

**Connecticut
Children's**
MEDICAL CENTER

August 15, 2011

Jewel Mullen, MD, MPH, MPA
Commissioner
Department of Public Health
410 Capitol Avenue
Hartford, CT 06106

RE: Public Act 11-029 Section (a)

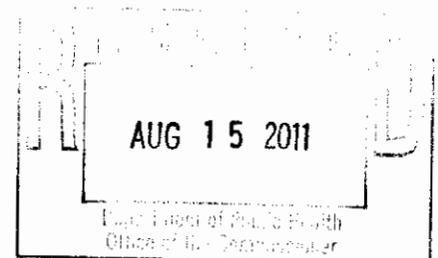
Dear Dr. Mullen:

In order to better serve the needs of our patients, Connecticut Children's Medical Center is developing a program to provide Extracorporeal Membrane Oxygenation (ECMO) services. We would like to use respiratory therapists as part of the ECMO clinical team, but the Department of Public Health (DPH) has made clear in prior conversations about this issue that a legislative change would be needed to add ECMO-related activities to the scope of practice for respiratory therapists. We respectfully request that DPH utilize the newly-enacted process for scope of practice determinations to explicitly add ECMO functions to the scope of practice for respiratory therapists.

The attached document follows the specifications in Public Act 11-029 Section (b). Thank you in advance for your time and consideration of our request. If you have questions about our request or require additional information, please contact Jane Baird, Director of Government Relations, at 860-545-8561 or jbaird@connecticutchildrens.org.

Sincerely,

Theresa Hendricksen, RN, MS, FACHE
Executive Vice President and COO



1. A plain language description of the request

CGS Sec. 20-162n, which defines Respiratory care, must be amended so Respiratory Therapists can participate as part of a team providing Extracorporeal Membrane Oxygenation (ECMO) services.

Section 20-162n of the general statutes is amended by adding subdivision (b) and amending subdivision (c) as follows (*Effective upon passage*):

(a) "Commissioner" means the Commissioner of Public Health;

(b) "Extracorporeal circulation" means the diversion of a patient's blood through a heart-lung machine or a similar device that assumes the functions of the patient's heart, lungs, kidney, liver or other organs to support the patient's cardiopulmonary functioning.

(c) "Respiratory care" means health care under the direction of a physician licensed pursuant to chapter 370 and in accordance with written protocols developed by said physician, employed in the therapy, management, rehabilitation, diagnostic evaluation and care of patients with deficiencies and abnormalities that affect the cardiopulmonary system and associated aspects of other system functions and that includes the following: (1) The therapeutic and diagnostic use of medical gases, administering apparatus, humidification and aerosols, administration of drugs and medications to the cardiorespiratory systems, ventilatory assistance and ventilatory control, postural drainage, chest physiotherapy and breathing exercises, respiratory rehabilitation, cardiopulmonary resuscitation and maintenance of natural airways as well as the insertion and maintenance of artificial airways, (2) the specific testing techniques employed in respiratory therapy to assist in diagnosis, monitoring, treatment and research, including the measurement of ventilatory volumes, pressures and flows, specimen collection of blood and other materials, pulmonary function testing and hemodynamic and other related physiological monitoring of cardiopulmonary systems, (3) performance of a purified protein derivative test to identify exposure to tuberculosis, (4) patient education in self-care procedures as part of the ongoing program of respiratory care of such patient, and (5) the use of extracorporeal circulation, long-term cardiopulmonary support techniques including extracorporeal carbon-dioxide removal and extracorporeal membrane oxygenation and associated therapeutic and diagnostic technologies in performance of the following activities: (a) the administration of pharmacological and therapeutic agents, or blood products or anesthetic agents through the extracorporeal circuit or through an intravenous line as ordered by a physician; (b) the performance and use of anticoagulation monitoring and analysis; physiologic monitoring and analysis; blood gas and chemistry monitoring and analysis; hematologic monitoring and analysis; hypothermia; hyperthermia; hemoconcentration and hemodilution; or modified extracorporeal circulatory hemodialysis, or (c) the observation of signs and symptoms related to perfusion services, the determination of whether the signs and symptoms exhibit abnormal characteristics, and the implementation of appropriate reporting, perfusion protocols, or changes in or the initiation of emergency procedures. The practice of respiratory therapy is not limited to the hospital setting;

(d) "Respiratory care practitioner" means a person who is licensed to practice respiratory care in this state pursuant to section 20-162o and who may transcribe and implement written and verbal orders for respiratory care issued by a physician licensed pursuant to chapter 370, or a physician assistant licensed pursuant to chapter 370 or an advanced practice registered nurse licensed pursuant to chapter 378 who is functioning within the person's respective scope of practice.

2. Public health and safety benefits that the requestor believes will occur if the request is implemented and, if applicable, a description of any harm to public health and safety if it is not implemented

Benefits that will result from the change:

Expanding the scope of practice for Respiratory Care will permit Connecticut Children's to operate an ECMO program that will better serve our patients and families by giving them the care they deserve closer to home. We propose a hybrid model which would combine both perfusionists and respiratory therapists running and monitoring the ECMO circuit under the direction of the designated ECMO attending physician. With this model, we can provide in house coverage from staff scheduled to cover "ECMO Call". There will be a person from the team always available to set up and initiate ECMO, as well as people on staff to monitor and run the ECMO circuit for the entire run. This will foster the team approach that is necessary to build a successful program. Also, with all ECMO team members in house there is always someone available for trouble shooting the circuit and technical support.

The team we propose will be made up of at least 5 perfusionists and at least 6 respiratory therapists. All will be trained by a comprehensive ECMO training program, and all will be obligated to complete retaining wet labs to maintain skills if they have not run an ECMO or set up an ECMO in a specified amount of time. Having the in house hybrid model will allow us to review each case with all team members after the ECMO run has completed.

Concerns if the change is not implemented:

Without a change in the scope of practice of Respiratory Care, the only option is to utilize an ECMO team made up exclusively of perfusionists.

1. *A perfusionist-only model is not the norm.* In August 2009, Connecticut Children's conducted a survey of ECMO Coordinators at independent children's hospitals across the country. Of the 36 programs listed as members of the Extracorporeal Life Support Organization, 26 responded. Of the respondents, only one—Children's Hospital Medical Center of Akron—uses a perfusionist-only model. In contrast, 17 of the 26 allow RTs to participate as ECMO Specialists.
2. *We cannot support a perfusionist-only model with in-house staff.* We anticipate in the first year we will perform at least 6 ECMO cases at an average run of 7 days. We would need to hire an additional 8-10 perfusionists to cover these cases. There would be no work for them otherwise until the ECMO cases come in and this will result in the perfusionists being unable to maintain their credentialing. We would need a more active cardiac program to justify hiring more perfusionists.
3. *Our ECMO program will be stronger if all team members are in-house staff.* Trained staff will always be available for set up and initiation, running the ECMO circuit, and trouble shooting and technical support. Using in-house staff exclusively will also

foster the team approach and permit the opportunity to review each case with all team members after the ECMO run has completed.

4. *A perfusionist-only model is not necessary to operate a high quality program.* The Extracorporeal Life Support Organization and the American Association for Respiratory Care both support the use of RTs as ECMO Specialists. In addition, 65% of the independent children's hospitals who responded to our survey use RTs as ECMO Specialists.
5. *The hybrid model that we propose will be more cost effective than the alternative.* We currently employ more than enough RTs who possess the required credentials and have an interest in pursuing ECMO training to fully staff our proposed hybrid model. Using outside perfusionists to fill these ECMO Specialist slots would add unnecessary costs to our program.

3. The impact on public access to health care

Connecticut Children's projects that at least six patients requiring ECMO services for an average of seven days each would be served in the first year. Without access to an ECMO program based at Connecticut Children's, these patients will need to be transferred to other facilities, possibly out of state, to receive the care they need. In addition, some patients may be unnecessarily transferred to other facilities because at the time of transfer the patient's condition warranted ECMO but after transfer, the patient's condition improves and ECMO is no longer necessary.

4. A brief summary of state or federal laws governing the profession

State law –Connecticut General Statutes, Sec. 20-162n (b)

National Guidelines

Extracorporeal Life Support Organization (ELSO) is an international consortium of health care professionals and scientists who are dedicated to the development and evaluation of novel therapies for support of failing organ systems.

ELSO Guidelines for ECMO Centers (February 2005) list the following criteria for ECMO clinical specialists, who should provide 1:1 or 1:2 care throughout the course of ECMO:

1. Strong intensive care background (at least one year of NICU or PICU experience preferred), and
2. One of the following:
 - a. Successful completion of an approved school of nursing and achievement of a passing score on the state written exam given by the Board of Nursing;
 - b. Successful completion of an accredited school of respiratory therapy and have successfully completed the registry examination for advanced level practitioners and be recognized as a Registered Respiratory Therapist by the National Board of Respiratory Care;
 - c. Successful completion of an accredited school of perfusion and national certification through the American Board of Cardiovascular Perfusion;
 - d. Physicians trained in ECMO who have successfully completed institutional training requirements for the clinical specialists.

ELSO guidelines also stipulate that “ECMO Centers should be located in geographic areas that can support a minimum of 6 ECMO patients per center per year”. Connecticut Children's will meet this minimum threshold.

The American Association for Respiratory Care endorses the use of qualified and appropriately educated Respiratory Therapists as Extracorporeal Membrane Oxygenation (ECMO) Specialists.

According to their position paper on Respiratory Therapists as ECMO Specialists, the requisite qualifications should include:

1. the successful completion of an accredited respiratory care educational program,
2. an earned Registered Respiratory Therapist (RRT) credential from the National Board for Respiratory Care (NBRC),
3. a state license (where required), and
4. clinical experience in critical care.

The position paper further states that the education as an ECMO Specialist should be in accordance with the Extracorporeal Life Support Organization's (ELSO) document entitled "Guidelines for Training and Continuing Education of ECMO Specialists."

5. The state's current regulatory oversight of the profession

The Department of Public Health oversees the licensure of Respiratory Care Practitioners under the statutory authority of the Respiratory Care Practice Act, CGS, Sec. 20-162n.

Respiratory Care Practitioner Licensure Requirements from the DPH web site:
<http://www.ct.gov/dph/cwp/view.asp?a=3121&q=389578>

An applicant for licensure must meet one (1) of the following eligibility routes:

Route 1—Completion of an educational program for Respiratory Therapists or Respiratory Therapy Technicians which, at the time of completion, was accredited by the Committee on Allied Health Education and Accreditation, or the Commission on Accreditation of Allied Health Education Programs, in cooperation with the Joint Review Committee for Respiratory Therapy Education, or was recognized by the Joint Review Committee for Respiratory Therapy Education; or the Committee on Accreditation for Respiratory Care; and

Successful completion of the Entry Level or Advanced Practitioner Respiratory Care examination administered by the National Board for Respiratory Care, Inc. (**NBRC**); and

Is currently credentialed by the National Board for Respiratory Care (**NBRC**) as a Certified Respiratory Therapy Technician or Registered Respiratory Therapist.

Route 2—Was credentialed by the **NBRC** as a Certified Respiratory Therapy Technician not later than June 30, 1978; or

Was credentialed by the **NBRC** as a Registered Respiratory Therapist not later than June 30, 1971; and

Has successfully completed the Entry Level or Advanced Practitioner Respiratory Care Examination administered by the **NBRC**; and

Is currently credentialed by the National Board for Respiratory Care **NBRC** as a Certified Respiratory Therapy Technician or Registered Respiratory Therapist.

Route 3—Has been registered as a Respiratory Therapist by the Canadian Society of Respiratory Therapists (**CSRT**);

Has passed the Clinical Simulation Examination of the **NBRC**; and

Is currently credentialed by the **NBRC** as a Registered Respiratory Therapist.

6. All current education, training, and examination requirements and any relevant certification requirements applicable to the profession

Requirements according to the National Board for Respiratory Care (www.nbrc.org)

Certified Respiratory Therapist (CRT)

To qualify for the examination:

1. Applicants shall be 18 years of age or older.
2. Applicants shall satisfy ONE of the following educational requirements:
 - a. Applicants shall have a minimum of an associate degree from a respiratory therapist education program 1) supported or accredited by the Commission on Accreditation for Respiratory Care (CoARC), or 2) accredited by the Commission on Accreditation of Allied Health Education Programs (CAAHEP) and graduated on or before November 11, 2009.
 - b. Applicants enrolled in an accredited respiratory therapy program in an institution offering a baccalaureate degree may be admitted to the CRT Examination with a "special certificate of completion" issued by a sponsoring educational institution. The CoARC will authorize such institutions to issue the "special certificate of completion" at the advanced-level following completion of the science, general academic and respiratory therapy coursework commensurate with the requirements for accreditation.

Registered Respiratory Therapist (RRT)

To qualify for the examination:

1. Applicants shall be 18 years of age or older.
2. Applicants shall satisfy ONE of the following educational requirements:
 - a. Be a CRT having earned a minimum of an associate degree* from a respiratory therapist educational program 1) supported or accredited by the Commission on Accreditation for Respiratory Care (CoARC), or 2) accredited by the Commission on Accreditation of Allied Health Education Programs (CAAHEP) and graduated on or before November 11, 2009. *Graduates of accredited 100-level respiratory therapist education programs are not eligible for admission to the RRT Examination under this admission provision.*
 - b. Be a CRT having been enrolled in an accredited respiratory therapy program in an institution offering a baccalaureate degree offering a "special certificate of completion" issued by a sponsoring educational institution. The CoARC will authorize such institutions to issue the "special certificate of completion" at the advanced level following completion of the science, general academic and respiratory therapy coursework commensurate with the requirements for accreditation.
 - c. Be a therapist Certified (CRT) by the NBRC who has four years* of full-time clinical in respiratory therapy under licensed medical supervision following Certification and prior to applying for the Registry Examination. In addition, the applicant shall have at least 62 semester hours of college credit from a college or university accredited by its regional association or its equivalent. The 62 semester hours of college credit must

include the following courses: anatomy and physiology, chemistry, microbiology, physics, and mathematics

d. Be a CRT having earned a minimum of an associate degree from an accredited entry-level respiratory therapist educational program with two years of full-time, clinical experience in respiratory care under licensed medical supervision following Certification and prior to applying for the examination.

e. Be a CRT with a baccalaureate degree in an area other than respiratory care, including college credit level courses in anatomy and physiology, chemistry, mathematics, microbiology and physics. In addition, they shall have two years of full-time clinical experience** in respiratory care under licensed medical supervision following Certification and before applying for the examination. In addition, the applicant shall have at least 62 semester hours of college credit from a college or university accredited by its regional association or its equivalent.

*Individuals certified (CRT) prior to January 1, 1983, are required to complete only three years of clinical experience.

**Clinical experience in respiratory care under licensed medical supervision is interpreted as a minimum of 21 hours per week. Clinical experience must be completed before the candidate applies for this examination.

Neonatal/Pediatric Respiratory Therapist

To qualify for the examination:

1. Applicants shall be Registered Respiratory Therapists (RRT);
OR
2. Applicants shall be Certified Respiratory Therapists (CRT) with one year of clinical experience* in neonatal/pediatric respiratory care following Certification.

* Clinical experience is defined as a minimum of 10 hours per week for a calendar year in neonatal/pediatric respiratory care under the supervision of a medical director of respiratory care or a special care area acceptable to the Board. Clinical experience must be completed before the candidate applies for this examination.

American Association for Respiratory Care guidelines regarding ECMO

A position paper by the American Association for Respiratory Care on the inclusion of respiratory therapists as ECMO Specialists lists these requisite qualifications:

1. the successful completion of an accredited respiratory care educational program,
2. an earned Registered Respiratory Therapist (RRT) credential from the National Board for Respiratory Care (NBRC),
3. a state license (where required), and
4. clinical experience in critical care.

7. A summary of known scope of practice changes requested or enacted concerning the profession in the five years preceding the request

According to Geri Bernacki, President of Connecticut Society for Respiratory Care, no requests have been made or enacted in the past five years.

8. The extent to which the request directly affects existing relationships within the health care delivery system

ECMO will be a new service at Connecticut Children's so no existing relationships will be impacted by a change to respiratory care scope of practice.

9. The anticipated economic impact on the health care delivery system

Using respiratory therapists as part of the ECMO program at Connecticut Children's will result in cost efficiencies. Connecticut Children's currently employs more than enough respiratory therapists who possess the required credentials and have an interest in pursuing ECMO training to fully staff our proposed hybrid model. Using perfusionists on a contractual basis to fill these ECMO Specialist slots would add unnecessary costs to our program.

The hybrid model would save an estimated \$22,240 per year or \$3,707 per patient as compared to a perfusion-only model.

10. Regional and national trends concerning licensing of the health profession making the request and a summary of relevant scope of practice provisions enacted in other states

In 2009, Connecticut Children's conducted an informal survey of ECMO programs at independent children's hospitals. 36 hospital ECMO coordinators were surveyed and 26 responded. Of the responders, 17 hospitals (65%) reported using Respiratory Therapists as part of their ECMO teams. Only one hospital (4%) reported using a Perfusionist-only model.

Survey Results: Independent Children's Hospitals' ECMO Programs

ECMO teams permit respiratory therapists	ECMO teams include only perfusionists
<ol style="list-style-type: none"> 1. The Children's Hospital of Alabama 2. Phoenix Children's Hospital (AZ) 3. Children's Hospital of Orange County (CA) 4. The Children's Hospital (CO) 5. Children's National Medical Center (DC) 6. Miami Children's Hospital (FL) 7. Children's Health Care of Atlanta (GA) 8. Children's Memorial Hospital (IL) 9. Children's Hospital New Orleans (LA) 10. Children's Hospital Boston (MA)* 11. Children's Hospital of Michigan* 12. Nationwide Children's Hospital (OH) 13. Children's Hospital of Philadelphia (PA) 14. Children's Hospital of Pittsburgh (PA) 15. LeBonheur Children's Medical Center (TN) 16. Children's Medical Center Dallas (TX) 17. Cook Children's Medical Center (TX) 	<ol style="list-style-type: none"> 1. Children's Medical Center of Akron (OH)

*ECMO teams at Children's Hospital Boston and Children's Hospital of Michigan include only respiratory therapists.

11. Identification of any health care professions that can reasonably be anticipated to be directly affected by the request, the nature of the impact, and efforts made by the requestor to discuss it with such health care professions

Perfusionists and physicians are currently the only professions in Connecticut whose scope of practice permits participation on an ECMO team. In conversations with DPH in 2009, it was suggested that we reach out to the Connecticut Society of Perfusion, which we did. On May 14, 2009, we met at Connecticut Children's with Ken Jeleniowski, President of the Connecticut Society of Perfusion, and two of his colleagues. At this meeting, Mr. Jeleniowski agreed to survey his membership to identify perfusionists who would be willing to serve as ECMO Specialists for Connecticut Children's. In an August 21, 2009 email to Dr. Philip Spinella, who was at that time one of our pediatric intensivists, Mr. Jeleniowski stated that his membership supports a perfusion-only ECMO model.

At present the Hartford Hospital perfusionist team is not willing to participate in Connecticut Children's ECMO program through the contract we have the University of Connecticut Health Center perfusionists.

12. A description of how the request relates to the health care profession's ability to practice to the full extent of the profession's education and training

National guidelines and the experience at other independent children's hospitals show that a hybrid model is a well-recognized approach for providing pediatric ECMO services. The extensive cooperation between Connecticut Children's ICU nursing, Respiratory Care and physician staff and the UCHC perfusionists, along with our recent hiring of an ECMO coordinator who has been a practicing pediatric perfusionist with extensive cardiovascular surgical case volume experience will result in an efficient and effective team. Our ability to utilize internal staff, all with specific expertise in pediatrics, will give Connecticut Children's the ability to provide the best possible care to our patients and families.