



NC DEPARTMENT OF  
**HEALTH AND  
HUMAN SERVICES**

ROY COOPER • Governor

MANDY COHEN, MD, MPH • Secretary

MARK PAYNE • Director, Division of Health Service Regulation

**MEMORANDUM**

**\*Revised June 29, 2020**

**DATE:** June 15, 2020  
**TO:** Interested Parties  
**FROM:** Nadine Pfeiffer, Rule Review Manager *NP*  
**RE:** Proposed Amendments and Repeal to Rules for the Licensing of Nursing Homes  
10A NCAC 13D

GS 150B-21.2 requires a rule-making body to notify certain individuals of its intent to adopt a permanent rule. It also requires notification of the date, time and location of the public hearing on the rule and any fiscal note that has been prepared in connection with the proposed rule. The proposed rule amendments are being made to be consistent with the federal regulations for Nursing Homes for ventilator assisted care. In addition, one rule is being repealed because of the rule's requirements being incorporated into another rule in the Subchapter.

The North Carolina Medical Care Commission has submitted form OAH 0300 to the Codifier of Rules, Office of Administrative Hearings, indicating its intent to proceed with the following rule-making actions:

Emergency Medical Services and Trauma 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)

In accordance with G.S. 150B-21.4, certification and approval of the fiscal note was received for these rules from the Office of State Budget and Management on March 12, 2020.

The proposed rule text is attached to this memo and was published in today's June 15, 2020 edition of the N.C. Register which can be found at the Office of Administrative Hearings web site at <https://www.oah.nc.gov/documents/nc-register>.

A public hearing is scheduled for July 14, 2020 at 10:00 a.m. \*In the abundance of caution, to address protective measures to help prevent the spread of COVID-19, rather than in an in-person meeting, the public hearing will be conducted by teleconference. If you would like to participate in the public hearing, please use the following conference telephone number: 1-877-848-7030, and access code: 5133201. Ms. Nadine Pfeiffer, DHSR Rule Review Manager, is accepting public comments on these rules and fiscal note from

**NC DEPARTMENT OF HEALTH AND HUMAN SERVICES • DIVISION OF HEALTH SERVICE REGULATION**

**OFFICE OF THE DIRECTOR**

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AN EQUAL OPPORTUNITY / AFFIRMATIVE ACTION EMPLOYER

June 15, 2020 – August 14, 2020. \*Comments will also be accepted via teleconference at the public hearing. The proposed effective date of these rules is January 1, 2021.

A copy of the proposed rules, fiscal note, and instructions for submitting comment can be found at the Division of Health Service Regulation web site at <https://info.ncdhhs.gov/dhsr/ruleactions.html>.

Please feel free to contact the Nursing Home Licensure and Certification Section at (919) 855-4520, should you have questions related to this memorandum or the proposed rule text and fiscal note.

#### Enclosures

cc: Dr. John Meier, IV, M.D., Chair, N.C. Medical Care Commission  
Mark Payne, Director, Health Service Regulation  
Emery Milliken, Deputy Director, DHSR  
Joel Johnson, Assistant General Counsel, DHHS  
Becky Wertz, Chief, Nursing Home Licensure and Certification  
Beverly Speroff, Assistant Chief, Nursing Home Licensure and Certification

1 10A NCAC 13D .2001 is proposed for amendment as follows:

2  
3 **SECTION .2000 – GENERAL INFORMATION**

4  
5 **10A NCAC 13D .2001 DEFINITIONS**

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

- 8 (1) "Abuse" means the willful infliction of injury, unreasonable confinement, intimidation or  
9 punishment with resulting physical harm, pain, or mental anguish.
- 10 (2) "Accident" means an unplanned event resulting in the injury or wounding, no matter how slight, of  
11 a patient or other individual.
- 12 (3) "Addition" means an extension or increase in floor area or height of a building.
- 13 (4) "Administrator" as defined in G.S. 90-276(4).
- 14 (5) "Alteration" means any construction or renovation to an existing structure other than repair,  
15 maintenance, or addition.
- 16 (6) "Brain injury long term care" means an interdisciplinary, intensive maintenance program for patients  
17 who have incurred brain damage caused by external physical trauma and who have completed a  
18 primary course of rehabilitative treatment and have reached a point of no gain or progress for more  
19 than three consecutive months. Brain injury long term care is provided through a medically  
20 supervised interdisciplinary process and is directed toward maintaining the individual at the optimal  
21 level of physical, cognitive, and behavioral functions.
- 22 (7) "Capacity" means the maximum number of patient or resident beds for which the facility is licensed  
23 to maintain at any given time.
- 24 (8) "Combination facility" means a combination home as defined in G.S. 131E-101.
- 25 (9) "Comprehensive, inpatient rehabilitation program" means a program for the treatment of persons  
26 with functional limitations or chronic disabling conditions who have the potential to achieve a  
27 significant improvement in activities of daily living, including bathing, dressing, grooming,  
28 transferring, eating, and using speech, language, or other communication systems. A  
29 comprehensive, inpatient rehabilitation program utilizes a coordinated and integrated,  
30 interdisciplinary approach, directed by a physician, to assess patient needs and to provide treatment  
31 and evaluation of physical, psychosocial, and cognitive deficits.
- 32 (10) "Department" means the North Carolina Department of Health and Human Services.
- 33 (11) "Director of nursing" means a registered nurse who has authority and ~~direct~~ responsibility for all  
34 nursing services and nursing care.
- 35 (12) "Discharge" means a physical relocation of a patient to another health care setting, the discharge of  
36 a patient to his or her home, or the relocation of a patient from a nursing bed to an adult care home  
37 bed, or from an adult care home bed to a nursing bed.

- 1 (13) "Existing facility" means a facility currently licensed, a proposed facility, a proposed addition to a  
2 licensed facility, or a proposed remodeled licensed facility that will be built according to design  
3 development drawings and specifications approved by the Department for compliance with the  
4 standards established in Sections .3100, .3200, and .3400 of this Subchapter, to the effective date of  
5 this Rule.
- 6 (14) "Facility" means a nursing facility or combination facility as defined in this Rule.
- 7 (15) "Incident" means any accident, event, or occurrence that is unplanned, or unusual, and has ~~actually~~  
8 caused harm to a patient, or has the potential for harm.
- 9 (16) "Inpatient rehabilitation facility or unit" means a free-standing facility or a unit (unit pertains to  
10 contiguous dedicated beds and spaces) within an existing licensed health service facility approved  
11 in accordance with G.S. 131E, Article 9 to establish inpatient, rehabilitation beds and to provide a  
12 comprehensive, inpatient rehabilitation program.
- 13 (17) "Interdisciplinary" means an integrated process involving representatives from disciplines of the  
14 health care team.
- 15 (18) "Licensee" means the person, firm, partnership, association, corporation, or organization to whom  
16 a license to operate the facility has been issued. The licensee is the legal entity that is responsible  
17 for the operation of the business.
- 18 (19) "Medication error rate" means the measure of discrepancies between medication that was ordered  
19 for a patient by the health care provider and medication that is ~~actually~~ administered to the patient.  
20 The medication error rate is calculated by dividing the number of errors observed by the surveyor  
21 by the opportunities for error, multiplied times 100.
- 22 (20) "Misappropriation of property" means the deliberate misplacement, exploitation, or wrongful,  
23 temporary or permanent use of a patient's belongings or money without the patient's consent.
- 24 (21) "Neglect" means a failure to provide goods and services necessary to avoid physical harm, mental  
25 anguish, or mental illness.
- 26 (22) "New facility" means a proposed facility, a proposed addition to an existing facility, or a proposed  
27 remodeled portion of an existing facility that will be built according to design development drawings  
28 and specifications approved by the Department for compliance with the standards established in  
29 Sections .3100, .3200, and .3400 of this Subchapter after the effective date of this Rule.
- 30 (23) "Nurse Aide" means a person who is listed on the N.C. Nurse Aide Registry and provides nursing  
31 or nursing-related services to patients in a nursing home. A nurse aide is not a licensed health  
32 professional. Nursing homes that participate in Medicare or Medicaid shall comply with 42 CFR  
33 Part 483.75(e), which is incorporated by reference, including subsequent amendments. The Code  
34 of Federal Regulations may be accessed at  
35 [http://www.access.gpo.gov/nara/cfr/waisidx\\_08/42cfr483\\_08](http://www.access.gpo.gov/nara/cfr/waisidx_08/42cfr483_08); <https://www.ecfr.gov>.
- 36 (24) "Nursing facility" means a nursing home as defined in G.S. 131E-101.
- 37 (25) "Patient" means any person admitted for nursing care.

- 1 (26) "Remodeling" means alterations, renovations, rehabilitation work, repairs to structural systems, and  
 2 replacement of building systems at a nursing or combination facility.
- 3 (27) "Repair" means reconstruction or renewal of any part of an existing building for the purpose of its  
 4 maintenance.
- 5 (28) "Resident" means any person admitted for care to an adult care home part of a combination ~~facility~~  
 6 ~~as defined in G.S. 131E-101.~~ facility.
- 7 (29) "Respite care" means services provided for a patient on a temporary basis, not to exceed 30 days.
- 8 (30) "Surveyor" means ~~an authorized~~ a representative of the Department who inspects nursing facilities  
 9 and combination facilities to determine compliance with ~~rules~~ rules, laws, and regulations as set  
 10 forth in G.S. 131E-117; Subchapters 13D and 13F of this Chapter; and 42 CFR Part 483,  
 11 Requirements for States and Long Term Care Facilities.
- 12 ~~(31) "Ventilator dependence" means a physiological dependency by a patient on the use of a ventilator~~  
 13 ~~for more than eight hours a day.~~
- 14 ~~(32)~~(31) "Violation" means a failure to comply with ~~the regulations, standards, and requirements~~ rules, laws,  
 15 and regulations as set forth in G.S. 131E-117 and 131D-21; Subchapters 13D and 13F of this  
 16 Chapter; or 42 CFR Part 483, Requirements for States and Long Term Care Facilities, that ~~directly~~  
 17 relates to a patient's or resident's health, safety, or welfare, or ~~which that~~ which creates a ~~substantial~~  
 18 risk that death, or ~~serious~~ physical harm ~~will~~ may occur.

19

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

1 10A NCAC 13D .2506 is proposed for repeal as follows:

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3 **10A NCAC 13D .2506 PHYSICIAN SERVICES FOR VENTILATOR DEPENDENT PATIENTS**

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5 *History Note: Authority G.S. 131E-104;*

6 *RRC objection due to lack of statutory authority and ambiguity Eff. July 13, 1995;*

7 *Eff. January 1, 1996;*

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

9 *~~2015- 2015;~~*

10 *Repealed Eff. January 1, 2021.*

1 10A NCAC 13D .3003 is proposed for amendment as follows:

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3 **10A NCAC 13D .3003 VENTILATOR ~~DEPENDENCE~~ ASSISTED CARE**

4 ~~(a) The general requirements in this Subchapter shall apply when applicable. In addition, facilities having patients~~  
5 ~~requiring the use of ventilators for more than eight hours a day shall meet the following requirements: For the purpose~~  
6 ~~of this Rule, ventilator assisted individuals, means as defined in 42 CFR Part 483.25(i), F695, herein incorporated by~~  
7 ~~reference including subsequent amendments and editions. Copies of the Code of Federal Regulations, Title 42, Public~~  
8 ~~Health, Part 482-End, 2019 may be accessed free of charge online at [https://www.cms.gov/Regulations-and-](https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_pp_guidelines_ltcf.pdf)~~  
9 ~~Guidance/Guidance/Manuals/downloads/som107ap\_pp\_guidelines\_ltcf.pdf.~~

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

- 11 (1) ~~The facility shall be located within 30 minutes of an acute care facility. administer respiratory care~~  
12 ~~in accordance with 42 CFR Part 483.25(i), F695;~~
- 13 (2) ~~Respiratory therapy shall be provided and supervised by a respiratory therapist currently registered~~  
14 ~~by the National Board for Respiratory Care. administer respiratory care in accordance with the scope~~  
15 ~~of practice for respiratory therapists defined in G.S. 90-648; and The respiratory therapist shall:~~
- 16 (a) ~~make, as a minimum, weekly on-site assessments of each patient receiving ventilator~~  
17 ~~support with corresponding progress notes;~~
- 18 (b) ~~be on-call 24 hours daily; and~~
- 19 (c) ~~assist the pulmonologist and nursing staff in establishing ventilator policies and~~  
20 ~~procedures, including emergency policies and procedures.~~
- 21 (3) ~~Direct nursing care staffing shall be in accordance with Rule .3005 of this Section. provide~~  
22 ~~pulmonary services from a physician who has training in pulmonary medicine according to The~~  
23 ~~American Board of Internal Medicine. The physician shall be responsible for respiratory services~~  
24 ~~and shall:~~
- 25 (A) ~~establish with the respiratory therapist and nursing staff, ventilator policies and procedures,~~  
26 ~~including emergency procedures;~~
- 27 (B) ~~assess each ventilator assisted patient's status at least monthly with corresponding progress~~  
28 ~~notes;~~
- 29 (C) ~~respond to emergency communications 24-hours a day; and~~
- 30 (D) ~~participate in individual care planning.~~

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

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36 *History Note: Authority G.S. 131E-104;*

37 *RRC objection due to lack of statutory authority Eff. July 13, 1995;*

1                   *Eff. January 1, 1996;*  
2                   *Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. March 22,*  
3                   *~~2015- 2015;~~*  
4                   *Amended Eff. January 1, 2021.*