



NORTH CAROLINA RESPIRATORY CARE BOARD
125 Edinburgh South Drive, Suite 100
Cary, NC 27511

NORTH CAROLINA RESPIRATORY CARE BOARD
POSITION STATEMENT

Off-Label Use of Respiratory Equipment, Respiratory Medications, and Medical Gases

The North Carolina Respiratory Care Board is issuing this position statement to provide guidance to its licensees and to other healthcare providers, both individuals, and organizations, concerning the Board's interpretation of the Respiratory Care Practice Act and the Board's Rules concerning the off-label use of respiratory equipment, medications, and medical gases. The Board is issuing this position statement to provide advance guidance to reduce confusion and save interested parties from having to prepare and present a specific request to the Board. This position statement will be posted on the Board's website, but the Board may change or supplement this position statement based on future developments or situations that come to its attention. If that occurs, the Board will post the revised statement on its website, and will issue notice that there has been a change to in the statement and to any other persons who have made written requests to receive notice of such changes.

The Respiratory Care Practice Act ("RCPA"), NCGS § 90-647, charges the Board with ensuring the public health, safety, and welfare by enforcing mandatory licensure of persons who engage in respiratory care and by ensuring a minimum standard of competency. Like all licensing boards, the Board is charged with the responsibility of maintaining the integrity of the profession that it regulates, and regulating the conduct of the individuals whom it licenses. This scope of the Board's responsibilities includes issues regarding the proper procedures for the set-up and use of respiratory care equipment, for delivery of medications, and the administration of medical gases by respiratory care practitioners ("RCPs").

NCGS § 90-648 (11) defines respiratory care: "As defined by the written order of a physician licensed under Article 1 of Chapter 90, the treatment, management, diagnostic testing, and care of patients with deficiencies and abnormalities associated with the cardiopulmonary system. Board Rule 21 NCAC 61 .0103 (3) provides more specifics within that statutory framework: "The practice of respiratory care" means the performance of assessments and diagnostic tests, and implementation of treatment procedures and protocols related to the cardiopulmonary system pursuant to G.S. 90-648(10) and the activities defined by the American Association of Respiratory Care clinical guidelines,



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incorporated by reference including subsequent amendments and editions, pursuant to G.S. 90-648(10)(f).”

Thus, the statutory definition of respiratory care establishes that there must always be a written order by a physician in order for any procedure to be implemented by any licensee. The Board’s rules require in carrying out the physician’s order that the licensee must adhere to evidence-based practice standards established by the AARC as those standards are embodied in the employing organization’s adopted policies and procedures. In subscribing to the minimum standard of competency, licensees are required to follow evidence-based practice standards adopted by the employing facility or organization.

From time to time, RCPs receive a physician’s order for a treatment that involves an off-label use of respiratory equipment, medications or medical gases. Off label use means the Food and Drug Administration (“FDA”) has not approved the particular respiratory equipment, medication or medical gas for the specific circumstance ordered. According to the FDA, “If physicians use a product for an indication, not in the approved labeling, they have the responsibility to be well informed about the product, to base its use on firm scientific rationale and on sound medical evidence, and to maintain records of the product’s use and effects (Food and Drug Administration, 2018).” The FDA’s position on off-label uses recognizes the primacy and the responsibility of the physician in making decisions for patient care. Thus it is consistent with the RCPA’s recognition of the physician’s role in directing patient care and the responsibilities of RCPs to act based upon physician orders.

In addition, RCPs working in facilities or other organizational settings provide their services in the broader context of a set of policies which ensure the effective and coordinated delivery of patient care by the organization’s entire clinical staff. While the Board does not have statutory authority to determine policy for a facility, the various declaratory rulings, position statements, and interpretive letters adopted by the Board often identify general elements that organization’s policies should address in certain circumstances; and those policies will always be another key criterion that RCPs must follow in all their actions, including off-label uses.



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Therefore, it is the position of the North Carolina Respiratory Care Board that an RCP will not place his or her license in jeopardy by following a physician's order and the applicable policies of the facility or organization in which they work, in the off-label use of respiratory equipment or in the administration of a medications or medical gases.

Adopted this 11th day of April 2019

Reference:

Food and Drug Administration. (2018). FDA Guidance Documents: "Off-Label" and Investigational Use Of Marketed Drugs, Biologics, and Medical Devices - Information Sheet [WebContent]. Retrieved March 4, 2019, from <https://www.fda.gov/regulatoryinformation/guidances/ucm126486.htm>