

**NORTH CAROLINA RESPIRATORY CARE BOARD
RALEIGH, NORTH CAROLINA**

**IN RE: REQUEST FOR DECLARATORY) DECLARATORY RULING
RULING BY CAROLINAS MEDICAL CENTER)**

I, Joseph Coyle, as Chair of the North Carolina Respiratory Care Board (the “Board”), and based on a duly adopted resolution by the Board of this date, do hereby issue this declaratory ruling pursuant to N.C. Gen. Stat. § 150B-4. This declaratory ruling will interpret the applicability of N.C. Gen. Stat. § 90-648 (10)(b) in regard to licensed Respiratory Care Practitioners (RCP’s) providing advanced practice procedures to patients who are receiving Extra Corporeal Membrane Oxygenation (ECMO).

Ms. Barbara Odom, RNC who is employed at Carolinas Medical Center, has requested this ruling and has provided the facts on which it is based. For the reasons set out below, the Board does conclude that RCP’s may provide certain advanced practice procedures and administer pharmacologic agents related to ECMO based on the information provided and within the limitations described in this Declaratory Ruling.

The basis for the Board’s conclusion is set forth below in the Analysis section of this declaratory ruling. This ruling is binding upon the Board so long as the facts that the Board deems to be material are accurately stated, but the ruling only pertains to this request. The Board also reserves the right, prospectively, to change the conclusion that is contained in this ruling.

FACTUAL BASIS FOR THE RULING

Based on the information submitted by Ms. Odom, RCP’s at Carolinas Medical Center are currently providing Advanced Practice Procedures to patients who are being treated with ECMO. Ms. Odom has provided a list of the facility’s Advanced Practice Skills for ECMO Specialists to the Board. The list identifies the advanced practice skills and the pharmacologic agents which are related to these procedures, and are being administered.

Ms. Odom has asked the Board to determine if the provision of the following Advance Practice Procedures, including the administration of the related pharmacologic agents that are identified below, is within the scope of practice by Respiratory Care Practitioners pursuant to the Respiratory Care Practice Act and Board Rules:

Advanced Practice Skills-

- Assemble and prime the ECMO circuit.
- Draw blood samples from the ECMO circuit.
- Administer blood products once verified with the bedside RN to the ECMO circuit.
 - PRBC
 - FFP
 - Platelets
 - Cryoprecipitate
 - 5% Albumin
 - 25% Albumin
- Administer medications and IV fluids once verified with RN assigned to the patient into the ECMO circuit.

- Run activated clotting times (ACT's) and adjust heparin drip to maintain ACT within set parameter by attending physician and/or intensivist.
- Adjust ECMO pump flow rate and oxygen blender/gas sweeps to maintain arterial blood gases within set parameters by attending physician and/or intensivist.
- Maintain integrity of ECMO circuit to include but not limited to:
 - Hourly circuit checks
 - Maintaining unused stopcocks off to circuit, and stopcocks in use replaced as needed.
 - Bladder pressure monitoring.
 - Walking the raceway as needed.
 - Pre and post membrane pressure monitoring
 - Oxygenator change outs as needed.
 - Other emergency management.
- Perform Point of Care Testing and calibration of ACT machine.
- Assemble, prime and manage Hemofiltration/dialysis within the ECMO circuit.

Ms. Odom has identified the following Pharmacologic Agents that are related to these advanced respiratory care procedures-

Aldactone	Dobutamine	Penicillin G Aqueous
Amiodarone	Dopamine	Phenobarbital
Amphotericin B	Epinephrine	Phenylephrine
Ampicillin	Fentanyl	Porcine Heparin
Ativan/Lorazepam	Gentamicin	Potassium Chloride
Bumex	Hyperalimentation/Lipids	Ranitidine
Calcium Chloride	Imipenem	Sodium Bicarbonate
Calcium Gluconate	Lasix	Solmedrol
Cefotaxime	Lidocaine	Tham
Cefoxitin	Magnesium Sulfate	Tobramycin
Ceftazidime	Milrinone/Primacor	Valium/Diazepam
Cimetidine	Morphine Sulfate	Vancomycin
Clindamycin	Nafcillin	Vecuronium/Norcuron
D5%/D10% c/s1/4 NaCl	Nipride/Nitroprusside	Versed/Midazolam
Decadron/Dexamethasone	Norepinephrine	
Digoxin	Pantoprazole Sodium	

ANALYSIS

The North Carolina Respiratory Care Practice Act recognizes that RCP's may perform new and innovative respiratory care procedures, but only in appropriately identified environments and under the training and practice guidelines established by the American Association for Respiratory Care. N.C. Gen. Stat. § 90-648 (10)(f). It is the American Association for Respiratory Care's (AARC) position that Respiratory Therapist education, which expands the scope or depth of respiratory care practice, should build upon a solid foundation of didactic and clinical respiratory care. Education leading to expanded practice should therefore take place following general respiratory therapist education. Expanded practice education may take place within college programs; in baccalaureate and/or graduate degree programs; in internships, residencies, or fellowships; or as experience-based learning. Credentialing, or recognition, for expanded practice expertise is in addition to the respiratory therapist credential and may be at either a state or national level.

The scope of practice of Respiratory Care Practitioners as defined in the North Carolina Respiratory Care Practice Act § 90-648 (10)(b) states that RCP's may administer pharmacological agents related to respiratory care procedures. The United States Drug Enforcement Association (DEA) has added Respiratory Care Practitioners to its list of licensed medical professionals who are authorized to administer controlled substances, provided the administration of the controlled substance has been ordered by a physician and such administration is related to a respiratory care procedure.

Based on the standards established by AARC and DEA, the North Carolina Respiratory Care Board agrees that RCP's may perform the following respiratory care procedures, and may also administer the related pharmacologic agents that are identified in the advanced practice list provided by Ms. Odom, in appropriately identified environments, and following the criteria that are outlined in this Declaratory Ruling. So long as the criteria set forth in this Declaratory Ruling are followed, the performance of these procedures and the administration of the related pharmacologic agents is within the scope of practice defined by the North Carolina Respiratory Care Practice Act under § 90-648.

GUIDELINES FOR ADVANCED RESPIRATORY CARE PROCEDURES

The Board's fundamental mission and foremost concern is the health, safety and welfare of the public. Therefore the Board concludes that the following guidelines must be followed by any RCP who is providing the advanced practice respiratory care procedures or administering the pharmacological agents described in this Declaratory Ruling:

- Any RCP who engages in these activities must have an active unencumbered license issued by the Board, and must also have the following individual qualifications.
- Any RCP who engages in these activities must also have completed a Baccalaureate Degree in Respiratory Care or have a minimum of 3 years experience in critical and emergency care after passing the RRT exam, and must also have an advanced practice credential, such as being registered by the National Board for Respiratory Care as a Registered Respiratory Therapist (RRT). Should any question arise about the appropriateness of any other advanced practice credential, the Board will provide guidance for individual situations on request, with sufficient advance notice.
- Any RCP who engages in these activities must be certified and maintain Advanced Cardiac Life Support (ACLS), Pediatric Advanced Life Support (PALS) and Neonatal Resuscitation Protocol (NRP) certification by the American Heart Association.
- Any RCP who engages in these activities must, at a minimum, attend an additional 10 hours of continuing education annually directly related to the advanced care procedures and the pharmacologic agents administered during each 12 month licensure period in order to maintain competency. The RCP is required to notify the Board annually that he/she provides the advanced care procedures and provide the Board documentation of the additional continuing education requirements.
- Any RCP who engages in these activities must have an annual documented competency evaluation by the individual's Medical Director, which includes an assessment of all advanced care procedures and pharmacologic agents that the RCP administers.

- The only practice setting in which the Board is addressing this issue is that of a North Carolina Licensed Hospital. Therefore, the procedures identified by this Declaratory Ruling as within the scope of practice may only be conducted by persons employed by a hospital licensed pursuant to Chapter 131E of the North Carolina General Statutes.
- Any RCP who engages in these activities must be certified in accordance with the hospital's policy as competent to provide advanced care procedures and to administer pharmacologic agents under medical supervision and the direct orders of a physician and/or protocols established by the hospital and approved by the RCP's Medical Director.
- While providing any advanced care procedure, or administering a pharmacologic agent, the RCP must consult with medical staff concerning the procedures and medications administered.
- The hospital must have written policies and procedures for the provision of each advanced care procedure, including procedures that specifically address the administration of pharmacologic agents by RCP's.
- Any RCP who engages in these activities must understand the pharmacology of the agents that are administered, and the role of any pharmacological antagonist that can be administered as well as techniques, medications, side effects, monitoring devices, response or untoward effects of medications, and documentation for any specific procedure.
- Any RCP who engages in these activities may only administer the pharmacologic agents approved by the hospital. The hospital must maintain a formulary of the pharmacologic agents approved by the provider's Medical Director for RCP's to administer.
- Any RCP who engages in these activities must closely monitor patients receiving any of these therapeutic interventions or pharmacologic agents and must be able to recognize the associated complications, consult with a physician and take appropriate actions under Medical Direction.
- The RCP and the hospital must complete and maintain the documentation required by this ruling for a period of 3 years after the relevant date of service.
- Any licensed RCP who is actively and continuously engaged in workplace training that can lead to eligibility to provide the advanced practice procedures enumerated in this ruling, and who is working at all times under the direct supervision of a Respiratory Care Practitioner who has already been approved by the Respiratory Care Board to provide advanced care procedures, or a Registered Nurse approved to provide advanced care procedures, may, so long as the workplace training continues, participate in providing the advanced practice procedures enumerated in this ruling, including the administration of pharmacologic agents; but only for a maximum period of ONE YEAR from the date of this ruling, or the first date that the trainee began the workplace training, whichever is later.

CONCLUSION

For the foregoing reasons, and based upon the information provided and within the limitations expressed above, the North Carolina Respiratory Care Board concludes that Respiratory Care Practitioners may provide advanced care procedures and administer pharmacologic agents related to the delivery of ECMO under the direct orders of a physician and protocols established by a hospital licensed pursuant to Chapter 131E of the North Carolina General Statutes.

This the 7th day of April, 2005.

Joseph Coyle, MD
Chair
North Carolina Respiratory Care Board