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.

Appendix

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.