

Fiscal Impact Analysis of
Nursing Home Ventilator Rules Permanent Rule Amendments

Agency Proposing Rule Change

North Carolina Medical Care Commission

Contact Persons

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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) $\$53.82 \times 3 \text{ hours} =$ \$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) $\$57.22 \times 16 \text{ hours} =$ \$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) $\$53.81 \times 16 \text{ hours} =$ \$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~~ which 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.