for National Registry credentialing especially for military personnel (and spouses). National Registry creates more mobility and employment opportunities by reducing barriers to achieve other state credentialing. Currently, 47 states require a National Registry credential for state certification or licensure. Failure for North Carolina to require accreditation for Paramedic Programs would constrain mobility of military personnel, spouses, and others from employment opportunities outside of North Carolina.

High-quality, accredited education programs are instrumental to expanding the role of EMS in the future. Accredited EMS Programs better prepare students by ensuring they meet uniform, nationally accepted standards. Effective January 1, 2018, the National Registry of Emergency Medical Technicians ceased eligibility for examination as a Paramedic for applicants in states that graduated from a non-CAAHEP accredited program[2]. The National Registry of Emergency Medical Technicians as well as the National Association of State EMS Officials (NASEMSO) have endorsed CAAHEP.[3] "The accreditation process promotes continual self-analysis and is in place to make the program, its graduates, and ultimately, the care they deliver to the public BETTER."[4] Additionally, when students choose an accredited program, they can have more confidence in the quality of the education they are receiving and investing their money in.

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[1] "Community Paramedicine Pilot Programs, Report to the Joint Legislative Oversight Committee on Health and Human Services and Fiscal Research Division," March 1, 2017. https://files.nc.gov/ncosbm/documents/files/DHHS_2017-10-19_AppendixB.pdf

[2] "Paramedic Program Accreditation Policy." https://nremt.org/rwd/public/document/policy-paramedic.

[3] "Resolution 2010-04 National EMS Certification and Program Accreditation." https://nasemso.org/wp-content/uploads/Resolution2010-04NationalCertificationandProgramAccreditation20101013.pdf

[4] "What do I need to know to become accredited?" https://coaemsp.org/why-become-accredited-benefits-caahep-accreditation

The OEMS Administration and Education staff have been actively communicating and promoting the accreditation process to teaching institutions for several years. Rule 10A NCAC 13P .0605, Accredited EMS Educational Institution Requirements, was adopted January 1, 2017. This rule permits OEMS to credential teaching institutions that possess CAAHEP accreditation without a formal OEMS institution review. The groundwork has been in place to prepare teaching institutions for accreditation requirement. The initial draft of this set of proposed rules was presented to the North Carolina EMS Advisory Council on February 12, 2019 for approval for the OEMS to enter the rule making process. The EMS Advisory Council recommended a task form be created from members of the EMS Advisory Council. The task force attended public hearings and made recommendations to the OEMS based on the responses received. Feedback from the public hearings strongly agreed that strengthening EMS programs would sustain a more reliable workforce for the future.

The public hearings were conducted at five community colleges across the state. Meetings were held at 1:00 pm and 7:00 pm at Bladen Community College (March 20, 2019), Pitt Community College (March 28, 2019), Durham Technical Community College (April 1, 2019), Mitchell Community College (April 4, 2019), and Haywood Community College (April 9, 2019). Written comments were also received during this period. Proposed draft education rules were posted on the OEMS website and hard copies were provided at each site. Public support voiced at the meetings strongly supported efforts to strengthen EMS programs through accreditation.

There are presently 62 educational institutions approved the OEMS for initial Paramedic education programs that are impacted by this proposed rule change. Currently, 32 educational institution EMS Programs are already CAAHEP accredited (1 University, 31Community Colleges and 1 military institution). Approximately 13 institutions are in the accreditation process, either scheduled for a site visit or in the process of completing a Letter of Review. Several institutions that are unable to comply with accreditation requirements have partnered to establish articulation agreements with accredited institutions. There are currently 17 OEMS credentialed educational institutions with Paramedic or AEMT courses that have taken no action toward accreditation. The institutions that have not taken steps to gain accreditation are spread throughout the state but are primarily smaller institutions.

Educational institutions already accredited have absorbed the costs associated with the initial accreditation. The OEMS staff cannot predict whether the 17 educational institutions will seek accreditation, enter into articulation agreements with other accredited institutions, or cease initial Paramedic program courses. Costs may be estimated for the 11 educational institutions in the process of accreditation.

The Committee on Accreditation for the EMS Professions (CoAEMSP) is the branch of CAAHEP used to grant accreditation specifically to EMS programs for preparing students for initial credentialing. The cost for the accreditation process of CoAEMSP is detailed on the website in Appendix E.

Utilizing the program fees provided by CoAEMSP, the initial accreditation cost for each of the 17 educational institutions would be approximately $6,350, for a total opportunity cost of

~$107,950. The accreditation is valid for five years. The annual ongoing fee for each institution is $1,700, for an annual recurring total cost of ~$28,900.

Impact – Federal Government
No impact associated with the amendment of this rule.

Impact – State Government
Community Colleges (15) costs: ~$95,250 during initial year, ongoing cost of $28,900

Impact – Local Government
Local Government licensed EMS Providers (two): ~$12,700 during initial year, ongoing cost of $3,400

Impact – Private Entities
No impact associated with the amendment of this rule.

Educational Institution Type	Number	Cost per Provider	Total Statewide Costs
State Government	15	~$6,350	~$95,250
County Government	2	~$6,350	~$12,700
TOTAL COSTS			~$107,950

Impact from Accreditation Requirements						
Year	0	1	2	3	4	5
Benefits						
State Government	Possible opportunity for significant savings in preventing readmissions, appropriate redirection of mental health patients, and other high utilizers of Emergency Departments; potential savings of $1.3M to $1.8M to NC Medicaid annually					
Local Government						
Private Entities	Reduction of barriers to mobility and licensure transfer; potential increased quality of education for AEMT and paramedic students; potential of increased quality of care and cost savings for patients					
Costs						
Federal Government						
State Government	(95,250)	(25,500)	(25,500)	(25,500)	(25,500)	(25,500)
Local Government	(12,700)	(3,400)	(3,400)	(3,400)	(3,400)	(3,400)
Private Entities						
Total Costs	(107,950)	(28,900)	(28,900)	(28,900)	(28,900)	(28,900)
Discount Rate	7%					
NPV of accreditation costs	(211,632)					

Rule .0502 - Initial Credentialing Requirements for EMR, EMT, AEMT, Paramedic, and EMD is being amended to strengthen the EMS workforce and enhance safety of the public. Candidates for examination who do not pass the credentialing examination after three attempts within six months will be required to repeat initial educational requirements set forth in Rule 10A NCAC 13P .0501. Shortening the time frame for examination from 9 months to 6 months is intended to urge the candidate to test earlier while the course content remains fresh.

EMS Educational Institutions may allow credit for courses completed previously. Examination results identify specific topics in which the individual may have tested poorly. The individual may only be required to complete specific courses in that area to again become eligible for examination. Currently, a "refresher course" is required after a candidate fails 3 attempts. The refresher course encompasses all topics and skills. The institution may use the examination results to "target" specific areas that require review or additional education. The OEMS cannot quantify or estimate the potential failures or specific areas of need of future individuals.

The proposed change also requires individuals with less than two years of experience who are seeking reciprocity, to complete a written examination administered by the OEMS. This amendment will strengthen the EMS workforce for North Carolina agencies through verification of competence and thereby enhance the safe care provided to the public. New paramedics applying for reciprocity will be required to confirm the education credentials used in the

application were issued through a CAAHEP accredited program referenced in Rule 10A NCAC 13P .0501.

Application information will be updated to include initial credential date and verification of EMS program completion (institution) to insure CAAHEP requirement.

Cost Impact

Unable to determine – it is unknown how many of previous number of reciprocity applicants had less than 2 years of experience, the information is not currently tracked. There were 343 paramedic applications received in calendar year 2019 and of those, 265 were approved. There will be a cost associated with the examination but unable to quantify the number that may be required to take the exam.

Rule .0504 - Renewal of Credentials for EMR, EMT, AEMT, Paramedic, and EMD is being amended for technical change only.

Impact

No impact associated with amending this rule.

Rule .0507 & .0508 - Credentialing Requirements for Level I EMS Instructors and Credentialing Requirements for Level II EMS instructors are both recommended for amendment to comply with requirements for CAAHEP accreditation as discussed under Rule 10A NCAC 13P .0501. The associate degree requirement will only pertain to new Level I applicants effective July1, 2021 and the required bachelor's degree will only apply to new Level II Instructor applicants effective July 1, 2021; therefore, the recommendation is to amend the title for "initial" credentialing.

The NCOEMS EMS Instructor Application currently requires the applicant to submit verification of a high school or GED diploma for Level I and associate degree for Level II respectively. The application will be updated to require verification of the applicable degree. Most teaching institutions have been meeting the requirement already. Potential cost impact is difficult to quantify since only new applicants will be required to have a degree. OEMS currently tracks Instructor applications for both Level I and Level II together, so we are unable to determine the amount of Level I instructor applications that were received in 2019. A total of 212 initial instructor applications were received in calendar year 2019.

Impact -Rules .0507 and .0508

There may be potential opportunity cost for instructors due to the proposed educational degree requirements. The OEMS staff are unable to estimate potential salary increases for the community college system, local government agencies, or private entities. OEMS is unable to quantify.

Rule .0510 - Renewal of Credentials for Level I and Level II EMS Instructors is being amended to more clearly define the breakdown of the 96 hours of EMS instruction for renewal. Allowing up to 72 hours to be focused on the institution's specific needs will strengthen the performance improvement process of the initial and ongoing accreditation requirement. The total 96 hours for renewal remain the same.

Impact

No cost impact associated with amending this rule.

Rule .0512 - Reinstatement of Lapsed EMS Credential is recommended for amendment to ensure the safety of the public by requiring individuals to maintain appropriate knowledge and skills in order to reinstate their credential. The current rule uses the credential level to determine the length of time of expiration and the reinstatement requirements. Prehospital medical care is constantly changing - EMS protocols, policies, procedures, medications, and skills are reviewed annually and frequently updated. In order to protect the public, EMS personnel should be up to date with best practices. Ensuring EMS personnel are knowledgeable and maintain the appropriate skills strengthens safe patient care to the public.

The current rule contains multiple processes, based on level of certification, for reinstatement of a lapsed credential. The recommended changes for reinstatement requirements affect all credential levels equally. The proposed amendment should not have a financial impact on the individual. The new rule requires individuals expired more than 12 months to complete educational requirements for initial credentialing in Rule 10A NCAC 13P .0502, as opposed to the current rule, where individuals must complete a refresher course and a course specific scope of practice. The institution may only require the individual to complete specific courses to qualify for the written examination. The OEMS cannot quantify or estimate the potential failures or specific areas of need of future individuals. The OEMS staff does anticipate the cost may closely align with current cost involving the hours associated with the current refresher courses.

Reinstatement of lapsed instructor credentials greater than 12 months would now require meeting the proposed degree requirements for initial instructor applicants as stated in Rules 10A NCAC 13P .0507 and .0508 respectively.

Impact

OEMS estimates no cost impact associated with amending this rule.

Rule .0601 - Continuing Education EMS Educational Institution Requirements is being amended from designation categorized as Institutions to Programs.

Currently, North Carolina OEMS has approved both community colleges and EMS agencies to provide continuing education that allows local credential renewal of system or agency EMS

personnel. Approving EMS systems and agencies to offer in-house continuing education to their employees allows the agencies or systems to ensure that their employees have appropriate continuing education opportunities based on needs identified through performance improvement data of the respective EMS System. Continuing education "program" more accurately reflects the goal of the rule which is to ensure adequate continuing education to properly recredentialed EMS personnel. The Continuing Education Programs do not, nor are they intended to offer "initial" EMS courses.

After thorough review and feedback from the OEMS Public Meetings held in 2019 , the proposed changes were refined. Continuing education is required for renewing EMS credentials (Rule 10A NCAC 13P .0504(a)(1)). According to Rule 10A NCAC 13P .0403(a)(4), the local EMS system Medical Director is responsible for providing the medical supervision of the continuing education for EMS personnel in that respective system. The EMS Peer Review Committee for the EMS system analyzes patient care data to make recommendations regarding the content of continuing education (Rule 10A NCAC 13P .0408(5)).

The new requirement of the Program Coordinator workshop provides direct interaction with OEMS education staff to strengthen program compliance with the educational requirements. Basic and Advanced teaching institutions (Rule 10A NCAC 13P .0602) must also meet this rule's requirements, therefore all designated program coordinators will be required to attend a workshop annually. The benefits of attending a workshop include but are not limited to, increased educational opportunities, networking opportunities, and best practices. OEMS staff conducted the pilot Program Coordinator workshop March 11, 2020 in Wilmington. The workshop was approximately 8 hours in length.

There are 165 active education programs and institution approved by OEMS. The average cost per hour for an agency program coordinator (EMS Training Officer) is approximately $35.77. The Community College Program Coordinator average costs is approximately $41.42. Under these time and cost assumptions, the annual total opportunity cost would be $61,487.

Job Titles	Average Salary	Benefits[5]	Total Employee Compensation Est.	Average Hourly Cost Estimate
Training Officer (EMS)[6]	$50,332	$22,649	$72,981	$35.77
Community College Program Coordinator[7]	$56,795 - $59,757	$25,558 - $26,891	$82,354 - $86,647	$40.37 - $42.47

[5] Benefits calculated using a 45% benefit rate

[6] Calculated using the UNC SOG County Salary Survey - https://www.sog.unc.edu/publications/reports/county-salaries-north-carolina-2019

[7] NC Community Colleges Website Job Listings, https://jobs.nccommunitycolleges.edu.

The OEMS staff assumption that there is one program coordinator for each of the 165 educational institutions/programs subject to the provisions of this rule. The proposed rule change will result in additional costs for time spent in traveling to and from the workshop, and the time the program coordinator spent during the workshop session. Since these workshops are offered regionally, any direct travel cost to the individual will be minimal, involving only fuel costs, vehicle depreciation, and related costs to travel to the workshop site. Based on the standard IRS mileage rates for 2020 of 57.5 cents per mile and an OEMS assumption that individuals will drive an average of 100 miles to and from the workshops, program coordinators' travel costs will equal approximately ~$58 per workshop. OEMS estimates that the total workshop travel costs annually for the 165 instructors would be ~$9,570.

Impact – Federal Government
No impact associated with amending this rule.

Impact – State Government
Hourly rate for class and mileage

Impact – Local Government
Hourly rate for class and mileage

Impact – Private Entities
Hourly rate for class time

Impact Summary: Class Time & Travel Costs

Provider Type	Number	Cost per Provider	Total Statewide Costs
State Government Educational Institutions	79	~$331.36	~$26,177
Local Government Educational Institutions	61	~$286.16	~$17,456
Private Entities	25	~$331.36[8]	~$8,284
TOTAL CLASS TIME COSTS			~$51,917

Total Travel Costs

	Costs	Benefits	Frequency of Costs/Benefits
Federal Government	$0	$0	
State Government	~$4,582	Unquantifiable	recurring
Local Government	~$3,538	Unquantifiable	recurring
Private Entities	~$1,450	Unquantifiable	recurring
Total	~$9,570	Unquantifiable	

[8] OEMS does not have data regarding the salaries for private entities, so choosing to use the higher cost related to community college staff results in a more conservative cost estimate for the private entities.

Rule .0602 - Basic and Advanced EMS Educational Institution Requirements has been amended to strengthen educational programs as well as roles and responsibilities of the educational institution oversight staff.

Language has been added to confirm educational institutions provide at least two initial courses for each program level offered (EMR, EMT, AEMT, or Paramedic). The OEMS education staff strongly recommend these educational institution changes to be more effective and proficient.

Specific roles and responsibilities have been more clearly defined and emphasize CAAHEP standards that are required for accreditation.

Cost Impact

Costs associated with the accreditation requirements in this amendment are addressed under rule 10A NCAC 13P .0501.

Rule .0904 - Initial Designation Process rules are being amended to more accurately reflect comprehensive criteria defined by the American College of Surgeons (ASC) for trauma center designation.

The admission criteria language is being updated to align with national standards. The ASC standards only require Level I Trauma Centers to comply with trauma patient admission requirements listed in Paragraph (b)(3) of this rule. The admission requirement as currently written in this rule presents a challenge for some Level III Trauma Centers that otherwise may meet all other criteria to obtain Level II designation. As part of a national federal initiative, this proposed change also provides better opportunity for military hospitals to build more community influence as state designated Trauma Centers. Additionally, the OEMS also does not evaluate the "cost effectiveness" of a designated Trauma Center.

Specific defined trauma data elements, Paragraphs (c)(1) – (5), are being deleted. The hospitals submit data established by national standards to the National Trauma Database. The data submitted is defined by the ASC and is recommended to be removed in this rule. Paragraph (d) is being amended since the OEMS does not "justify" the need for designated trauma centers. Notification of the "respective Board of County Commissioners" in the applicant's primary catchment area is recommended for removal, Paragraph (e). The notification does not impact the process for approval. Comments may still be received during the 30-day comment period through the applicant's Primary RAC. The Requests for Proposal (RFP) no longer require a written "signature" for electronic submission. These recommended changes will further streamline the application process.

The timeline criteria for a site visit after approval as described in Paragraph (j) is recommended to be deleted. The specified timeframe does not allow for flexibility if needed due to unforeseen

circumstances that may adversely impact the process. Coordinating with hospitals and out of state ASC survey team members pose scheduling challenges. The scheduling should be an internal process policy rather than defined in Rule. OEMS staff will continue to coordinate with the survey team members and appropriate hospital staff to schedule a date agreeable to all parties for the required visit.

Impact

Unable to determine – OEMS primarily expects new applications for Level II Trauma Centers for military hospitals. Overall, OEMS expects positive impacts from the military hospitals being able to achieve Level II Trauma Center designations, but does not expect substantial economic impacts.

.0905 - Renewal Designation Process is recommended for amendment to remove Paragraph (c)(3), requiring notification of the "Board of County Commissioners." This change coincides the amendments to 10A NCAC 13P .0904.

Impact

No impact associated with amending this rule.

Rule .1101 - State Trauma System is being amended to reflect a more accurate and efficient process for annual membership and updates. Each of the eight Trauma Regional Advisory Committees (RAC) are familiar with and communicate routinely with their respective hospital and EMS System members. Annual notification of membership rosters from the OEMS to the RAC for confirmation is inefficient. Having the RAC coordinator send the OEMS membership information streamlines the notification process. The proposed change also removes the unnecessary restriction of only changing RAC affiliation during the annual update. The amendment simply reverses the notification process, therefore there is no projected cost impact.

Impact

No impact associated with amending this rule.

Rule .1401 - Chemical Addiction or Abuse Treatment Program Requirements is being amended to more accurately define the "Recovery" Program. The "Chemical Addiction or Abuse Treatment Program" is authorized by G.S. 143-509(13) to monitor participants for safe practice. This program is intended to provide an individual, who would otherwise be subject to loss of their EMS credential for a confirmed addiction problem, with a mechanism to remain eligible for retention of their credential, provided they successfully complete all aspects of a structured treatment program. This program is comprehensive and extremely structured, consisting of required random drug screenings, active participation in an approved treatment program, attendance at support meetings, and authorization to return to limited practice with an

encumbered credential until the individual is restored to full practice. This program is a minimum of three years in length. An individual's participation in the program is confidential and non-punitive. However, failure to complete the program subjects the individual to enforcement action by OEMS.

Existing rule is cumbersome and inefficient for the OEMS and the EMS credentialed personnel enrolled in the program. Healthcare professionals specialized in chemical dependency develop treatment plans based on the initial assessment. The recommendation is to utilize the specific treatment plan for that individual to establish a consent agreement between the Department and the individual entering the program. The consent agreement will be used by the OEMS staff to "monitor" compliance of the individual. The change removes specific required criteria that could potentially be outside the treatment plan developed by the healthcare professionals specialize in chemical dependency.

Removing the numerous OEMS mandated body fluid screenings and OEMS mandated self-help recovery meetings may produce an opportunity cost savings. Due to the extremely low rate of participation in the program and the unknown of the individual specific treatment plans, potential savings are not quantifiable. Due to employer "zero tolerance" policies, most of these individuals are terminated. The OEMS administration has partnered with the North Carolina Association of EMS Administrators in efforts to present program information and open dialogue for potential employment options to the North Carolina Association of County Commissioners and other related groups.

Impact
Unable to determine – likely net benefit to affected individual

Rule 1403. - Conditions for Restricted Practice with Limited Privileges is proposed for amendment to enhance efficiency of the process. Removing the Reinstatement Committee will streamline the process, eliminate the Committee "interviewing" the individual, and forwarding recommendations for restrictions or limitations. Under current rule the Chief of the OEMS has the final decision for such actions. The proposed language places the final accountability on the Chief to ensure all requirements of the consent agreement to determine if an encumbered credential is warranted.

Removing the Reinstatement Committee requirement would reduce the cost of members' time and travel for potential meetings, avoid scheduling conflicts or delays, as well as creating an opportunity cost for the individual to return to work more quickly. Due to the very low rate of participation in the program and the unknown of the individual treatment plans, potential savings are not quantifiable.

Impact
Unable to determine – likely net benefit to affected individual and state government

.1404 - Reinstatement of an Unencumbered EMS Credential and

.1405 - Failure to Complete the Chemical Addiction or Abuse Program are recommended for amendment with technical changes in response to the proposed change to "consent agreement" in Rule 10A NCAC 13P .1401. In addition, the title of Rule 10A NCAC 13P .1405 is proposed for a change to accurately reflect the program.

Impact

No cost impact associated with amending this rule.

.1505 EMS - Educational Institutions is being amended to allow more appropriate action against an institution as necessary. Current rule only allows denial of the initial or renewal designation, and revocation of designation for significant failure to comply with education rules. Language has been revised to add amend and suspends as alternate actions versus only revocation. These actions allow the Department to take action on the designation, but also work with the institution to develop a corrective action plan to achieve full compliance with applicable rules. The OEMS provides technical assistance to educational institutions and routinely audits institutions to ensure the programs maintain documentation of pre-requisites, didactic hours, clinical hours, exams, and skills verification. As a result of complaints received by the OEMS and audits, several institutions were found to have significant compliance concerns that warranted investigations and corrective action plans to continue the approved programs. Adding the options to amend or suspend provides more efficient authority to the OEMS to take action on the institution designation without shutting the program down completely. The change would not increase cost as OEMS staff presently work with educational institution staff currently conducting audits, investigating complaints, and developing or monitoring corrective action plans as necessary.

Impact

No cost impact associated with amending this rule.

.1507 - EMS Personnel Credentials is being amended to more accurately focus on specific actions of EMS personnel formally investigated by the OEMS and may be required to appear before the Emergency Medical Services Disciplinary Committee defined in G.S. 143-519. A growing number of specific concerns leading to action against EMS personnel credentials are not adequately addressed in the current rule. These include theft from a patient, agency, or institution; medication diversion; and filing false complaints against individuals, EMS agencies, or educational institutions. OEMS compliance staff, the Disciplinary Committee, and the Chief are faced with relying on "unprofessional conduct" since such egregious actions such as these are not defined in the rule. Defining these behaviors potentially strengthens the "authority" if formal action against the EMS personnel is warranted. The Disciplinary Committee, the Chief of OEMS, and the Department seek action when the safety and welfare of the individual, agency, or public is jeopardized as a result of these actions by the individual. Relying on "unprofessional conduct" because these acts are not defined in rule trivialize the threat to the public. There is no

impact with this change as these complaints continue to be investigated and presented for potential action.

An additional challenge to the complaint/investigation/disciplinary process has been the absence of any requirement to report any of the violations as listed in this rule, Paragraph (h). EMS administrators and medical directors have expressed concern that county, agency, hospital or other human resources or administrative decisions have discouraged or halted reporting violations to the OEMS. During an EMS Medical Directors meeting at the 2019 EMSEXPO conference (sponsored by the NCOEMS), numerous Medical Directors complained they felt their "hands were tied" by administrative and legal channels since there was no state requirement for reporting these violations.

Failure to approve the recommended amendment for reporting violations will only allow the current concerns to continue and potentially decrease safety to the general public. Credentialed EMS personnel may have privileges revoked by the Medical Director locally or be subject to termination by the employer for violations listed in rule. The individual may move from one EMS System or employer to another without divulging details that led to the actions from the previous employer and or Medical Director. Certain violations create serious concerns for the safety of the general public and greater potential liability to the future Medical Director or employer.

The OEMS cannot appropriately estimate any potential increase of investigations, Disciplinary Committee hearings, or actions based on the recommended change.

Impact

Unable to determine.

.1511 - Procedures for Qualifying for an EMS Credential Following Enforcement Action is being amended for technical correction. "Denial" is not applicable in Paragraph (a) as this rule addresses enforcement action. Rule 10A NCAC 13P .1507 EMS Personnel Credentials establishes criteria to "amend, deny, suspend, or revoke" credentials and provides information for the "individual's right to a consent hearing." Enforcement action on a credential, as the rule is written, implies a credential was previously issued. It is the opinion of the OEMS this rule sets forth the criteria for qualifying to be recredentialed after action was taken for violations listed in Rule 10A NCAC 13P .1507.

Impact

No cost impact associated with amending this rule.

Conclusion

The revisions to the EMS and trauma rules have been drafted to address all areas required for supporting the growth in the EMS industry and changes that have occurred with national EMS and

trauma standards. Additionally, every effort has been made to minimize any financial burden that may be associated with compliance with these revised rules. Although there will be an increase in state government, local government, and private expenditures and opportunity costs associated with many of the changes, there are also many benefits associated with the proposed rules, many of which OEMS was unable to quantify. Overall, OEMS believes that the effect of incorporating these changes will benefit the quality of care provided and enhance safety for the citizens of North Carolina.

APPENDIX A

10A NCAC 13P .0101 is proposed for amendment as follows:

10A NCAC 13P .0101 ABBREVIATIONS

As used in this Subchapter, the following abbreviations mean:

(1) ACS: American College of Surgeons;

(2) AEMT: Advanced Emergency Medical Technician;

(3) AHA: American Heart Association;

(4) ASTM: American Society for Testing and Materials;

(5) CAAHEP: Commission on Accreditation of Allied Health Education Programs;

(6) CPR: Cardiopulmonary Resuscitation;

(7) ED: Emergency Department;

(8) EMD: Emergency Medical Dispatcher;

(9) EMR: Emergency Medical Responder;

(10) EMS: Emergency Medical Services;

(11) EMS-NP: EMS Nurse Practitioner;

(12) EMS-PA: EMS Physician Assistant;

(13) EMT: Emergency Medical Technician;

(14) FAA: Federal Aviation Administration;

~~(15) FAR: Federal Aviation Regulation;~~

~~(16)~~(15) FCC: Federal Communications Commission;

~~(17) GCS: Glasgow Coma Scale;~~

~~(18)~~(16) ICD: International Classification of Diseases;

~~(19)~~(17) ISS: Injury Severity Score;

~~(20) ICU: Intensive Care Unit;~~

~~(21) IV: Intravenous;~~

~~(22) LPN: Licensed Practical Nurse;~~

~~(23)~~(18) MICN: Mobile Intensive Care Nurse;

~~(24)~~(19) NHTSA: National Highway Traffic Safety Administration;

~~(25)~~(20) OEMS: Office of Emergency Medical Services;

~~(26)~~(21) OR: Operating Room;

~~(27)~~(22) PSAP: Public Safety Answering Point;

~~(28)~~(23) RAC: Regional Advisory Committee;

~~(29)~~(24) RFP: Request For Proposal;

~~(30) RN: Registered Nurse;~~

~~(31)~~(25) SCTP: Specialty Care Transport Program;

~~(32)~~(26) SMARTT: State Medical Asset and Resource Tracking Tool;

~~(33)~~(27) STEMI: ST Elevation Myocardial Infarction; and

~~(34) TR: Trauma Registrar;~~

~~(35) TPM: Trauma Program Manager; and~~

~~(36)~~(28) US DOT: United States Department of Transportation.

History Note: *Authority G.S. 143-508(b);*
Temporary Adoption Eff. January 1, 2002;
Eff. April 1, 2003;
Amended Eff. January 1, 2009; January 1, 2004;
Readopted Eff. January 1, ~~2017.~~ 2017;
Amended Eff. July 1, 2021.

10A NCAC 13P .0102 is proposed for amendment as follows:

10A NCAC 13P .0102 DEFINITIONS

In addition to the definitions in G.S. 131E-155, the following definitions apply throughout this Subchapter:

(1) "Affiliated EMS Provider" means the firm, corporation, agency, organization, or association identified with a specific county EMS system as a condition for EMS Provider Licensing as required by Rule .0204 of this Subchapter.

(2) "Affiliated Hospital" means a non-trauma center hospital that is owned by the Trauma Center or there is a contract or other agreement to allow for the acceptance or transfer of the Trauma Center's patient population to the non-trauma center hospital.

(3) "Affiliate" or "Affiliation" means a reciprocal agreement and association that includes active participation, collaboration, and involvement in a process or system between two or more parties.

(4) "Alternative Practice Setting" means a practice setting that utilizes credentialed EMS personnel that may not be affiliated with or under the oversight of an EMS System or EMS System Medical Director.

(5) "Air Medical Ambulance" means an aircraft configured and medically equipped to transport patients by air. The patient care compartment of air medical ambulances shall be staffed by medical crew members approved for the mission by the Medical Director.

(6) "Air Medical Program" means a SCTP or EMS System utilizing rotary-wing or fixed-wing aircraft configured and operated to transport patients.

(7) "Assistant Medical Director" means a physician, EMS-PA, or EMS-NP who assists the Medical Director with the medical aspects of the management of a practice setting utilizing credentialed EMS personnel or medical crew members.

(8) "Bypass" means a decision made by the patient care technician to transport a patient from the scene of an accident or medical emergency past a receiving facility for the purposes of accessing a facility with a higher level of care, or a hospital of its own volition reroutes a patient from the scene of an accident or medical emergency or referring hospital to a facility with a higher level of care.

(9) "Community Paramedicine" means an EMS System utilizing credentialed personnel who have received additional training as determined by the EMS system Medical Director to provide knowledge and skills for the community needs beyond the 911 emergency response and transport operating guidelines defined in the EMS system plan.

(10) "Contingencies" mean conditions placed on a designation that, if unmet, may result in the loss or amendment of a designation.

(11) "Convalescent Ambulance" means an ambulance used on a scheduled basis solely to transport patients having a known non-emergency medical condition. Convalescent ambulances shall not be used in place of any other category of ambulance defined in this Subchapter.

(12) "Deficiency" means the failure to meet essential criteria for a designation that can serve as the basis for a focused review or denial of a designation.

(13) "Department" means the North Carolina Department of Health and Human Services.

(14) "Diversion" means the hospital is unable to accept a patient due to a lack of staffing or resources.

(15) "Educational Medical Advisor" means the physician responsible for overseeing the medical aspects of approved EMS educational programs.

(16) "EMS Care" means all services provided within each EMS System by its affiliated EMS agencies and personnel that relate to the dispatch, response, treatment, and disposition of any patient.

(17) "EMS Educational Institution" means any agency credentialed by the OEMS to offer EMS educational programs.

(18) "EMS Non-Transporting Vehicle" means a motor vehicle operated by a licensed EMS provider dedicated and equipped to move medical equipment and EMS personnel functioning within the scope of practice of an AEMT or Paramedic to the scene of a request for assistance. EMS nontransporting vehicles shall not be used for the transportation of patients on the streets, highways, waterways, or airways of the state.

(19) "EMS Peer Review Committee" means a committee as defined in G.S. 131E-155(6b).

(20) "EMS Performance Improvement Self-Tracking and Assessment of Targeted Statistics" means one or more reports generated from the State EMS data system analyzing the EMS service delivery, personnel performance, and patient care provided by an EMS system and its associated EMS agencies and personnel. Each EMS Performance Improvement Self-Tracking and Assessment of Targeted Statistics focuses on a topic of care such as trauma, cardiac arrest, EMS response times, stroke, STEMI (heart attack), and pediatric care.

(21) "EMS Provider" means those entities defined in G.S. 131E-155(13a) that hold a current license issued by the Department pursuant to G.S. 131E-155.1.

(22) "EMS System" means a coordinated arrangement of local resources under the authority of the county government (including all agencies, personnel, equipment, and facilities) organized to respond to medical emergencies and integrated with other health care providers and networks including public health, community health monitoring activities, and special needs populations.

(23) "Essential Criteria" means those items that are the requirements for the respective level of trauma center designation (I, II, or III), as set forth in Rule .0901 of this Subchapter.

(24) "Focused Review" means an evaluation by the OEMS of corrective actions to remove contingencies that are a result of deficiencies following a site visit.

(25) "Ground Ambulance" means an ambulance used to transport patients with traumatic or medical conditions or patients for whom the need for specialty care, emergency, or non-emergency medical care is anticipated either at the patient location or during transport.

(26) "Hospital" means a licensed facility as defined in G.S. 131E-176 or an acute care in-patient diagnostic and treatment facility located within the State of North Carolina that is owned and operated by an agency of the United States government.

~~(27) "Immediately Available" means the physical presence of the health professional or the hospital resource within the trauma center to evaluate and care for the trauma patient.~~

~~(28)~~(27) "Inclusive Trauma System" means an organized, multi-disciplinary, evidence-based approach to provide quality care and to improve measurable outcomes for all defined injured patients. EMS, hospitals, other health systems, and clinicians shall participate in a structured manner through leadership, advocacy, injury prevention, education, clinical care, performance improvement, and research resulting in integrated trauma care.

~~(29)~~(28) "Infectious Disease Control Policy" means a written policy describing how the EMS system will protect and prevent its patients and EMS professionals from exposure and illness associated with contagions and infectious disease.

~~(30)~~(29) "Lead RAC Agency" means the agency (comprised of one or more Level I or II trauma centers) that provides staff support and serves as the coordinating entity for trauma planning.

~~(31)~~(30) "Level I Trauma Center" means a hospital that has the capability of providing guidance, research, and total care for every aspect of injury from prevention to rehabilitation.

~~(32)~~(31) "Level II Trauma Center" means a hospital that provides trauma care regardless of the severity of the injury, but may lack the comprehensive care as a Level I trauma center, and does not have trauma research as a primary objective.

~~(33)~~(32) "Level III Trauma Center" means a hospital that provides assessment, resuscitation, emergency operations, and stabilization, and arranges for hospital transfer as needed to a Level I or II trauma center.

~~(34) "Licensed Health Care Facility" means any health care facility or hospital licensed by the Department of Health and Human Services, Division of Health Service Regulation.~~

~~(35)~~(33) "Medical Crew Member" means EMS personnel or other health care professionals who are licensed or registered in North Carolina and are affiliated with a SCTP.

~~(36)~~(34) "Medical Director" means the physician responsible for the medical aspects of the management of a practice setting utilizing credentialed EMS personnel or medical crew members, or a Trauma Center.

~~(37)~~(35) "Medical Oversight" means the responsibility for the management and accountability of the medical care aspects of a practice setting utilizing credentialed EMS personnel or medical crew members. Medical Oversight includes physician direction of the initial education and continuing education of EMS personnel or medical crew members; development and monitoring of both operational and treatment protocols; evaluation of the medical care rendered by EMS personnel or medical crew members; participation in system or program evaluation; and directing, by two-way voice communications, the medical care rendered by the EMS personnel or medical crew members.

~~(38)~~(36) "Mobile Integrated Healthcare" means utilizing credentialed personnel who have received additional training as determined by the Alternative Practice Setting medical director to provide knowledge and skills for the healthcare provider program needs.

~~(39) "Off-line Medical Control" means medical supervision provided through the EMS System Medical Director or SCTP Medical Director who is responsible for the day-to-day medical care provided by EMS personnel. This includes EMS personnel education, protocol development, quality management, peer review activities, and EMS administrative responsibilities related to assurance of quality medical care.~~

~~(40)~~(37) "Office of Emergency Medical Services" means a section of the Division of Health Service Regulation of the North Carolina Department of Health and Human Services located at 1201 Umstead Drive, Raleigh, North Carolina 27603.

~~(41)~~(38) "On-line Medical Control" means the medical supervision or oversight provided to EMS personnel through direct communication in-person, via radio, cellular phone, or other communication device during the time the patient is under the care of an EMS professional.

~~(42)~~(39) "Operational Protocols" means the administrative policies and procedures of an EMS System or that provide guidance for the day-to-day operation of the system.

~~(43) "Participating Hospital" means a hospital that supplements care within a larger trauma system by the initial evaluation and assessment of injured patients for transfer to a designated trauma center if needed.~~

~~(44)~~(40) "Physician" means a medical or osteopathic doctor licensed by the North Carolina Medical Board to practice medicine in the state of North Carolina.

~~(45)~~(41) "Regional Advisory Committee" means a committee comprised of a lead RAC agency and a group representing trauma care providers and the community, for the purpose of regional planning, establishing, and maintaining a coordinated trauma system.

~~(46)~~(42) "Request for Proposal" means a State document that must be completed by each hospital seeking initial or renewal trauma center designation.

~~(47)~~(43) "Significant Failure to Comply" means a degree of non-compliance determined by the OEMS during compliance monitoring to exceed the ability of the local EMS System to correct, warranting enforcement action pursuant to Section .1500 of this Subchapter.

~~(48)~~(44) "State Medical Asset and Resource Tracking Tool" means the Internet web-based program used by the OEMS both in its daily operations and during times of disaster to identify, record, and monitor EMS, hospital, health care, and sheltering resources statewide, including facilities, personnel, vehicles, equipment, and pharmaceutical and supply caches.

~~(49)~~(45) "Specialty Care Transport Program" means a program designed and operated for the transportation of a patient by ground or air requiring specialized interventions, monitoring, and staffing by a paramedic who has received additional training as determined by the program Medical Director beyond the minimum training prescribed by the OEMS, or by one or more other healthcare professional(s) qualified for the provision of specialized care based on the patient's condition.

~~(50)~~(46) "Specialty Care Transport Program Continuing Education Coordinator" means a ~~Level I~~ Level II EMS Instructor within a SCTP who is responsible for the coordination of EMS continuing education programs for EMS personnel within the program.

~~(51)~~(47) "Stretcher" means any wheeled or portable device capable of transporting a person in a recumbent position and may only be used in an ambulance vehicle permitted by the Department.

~~(52)~~(48) "Stroke" means an acute cerebrovascular hemorrhage or occlusion resulting in a neurologic deficit.

~~(53)~~(49) "System Continuing Education Coordinator" means the ~~Level I~~ Level II EMS Instructor designated by the local EMS System who is responsible for the coordination of EMS continuing education programs.

~~(54)~~(50) “System Data" means all information required for daily electronic submission to the OEMS by all EMS Systems using the EMS data set, data dictionary, and file format as specified in "North Carolina College of Emergency Physicians: Standards for Medical Oversight and Data Collection," incorporated herein by reference including subsequent amendments and editions. This document is available from the OEMS, 2707 Mail Service Center, Raleigh, North Carolina 27699- 2707, at no cost and online at www.ncems.org at no cost.

~~(55)~~(51) "Trauma Center" means a hospital designated by the State of North Carolina and distinguished by its ability to manage, on a 24-hour basis, the severely injured patient or those at risk for severe injury.

~~(56) "Trauma Center Criteria" means essential criteria to define Level I, II, or III trauma centers.~~

~~(57) "Trauma Center Designation" means a process of approval in which a hospital voluntarily seeks to have its trauma care capabilities and performance evaluated by experienced on-site reviewers.~~

~~(58) "Trauma Diversion" means a trauma center of its own volition declines to accept an acutely injured patient due to a lack of staffing or resources.~~

~~(59) "Trauma Guidelines" mean standards for practice in a variety of situations within the trauma system.~~

~~(60) "Trauma Minimum Data Set" means the basic data required of all hospitals for submission to the Trauma Registry.~~

~~(61)~~(52) "Trauma Patient" means any patient with an ICD-CM discharge diagnosis as defined in the "North Carolina Trauma Registry Data Dictionary," incorporated herein by reference, including subsequent amendments and editions. This document is available from the OEMS, 2707 Mail Service Center, Raleigh, North Carolina 27699-2707, at no cost and online at https://info.ncdhhs.gov/dhsr/EMS/trauma/traumaregistry.html at no cost.

~~(62)~~(53) "Trauma Program" means an administrative entity that includes the trauma service and coordinates other trauma-related activities. It shall also include the trauma Medical Director, trauma program manager/trauma coordinator, and trauma registrar. This program's reporting structure shall give it the ability to interact with at least equal authority with other departments in the hospital providing patient care.

~~(63)~~(54) "Trauma Registry" means a disease-specific data collection composed of a file of uniform data elements that describe the injury event, demographics, pre-hospital information, diagnosis, care, outcomes, and costs of treatment for injured patients collected and electronically submitted as defined by the OEMS. The elements of the Trauma Registry can be accessed at https://info.ncdhhs.gov/dhsr/EMS/trauma/traumaregistry.html at no cost.

~~(64)~~(55) "Treatment Protocols" means a document approved by the Medical Directors of the local EMS System, Specialty Care Transport Program, Alternative Practice Setting, or Trauma Center and the OEMS specifying the diagnostic procedures, treatment procedures, medication administration, and patient-care-related policies that shall be completed by EMS personnel or medical crew members based upon the assessment of a patient.

~~(65)~~(56) "Triage" means the assessment and categorization of a patient to determine the level of EMS and healthcare facility based care required.

~~(66)~~(57) "Water Ambulance" means a watercraft specifically configured and medically equipped to transport patients.

History Note: *Authority G.S. 131E-155(6b); 131E-162; 143-508(b), 143-508(d)(1); 143-508(d)(2); 143-508(d)(3); 143-508(d)(4); 143-508(d)(5); 143-508(d)(6); 143-508(d)(7); 143-508(d)(8); 143-508(d)(13); 143-518(a)(5);*
Temporary Adoption Eff. January 1, 2002;
Eff. April 1, 2003;
Amended Eff. March 3, 2009 pursuant to E.O. 9, Beverly Perdue, March 3, 2009;
Pursuant to G.S. 150B-21.3(c), a bill was not ratified by the General Assembly to disapprove this rule;
Readopted Eff. January 1, 2017;

Amended Eff. July 1, 2021; September 1, 2019; July 1, 2018.

10A NCAC 13P .0222 is proposed for amendment as follows:

10A NCAC 13P .0222 TRANSPORT OF STRETCHER BOUND PATIENTS

(a) Any person transported on a stretcher as defined in Rule .0102 of this Subchapter meets the definition of patient as defined in G.S. 131E-155(16).

(b) Stretchers may only be utilized for patient transport in an ambulance permitted by the OEMS in accordance with G.S. 131E-156 and Rule .0211 of this Section.

(c) The Medical Care Commission exempts wheeled chair devices used solely for the transportation of mobility impaired persons seated in an upright position in non-permitted vehicles from the definition of stretcher.

History Note: *Authority G.S. 131E-156; 131E-157; 143-508(d)(8);*
Eff. January 1, 2017;
Amended Eff. July 1, 2021; July 1, 2018.

10A NCAC 13P .0501 is proposed for amendment as follows:

10A NCAC 13P .0501 EDUCATIONAL PROGRAMS

(a) EMS educational programs that qualify credentialed EMS personnel to perform within their scope of practice shall be offered by an EMS educational institution as set forth in Section .0600 of this Subchapter, or by an EMS educational institution in another state where the education and credentialing requirements have been approved for legal recognition by the Department pursuant to G.S. 131E-159 as determined using the professional judgment of OEMS staff following comparison of out-of-state standards with the program standards set forth in this Rule.

(b) Educational programs approved to qualify EMS personnel for credentialing shall meet the educational content of the "US DOT NHTSA National EMS Education Standards," which is hereby incorporated by reference, including subsequent amendments and editions. This document is available online at no cost at www.ems.gov/education.html.

(c) Educational programs approved to qualify EMS personnel for AEMT and Paramedic credentialing shall meet the requirements of Paragraph (b) of this Rule and possess verification of accreditation or a valid letter of review from the Commission on Accreditation of Allied Health Education Programs (CAAHEP) or other accrediting agency determined using the professional judgment of OEMS staff following a comparison of standards.

~~(c)~~ (d) Educational programs approved to qualify EMD personnel for credentialing shall conform with the "ASTM ~~F1258 – 95(2006).~~ F1258 – 95(2014): Standard Practice for Emergency Medical ~~"Dispatch"~~ Dispatch" incorporated by reference including subsequent amendments and editions. This document is available from ASTM International, 100 Barr Harbor Drive, PO Box C700, West Conshohocken, PA, 19428-2959 USA, at a cost of forty eight dollars ~~($40.00)~~ ($48.00) per copy.

~~(d)~~ (e) Instructional methodology courses approved to qualify Level I EMS instructors shall conform with the "US DOT NHTSA 2002 National Guidelines for Educating EMS Instructors" incorporated by reference including subsequent amendments and additions. This document is available online at no cost at www.ems.gov/education.html.
~~(e)~~ (f) Continuing educational programs approved by the OEMS to qualify EMS personnel for renewal of credentials shall be approved by demonstrating the ability to assess cognitive competency in the skills and medications for the level of application as defined by the North Carolina Medical Board pursuant to G.S. 143-514.
~~(f)~~ (g) Refresher courses shall comply with the requirements defined in Rule .0513 of this Section.

History Note: *Authority G.S. 143-508(d)(3); 143-508(d)(4); 143-514;*
Temporary Adoption Eff. January 1, 2002;
Eff. January 1, 2004;
Amended Eff. January 1, 2009;
Readoption Eff. January 1, ~~2017.~~ 2017;
Amended Eff. July 1, 2021.

10A NCAC 13P .0502 is proposed for amendment as follows:

10A NCAC 13P .0502 INITIAL CREDENTIALING REQUIREMENTS FOR EMR, EMT, AEMT, PARAMEDIC, AND EMD

(a) In order to be credentialed by the OEMS as an EMR, EMT, AEMT, or Paramedic, individuals shall:

(1) ~~be~~ Be at least 18 years of age. An examination may be taken at age 17; however, the EMS credential shall not be issued until the applicant has reached the age of 18.

(2) ~~complete~~ Complete an approved educational program as set forth in Rule ~~.0501(b)~~ .0501 of this Section for their level of application.

(3) ~~complete~~ Complete a scope of practice performance evaluation that uses performance measures based on the cognitive, psychomotor, and affective educational objectives set forth in Rule ~~.0501(b)~~ .0501 of this Section and that is consistent with their level of application, and approved by the OEMS. This scope of practice evaluation shall be completed no more than one year prior to examination. This evaluation shall be conducted by a Level I or Level II EMS Instructor credentialed at or above the level of application or under the direction of the primary credentialed EMS instructor or educational medical advisor for the approved educational program.

(4) ~~within~~ Within 90 days from their course graded date as reflected in the OEMS credentialing database, complete a written examination administered by the OEMS. If the applicant fails to register and complete a written examination within the ~~90-day~~ 90-day period, the applicant shall obtain a letter of authorization to continue eligibility for testing from his or her EMS Educational Institution's program coordinator to qualify for an extension of the ~~90-day~~ 90-day requirement set forth in this Paragraph. If the EMS Educational Institution's program coordinator declines to provide

a letter of authorization, the applicant shall be disqualified from completing the credentialing process. Following a review of the applicant's specific circumstances, OEMS staff will determine, based on professional judgment, if the applicant qualifies for EMS credentialing eligibility. The OEMS shall notify the applicant in writing within 10 business days of the decision.

(A) a maximum of three attempts within ~~nine~~ six months shall be allowed.

~~(B) if the individual fails to pass a written examination, the individual may continue eligibility for examination for an additional three attempts within the following nine months by submitting to the OEMS evidence the individual repeated a course specific scope of practice evaluation as set forth in Subparagraph (a)(3) of this Rule, and evidence of completion of a refresher course as set forth in Rule .0513 of this Section for the level of application; or~~

~~(C)~~(B) if unable to pass the written examination requirement after ~~six attempts~~ three attempts, ~~within an 18 period following course grading date as reflected in the OEMS credentialing database,~~ the educational program shall become invalid and the individual may only become eligible for credentialing by repeating the requirements set forth in Rule .0501 of this Section.

(5) ~~submit~~ Submit to a criminal background history check as set forth in Rule .0511 of this Section.

(6) ~~submit~~ Submit evidence of completion of all court conditions resulting from any misdemeanor or felony conviction(s).

(b) An individual seeking credentialing as an EMR, EMT, ~~AEMT~~ AEMT, or Paramedic may qualify for initial credentialing under the legal recognition option set forth in G.S. 131E-159(c).

(1) Individuals possessing a credential for less than two years being used for the level of application shall complete a written examination administered by the OEMS as set forth in this Rule.

(2) Individuals seeking credentialing as an AEMT or Paramedic shall submit documentation that the credential being used for application is from a CAAHEP Accredited program.

(c) In order to be credentialed by the OEMS as an EMD, individuals shall:

(1) be at least 18 years of age;

(2) complete the educational requirements set forth in Rule ~~.0501(c)~~ .0501 of this Section;

(3) complete, within one year prior to application, an AHA CPR course or a course determined by the OEMS to be equivalent to the AHA CPR course, including infant, child, and adult CPR;

(4) submit to a criminal background history check as defined in Rule .0511 of this Section;

(5) submit evidence of completion of all court conditions resulting from any misdemeanor or felony conviction(s); and

(6) possess an EMD nationally recognized credential pursuant to G.S. 131E-159(d).

(d) Pursuant to G.S. 131E-159(h), the Department shall not issue an EMS credential for any person listed on the Department of Public Safety, Sex Offender and Public Protection Registry, or who was convicted of an offense that would have required registration if committed at a time when registration would have been required by law.

History Note: *Authority G.S. 131E-159(a); 131E-159(b); 131E-159(g); 131E-159(h); 143-508(d)(3); 143B-952;*
Temporary Adoption Eff. January 1, 2002;
Eff. February 1, 2004;
Amended Eff. January 1, 2009;
Readopted Eff. January 1, ~~2017.~~ 2017;
Amended Eff. July 1, 2021.

10A NCAC 13P .0504 is proposed for amendment as follows:

10A NCAC 13P .0504 RENEWAL OF CREDENTIALS FOR EMR, EMT, AEMT, PARAMEDIC, AND EMD

(a) EMR, EMT, AEMT, and Paramedic applicants shall renew credentials by meeting the following criteria:

(1) presenting documentation to the OEMS or an approved EMS educational institution or program as set forth in Rule .0601 or .0602 of this Subchapter that they have completed an approved educational program as described in Rule ~~.0501(e) or (f)~~ .0501 of this Section;

(2) submit to a criminal background history check as set forth in Rule .0511 of this Section;

(3) submit evidence of completion of all court conditions resulting from applicable misdemeanor or felony conviction(s); and

(4) be a resident of North Carolina or affiliated with an EMS provider approved by the Department.

(b) An individual may renew credentials by presenting documentation to the OEMS that he or she holds a valid EMS credential for his or her level of application issued by the National Registry of Emergency Medical Technicians or by another state where the education and credentialing requirements have been determined by OEMS staff in their professional judgment to be equivalent to the educations and credentialing requirements set forth in this Section.

(c) EMD applicants shall renew credentials by presenting documentation to the OEMS that he or she holds a valid EMD credential issued by a national credentialing agency using the education criteria set forth in Rule ~~.0501(c)~~ .0501 of this Section.

(d) Upon request, an EMS professional may renew at a lower credentialing level by meeting the requirements defined in Paragraph (a) of this Rule. To restore the credential held at the higher level, the individual shall meet the requirements set forth in Rule .0512 of this Section.

(e) EMS credentials may not be renewed through a local credentialed institution or program more than 90 days prior to the date of expiration.

(f) Pursuant to G.S. 150B-3(a), if an applicant makes a timely and sufficient application for renewal, the EMS credential shall not expire until a decision on the credential is made by the Department. If the application is denied, the credential shall remain effective until the last day for applying for judicial review of the Department's order.

(g) Pursuant to G.S. 131E-159(h), the Department shall not renew the EMS credential for any person listed on the North Carolina Department of Public Safety, Sex Offender and Public Protection Registry, or who was convicted of an offense that would have required registration at a time when registration would have been required by law.

History Note: *Authority G.S. 131E-159(a); 131E-159(g); 131E-159(h); 143-508(d)(3); 143B-952; 150B-3(a);*
Temporary Adoption Eff. January 1, 2002;
Eff. February 1, 2004;
Amended Eff. January 1, 2009;
Readopted Eff. January 1, ~~2017.~~ 2017;
Amended Eff. July 1, 2021.

10A NCAC 13P .0507 is proposed for amendment as follows:

10A NCAC 13P .0507 INITIAL CREDENTIALING REQUIREMENTS FOR LEVEL I EMS INSTRUCTORS

(a) Applicants for credentialing as a Level I EMS Instructor shall:

(1) be currently credentialed by the OEMS as an EMT, AEMT, or Paramedic;

(2) have completed post-secondary level education equal to or exceeding a minimum of an Associate Degree from an institution accredited by an approved agency listed on the U.S. Department of Education website, www.ed.gov:

(A) The Department shall accept degrees from programs accredited by the Accreditation Commission for Education in Nursing (ACEN) and the Commission on Accreditation of Allied Health Education Programs.

(B) Additional degrees may be accepted based on the professional judgment of OEMS staff following a comparison of standards;

~~(2)~~(3) have three years experience at the scope of practice for the level of application;

~~(3)~~(4) within one year prior to application, complete an in-person evaluation that demonstrates the applicant's ability to provide didactic and clinical instruction based on the cognitive, psychomotor, and affective educational objectives in Rule ~~.0501(b)~~ .0501 of this Section consistent with their level of application and approved by the OEMS:

(A) for a credential to teach at the EMT level, this evaluation shall be conducted under the direction of a Level II EMS Instructor credentialed at or above the level of application; and

(B) for a credential to teach at the AEMT or Paramedic level, this evaluation shall be conducted under the direction of the educational medical advisor, or a Level II EMS Instructor credentialed at or above the level of application and designated by the educational medical advisor;

~~(4)~~(5) have 100 hours of teaching experience at or above the level of application in an approved EMS educational program or a program determined by OEMS staff in their professional judgment equivalent to an EMS education program;

~~(5)~~(6) complete an educational program as described in Rule ~~.0501(d)~~ .0501 of this Section; and

~~(6)~~(7) within one year prior to application, attend an OEMS Instructor workshop sponsored by the OEMS. A listing of scheduled OEMS Instructor workshops is available from the OEMS at ~~www.ncems.org; and~~ https://info.ncdhhs.gov/dhsr/ems.

~~(7) have a high school diploma or General Education Development certificate.~~

(b) An individual seeking credentialing for Level I EMS Instructor may qualify for initial credentialing under the legal recognition option defined in G.S. 131E-159(c).

(c) The credential of a Level I EMS Instructor shall be valid for four years, or less pursuant to G.S. ~~131E-159(c)~~ 131E-159(c), unless any of the following occurs:

(1) the OEMS imposes an administrative action against the instructor credential; or

(2) the instructor fails to maintain a current EMT, AEMT, or Paramedic credential at the highest level that the instructor is approved to teach.

(d) Pursuant to the provisions of G.S. 131E-159(h), the Department shall not issue an EMS credential for any person listed on the Department of Public Safety, Sex Offender and Public Protection Registry, or who was convicted of an offense that would have required registration if committed at a time when registration would have been required by law.

History Note: *Authority G.S. 131E-159; 143-508(d)(3);*
Temporary Adoption Eff. January 1, 2002;
Eff. February 1, 2004;
Amended Eff. January 1, 2009;
Readopted Eff. January 1, 2017;
Amended Eff. July 1, 2021; September 1, 2019.

10A NCAC 13P .0508 is proposed for amendment as follows:

10A NCAC 13P .0508 INITIAL CREDENTIALING REQUIREMENTS FOR LEVEL II EMS INSTRUCTORS

(a) Applicants for credentialing as a Level II EMS Instructor shall:

(1) be currently credentialed by the OEMS as an EMT, AEMT, or Paramedic;

(2) be currently credentialed by the OEMS as a Level I Instructor at the EMT, AEMT, or Paramedic level;

~~(2)~~(3) have completed post-secondary level education equal to or exceeding ~~an Associate Degree;~~ a Bachelor's Degree from an institution accredited by an approved agency listed on the U.S. Department of Education website, www.ed.gov:

(A) The Department shall accept degrees from programs accredited by the Accreditation Commission for Education in Nursing (ACEN) and the Commission on Accreditation of Allied Health Education Programs.

(B) Additional degrees may be accepted based on the professional judgment of OEMS staff following a comparison of standards;

~~(3)~~(4) within one year prior to application, complete an in-person evaluation that demonstrates the applicant's ability to provide didactic and clinical instruction based on the cognitive, psychomotor, and affective educational objectives in Rule ~~.0501(b)~~ .0501 of this Section consistent with their level of application and approved by the OEMS:

(A) for a credential to teach at the EMT level, this evaluation shall be conducted under the direction of a Level II EMS Instructor credentialed at or above the level of application; and

(B) for a credential to teach at the AEMT or Paramedic level, this evaluation shall be conducted under the direction of the educational medical advisor, or a Level II EMS Instructor credentialed at or above the level of application and designated by the educational medical advisor;

~~(4)~~(5) ~~have two~~ a minimum two concurrent years teaching experience as a Level I EMS Instructor at or above the level of ~~application~~ application, or as a Level II EMS Instructor at a lesser credential level applying for a higher level in an approved EMS educational ~~program~~ program, or teaching experience determined by OEMS staff in their professional judgment to be equivalent to an EMS Level I education program;

~~(5)~~(6) complete the "EMS Education Administration Course conducted by a North Carolina Community College or the National Association of EMS Educators Level II Instructor ~~Course;~~ Course that is valid for the duration of the active Level II Instructor credential; and

~~(6)~~(7) within one year prior to application, attend an OEMS Instructor workshop sponsored by the OEMS. A listing of scheduled OEMS Instructor workshops is available from the OEMS at ~~www.ncems.org.~~ https://info.ncdhhs.gov/dhsr/ems.

(b) An individual seeking credentialing for Level II EMS Instructor may qualify for initial credentialing under the legal recognition option defined in G.S. 131E-159(c).

(c) The credential of a Level II EMS Instructor is valid for four years, or less pursuant to ~~G.S. 131E-159(c)~~ 131E-159(c), unless any of the following occurs:

(1) the OEMS imposes an administrative action against the instructor credential; or

(2) the instructor fails to maintain a current EMT, AEMT, or Paramedic credential at the highest level that the instructor is approved to teach.

(d) Pursuant to the provisions of G.S. 131E-159(h) the Department shall not issue an EMS credential for any person listed on the Department of Public Safety, Sex Offender and Public Protection Registry, or who was convicted of an offense that would have required registration if committed at a time when registration would have been required by law.

History Note: *Authority G.S. 131E-159; 143-508(d)(3);*
Temporary Adoption Eff. January 1, 2002;
Eff. February 1, 2004;
Amended Eff. January 1, 2009;
Readopted Eff. January 1, 2017;
Amended Eff. July 1, 2021; September 1, 2019.

10A NCAC 13P .0510 is proposed for amendment as follows:

10A NCAC 13P .0510 RENEWAL OF CREDENTIALS FOR LEVEL I AND LEVEL II EMS INSTRUCTORS

(a) Level I and Level II EMS Instructor applicants shall renew credentials by presenting documentation to the OEMS that they:

(1) are credentialed by the OEMS as an EMT, ~~AEMT~~ AEMT, or Paramedic;

(2) within one year prior to application, complete an evaluation that demonstrates the applicant's ability to provide didactic and clinical instruction based on the cognitive, psychomotor, and affective educational objectives in Rule ~~.0501(b)~~ .0501 of this Section consistent with their level of application and approved by the OEMS:

(A) to renew a credential to teach at the EMT level, this evaluation shall be conducted under the direction of a Level II EMS Instructor credentialed at or above the level of application; and

(B) to renew a credential to teach at the AEMT or Paramedic level, this evaluation shall be conducted under the direction of the educational medical advisor, or a Level II EMS Instructor credentialed at or above the level of application and designated by the educational medical advisor;

(3) completed 96 hours of EMS instruction at the level of ~~application; and~~ application. Individuals identified as EMS program coordinators or positions determined by OEMS staff in the professional judgment to the equivalent to an EMS program coordinator may provide up to 72 hours related to the institution's needs, with the remaining 24 hours in EMS instruction;

(4) completed 24 hours of educational professional development as defined by the educational institution that provides for:

(A) enrichment of knowledge;

(B) development or change of attitude in students; or

(C) acquisition or improvement of skills; and

(5) within one year prior to renewal application, attend an OEMS Instructor workshop sponsored by the OEMS.

(b) An individual may renew a Level I or Level II EMS Instructor credential under the legal recognition option defined in G.S. 131E-159(c).

(c) The credential of a Level I or Level II EMS Instructor is valid for four years, or less pursuant to G.S. 131E-159(c) unless any of the following occurs:

(1) the OEMS imposes an administrative action against the instructor credential; or

(2) the instructor fails to maintain a current EMT, AEMT, or Paramedic credential at the highest level that the instructor is approved to teach.

(d) Pursuant to the provisions of G.S. 131E-159(h), the Department shall not issue an EMS credential for any person listed on the Department of Public Safety, Sex Offender and Public Protection Registry, or who was convicted of an offense that would have required registration if committed at a time when registration would have been required by law.

History Note: *Authority G.S. 131E-159(a); 131E-159(b); 143-508(d)(3);*
Eff. February 1, 2004;
Amended Eff. February 1, 2009;
Readopted Eff. January 1, ~~2017.~~ 2017;
Amended Eff. July 1, 2021.

10A NCAC 13P .0512 is proposed for amendment as follows:

10A NCAC 13P .0512 REINSTATEMENT OF LAPSED EMS CREDENTIAL

(a) EMS personnel enrolled in an OEMS approved continuing education program as set forth in Rule .0601 of this Subchapter and ~~that~~ who was eligible for renewal of an EMS credential prior to expiration, may request the EMS educational institution submit documentation of the continuing education record to the OEMS. OEMS shall renew the EMS credential to be valid for four years from the previous expiration date.

(b) An individual with a lapsed North Carolina EMS credential is eligible for reinstatement through the legal recognition option defined in G.S. 131E-159(c) and Rule .0502 of this Section.

(c) EMR, EMT, AEMT, and Paramedic applicants for reinstatement of an EMS credential, lapsed up to ~~24~~ 12 months, shall:

(1) be ineligible for legal recognition pursuant to G.S. 131E-159(c);

(2) be a resident of North Carolina or affiliated with a North Carolina EMS Provider;

(3) at the time of application, present evidence that renewal education requirements were met prior to expiration or complete a refresher course at the level of application taken following expiration of the credential;

(4) ~~EMRs and EMTs shall~~ complete an OEMS administered written examination for the individual's level of credential application;

(5) undergo a criminal history check performed by the OEMS; and

(6) submit evidence of completion of all court conditions resulting from applicable misdemeanor or felony conviction(s).

~~(d) EMR and EMT applicants for reinstatement of an EMS credential, lapsed more than 24 months, must:~~

~~(1) be ineligible for legal recognition pursuant to G.S. 131E-159(c); and~~

~~(2) meet the provisions for initial credentialing set forth in Rule .0502 of this Section~~

~~(e) AEMT and Paramedic applicants for reinstatement of an EMS credential, lapsed between 24 and 48 months, shall:~~

~~(1) be ineligible for legal recognition pursuant to G.S. 131E-159(c);~~

~~(2) be a resident of North Carolina or affiliated with a North Carolina EMS Provider;~~

~~(3) present evidence of completion of a refresher course at the level of application taken following expiration of the credential;~~

~~(4) complete an OEMS administered written examination for the individuals level of credential application;~~

~~(5) undergo a criminal history check performed by the OEMS; and~~

~~(6) submit evidence of completion of all court conditions resulting from applicable misdemeanor or felony conviction(s).~~

~~(f)~~(d) ~~AEMT~~ EMR, EMT, AEMT, and Paramedic applicants for reinstatement of an EMS credential, lapsed more than ~~48~~ 12 months, shall:

(1) be ineligible for legal recognition pursuant to G.S. 131E-159(c); and

(2) meet the provisions for initial credentialing set forth in Rule .0502 of this Section.

(e) EMT, AEMT, and Paramedic applicants for reinstatement of an EMS Instructor Credential, lapsed up to 12 months, shall:

(1) be ineligible for legal recognition pursuant to G.S. 131E-159(c);

(2) be a resident of North Carolina or affiliated with a North Carolina EMS Provider; and

(3) at the time of application, present evidence that renewal requirements were met prior to expiration or within six months following the expiration of the Instructor credential.

(f) EMT, AEMT, and Paramedic applicants for reinstatement of an EMS Instructor credential, lapsed greater than 12 months, shall:

(1) be ineligible for legal recognition pursuant to G.S. 131E-159(c); and

(2) meet the requirements for initial Instructor credentialing set forth in Rules .0507 and .0508 of this Section. Degree requirements that were not applicable to EMS Instructors initially credentialed prior to April 1, 2021 shall be required for reinstatement of a lapsed credential.

(g) EMD applicants shall renew a lapsed credential by meeting the requirements for initial credentialing set forth in Rule .0502 of this Section.

(h) Pursuant to G.S. 131E-159(h), the Department shall not issue or renew an EMS credential for any person listed on the Department of Public Safety, Sex Offender and Public Protection Registry, or who was convicted of an offense that would have required registration if committed at a time when registration would have been required by law.

History Note: *Authority G.S. 131E-159; 143-508(d)(3); 143B-952;*
Eff. January 1, ~~2017.~~ 2017;
Amended Eff. July 1, 2021.

10A NCAC 13P .0601 is proposed for amendment as follows:

SECTION .0600 – EMS EDUCATIONAL INSTITUTIONS AND PROGRAMS

10A NCAC 13P .0601 CONTINUING EDUCATION EMS EDUCATIONAL ~~INSTITUTION~~ PROGRAM REQUIREMENTS

(a) Continuing Education EMS Educational ~~Institutions~~ Programs shall be credentialed by the OEMS to provide only EMS continuing ~~education programs.~~ education. An application for credentialing as an approved EMS continuing education ~~institution~~ program shall be submitted to the OEMS for review.

(b) Continuing Education EMS Educational ~~Institutions~~ Programs shall have:

(1) at least a Level I EMS Instructor as program coordinator and shall hold a Level I EMS Instructor credential at a level equal to or greater than the highest level of continuing education program offered in the EMS ~~System or~~ System, Specialty Care Transport ~~Program;~~ Program, or Agency;

(2) a continuing education program shall be consistent with the services offered by the EMS ~~System or~~ System, Specialty Care Transport ~~Program;~~ Program, or Agency;

(A) In an EMS System, the continuing education programs shall be reviewed and approved by the system continuing education coordinator and Medical Director; ~~and~~

(B) In a Specialty Care Transport Program, the continuing education program shall be reviewed and approved by Specialty Care Transport Program Continuing Education Coordinator and the Medical Director; and

(C) In an Agency not affiliated with an EMS System or Specialty Care Transport Program, the continuing education program shall be reviewed and approved by the Agency Program Medical Director;

(3) written educational policies and procedures to include each of the following;

(A) the delivery of educational programs in a manner where the content and material is delivered to the intended audience, with a limited potential for exploitation of such content and material;

(B) the record-keeping system of student attendance and performance;

(C) the selection and monitoring of EMS instructors; and

(D) student evaluations of faculty and the program's courses or components, and the frequency of the evaluations;

(4) access to instructional supplies and equipment necessary for students to complete educational programs as defined in Rule ~~.0501(b)~~ .0501 of this Subchapter;

(5) meet ~~at a minimum,~~ the educational program requirements as defined in Rule ~~.0501(c)~~ .0501 of this Subchapter;

(6) Upon request, the approved EMS continuing education ~~institution~~ program shall provide records to the OEMS in order to verify compliance and student eligibility for credentialing; and

(7) ~~unless accredited in accordance with Rule .0605 of this Section,~~ approved education ~~institution~~ program credentials are valid for a period not to exceed four years.

(c) Program coordinators shall attend an OEMS Program Coordinator workshop annually. A listing of scheduled OEMS Program Coordinator Workshops is available at https://emspic.org.

~~(c)~~(d) Assisting physicians delegated by the EMS System Medical Director as authorized by Rule ~~.0403(b)~~ .0403 of this Subchapter or SCTP Medical Director as authorized by Rule ~~.0404(b)~~ .0404 of this Subchapter for provision of medical oversight of continuing education programs must meet the Education Medical Advisor criteria as defined in the "North Carolina College of Emergency Physicians: Standards for Medical Oversight."

History Note: *Authority G.S. 143-508(d)(4); 143-508(d)(13);*
Temporary Adoption Eff. January 1, 2002;
Eff. January 1, 2004;
Amended Eff. January 1, 2009;
Readopted Eff. January 1, ~~2017.~~ 2017;
Amended Eff. July 1, 2021.

10A NCAC 13P .0602 is proposed for amendment as follows:

10A NCAC 13P .0602 BASIC AND ADVANCED EMS EDUCATIONAL INSTITUTION REQUIREMENTS

(a) Basic and Advanced EMS Educational Institutions may offer educational programs for which they have been credentialed by the OEMS.

(1) EMS Educational Institutions shall complete a minimum of two initial courses for each educational program approved for the Educational Institution's credential approval period.

(2) EMS Educational Institutions that do not complete two initial courses for each educational program approved shall be subject to action as set forth in in Rule .1505 of this Subchapter.

(b) For initial courses, Basic EMS Educational Institutions shall meet all of the requirements for continuing EMS educational ~~institutions~~ programs defined in Rule .0601 of this Section and shall have:

(1) at least a Level I EMS Instructor as each lead course instructor for ~~EMR and EMT~~ all courses. The lead course instructor must be credentialed at a level equal to or higher than the course ~~offered;~~ and shall meet the lead instructor responsibilities under Standard III of the CAAHEP Standards and Guidelines for the Accreditation of Educational Programs in the Emergency Medical Services Professions. The lead instructor shall:

(A) perform duties assigned under the direction and delegation of the program director.

(B) assist in coordination of the didactic, lab, clinical, and field internship instruction.

(2) a lead EMS educational program coordinator. This individual ~~may be either~~ shall be a Level II EMS Instructor credentialed at or above the highest level of course offered by the ~~institution, or a combination of staff who cumulatively meet the requirements of the Level II EMS Instructor set forth in this Subparagraph. These individuals may share the responsibilities of the lead EMS educational coordinator. The details of this option shall be defined in the educational plan required in Subparagraph (b)(5) of this Rule;~~ institution, and:

(A) have EMS or related allied health education, training, and experience;

(B) be knowledgeable about methods of instruction, testing, and evaluation of students;

(C) have field experience in the delivery of pre-hospital emergency care;

(D) have academic training and preparation related to emergency medical services, at least equivalent to that of a paramedic; and

(E) be knowledgeable of current versions of the National EMS Scope of Practice and National EMS Education Standards as defined by USDOT NHTSA National EMS, evidenced-informed clinical practice, and incorporated by Rule .0501 of this Section;

(3) a lead EMS educational program coordinator responsible for the following:

(A) the administrative oversight, organization, and supervision of the program;

(B) the continuous quality review and improvement of the program;

(C) the long-range planning on ongoing development of the program;

(D) evaluating the effectiveness of the instruction, faculty, and overall program;

(E) the collaborative involvement with the Education Medical Advisor;

(F) the training and supervision of clinical and field internship preceptors; and

(G) the effectiveness and quality of fulfillment of responsibilities delegated to another qualified individual;

~~(3)~~(4) written educational policies and procedures that include:

(A) the written educational policies and procedures set forth in Rule ~~.0601(b)(4)~~ .0601 of this Section;

(B) the delivery of cognitive and psychomotor examinations in a manner that will protect and limit the potential for exploitation of such content and material;

(C) the exam item validation process utilized for the development of validated cognitive examinations;

(D) the selection and monitoring of all in-state and out-of-state clinical education and field internship sites;

(E) the selection and monitoring of all educational institutionally approved clinical education and field internship preceptors;

(F) utilization of EMS preceptors providing feedback to the student and EMS program;

(G) the evaluation of preceptors by their students, including the frequency of evaluations;

(H) the evaluation of the clinical education and field internship sites by their students, including the frequency of evaluations; and

(I) completion of an annual evaluation of the program to identify any correctable deficiencies;

~~(4)~~(5) an Educational Medical Advisor that meets the criteria as defined in the "North Carolina College of Emergency Physicians: Standards for Medical Oversight and Data ~~Collection;" and~~ Collection" who is responsible for the following;

(A) medical oversight of the program;

(B) collaboration to provide appropriate and updated educational content for the program curriculum;

(C) establishing minimum requirements for program completion;

(D) oversight of student evaluation, monitoring, and remediation as needed;

(E) ensuring entry level competence;

(F) ensuring interaction of physician and students; and

~~(5)~~(6) written educational policies and procedures describing the delivery of educational programs, the record-keeping system detailing student attendance and performance, and the selection and monitoring of EMS instructors.

(c) For initial courses, Advanced Educational Institutions shall meet all requirements ~~defined~~ set forth in Paragraph (b) of this ~~Rule, and have a Level II EMS Instructor as lead instructor for AEMT and Paramedic initial courses. The lead instructor shall be credentialed at a level equal to or higher than the course offered.~~ Rule, standard III of the CAAHEP Standards and Guidelines for the Accreditation of Educational Programs in the Emergency Medical Services Professions shall apply, and;

(1) The faculty must be knowledgeable in course content and effective in teaching their assigned subjects, and capable through academic preparation, training, and experience to teach the courses or topics to which they are assigned.

(2) A faculty member to assist in teaching and clinical coordination in addition to the program coordinator.

(d) Basic and Advanced EMS Educational Institution credentials shall be valid for a period of four years, unless the institution is accredited in accordance with Rule .0605 of this Section.

History Note: *Authority G.S. 143-508(d)(4); 143-508(d)(13);*
Temporary Adoption Eff. January 1, 2002;
Eff. January 1, 2004;
Amended Eff. January 1, 2009;
Readopted Eff. January 1, ~~2017.~~ 2017;
Amended Eff. July 1, 2021.

10A NCAC 13P .0904 is proposed for amendment as follows:

10A NCAC 13P .0904 INITIAL DESIGNATION PROCESS

(a) For initial Trauma Center designation, the hospital shall request a consult visit by OEMS and the consult shall occur within one year prior to submission of the RFP.

(b) A hospital interested in pursuing Trauma Center designation shall submit a letter of intent 180 days prior to the submission of an RFP to the OEMS. The letter shall define the hospital's primary trauma catchment area. Simultaneously, Level I or II applicants shall also demonstrate the need for the Trauma Center designation by submitting one original and three copies of documents that include:

(1) the population to be served and the extent that the population is underserved for trauma care with the methodology used to reach this conclusion;

(2) geographic considerations, to include trauma primary and secondary catchment area and distance from other Trauma Centers; and

(3) ~~evidence~~ for Level 1 applicants, evidence the Trauma Center will admit at least 1200 trauma patients annually or show that its trauma service will be taking care of at least 240 trauma patients yearly with an ISS greater than or equal to ~~15 yearly.~~ 15. ~~These criteria shall be met without compromising the quality of care or cost effectiveness of any other designated Level I or II Trauma Center sharing all or part of its catchment area or by jeopardizing the existing Trauma Center's ability to meet this same 240 patient minimum.~~

(c) The hospital shall be participating in the State Trauma Registry as defined in Rule .0102 of this Subchapter, and submit data to the OEMS weekly a minimum of 12 months prior to application that includes all the Trauma Center's trauma patients as defined in Rule .0102 of this ~~Subchapter who are:~~ Subchapter.

~~(1) diverted to an affiliated hospital;~~

~~(2) admitted to the Trauma Center for greater than 24 hours from an ED or hospital;~~

~~(3) die in the ED;~~

~~(4) are DOA; or~~

~~(5) are transferred from the ED to the OR, ICU, or another hospital (including transfer to any affiliated hospital).~~

(d) ~~OEMS shall review the regional Trauma Registry data from both the applicant and the existing trauma center(s), and ascertain the applicant's ability to satisfy the justification of need information required in Paragraph (b) of this~~

~~Rule.~~ The OEMS shall notify the applicant's primary RAC of the ~~application and provide the regional data submitted by the applicant in Paragraph (b) of this Rule for review and comment.~~ application. ~~The~~ The applicant's primary RAC shall be given 30 days to submit written comments to the OEMS.

~~(e) OEMS shall notify the respective Board of County Commissioners in the applicant's primary catchment area of the request for initial designation to allow for comment during the same 30 day comment period.~~

~~(f)~~(e) OEMS shall notify the hospital in writing of its decision to allow submission of an RFP. ~~If approved, the RAC and Board of County Commissioners in the applicant's primary catchment area shall also be notified by the OEMS that an RFP will be submitted.~~

~~(g)~~(f) Once the hospital is notified that an RFP will be accepted, the hospital shall complete and submit an electronic copy of the completed RFP ~~with signatures~~ to the OEMS at least 45 days prior to the proposed site visit date.

~~(h)~~(g) The RFP shall demonstrate that the hospital meets the standards for the designation level applied for as found in Rule .0901 of this Section.

~~(i)~~(h) If OEMS does not recommend a site visit based upon failure to comply with Rule .0901 of this Section, the OEMS shall send the written reasons to the hospital within 30 days of the decision. The hospital may reapply for designation within six months following the submission of an updated RFP. If the hospital fails to respond within six months, the hospital shall reapply following the process outlined in Paragraphs (a) through ~~(h)~~ (g) of this Rule.

~~(j) If after review of the RFP, the OEMS recommends the hospital for a site visit, the OEMS shall notify the hospital within 30 days and the site visit shall be conducted within six months of the recommendation. The hospital and the OEMS shall agree on the date of the site visit.~~

~~(k)~~(i) Except for OEMS representatives, any in-state reviewer for a Level I or II visit shall be from outside the local or adjacent RAC, unless mutually agreed upon by the OEMS and the trauma center seeking designation where the hospital is located. The composition of a Level I or II state site survey team shall be as follows:

(1) one out-of-state trauma surgeon who is a Fellow of the ACS, experienced as a site surveyor, who shall be the primary reviewer;

(2) one in-state emergency physician who currently works in a designated trauma center, is a member of the American College of Emergency Physicians or American Academy of Emergency Medicine, and is boarded in emergency medicine by the American Board of Emergency Medicine or the American Osteopathic Board of Emergency Medicine;

(3) one in-state trauma surgeon who is a member of the North Carolina Committee on Trauma;

(4) for Level I designation, one out-of-state trauma program manager with an equivalent license from another state;

(5) for Level II designation, one in-state program manager who is licensed to practice nursing in North Carolina in accordance with the Nursing Practice Act, Article 9A, Chapter 90 of the North Carolina General Statutes; and

(6) OEMS Staff.

~~(l)~~(j) All site team members for a Level III visit shall be from in-state, and, except for the OEMS representatives, shall be from outside the local or adjacent RAC where the hospital is located. The composition of a Level III state site survey team shall be as follows:

(1) one trauma surgeon who is a Fellow of the ACS, who is a member of the North Carolina Committee on Trauma and shall be the primary reviewer;

(2) one emergency physician who currently works in a designated trauma center, is a member of the North Carolina College of Emergency Physicians or American Academy of Emergency Medicine, and is boarded in emergency medicine by the American Board of Emergency Medicine or the American Osteopathic Board of Emergency Medicine;

(3) one trauma program manager who is licensed to practice nursing in North Carolina in accordance with the Nursing Practice Act, Article 9A, Chapter 90 of the North Carolina General Statutes; and

(4) OEMS Staff.

~~(m)~~(k) On the day of the site visit, the hospital shall make available all requested patient medical charts.

~~(n)~~(l) The primary reviewer of the site review team shall give a verbal post-conference report representing a consensus of the site review team. The primary reviewer shall complete and submit to the OEMS a written consensus report within 30 days of the site visit.

~~(o)~~(m) The report of the site survey team and the staff recommendations shall be reviewed by the State Emergency Medical Services Advisory Council at its next regularly scheduled meeting following the site visit. Based upon the site visit report and the staff recommendation, the State Emergency Medical Services Advisory Council shall recommend to the OEMS that the request for Trauma Center designation be approved or denied.

~~(p)~~(n) All criteria defined in Rule .0901 of this Section shall be met for initial designation at the level requested.

~~(q)~~(o) Hospitals with a deficiency(ies) resulting from the site visit shall be given up to 12 months to demonstrate compliance. Satisfaction of deficiency(ies) may require an additional site visit. The need for an additional site visit shall be determined on a case-by-case basis based on the type of deficiency. If compliance is not demonstrated within the time period set by OEMS, the hospital shall submit a new application and updated RFP and follow the process outlined in Paragraphs (a) through ~~(h)~~ (g) of this Rule.

~~(r)~~(p) The final decision regarding Trauma Center designation shall be rendered by the OEMS.

~~(s)~~(q) The OEMS shall notify the hospital in writing of the State Emergency Medical Services Advisory Council's and OEMS' final recommendation within 30 days of the Advisory Council meeting.

~~(t)~~(r) If a trauma center changes its trauma program administrative structure such that the trauma service, trauma Medical Director, trauma program manager, or trauma registrar are relocated on the hospital's organizational chart at any time, it shall notify OEMS of this change in writing within 30 days of the occurrence.

~~(u)~~(s) Initial designation as a trauma center shall be valid for a period of three years.

History Note: *Authority G.S. 131E-162; 143-508(d)(2);*
Temporary Adoption Eff. January 1, 2002;
Eff. April 1, 2003;

Amended Eff. January 1, 2009;
Readopted Eff. January 1, 2017;
Amended Eff. July 1,2021; July 1, 2018.

10 NCAC 13P .0905 is proposed for amendment as follows:

10A NCAC 13P .0905 RENEWAL DESIGNATION PROCESS

(a) Hospitals may utilize one of two options to achieve Trauma Center renewal:

(1) undergo a site visit conducted by OEMS to obtain a four-year renewal designation; or

(2) undergo a verification visit by the ACS, in conjunction with the OEMS, to obtain a three-year renewal designation.

(b) For hospitals choosing Subparagraph (a)(1) of this Rule:

(1) prior to the end of the designation period, the OEMS shall forward to the hospital an RFP for completion. The hospital shall, within 10 business days of receipt of the RFP, define for OEMS the Trauma Center's trauma primary catchment area. Upon this notification, OEMS shall notify the respective Board of County Commissioners in the applicant's trauma primary catchment area of the request for renewal to allow 30 days for comment.

(2) hospitals shall complete and submit an electronic copy of the RFP to the OEMS and the specified site surveyors at least 30 days prior to the site visit. The RFP shall include information that supports compliance with the criteria contained in Rule .0901 of this Section as it relates to the Trauma Center's level of designation.

(3) all criteria defined in Rule .0901 of this Section, as it relates to the Trauma Center's level of designation, shall be met for renewal designation.

(4) a site visit shall be conducted within 120 days prior to the end of the designation period. The hospital and the OEMS shall agree on the date of the site visit.

(5) the composition of a Level I or II site survey team shall be the same as that specified in Rule.0904(k) of this Section.

(6) the composition of a Level III site survey team shall be the same as that specified in Rule .0904(l) of this Section.

(7) on the day of the site visit, the hospital shall make available all requested patient medical charts.

(8) the primary reviewer of the site review team shall give a verbal post-conference report representing a consensus of the site review team. The primary reviewer shall complete and submit to the OEMS a written consensus report within 30 days of the site visit.

(9) the report of the site survey team and a staff recommendation shall be reviewed by the NC Emergency Medical Services Advisory Council at its next regularly scheduled meeting following the site visit. Based upon the site visit report and the staff recommendation, the NC Emergency

Medical Services Advisory Council shall recommend to the OEMS that the request for Trauma Center renewal be:

(A) approved;

(B) approved with a contingency(ies) due to a deficiency(ies) requiring a focused review;

(C) approved with a contingency(ies) not due to a deficiency(ies) requiring a consultative visit; or

(D) denied.

(10) hospitals with a deficiency(ies) shall have up to 10 business days prior to the NC Emergency Medical Services Advisory Council meeting to provide documentation to demonstrate compliance. If the hospital has a deficiency that cannot be corrected in this period prior to the NC Emergency Medical Services Advisory Council meeting, the ~~hospital,~~ hospital shall be given 12 months by the OEMS to demonstrate compliance and undergo a focused review that may require an additional site visit. The need for an additional site visit is on a case-by-case basis based on the type of deficiency. The hospital shall retain its Trauma Center designation during the focused review period. If compliance is demonstrated within the prescribed time period, the hospital shall be granted its designation for the four-year period from the previous designation's expiration date. If compliance is not demonstrated within the 12 month time period, the Trauma Center designation shall not be renewed. To become redesignated, the hospital shall submit an updated RFP and follow the initial applicant process outlined in Rule .0904 of this Section.

(11) the final decision regarding trauma center renewal shall be rendered by the OEMS.

(12) the OEMS shall notify the hospital in writing of the NC Emergency Medical Services Advisory Council's and OEMS' final recommendation within 30 days of the NC Emergency Medical Services Advisory Council meeting.

(13) hospitals with a deficiency(ies) shall submit an action plan to the OEMS to address the deficiency(ies) within 10 business days following receipt of the written final decision on the trauma recommendations.

(c) For hospitals choosing Subparagraph (a)(2) of this Rule:

(1) at least six months prior to the end of the Trauma Center's designation period, the trauma center shall notify the OEMS of its intent to undergo an ACS verification visit. It shall simultaneously define in writing to the OEMS its trauma primary catchment area. Trauma Centers choosing this option shall then comply with all the ACS' verification procedures, as well as any additional state criteria as defined in Rule .0901 of this Section, that apply to their level of designation.

(2) when completing the ACS' documentation for verification, the Trauma Center shall ensure access to the ACS on-line PRQ (pre-review questionnaire) to OEMS. The Trauma Center shall simultaneously complete any documents supplied by OEMS and forward these to the OEMS.

~~(3) the OEMS shall notify the Board of County Commissioners within the trauma center's trauma primary catchment area of the Trauma Center's request for renewal to allow 30 days for comments.~~

~~(4)~~(3) the Trauma Center shall make sure the site visit is scheduled to ensure that the ACS' final written report, accompanying medical record reviews and cover letter are received by OEMS at least 30 days prior to a regularly scheduled NC Emergency Medical Services Advisory Council meeting to ensure that the Trauma Center's state designation period does not terminate without consideration by the NC Emergency Medical Services Advisory Council.

~~(5)~~(4) any in-state review for a hospital choosing Subparagraph (a)(2) of this Rule, except for the OEMS staff, shall be from outside the local or adjacent RAC in which the hospital is located.

~~(6)~~(5) the composition of a Level I, II, or III site survey team for hospitals choosing Subparagraph (a)(2) of this Rule shall be as follows:

(A) one out-of-state trauma surgeon who is a Fellow of the ACS, experienced as a site surveyor, who shall be the primary reviewer;

(B) one out-of-state emergency physician who works in a designated trauma center, is a member of the American College of Emergency Physicians or the American Academy of Emergency Medicine, and is boarded in emergency medicine by the American Board of Emergency Physicians or the American Osteopathic Board of Emergency Medicine;

(C) one out-of-state trauma program manager with an equivalent license from another state; and

(D) OEMS staff.

~~(7)~~(6) the date, time, and all proposed members of the site visit team shall be submitted to the OEMS for review at least 45 days prior to the site visit. The OEMS shall approve the site visit schedule if the schedule does not conflict with the ability of attendance by required OEMS staff. The OEMS shall approve the proposed site visit team members if the OEMS determines there is no conflict of interest, such as previous employment, by any site visit team member associated with the site visit.

~~(8)~~(7) all state Trauma Center criteria shall be met as defined in Rule .0901of this Section for renewal of state designation. ACS' verification is not required for state designation. ACS' verification does not ensure a state designation.

~~(9)~~(8) The ACS final written report and supporting documentation described in Subparagraph (c)(4) of this Rule shall be used to generate a report following the post conference meeting for presentation to the NC Emergency Medical Services Advisory Council for renewal designation.

~~(10)~~(11) the final written report issued by the ACS' verification review committee, the accompanying medical record reviews from which all identifiers shall be removed and cover letter shall be forwarded to OEMS within 10 business days of its receipt by the Trauma Center seeking renewal.

~~(11)~~(10) the OEMS shall present its summary of findings report to the NC Emergency Medical Services Advisory Council at its next regularly scheduled meeting. The NC Emergency Medical Services Advisory Council shall recommend to the Chief of the OEMS that the request for Trauma Center renewal be:

(A) approved;

(B) approved with a contingency(ies) due to a deficiency(ies) requiring a focused review;

(C) approved with a contingency(ies) not due to a deficiency(ies); or

(D) denied.

~~(12)~~(11) the OEMS shall send the hospital written notice of the NC Emergency Medical Services Advisory Council's and OEMS' final recommendation within 30 days of the NC Emergency Medical Services Advisory Council meeting.

~~(13)~~(12) the final decision regarding trauma center designation shall be rendered by the OEMS.

~~(14)~~(13) hospitals with contingencies as the result of a deficiency(ies), as determined by OEMS, shall have up to 10 business days prior to the NC Emergency Medical Services Advisory Council meeting to provide documentation to demonstrate compliance. If the hospital has a deficiency that cannot be corrected in this time period, the hospital, may undergo a focused review to be conducted by the OEMS whereby the Trauma Center shall be given 12 months by the OEMS to demonstrate compliance. Satisfaction of contingency(ies) may require an additional site visit. The need for an additional site visit is on a case-by-case basis based on the type of deficiency. The hospital shall retain its Trauma Center designation during the focused review period. If compliance is demonstrated within the prescribed time period, the hospital shall be granted its designation for the three-year period from the previous designation's expiration date. If compliance is not demonstrated within the 12 month time period, the Trauma Center designation shall not be renewed. To become redesignated, the hospital shall submit a new RFP and follow the initial applicant process outlined in Rule .0904 of this Section.

~~(15)~~(14) hospitals with a deficiency(ies) shall submit an action plan to the OEMS to address the deficiency(ies) within 10 business days following receipt of the written final decision on the trauma recommendations.

(d) If a Trauma Center currently using the ACS' verification process chooses not to renew using this process, it must notify the OEMS at least six months prior to the end of its state trauma center designation period of its intention to exercise the option in Subparagraph (a)(1) of this Rule. Upon notification, the OEMS shall extend the designation for one additional year to ensure consistency with hospitals using Subparagraph (a)(1) of this Rule.

History Note: *Authority G.S. 131E-162; 143-508(d)(2);*
Temporary Adoption Eff. January 1, 2002;
Eff. April 1, 2003;
Amended Eff. April 1, 2009; January 1, 2009; January 1, 2004;
Readoption Eff. January 1, ~~2017.~~ 2017;
Amended Eff. July 1, 2021.

10A NCAC 13P .1101 is proposed for amendment as follows:

10A NCAC 13P .1101 STATE TRAUMA SYSTEM

(a) The state trauma system shall consist of regional plans, policies, guidelines, and performance improvement initiatives by the RACs to create an Inclusive Trauma System monitored by the OEMS.

(b) Each hospital and EMS System shall affiliate as defined in Rule ~~.0102(3)~~ .0102 of this Subchapter and participate with the RAC that includes the Level I or II Trauma Center where the majority of trauma patient referrals and transports occur. Each hospital and EMS System shall submit to the OEMS upon request patient transfer patterns from data sources that support the choice of their primary RAC affiliation. Each RAC shall include at least one Level I or II Trauma Center.

~~(c) The OEMS shall notify each RAC of its hospital and EMS System membership annually.~~

~~(d)~~(c) Each ~~hospital and each EMS System~~ Lead RAC Coordinator shall update and submit ~~its~~ RAC affiliation ~~information~~ membership for hospitals and EMS Systems to the OEMS no later than July 1 of each year. Each hospital or EMS System shall submit written notification to the OEMS for any RAC affiliation change. RAC affiliation may ~~only~~ be changed ~~during this annual update and~~ only if supported by a change in the majority of transfer patterns to a Level I or Level II Trauma Center. Documentation of these new transfer patterns shall be included in the request to change affiliation. ~~If no change is made in RAC affiliation, written notification shall be required annually to the OEMS to maintain current RAC affiliation.~~

History Note: *Authority G.S. 131E-162;*
Temporary Adoption Eff. January 1, 2002;
Eff. April 1, 2003;
Amended Eff. January 1, 2009;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016;
Amended Eff. July 1, 2021; January 1, 2017.

10A NCAC13P .1401 is proposed for amendment as follows:

10A NCAC 13P .1401 CHEMICAL ADDICTION OR ABUSE ~~TREATMENT~~ RECOVERY PROGRAM REQUIREMENTS

(a) The OEMS shall provide a ~~treatment~~ monitoring program for aiding in the recovery ~~and rehabilitation~~ of EMS personnel subject to disciplinary action for being unable to perform as credentialed EMS personnel with reasonable skill and safety to patients and the public by reason of use of alcohol, drugs, chemicals, or any other type of material as set forth in Rule ~~.1507(b)(9)~~ .1507 of this Subchapter.

(b) This program requires:

(1) an initial assessment by a healthcare professional ~~specialized~~ specializing in chemical dependency approved by the ~~treatment~~ program;

(2) a treatment plan developed ~~by the healthcare professional described in Subparagraph (b)(1) of this Rule~~ by a healthcare professional specializing in chemical dependency for the individual using the findings of the initial ~~assessment;~~ assessment. The Department and individual will enter into a consent agreement based up on the treatment plan; and

~~(3) random body fluid screenings using a standardized methodology designed by OEMS program staff to ensure reliability in verifying compliance with program standards;~~

~~(4) the individual attend three self-help recovery meetings each week for the first year of participation, and two each week for the remainder of participation in the treatment program;~~

~~(5)~~(3) monitoring by OEMS program staff of the individual for compliance with the ~~treatment program;~~ consent agreement entered into by the Department and the individual entering the program.

~~(6) written progress reports, shall be made available for review by OEMS upon completion of the initial assessment of the treatment program, upon request by OEMS throughout the individual's participation in the treatment program, and upon completion of the treatment program. Written progress reports shall include:~~

~~(A) progress or response to treatment and when the individual is safe to return to practice;~~

~~(B) compliance with program criteria;~~

~~(C) a summary of established long-term program goals; and~~

~~(D) contain pertinent medical, laboratory, and psychiatric records with a focus on chemical dependency.~~

History Note: *Authority G.S. 131E-159(f); 143-508(b); 143-508(d)(10);*
Eff. October 1, 2010;
Readopted Eff. January 1, ~~2017.~~ 2017;
Amended Eff. July 1, 2021.

10A NCAC 13P .1403 is proposed for amendment as follows:

10A NCAC 13P .1403 CONDITIONS FOR RESTRICTED PRACTICE WITH LIMITED PRIVILEGES

(a) In order to assist in determining eligibility for an individual to return to restricted practice, ~~the OEMS shall create a standing Reinstatement Committee that shall consist of at least the following members:~~ completion of all requirements outlined in the individual's consent agreement with the Department as described in Rule .1401 of this Section shall be presented to the Chief of the OEMS.

~~(1) one physician licensed by the North Carolina Medical Board, representing EMS Systems, who shall serve as Chair of this committee;~~

~~(2) one counselor trained in chemical addiction or abuse therapy; and~~

~~(3) the OEMS staff member responsible for managing the treatment program as set forth in Rule.1401 of this Section.~~

(b) Individuals who have surrendered his or her EMS credential(s) as a condition of entry into the ~~treatment~~ recovery program, as required in Rule ~~.1402(4)~~ .1402 of this Section, shall be reviewed by the OEMS ~~Reinstatement Committee~~ Chief to determine if ~~a recommendation to the OEMS for~~ issuance of an encumbered EMS credential is warranted by the Department.

(c) In order to obtain an encumbered credential with limited privileges, an individual shall:

(1) be compliant for a minimum of 90 consecutive days with the treatment program described in Rule ~~.1401(b)~~ .1401 of this Section; and

(2) be recommended in writing for review by the individual's ~~treatment counselor;~~ recovery healthcare professional overseeing the treatment plan developed as described in Rule .1401 of this Section.

~~(3) be interviewed by the OEMS Reinstatement Committee; and~~

~~(4) be recommended in writing by the OEMS Reinstatement Committee for issuance of an encumbered EMS credential. The OEMS Reinstatement Committee shall detail in their recommendation all restrictions and limitations to the individual's practice privileges.~~

(d) The individual shall agree to sign a consent agreement with the OEMS that details the practice restrictions and privilege limitations of the encumbered EMS credential, and that contains the consequences of failure to abide by the terms of this agreement.

(e) The individual shall be issued the encumbered credential by the OEMS within 10 business days following execution of the consent agreement described in Paragraph (d) of this Rule.

(f) The encumbered EMS credential shall be valid for a period not to exceed four years.

History Note: *Authority G.S. 131E-159(f); 143-508(b); 143-508(d)(10);*
Eff. October 1, 2010;
Readopted Eff. January 1, ~~2017.~~ 2017;
Amended Eff. July 1, 2021.

10A NCAC 13P .1404 is proposed for amendment as follows:

10A NCAC 13P .1404 REINSTATEMENT OF AN UNENCUMBERED EMS CREDENTIAL

Reinstatement of an unencumbered EMS credential is ~~dependant~~ dependent upon the individual successfully completing all requirements of the ~~treatment program~~ consent agreement as ~~defined in~~ set forth in Rule .1401 of this Section.

History Note: *Authority G.S. 131E-159(f); 143-508(d)(10); 143-509(13);*
Eff. October 1, 2010;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, ~~2016.~~ 2016;
Amended Eff. July 1, 2021.

10A NCAC 13P .1405 is proposed for amendment as follows:

10A NCAC 13P .1405 FAILURE TO COMPLETE THE CHEMICAL ADDICTION OR ABUSE ~~TREATMENT~~ RECOVERY PROGRAM

Individuals who fail to complete the ~~treatment program~~ consent agreement established in Rule .1401 of this Section, upon review by the OEMS, are subject to revocation of their EMS credential.

History Note: *Authority G.S. 131E-159(f); 143-508(b); 143-508(d)(10);*
Eff. October 1, 2010;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016;
Amended Eff. July 1, 2021; January 1, 2017.

10A NCAC 13P .1505 is proposed for amendment as follows:

10A NCAC 13P .1505 EMS EDUCATIONAL INSTITUTIONS

(a) For the purpose of this Rule, "focused review" means an evaluation by the OEMS of an educational institution's corrective actions to remove contingencies that are a result of deficiencies identified in the initial or renewal application process.

(b) The Department shall deny the initial or renewal designation, without first allowing a focused review, of an EMS Educational Institution for any of the following reasons:

(1) significant failure to comply with the provisions of ~~Section .0600~~ Sections .0500 and .0600 of this Subchapter; or

(2) attempting to obtain an EMS Educational Institution designation through fraud or misrepresentation.

(c) When an EMS Educational Institution is required to have a focused review, it shall demonstrate compliance with the provisions of ~~Section .0600~~ Sections .0500 and .0600 of this Subchapter within ~~12~~ six months or less.

(d) The Department shall amend, suspend, or revoke an EMS Educational Institution designation at any time whenever the Department finds that the EMS Educational Institution has significant failure to comply, as defined in Rule .0102 of this Subchapter, with the provisions of Section .0600 of this Subchapter, and:

(1) it is not probable that the EMS Educational Institution can remedy the deficiencies within ~~12~~ six months or less as determined by OEMS staff based upon analysis of the educational institution's ability to take corrective measures to resolve the issue of non-compliance with Section .0600 of this Subchapter;

(2) although the EMS Educational Institution may be able to remedy the deficiencies, it is not probable that the EMS Educational Institution shall be able to remain in compliance with credentialing rules;

(3) failure to produce records upon request as required in Rule ~~.0601(b)(6)~~ .0601 of this Subchapter;

(4) the EMS Educational Institution failed to meet the requirements of a focused review within ~~12~~ six months, as set forth in Paragraph (c) of this Rule;

(5) the failure to comply endangered the health, safety, or welfare of patients cared for as part of an EMS educational program as determined by OEMS staff in their professional judgment based upon a complaint investigation, in consultation with the Department and Department of Justice, to verify the results of the investigations are sufficient to initiate enforcement action pursuant to G.S. 150B; or

(6) the EMS Educational Institution altered, destroyed, or attempted to destroy evidence needed for a complaint investigation.

(e) The Department shall give the EMS Educational Institution written notice of ~~revocation and denial.~~ action taken on the Institution designation. This notice shall be given personally or by certified mail and shall set forth:

(1) the factual allegations;

(2) the statutes or rules alleged to be violated; and

(3) notice of the EMS Educational Institution's right to a contested case hearing, set forth in Rule .1509 of this Section, on the revocation of the designation.

(f) Focused review is not a procedural prerequisite to the revocation of a designation as set forth in Rule .1509 of this Section.

(g) If determined by the educational institution that suspending its approval to offer EMS educational programs is necessary, the EMS Educational Institution may voluntarily surrender its credential without explanation by submitting a written request to the OEMS stating its intention. The voluntary surrender shall not affect the original expiration date of the EMS Educational Institution's designation. To reactivate the designation:

(1) the institution shall provide OEMS written documentation requesting reactivation; and

(2) the OEMS shall verify the educational institution is compliant with all credentialing requirements set forth in Section .0600 of this Subchapter prior to reactivation of the designation by the OEMS.

(h) If the institution fails to resolve the issues that resulted in a voluntary surrender, the Department shall revoke the EMS Educational Institution designation.

(i) In the event of a revocation or voluntary surrender, the Department shall provide written notification to all EMS Systems within the EMS Educational Institution's defined service area. The Department shall provide written notification to all EMS Systems within the EMS Educational Institution's defined service area when the voluntary surrender reactivates to full credential.

(j) When an accredited EMS Educational Institution as defined in Rule .0605 of this Subchapter has administrative action taken against its accreditation, the OEMS shall determine if the cause of action is sufficient for revocation of the EMS Educational Institution designation or imposing a focused review pursuant to Paragraphs (b) and (c) of this Rule is warranted.

History Note: *Authority G.S. 143-508(d)(4); 143-508(d)(10);*
Eff. January 1, 2013;

Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016;

Amended Eff. July 1, 2021; July 1, 2018; January 1, 2017.

10A NCAC 13P .1507 EMS PERSONNEL CREDENTIALS

(a) ~~An~~ Any EMS credential that has been forfeited under G.S. 15A-1331.1 may not be reinstated until the person has complied with the court's requirements, has petitioned the Department for reinstatement, has completed the disciplinary process, and has received Department reinstatement approval.

(b) The Department shall amend, deny, suspend, or revoke the credentials of EMS personnel for any of the following:

(1) significant failure to comply with the applicable performance and credentialing requirements as found in this Subchapter;

(2) making false statements or representations to the Department, or concealing information in connection with an application for credentials;

(3) making false statements or representations, concealing information, or failing to respond to inquiries from the Department during a complaint investigation;

(4) tampering with, or falsifying any record used in the process of obtaining an initial EMS credential, or in the renewal of an EMS credential;

(5) in any manner or using any medium, engaging in the stealing, manipulating, copying, reproducing, or reconstructing of any written EMS credentialing examination questions, or scenarios;

(6) cheating, or assisting others to cheat while preparing to take, or when taking a written EMS credentialing examination;

(7) altering an EMS credential, using an EMS credential that has been altered, or permitting or allowing another person to use his or her EMS credential for the purpose of alteration. "Altering" includes changing the name, expiration date, or any other information appearing on the EMS credential;

(8) unprofessional conduct, including a significant failure to comply with the rules relating to the function of credentialed EMS personnel contained in this Subchapter, or the performance of or attempt to perform a procedure that is detrimental to the health and safety of any person, or that is beyond the scope of practice of credentialed EMS personnel or EMS instructors;

(9) being unable to perform as credentialed EMS personnel with reasonable skill and safety to patients and the public by reason of illness that will compromise skill and safety, use of alcohol, drugs, chemicals, or any other type of material, or by reason of any physical impairment;

(10) conviction in any court of a crime involving moral turpitude, a conviction of a felony, a conviction requiring registering on a sex offender registry, or conviction of a crime involving the scope of practice of credentialed EMS personnel;

(11) by theft or false representations obtaining or attempting to obtain, money or anything of value from a ~~patient;~~ patient, EMS Agency, or educational institution;

(12) adjudication of mental incompetence;

(13) lack of competence to practice with a reasonable degree of skill and safety for patients, including a failure to perform a prescribed procedure, failure to perform a prescribed procedure competently, or performance of a procedure that is not within the scope of practice of credentialed EMS personnel or EMS instructors;

(14) performing as a credentialed EMS personnel in any EMS System in which the individual is not affiliated and authorized to function;

(15) performing or authorizing the performance of procedures, or administration of medications detrimental to a student or individual;

(16) delay or failure to respond when on-duty and dispatched to a call for EMS assistance;

(17) testing positive, whether for-cause or at random, through urine, blood, or breath sampling, for any substance, legal or illegal, that is likely to impair the physical or psychological ability of the credentialed EMS personnel to perform all required or expected functions while on duty;

(18) failure to comply with G.S. 143-518 regarding the use or disclosure of records or data associated with EMS Systems, Specialty Care Transport Programs, Alternative Practice Settings, or patients;

(19) refusing to consent to any criminal history check required by G.S. 131E-159;

(20) abandoning or neglecting a patient who is in need of care, without making arrangements for the continuation of such care;

(21) falsifying a patient's record or any controlled substance records;

(22) harassing, abusing, or intimidating a patient, student, bystander, or OEMS staff, either physically, verbally, or in writing;

(23) engaging in any activities of a sexual nature with a patient, including kissing, fondling, or touching while responsible for the care of that individual;

(24) any criminal arrests that involve charges that have been determined by the Department to indicate a necessity to seek action in order to further protect the public pending adjudication by a court;

(25) altering, destroying, or attempting to destroy evidence needed for a complaint investigation being conducted by the OEMS;

(26) significant failure to comply with a condition to the issuance of an encumbered EMS credential with limited and restricted practices for persons in the chemical addiction or abuse treatment program;

(27) unauthorized possession of lethal or non-lethal weapons, chemical irritants to include mace, pepper (oleoresin capsicum) spray and tear gas, or explosives while in the performance of providing emergency medical services;

(28) significant failure to comply to provide EMS care records to the licensed EMS provider for submission to the OEMS as required by Rule .0204 of this Subchapter;

(29) continuing to provide EMS care after local suspension of practice privileges by the local EMS System, Medical Director, or Alternative Practice Setting; ~~or~~

(30) representing or allowing others to represent that the credentialed EMS personnel has a credential that the credentialed EMS personnel does not in fact ~~have.~~ have;

(31) diversion of any medication requiring medical oversight for credentialed EMS personnel; or

(32) filing a knowingly false complaint against an individual, EMS Agency, or educational institution.

(c) Pursuant to the provisions of G.S. 131E-159(h), the OEMS shall not issue an EMS credential for any person listed on the North Carolina Department of Public Safety, Sex Offender and Public Protection Registry, or who was convicted of an offense that would have required registration if committed at a time when the registration would have been required by law.

(d) Pursuant to the provisions of G.S. 50-13.12, upon notification by the court, the OEMS shall revoke an individual's EMS credential until the Department has been notified by the court that evidence has been obtained of compliance with a child support order. The provisions of G.S. 50-13.12 supersede the requirements of Paragraph (f) of this Rule.

(e) When a person who is credentialed to practice as an EMS professional is also credentialed in another jurisdiction and the other jurisdiction takes disciplinary action against the person, the Department shall summarily impose the same or lesser disciplinary action upon receipt of the other jurisdiction's action. The EMS professional may request a hearing before the EMS Disciplinary Committee. At the hearing the issues shall be limited to:

(1) whether the person against whom action was taken by the other jurisdiction and the Department are the same person;

(2) whether the conduct found by the other jurisdiction also violates the rules of the N.C. Medical Care Commission; and

(3) whether the sanction imposed by the other jurisdiction is lawful under North Carolina law.

(f) The OEMS shall provide written notification of the amendment, denial, suspension, or revocation. This notice shall be given personally or by certified mail, and shall set forth:

(1) the factual allegations;

(2) the statutes or rules alleged to have been violated; and

(3) notice of the individual's right to a contested hearing, set forth in Rule .1509 of this Section, on the revocation of the credential.

(g) The OEMS shall provide written notification to the EMS professional within five business days after information has been entered into the National Practitioner Data Bank and the Healthcare Integrity and Protection Integrity Data Bank.

(h) The EMS System Administrator, Primary Agency Contact, Medical Director, Educational Institution Program Coordinator, or Medical Advisor shall notify the OEMS of any violation listed in Paragraph (b) of this Rule.

History Note: *Authority G.S. 131E-159; 143-508(d)(10); 143-519;*
Eff. January 1, 2013;
Readopted Eff. January 1, ~~2017.~~ 2017;
Amended Eff. July 1, 2021.

10 NCAC 13P .1511 is proposed for amendment as follows:

10A NCAC 13P .1511 PROCEDURES FOR QUALIFYING FOR AN EMS CREDENTIAL FOLLOWING ENFORCEMENT ACTION

(a) Any individual who has been subject to ~~denial,~~ suspension, revocation, or amendment of an EMS credential shall submit in writing to the OEMS a request for review to determine eligibility for credentialing.

(b) Factors the Department shall consider when determining eligibility shall include:

(1) the reason for administrative action, including:

(A) criminal history;

(B) patient care;

(C) substance abuse; and

(D) failure to meet credentialing requirements;

(2) the length of time since the administrative action was taken; and

(3) any mitigating or aggravating factors relevant to obtaining a valid EMS credential.

(c) In order to be considered for eligibility, the individual shall:

(1) wait a minimum of 36 months following administrative action before seeking review; and

(2) undergo a criminal history background check. If the individual has been charged or convicted of a misdemeanor or felony in this or any other state or country within the previous 36 months, the 36 month waiting period shall begin from the date of the latest charge or conviction.

(d) If determined to be eligible, the Department shall grant authorization for the individual to begin the process for EMS credentialing as set forth in Rule .0502 of this Subchapter.

(e) Prior to enrollment in an EMS educational program, the individual shall disclose the prior administrative action taken against the individual's credential in writing to the EMS Educational Institution.

(f) An individual who has undergone administrative action against his or her EMS credential is not eligible for legal recognition as defined in G.S. 131E-159(d) or issuance of a temporary EMS credential as defined in G.S. 131E159(e).

(g) For a period of 10 years following restoration of the EMS credential, the individual shall disclose the prior administrative action taken against his or her credential to every EMS System, Medical Director, EMS Provider, and EMS Educational Institution where he or she is affiliated and provide a letter to the OEMS from each verifying disclosure.

(h) If the Department determines the individual is ineligible for EMS credentialing pursuant to this Rule, the Department shall provide in writing the reason(s) for denial and inform him or her of the procedures for contested case hearing as set forth in Rule .1509 of this Section.

History Note: *Authority G.S. 131E-159(g); 143-508(d)(3); 143-508(d)(10);*
Eff. January 1, ~~2017.~~ 2017;
Amended Eff. July 1, 2020

10A NCAC 13F .0403 is proposed for readoption with substantive changes as follows:

10A NCAC 13F .0403 QUALIFICATIONS OF MEDICATION STAFF

(a) Adult care home staff who administer medications, hereafter referred to as medication aides, and ~~staff who directly supervise the administration of medications~~ their direct supervisors shall ~~have documentation of successfully completing the clinical skills validation portion of the competency evaluation according to Paragraphs (d) and (e) of Rule 10A NCAC 13F .0503 prior to the administration or supervision of the administration of medications.~~ complete training, clinical skills validation, and pass the written examination as set forth in G.S. 131D-4.5B.

~~(b) Medication aides and their direct supervisors, except persons authorized by state occupational licensure laws to administer medications, shall successfully pass the written examination within 90 days after successful completion of the clinical skills validation portion of a competency evaluation according to Rule .0503 of this Section.~~

(c) Medication aides and ~~staff who directly supervise the administration of medications,~~ their direct supervisors, except persons authorized by state occupational licensure laws to administer medications, shall complete six hours of continuing education annually related to medication administration.

History Note: *Authority G.S. 131D-2.16; 131D-4.5; G.S. 131D-4.5B; 143B-165;*
Temporary Adoption Eff. January 1, 2000; December 1, 1999;
Eff. July 1, 2000;
Temporary Amendment Eff. July 1, 2004;
Amended Eff. July 1, ~~2005.~~ 2005;
Readopted Eff. July 1, 2021.

10A NCAC 13F .0406 is proposed for amendment as follows:

10A NCAC 13F .0406 TEST FOR TUBERCULOSIS

(a) Upon employment or living in an adult care home, the ~~administrator and~~ administrator, all other ~~staff~~ staff, and any ~~live-in non-residents~~ persons living in the adult care home shall be tested for tuberculosis disease in compliance with control measures adopted by the Commission for Public Health as specified in 10A NCAC 41A ~~.0205~~ .0205, including subsequent amendments and editions. Copies of the rule ~~are available at no charge by contacting the Department of Health and Human Services Tuberculosis Control Program, 1902 Mail Service Center, Raleigh, NC 27699-1902.~~ may be accessed at http://reports.oah.state.nc.us/ncac.asp at no charge.

(b) There shall be documentation on file in the adult care home that the administrator, all other ~~staff~~ staff, and any ~~live-in non-residents~~ persons living in the adult care home are free of tuberculosis ~~disease that poses a direct threat to the health or safety of others.~~ disease.

History Note: *Authority G.S. 131D-2.16; 131D-4.5; 143B-165;*
Eff. January 1, 1977;
Readopted Eff. October 31, 1977;
Temporary Amendment Eff. September 1, 2003; July 1, 2003;
Amended Eff. June 1, 2004;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. March 6, ~~2018.~~ 2018;
Amended Eff. July 1, 2021.

10A NCAC 13G .0402 is proposed for readoption with substantive changes as follows:

10A NCAC 13G .0402 QUALIFICATIONS OF SUPERVISOR-IN-CHARGE

The ~~supervisor in charge~~ supervisor-in-charge, who is responsible to the administrator for carrying out the program in ~~the~~ a family care home in the absence of the ~~administrator. All of~~ administrator, shall meet the following ~~requirements must be met:~~ requirements:

~~(1) The applicant must complete the Application for Supervisor in Charge (DSS-1862);~~

(1) be 21 years or older, employed on or after the effective date of this Rule;

(2) ~~The qualifications of the administrator and co-administrator referenced in Paragraphs (2), (5), (6), and (7) of Rule .0401 of this Subchapter shall apply to the supervisor in charge. The supervisor in charge~~ the supervisor-in-charge, ~~(employed~~ employed on or after August 1, ~~1991) must meet a minimum educational requirement by being at least~~ 1991, shall be a high school graduate or certified under the GED ~~Program or by passing an alternative examination established by the Department of Health and Human Services. Documentation that these qualifications have been met must be on file in the home prior to employing the supervisor in charge;~~ Program or passed the alternative examination established by the Department of Health and Human Services prior to the effective date of this Rule; and

~~(3) The supervisor in charge must be willing to work with bonafide inspectors and the monitoring and licensing agencies toward meeting and maintaining the rules of this Subchapter and other legal requirements;~~

~~(4)~~ (3) ~~The supervisor in charge must verify that he earns~~ earn 12 hours a year of continuing education credits related to the management of ~~domiciliary~~ adult care homes and care of aged and disabled ~~persons in accordance with procedures established by the Department of Health and Human Services;~~ persons.

~~(5) When there is a break in employment as a supervisor in charge of one year or less, the educational qualification under which the person was last employed will apply.~~

History Note: *Authority G.S. 131D-2.16; 131D-4.5; 143B-165;*
Eff. January 1, 1977;
Readopted Eff. October 31, 1977;
ARRC Objection June 16, 1988;
Amended Eff. July 1, 1990; December 1, 1988; April 1, 1987; January 1, 1985;
ARRC Objection Lodged January 18, 1991;
Amended Eff. August 1, ~~1991.~~ 1991;
Readopted Eff. July 1, 2021.

10A NCAC 13G .0403 is proposed for readoption with substantive changes as follows:

10A NCAC 13G .0403 QUALIFICATIONS OF MEDICATION STAFF

(a) Family care home staff who administer medications, hereafter referred to as medication aides, and ~~staff who directly supervise the administration of medications~~ their direct supervisors shall ~~have documentation of successfully completing the clinical skills validation portion of the competency evaluation according to Paragraphs (d) and (e) of Rule .0503 of this Subchapter prior to the administration or supervision of the administration of medications.~~ complete training, clinical skills validation, and pass the written examination as set forth in, G.S. 131D-4.5B. Persons authorized by state occupational licensure laws to administer medications are exempt from this requirement.

~~(b) Medication aides and their direct supervisors, except persons authorized by state occupational licensure laws to administer medications, shall successfully pass the written examination within 90 days after successful completion of the clinical skills validation portion of a competency evaluation according to Rule .0503 of this Subchapter.~~

~~(c)~~(b) Medication aides and ~~staff who directly supervise the administration of medications,~~ their direct supervisors, except persons authorized by state occupational licensure laws to administer medications, shall complete six hours of continuing education annually related to medication administration.

History Note: *Authority G.S. 131D-2.16; 131D-4.5; G.S. 131D-4.5B; 143B- 165;*
Temporary Adoption Eff. January 1, 2000; December 1, 1999;
Eff. July 1, 2000;
Temporary Amendment Eff. July 1, 2004;
Amended Eff. July 1, ~~2005.~~ 2005;
Readopted Eff. July 1, 2021.

10A NCAC 13G .0405 is proposed for readoption without substantive changes as follows:

10A NCAC 13G .0405 TEST FOR TUBERCULOSIS

(a) Upon employment or living in a family care home, the administrator, all other ~~staff~~ staff, and any ~~live-in non-residents~~ persons living in the family care home shall be tested for tuberculosis disease in compliance with control measures adopted by the Commission for Public Health as specified in 10A NCAC 41A ~~.0205~~ .0205, including subsequent amendments and editions. Copies of the rule ~~are available at no charge by contacting the Department of Health and Human Services. Tuberculosis Control Program, 1902 Mail Service Center, Raleigh, NC 27699-1902.~~ may be accessed at http://reports.oah.state.nc.us/ncac.asp at no charge.

(b) There shall be documentation on file in the family care home that the administrator, all other ~~staff~~ staff, and any ~~live-in non-residents~~ persons living in the family care home are free of tuberculosis ~~disease that poses a direct threat to the health or safety of others.~~ disease.

History Note: *Authority G.S. 131D-2.16; 131D-4.5; 143B-165;*
Eff. January 1, 1977;
Amended Eff. October 1, 1977; April 22, 1977;
Readopted Eff. October 31, 1977;
Amended Eff. December 1, 1993; April 1, 1984;
Temporary Amendment Eff. September 1, 2003;
Amended Eff. June 1, ~~2004.~~ 2004;
Readopted Eff. July 1, 2021.

DHSR Adult Care Licensure Section
Fiscal Impact Analysis
Permanent Rule Readoption and Amendment without Substantial Economic Impact

Agency: North Carolina Medical Care Commission

Contact Persons: Nadine Pfeiffer, DHSR Rules Review Manager, (919) 855-3811
Megan Lamphere, Adult Care Licensure Section Chief, (919) 855-3784
Tichina Hamer, Director of Programs, (919) 855-3782
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Impact:

Federal Government: No
State Government: No
Local Government: No
Private Entities: Yes
Substantial Impact: No

Titles of Rule Changes and N.C. Administrative Code Citation

Rule Readoptions (*See proposed text of these rules in Appendix)*
10A NCAC 13G .0402 Qualifications of Supervisor-In-Charge
10A NCAC 13G .0403 Qualifications of Medication Staff
10A NCAC 13G .0405 Test for Tuberculosis
10A NCAC 13F .0403 Qualifications of Medication Staff
10A NCAC 13F .0406 Test for Tuberculosis

Authorizing Statutes: G.S. 131D-2.16; 131D-4.5; 131D-4.5B, 143B-165

Introduction and Background

The Adult Care Licensure Section is proposing to increase the minimum age of a Supervisor-In-Charge of a family care home from 18 years to 21 years old in an effort to improve the quality of care and services and improve the overall management of the family care homes. A proposed change in education will end the use of the alternative exam to better reflect current industry standards. Additional technical changes are proposed for clarity and consistency but do not affect current operations. The proposed changes will have limited fiscal impact on family care homes as they are privately owned and are mostly in current practice based on recent surveys. The proposed changes will have no fiscal impact on the Adult Care Licensure Section.

Under the authority of G.S. 150B-21.3A, Periodic review of existing rules. The North Carolina Medical Care Commission and Rule Review Commission approved the Subchapter reports with classifications for the rules under 10A NCAC 13F Licensing of Adult Care Homes of Seven or More Beds and 10 NCAC 13G Licensing of Family Care Homes. The rules were classified in the reports as necessary with substantive public interest. Rules 10A NCAC 13F .0403, 13G .0402 and .0403 are being

presented for readoption with substantive changes. Rule 13G .0405 is being presented for readoption without substantive changes and therefore not discussed in this analysis per statute. The following rule was not identified for readoption with substantive changes based on public comment but is being proposed for amendment to correlate with the 13G rule of the same title and similar content being proposed for readoption: 10A NCAC 13F .0406. Most of the rules for both types of assisted living residences, adult care homes of seven beds or more and family care homes, are the same with the primary exception of staffing and physical plant requirements since they serve the same population based on need for care and services. Therefore, the 13F rules corresponding to the 13G rules being proposed for readoption with substantive changes are being amended concurrently to assure this traditional consistency. The rule proposed for amendment, while not receiving comment for substantive change, is being amended for clarification and updating purposes.

Rules Summary and Anticipated Fiscal Impact

10A NCAC 13F .0406 Test for Tuberculosis: This rule specifies who is required to obtain a test for tuberculosis prior to employment or living in an adult care home. The rule addresses the testing of staff of licensed assisted living facilities for tuberculosis disease and documentation of that testing.

1. In Paragraph (a) and Paragraph (b), the rule as currently written requires any live in non-residents to obtain a tuberculosis test. The proposed language clarifies the rule as any person living in the home is required to obtain a test for tuberculosis.

Rationale: According to the North Carolina Tuberculosis Control Program, tuberculosis is a "communicable, potentially deadly disease that usually affects the lungs but can attack other parts of the body as well. It is spread when a person with an active case of TB breathes out the disease-causing bacteria, which are then inhaled by another person". The proposed language does not change the current requirement to test for tuberculosis for people living in the home. The proposed rule language simplifies the language of "live in non-resident" to "persons" living in the home must obtain a test for tuberculosis. The proposed change will avoid any ambiguity while it does not signify additional persons to be tested from what the rule currently requires. Testing for tuberculosis will help to protect everyone living in adult care home. The rule has no impact. Only technical changes were made.

Fiscal Impact: None

2. The rule as written provides a mailing address for copies of the rule 10A NCAC 41A .0205 and subsequent amendments. The proposed language is an update to remove the mailing address and provide the website address where the rule and subsequent amendments are available free of charge.

Rationale: The proposed language updates the access to copies of 10A NCAC 41A .0205 and subsequent amendments.

Fiscal Impact: None

10A NCAC 13F .0403 and 10A NCAC 13G .0403 Qualifications of Medication Staff: This rule specifies the qualifications of staff responsible for administering medications and their direct supervisors.

1. In Paragraph (a), the reference to Subchapter Rule .0503 is proposed for deletion since the implementation of NC Gen. Stat. § 131D-4.5B regarding medication aides training and competency

evaluation requirements. Paragraph (a) will reference NC Gen. Stat. § 131D-4.5B since the statute supersedes the rule. The rule has no impact. Changes to the rule are proposed to bring the rule in alignment with the statute and make technical changes.

Fiscal Impact: None

2. In Paragraph (a) and Paragraph (c), the current rule lists qualification requires for staff who directly supervise medication administration. The proposed language changes the reference from staff who directly supervise medication administration to direct supervisors.

Rationale: The change reorganizes the language in the previous rule and provides clarify by referring to staff who directly supervise medication administration as direct supervisors. The proposed language does not change any current requirements.

Fiscal Impact: None

10A NCAC 13G .0402 Qualifications of Supervisor-In-Charge: This rule addresses the qualifications of supervisors working in licensed adult care homes categorized as family care.

1. Changes to the rule are proposed to bring the rule in alignment with the repeal of 10A NCAC 13G .0401 and make technical changes. Technical changes are proposed to simplify the rule text. The proposed changes in Item (1) removes the requirement for family care home providers to utilize a specific employment application for potential supervisory employees. The change proposes a deletion of Item (1) as written. An objection was raised to this rule on January 18, 1991. This objection has been resolved as a result of NC Gen. Stat. § 131D-4.5(3) Rules adopted by Medical Care Commission. The changes proposed have no impact.

Rationale: The proposed change allows family care home providers to utilize applications that align with their policies and hiring practices and does not limit them to a utilizing the DSS-1862 which was developed in the year of 1987.

Fiscal Impact: None

2. A new Item (1) is proposed to this rule to require the age of family care home employees working as a Supervisor-In-Charge change from 18 years old to 21 years of age of older when hired.

Rationale:
The Adult Care Licensure Section is proposing to increase the staff qualifications of the Supervisor-in-Charge from a minimum age of 18 years to 21 years old. The Supervisor-in-Charge is often the only staff member in the facility to provide care to two to six residents with varied cognitive, medical and physical needs. The amount of care needed for residents of adult care homes has increased over time and at least 54 instances of management-related violations resulting in serious risk or harm occurred in the last three years. The Adult Care Licensure Section is proposing the change in staff qualification in an effort to improve the quality of care and services and improve the overall management of the family care homes.

The increase in age from 18 years old to at least 21 years old is a trend occurring in hiring practices of family care home providers. Based on a recent survey of family care homes, 96% of employees hired within the past 3 years as Supervisors-in-Charge were at least 21 years or older. Family care homes are often staffed with one staff member who provides care and supervision to two to six residents. The staff is

responsible for performing multiple tasks for residents which include administering medications, meal preparation, assistance with activities of daily living and ensuring safety. The proposed change increases opportunities for potential Supervisors-in-Charge to gain work experiences prior to caring for a vulnerable population.

Fiscal Impact:
Currently, approximately 4% of new hires for a supervisor in charge (SIC) are under age 21. Increasing the minimum age of a SIC would disqualify these applicants, a lost employment opportunity. The change could also increase hiring costs for care facilities.

There are currently 577 licensed family care home, and hourly rates for hiring SICs vary. According to respondents of the survey, the average hourly rate when hiring a SIC ranges from $10.10 for age 18 to an average of $11.88 for age 21. Based on the age at hire, the difference in hourly rate is $1.78 or $3,702.40 annually at 40 hours per week for 52 weeks.

Twenty-one (21) years and older	$11.88 average hourly rate
Eighteen (18) years old	$10.10 average hourly rate

Assuming the individual was hired at 18, the cumulative cost increase over the three year period could average $11,107.20 per hire. Roughly 4% of new hires in the recent past were under age 21. This analysis assumes this proportion of hires under age 21 would remain constant in absence of the proposed rule change. Respondents to the survey reported 100% of Supervisors-in-Charge are currently over 18 years old. Therefore, the proposed rule change affects only future hires.

3. The change to Paragraph 2 proposes an update to the educational qualification for a Supervisor-in-Charge by ending the use of an alternative exam.

Rationale: As the rule is currently written, the educational qualification for hiring a Supervisor-in-Charge are be a high school graduate, be certified under the GED Program or pass an alternative exam established by the Department. Review of the data provided by the NC Division of Health Service Regulation, Health Care Personnel Education and Credentialing Section, reveals a 97% decrease in test takers over the past 3 years.

Year 2017 - Total Test Takers for Alternative Exam	296
Year 2018 - Total Test Takers for Alternative Exam	34
Year 2019 - Total Test Takers for Alternative Exam	9

Based on a recent survey, 100% of Supervisors-in-Charge hired in the past three years have at least a GED. The survey also revealed 93% of Supervisors-in-Charge currently employed have at least a GED. This is based on family care home policies and preferences for Supervisor-in-Charge to have a GED or higher level of education. The educational changes are proposed to better reflect current industry standards. Requiring a GED or high school diploma will have minimum impact because the industry is already requiring at least a GED as part of general hiring practices.

[5]

Appendix 1: Proposed Rule Text

10A NCAC 13F .0403 is proposed for readoption with substantive changes as follows:

10A NCAC 13F .0403 QUALIFICATIONS OF MEDICATION STAFF

(a) Adult care home staff who administer medications, hereafter referred to as medication aides, and ~~staff who directly supervise the administration of medications~~ their direct supervisors shall ~~have documentation of successfully completing the clinical skills validation portion of the competency evaluation according to Paragraphs (d) and (e) of Rule 10A NCAC 13F .0503 prior to the administration or supervision of the administration of medications.~~ complete training, clinical skills validation, and pass the written examination as set forth in G.S. 131D-4.5B.

~~(b) Medication aides and their direct supervisors, except persons authorized by state occupational licensure laws to administer medications, shall successfully pass the written examination within 90 days after successful completion of the clinical skills validation portion of a competency evaluation according to Rule .0503 of this Section.~~

(c) Medication aides and ~~staff who directly supervise the administration of medications,~~ their direct supervisors, except persons authorized by state occupational licensure laws to administer medications, shall complete six hours of continuing education annually related to medication administration.

History Note: *Authority G.S. 131D-2.16; 131D-4.5; G.S. 131D-4.5B; 143B-165;*
Temporary Adoption Eff. January 1, 2000; December 1, 1999;
Eff. July 1, 2000;
Temporary Amendment Eff. July 1, 2004;
Amended Eff. July 1, ~~2005.~~ 2005;
Readopted Eff. July 1, 2021.

10A NCAC 13F .0406 is proposed for amendment as follows:

10A NCAC 13F .0406 TEST FOR TUBERCULOSIS

(a) Upon employment or living in an adult care home, the ~~administrator and~~ administrator, all other ~~staff~~ staff, and any ~~live-in non-residents~~ persons living in the adult care home shall be tested for tuberculosis disease in compliance with control measures adopted by the Commission for Public Health as specified in 10A NCAC 41A ~~.0205~~ .0205, including subsequent amendments and editions. Copies of the rule ~~are available at no charge by contacting the Department of Health and Human Services Tuberculosis Control Program, 1902 Mail Service Center, Raleigh, NC 27699-1902.~~ may be accessed at http://reports.oah.state.nc.us/ncac.asp at no charge.

(b) There shall be documentation on file in the adult care home that the administrator, all other ~~staff~~ staff, and any ~~live-in non-residents~~ persons living in the adult care home are free of tuberculosis ~~disease that poses a direct threat to the health or safety of others.~~ disease.

History Note: *Authority G.S. 131D-2.16; 131D-4.5; 143B-165;*
Eff. January 1, 1977;
Readopted Eff. October 31, 1977;
Temporary Amendment Eff. September 1, 2003; July 1, 2003;
Amended Eff. June 1, 2004;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. March 6, ~~2018.~~ 2018;
Amended Eff. July 1, 2021.

10A NCAC 13G .0402 is proposed for readoption with substantive changes as follows:

10A NCAC 13G .0402 QUALIFICATIONS OF SUPERVISOR-IN-CHARGE

The ~~supervisor-in-charge~~ supervisor-in-charge, who is responsible to the administrator for carrying out the program in ~~the~~ a family care home in the absence of the ~~administrator. All of~~ administrator, shall meet the following ~~requirements must be met:~~ requirements:

~~(1) The applicant must complete the Application for Supervisor-in-Charge (DSS-1862);~~

(1) be 21 years or older, employed on or after the effective date of this Rule;

(2) ~~The qualifications of the administrator and co-administrator referenced in Paragraphs (2), (5), (6), and (7) of Rule .0401 of this Subchapter shall apply to the supervisor-in-charge. The supervisor-in-charge~~ the supervisor-in-charge, ~~(employed~~ employed on or after August 1, ~~1991) must meet a minimum educational requirement by being at least~~ 1991, shall be a high school graduate or certified under the GED ~~Program or by passing an alternative examination established by the Department of Health and Human Services. Documentation that these qualifications have been met must be on file in the home prior to employing the supervisor-in-charge;~~ Program or passed the alternative examination established by the Department of Health and Human Services prior to the effective date of this Rule; and

~~(3) The supervisor-in-charge must be willing to work with bonafide inspectors and the monitoring and licensing agencies toward meeting and maintaining the rules of this Subchapter and other legal requirements;~~

~~(4)~~ (3) ~~The supervisor-in-charge must verify that he earns~~ earn 12 hours a year of continuing education credits related to the management of ~~domiciliary~~ adult care homes and care of aged and disabled ~~persons in accordance with procedures established by the Department of Health and Human Services;~~ persons.

~~(5) When there is a break in employment as a supervisor-in-charge of one year or less, the educational qualification under which the person was last employed will apply.~~

History Note: *Authority G.S. 131D-2.16; 131D-4.5; 143B-165;*
Eff. January 1, 1977;
Readopted Eff. October 31, 1977;
ARRC Objection June 16, 1988;
Amended Eff. July 1, 1990; December 1, 1988; April 1, 1987; January 1, 1985;
ARRC Objection Lodged January 18, 1991;

Amended Eff. August 1, ~~1991.~~ 1991;
Readopted Eff. July 1, 2021.

10A NCAC 13G .0403 is proposed for readoption with substantive changes as follows:

10A NCAC 13G .0403 QUALIFICATIONS OF MEDICATION STAFF

(a) Family care home staff who administer medications, hereafter referred to as medication aides, and ~~staff who directly supervise the administration of medications~~ their direct supervisors shall ~~have documentation of successfully completing the clinical skills validation portion of the competency evaluation according to Paragraphs (d) and (e) of Rule .0503 of this Subchapter prior to the administration or supervision of the administration of medications.~~ complete training, clinical skills validation, and pass the written examination as set forth in, G.S. 131D-4.5B. Persons authorized by state occupational licensure laws to administer medications are exempt from this requirement.

~~(b) Medication aides and their direct supervisors, except persons authorized by state occupational licensure laws to administer medications, shall successfully pass the written examination within 90 days after successful completion of the clinical skills validation portion of a competency evaluation according to Rule .0503 of this Subchapter.~~

~~(c)~~(b) Medication aides and ~~staff who directly supervise the administration of medications,~~ their direct supervisors, except persons authorized by state occupational licensure laws to administer medications, shall complete six hours of continuing education annually related to medication administration.

History Note: *Authority G.S. 131D-2.16; 131D-4.5; G.S. 131D-4.5B; 143B- 165;*
Temporary Adoption Eff. January 1, 2000; December 1, 1999;
Eff. July 1, 2000;
Temporary Amendment Eff. July 1, 2004;
Amended Eff. July 1, ~~2005.~~ 2005;
Readopted Eff. July 1, 2021.

10A NCAC 13G .0405 is proposed for readoption without substantive changes as follows:

10A NCAC 13G .0405 TEST FOR TUBERCULOSIS

(a) Upon employment or living in a family care home, the administrator, all other ~~staff~~ staff, and any ~~live-in non-residents~~ persons living in the family care home shall be tested for tuberculosis disease in compliance with control measures adopted by the Commission for Public Health as specified in 10A NCAC 41A ~~.0205~~ .0205, including subsequent amendments and editions. Copies of the rule ~~are available at no charge by contacting the Department of Health and Human Services. Tuberculosis Control Program, 1902 Mail Service Center, Raleigh, NC 27699-1902.~~ may be accessed at http://reports.oah.state.nc.us/ncac.asp at no charge.

(b) There shall be documentation on file in the family care home that the administrator, all other ~~staff~~ staff, and any ~~live-in non-residents~~ persons living in the family care home are free of tuberculosis ~~disease that poses a direct threat to the health or safety of others.~~ disease.

History Note: *Authority G.S. 131D-2.16; 131D-4.5; 143B-165;*
Eff. January 1, 1977;
Amended Eff. October 1, 1977; April 22, 1977;
Readopted Eff. October 31, 1977;
Amended Eff. December 1, 1993; April 1, 1984;
Temporary Amendment Eff. September 1, 2003;
Amended Eff. June 1, ~~2004.~~ 2004;
Readopted Eff. July 1, 2021.

EXHIBIT E

New Policy:

(A) A health care entity shall have fifteen (15) days to provide a response to the Commission upon notice of a compliance deficiency acknowledging the notice of deficiency.
(B) A health care entity shall have thirty (30) days after acknowledging the notice of deficiency under A to remedy the compliance deficiency or provide satisfactory information on when and how the compliance deficiency will be remedied.
(C) The Commission will not issue debt for a health care entity which has violated A or B in the past 18 months.
(D) A health care entity which is denied the issuance of debt under C may petition the Commission for consideration of an exemption to the policy, if the health care entity provides documentation of mitigating circumstances warranting consideration by the Commission.
(E) The Commission, may at its discretion, grant an exemption to the entire policy.

Application Changes:

The NCMCC Application will contain the following questions:

1) Does organization have a formal post tax issuance compliance policy?
2) Who in the organization will be designated to ensure appropriate compliance with the issuance?
3) What is your organization's compliance monitoring plan?
4) How will the organization report compliance deficiencies to leadership and the Board?