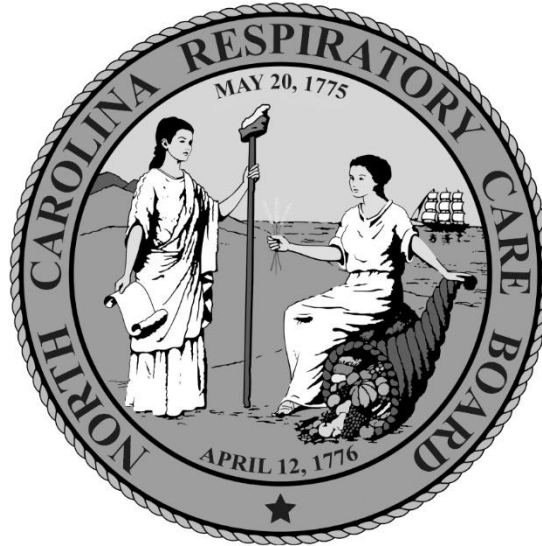


NORTH CAROLINA RESPIRATORY CARE BOARD

White Paper No. 2026-01

Emerging Respiratory Care Delivery Models

Patient Safety, Practitioner Competency, and Public Protection Considerations



Prepared by

Dr. William L. Croft, EdD, PhD, RRT, RCP, FAARC
Executive Director
North Carolina Respiratory Care Board

Reviewed and Approved by

The North Carolina Respiratory Care Board

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I. EXECUTIVE SUMMARY

Healthcare delivery systems continue to evolve through the implementation of telehealth technologies, remote patient monitoring, artificial intelligence-assisted clinical surveillance, virtual nursing programs, and other emerging care delivery models. Respiratory care services are among the healthcare disciplines evaluating how such technologies may supplement traditional clinical operations.

The North Carolina Respiratory Care Board ("NCRCB" or "Board") was established by the North Carolina General Assembly to protect the public by licensing and regulating respiratory care practitioners.¹ The Board recognizes that innovation can improve patient outcomes, enhance access to care, and support healthcare professionals in delivering respiratory care services. At the same time, respiratory care frequently involves clinical assessment, ventilator and airway management, tracheostomy care, suctioning, emergency response, and other services that require professional judgment, technical competency, and timely intervention.

The purpose of this White Paper is to identify the legal, regulatory, and patient-safety considerations relevant to emerging respiratory care delivery models and to provide a framework for evaluating these models consistent with the Board's public protection mission.

II. BOARD AUTHORITY AND PUBLIC PROTECTION MISSION

The North Carolina Respiratory Care Practice Act establishes the Board's responsibility to protect the public by ensuring that respiratory care services are provided by qualified, competent, and licensed practitioners.²

The Board fulfills this responsibility through:

- Licensure of respiratory care practitioners;
- Enforcement of professional standards;
- Investigation of complaints;
- Disciplinary oversight; and
- Regulatory administration of the Respiratory Care Practice Act.

The Board does not regulate hospital staffing decisions, reimbursement methodologies, workforce allocation, or operational management of healthcare facilities. Nevertheless, the Board has a legitimate public protection interest in evaluating how evolving care delivery models may affect the provision of respiratory care services to patients located within North Carolina.

III. SCOPE AND LIMITATIONS OF THIS WHITE PAPER

This White Paper does not advocate specific staffing ratios, employment practices, workforce models, reimbursement methodologies, or operational decisions.

The Board recognizes that healthcare facilities retain responsibility for operational management and staffing decisions consistent with applicable federal and state laws, accreditation standards, and professional practice requirements.

The purpose of this document is to identify public protection considerations associated with respiratory care delivery and to evaluate regulatory principles that may be relevant when healthcare organizations adopt alternative respiratory care delivery models.

IV. THE EVOLVING HEALTHCARE ENVIRONMENT

Healthcare organizations across the United States face workforce shortages, rising patient acuity, increasing healthcare costs, and growing demand for specialized services.

In response, healthcare organizations increasingly utilize:

- Telehealth technologies;
- Remote patient monitoring systems;
- Centralized clinical surveillance centers;
- Virtual nursing services;
- Artificial intelligence-assisted monitoring systems;
- Remote specialty consultation services; and
- Virtual respiratory therapy support programs.

These technologies may improve communication, increase access to expertise, and help healthcare professionals identify patient needs. Technology may enhance the delivery of care. Technology, however, does not eliminate the need for qualified healthcare professionals capable of exercising clinical judgment and providing patient care interventions when necessary.

V. CLINICAL PRACTICE BEYOND MONITORING

Respiratory care is often characterized as a monitoring function. Such characterization fails to fully capture the scope and complexity of modern respiratory care practice.

Respiratory care practitioners routinely perform functions that include:

- Respiratory assessment and reassessment;
- Ventilator management and troubleshooting;
- Airway management;
- Tracheostomy care;
- Oxygen therapy management;
- Aerosol medication administration;
- Airway clearance therapies;
- Suctioning procedures;
- Emergency respiratory interventions;
- Participation in rapid response and code teams; and
- Interdisciplinary clinical decision-making.

Many of these activities require direct patient interaction, physical assessment, technical expertise, and immediate clinical intervention. Accordingly, the ability to identify a respiratory emergency and provide timely intervention is critical for patient safety.

VI. LEGAL AND REGULATORY FRAMEWORK

A. North Carolina Regulatory Requirements

North Carolina regulations recognize respiratory care as a distinct healthcare service requiring qualified personnel, supervision, and established clinical policies.

Hospital respiratory care services must be organized and supervised in accordance with 10A NCAC 13B .4401.³

Further, 10A N.C.A.C. 13B .4402(b) provides:

"The director of the service shall provide for the availability of trained respiratory technicians, Certified Respiratory Therapy Technicians, registry eligible, or Registered Respiratory Therapists needed for the scope of services offered."⁴

This provision reflects an important regulatory principle: respiratory care resources must be sufficient to meet the complexity and clinical demands of the services offered by the facility.

Additionally, 10A NCAC 13B .4403 requires healthcare facilities to establish and maintain policies governing respiratory care services, including the care and supervision of ventilated patients.⁵

North Carolina home care regulations similarly require respiratory services to be provided by or under the supervision of qualified personnel and require respiratory emergency response capability on a twenty-four-hour basis.⁶

B. Federal Conditions of Participation

Federal Conditions of Participation likewise recognize respiratory care as a specialized healthcare service that requires qualified personnel and an appropriate organizational structure.

42 C.F.R. § 482.57(a)(1) provides:

"The organization of the respiratory care services must be appropriate to the scope and complexity of the services offered."⁷

Furthermore, the regulation requires:

"There must be adequate numbers of respiratory therapists, respiratory therapy technicians, and other personnel who meet the qualifications specified by the medical staff, consistent with State law."⁸

Federal regulations also require healthcare organizations to designate in writing personnel qualified to perform specific procedures and the supervision required for those procedures.⁹

Collectively, these provisions establish that respiratory care services must be appropriately organized, staffed by qualified personnel, and capable of meeting patient needs consistent with the complexity of services offered.

VII. CMS INTERPRETIVE GUIDANCE AND RESPIRATORY CARE COMPETENCY

In addition to the Conditions of Participation, the Centers for Medicare & Medicaid Services ("CMS") has issued interpretive guidance addressing respiratory care services, including tracheostomy care, tracheal suctioning, ventilator management, and respiratory emergency response.¹⁰

CMS guidance emphasizes that healthcare facilities providing respiratory care services must ensure:

- Sufficient numbers of qualified personnel;
- Competency in respiratory care procedures;
- Appropriate supervision and oversight;
- Emergency response capabilities; and
- Safe management of patients requiring ventilatory support or advanced airway management.¹¹

CMS further recognizes that patients receiving respiratory care services frequently require interventions beyond monitoring, including airway management, ventilator support, suctioning procedures, and emergency response interventions.¹² The significance of this guidance lies not in endorsing any particular staffing model. Rather, CMS consistently focuses on a facility's ability to maintain patient safety through competent personnel capable of responding to clinical needs and emergencies.

VIII. ACCREDITATION STANDARDS AND PATIENT SAFETY

National accreditation standards recognize that patient safety depends upon competent healthcare personnel, effective organizational leadership, and the availability of resources necessary to meet patient care needs. The Joint Commission requires healthcare organizations to ensure that staff and licensed practitioners possess and maintain the competencies necessary to safely perform their assigned responsibilities. Competency assessment is expected to be ongoing and based upon the knowledge, skills, abilities, and performance expectations associated with each individual's role.¹³

¹⁴

The Joint Commission's leadership standards further emphasize the responsibility of healthcare organizations to maintain systems that support the safe and effective delivery of patient care. Organizational leaders are expected to provide oversight, define responsibilities, allocate resources, and implement processes designed to promote patient safety and quality outcomes.¹⁵

Although accreditation standards generally do not prescribe specific staffing models, they consistently place responsibility on healthcare organizations to ensure that staffing structures, care delivery systems, and operational processes are capable of safely meeting the needs of the patient population served.

Collectively, accreditation standards reinforce several important principles:

- Staff competency is a fundamental component of patient safety;
- Staffing and resource allocation should be aligned with patient care needs and clinical demands;
- Healthcare organizations retain responsibility for maintaining systems that support safe and effective care delivery; and
- Alternative care delivery models should be evaluated based upon their effect on patient safety, quality of care, and clinical outcomes.

IX. REGULATORY PRINCIPLES APPLICABLE TO EMERGING CARE DELIVERY MODELS

A review of state regulations, Federal Conditions of Participation, CMS interpretive guidance, and accreditation standards reveals multiple recurring principles.

1. Respiratory care services must be organized and supervised by qualified personnel.¹⁶
2. Healthcare facilities must maintain access to appropriately trained practitioners capable of performing respiratory care services consistent with patient needs.¹⁷
3. Patients requiring ventilatory support, advanced airway management, or respiratory interventions must have access to timely clinical response and intervention.¹⁸
4. Competency requirements apply regardless of the technologies or care delivery models utilized.¹⁹
5. Patient safety remains the central objective of respiratory care regulation, accreditation, and professional practice standards.²⁰

Importantly, these principles focus less on a particular staffing configuration and more on a healthcare organization's ability to demonstrate that safe, effective, and timely respiratory care services remain available to patients.

X. PUBLIC PROTECTION CONSIDERATIONS

The Board's responsibility is not to determine whether healthcare organizations should adopt particular technologies or operational models. Rather, the Board's responsibility is to evaluate whether emerging respiratory care delivery models continue to protect the public by ensuring that respiratory care services are provided by qualified, competent, and appropriately licensed practitioners.

Factors that may be relevant in evaluating emerging respiratory care delivery models include:

- Whether respiratory care services are provided by appropriately licensed practitioners when required by law;
- Whether practitioners possess the education, training, and competency necessary to perform assigned responsibilities;
- Whether patients have timely access to respiratory care services;
- Whether facilities maintain adequate emergency response capabilities;
- Whether qualified personnel remain available to perform necessary respiratory interventions;
- Whether clinical accountability remains clearly defined; and
- Whether the model complies with applicable statutes, regulations, accreditation standards, and professional standards of practice.

The Board recognizes that technological innovation may enhance patient care and improve access to specialized expertise. However, adopting technology does not eliminate the responsibility to ensure the availability of qualified practitioners who can provide respiratory care when direct clinical intervention is required.

XI. BOARD POSITION

The North Carolina Respiratory Care Board supports responsible innovation that improves patient outcomes, enhances access to care, and promotes the effective use of healthcare resources.

The Board recognizes that healthcare organizations may employ a variety of staffing structures, telehealth technologies, remote monitoring systems, and other innovative care delivery models. However, the responsibility to ensure the availability of qualified personnel and the capacity for timely clinical intervention remains unchanged regardless of the model employed.

Respiratory care frequently involves assessment, clinical decision-making, airway and ventilator management, suctioning, tracheostomy care, and emergency intervention, many of which require direct patient interaction, hands-on clinical skills, and timely bedside response. Accordingly, any model that substantially alters the delivery of respiratory care services should be evaluated based upon its demonstrated ability to:

- Maintain patient safety;
- Ensure access to qualified personnel;
- Preserve the capacity for timely clinical intervention;
- Maintain clinical accountability; and
- Comply with applicable North Carolina and federal law.

Consistent with its mission to protect the public, the Board will continue to evaluate emerging respiratory care delivery models through the lens of patient safety, practitioner competency, and regulatory compliance.

XII. CONCLUSION

Healthcare delivery models will continue to evolve as technology advances and patient care needs change. The North Carolina Respiratory Care Board supports innovation that improves healthcare delivery and enhances patient outcomes. At the same time, the Board's statutory responsibility to protect the public remains unchanged.

State regulations, federal Conditions of Participation, CMS interpretive guidance, and accreditation standards collectively emphasize the importance of qualified personnel, professional competency, patient safety, emergency response capability, and clinical accountability.

Regardless of the technologies employed or the staffing models adopted, North Carolina patients should continue to receive respiratory care services from qualified, competent, and appropriately licensed practitioners who can provide safe and effective care consistent with professional standards and applicable law.

Innovation can enhance respiratory care delivery, but it cannot replace the need for clinical judgment, hands-on assessment, and timely intervention when patient care requires it.

ENDNOTES

1. N.C. Gen. Stat. ch. 90, art. 38.
2. Id.
3. 10A N.C. Admin. Code 13B .4401.
4. 10A N.C. Admin. Code 13B .4402(b).
5. 10A N.C. Admin. Code 13B .4403.
6. 10A N.C. Admin. Code 13J .1109.
7. 42 C.F.R. § 482.57(a)(1).
8. 42 C.F.R. § 482.57(a)(2).
9. 42 C.F.R. § 482.57(a)(3).
10. Centers for Medicare & Medicaid Services, State Operations Manual, Appendix PP, F695 (Respiratory Care, Including Tracheostomy Care and Tracheal Suctioning).
11. Id.
12. Id.
13. The Joint Commission, Human Resources Standard HR.01.06.01.
14. The Joint Commission, Human Resources Standard HR.01.06.03.
15. The Joint Commission, Leadership Standards, LD Chapter.
16. 10A N.C. Admin. Code 13B .4401; 42 C.F.R. § 482.57(a)(1).
17. 10A N.C. Admin. Code 13B .4402(b); 42 C.F.R. § 482.57(a)(2).
18. 10A N.C. Admin. Code 13J .1109; CMS State Operations Manual, F695.
19. 42 C.F.R. § 482.57(a)(3); Joint Commission HR.01.06.01; HR.01.06.03.
20. N.C. Gen. Stat. ch. 90, art. 38; CMS Conditions of Participation; Joint Commission Accreditation Standards.

REFERENCES AND AUTHORITIES

I. North Carolina Statutory Authority

- North Carolina Respiratory Care Practice Act, N.C. Gen. Stat. Chapter 90, Article 38.

II. North Carolina Administrative Rules

- 10A NCAC 13B .4401 – Organization of Respiratory Care Services.
- 10A NCAC 13B .4402 – Staffing of Respiratory Care Services.
- 10A NCAC 13B .4403 – Policies and Procedures for Respiratory Care Services
- 10A NCAC 13J .1109 – Clinical Respiratory Services, Including Pulmonary or Ventilation Services.

III. Federal Regulations

- Medicare Conditions of Participation for Hospitals, 42 C.F.R. § 482.57 (Respiratory Care Services).
- Medicare Conditions of Participation for Hospitals, 42 C.F.R. Part 482.
- Medicare Conditions of Participation for Critical Access Hospitals, 42 C.F.R. Part 485.

IV. Federal Interpretive Guidance

- Centers for Medicare & Medicaid Services, State Operations Manual.
- CMS State Operations Manual, Appendix PP, F695 – Respiratory Care, Including Tracheostomy Care and Tracheal Suctioning.

V. Accreditation Standards

- The Joint Commission, Leadership Standards (LD).
- The Joint Commission, Human Resources Standard HR.01.06.01.
- The Joint Commission, Human Resources Standard HR.01.06.03.
- The Joint Commission, National Performance Goal for Health Professional Resource Management.

VI. Professional Standards and References

- National Board for Respiratory Care (NBRC) Credentialing Standards.
- Commission on Accreditation for Respiratory Care (CoARC) Accreditation Standards.
- American Association for Respiratory Care (AARC) Clinical Practice Guidance.