



August 15, 2013

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 give our patients and families the care they deserve, Connecticut Children's Medical Center operates a program to provide Extracorporeal Membrane Oxygenation (ECMO) services. We respectfully request that the Department of Public Health utilize the scope of practice determinations process to explicitly add ECMO functions to the scope of practice for nurses. In 2011, Connecticut Children's submitted a request that the Department utilize the scope of practice determinations process to explicitly add ECMO functions to the scope of practice for Respiratory Care, but that request was not selected to move forward.

Since our last request, Connecticut Children's ECMO program has formally launched. This request, which would permit Connecticut Children's to use a hybrid staffing model that includes perfusionists and nurses, is in line with the recommendations of national experts and it would permit the optimal care team to serve our most vulnerable patients. Of the 26 children's hospitals ECMO programs that Connecticut Children's surveyed in 2009, only one used a perfusionist-only model. In contrast, 24 of the programs (92%) used nurses, respiratory therapists or both on their ECMO teams.

The full care team available to patients utilizing Connecticut Children's ECMO services includes neonatologists, cardiologists, intensivists, surgeons, perfusionists, nurses, nutritionists, pharmacists and respiratory therapists. If this request is approved, Connecticut Children's will implement a hybrid staffing model where perfusionists and nurses run and monitor the ECMO circuit under the direction of the designated ECMO attending physician. With this model, Connecticut Children's would be able to provide 24/7 in-house coverage from staff scheduled to cover "ECMO Call". The hybrid staffing model permits the use of a consistent team and it will lead to an optimally successful program.

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 860-837-5557 or jbaird@connecticutchildrens.org.

Sincerely,

Theresa Hendricksen, RN, BSN, MS, FACHE
Executive Vice President and Chief Operating Officer

1. A plain language description of the request

CGS Sec. 20-87a, which defines Nursing scope of practice, must be amended so Registered Nurses and Advanced Practice Registered Nurses can participate as part of a team providing Extracorporeal Membrane Oxygenation (ECMO) services.

Section 20-87a of the general statutes is amended by adding subdivision (a) and amending subdivisions (b) and (c) as follows (*Effective upon passage*):

Sec. 20-87a. Definitions. Scope of practice. (a) "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 systems

(b) The practice of nursing by a registered nurse is defined as the process of diagnosing human responses to actual or potential health problems, providing supportive and restorative care, health counseling and teaching, case finding and referral, collaborating in the implementation of the total health care regimen, and executing the medical regimen under the direction of a licensed physician, dentist or advanced practice registered nurse. A registered nurse may also execute orders issued by licensed physician assistants, podiatrists and optometrists, provided such orders do not exceed the nurse's or the ordering practitioner's scope of practice. A registered nurse may also participate as an ECMO specialist performing functions including: 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.

(c) Advanced nursing practice is defined as the performance of advanced level nursing practice activities that, by virtue of post basic specialized education and experience, are appropriate to and may be performed by an advanced practice registered nurse. The advanced practice registered nurse performs acts of diagnosis and treatment of alterations in health status, as described in subsection (a) of this section, and shall collaborate with a physician licensed to practice medicine in this state. In all settings, the advanced practice registered nurse may, in collaboration with a physician licensed to practice medicine in this state, prescribe, dispense and administer medical therapeutics

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and corrective measures and may request, sign for, receive and dispense drugs in the form of professional samples in accordance with sections 20-14c to 20-14e, inclusive, except that an advanced practice registered nurse licensed pursuant to section 20-94a and maintaining current certification from the American Association of Nurse Anesthetists who is prescribing and administering medical therapeutics during surgery may only do so if the physician who is medically directing the prescriptive activity is physically present in the institution, clinic or other setting where the surgery is being performed. For purposes of this subsection, "collaboration" means a mutually agreed upon relationship between an advanced practice registered nurse and a physician who is educated, trained or has relevant experience that is related to the work of such advanced practice registered nurse. The collaboration shall address a reasonable and appropriate level of consultation and referral, coverage for the patient in the absence of the advanced practice registered nurse, a method to review patient outcomes and a method of disclosure of the relationship to the patient. Relative to the exercise of prescriptive authority, the collaboration between an advanced practice registered nurse and a physician shall be in writing and shall address the level of schedule II and III controlled substances that the advanced practice registered nurse may prescribe and provide a method to review patient outcomes, including, but not limited to, the review of medical therapeutics, corrective measures, laboratory tests and other diagnostic procedures that the advanced practice registered nurse may prescribe, dispense and administer. An advanced practice registered nurse licensed under the provisions of this chapter may make the determination and pronouncement of death of a patient, provided the advanced practice registered nurse attests to such pronouncement on the certificate of death and signs the certificate of death no later than twenty-four hours after the pronouncement. **An advanced practice registered nurse may also participate as an ECMO specialist performing functions including: 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.**

(d) The practice of nursing by a licensed practical nurse is defined as the performing of selected tasks and sharing of responsibility under the direction of a registered nurse or an advanced practice registered nurse and within the framework of supportive and restorative care, health counseling and teaching, case finding and referral, collaborating in the implementation of the total health care regimen and executing the medical regimen under the direction of a licensed physician or dentist.

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(e) In the case of a registered or licensed practical nurse employed by a home health care agency, the practice of nursing includes, but is not limited to, executing the medical regimen under the direction of a physician licensed in a state that borders Connecticut.

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

Connecticut Children's current ECMO program

Connecticut Children's ECMO program was launched in June, 2012. In the first year of operation, the ECMO team cared for five patients who utilized a total of 1,194 hours of ECMO services, or approximately 50 days of run time. The ECMO team is currently staffed by perfusionists—two of whom have pediatric expertise and are on staff with the remainder being either part of our core group of salaried perfusionists or those who work on a per diem basis. The full care team available to patients utilizing Connecticut Children's ECMO services includes neonatologists, cardiologists, intensivists, surgeons, perfusionists, nurses, nutritionists, pharmacists and respiratory therapists. The program is designed from a "best in class" perspective following guidelines of evidenced based best practices and recommendations by the Extracorporeal Life Support Organization (ELSO). Connecticut Children's participates in the ELSO registry to facilitate comparison of our performance and outcomes to national benchmarks.

The proposed hybrid staffing model

If this scope of practice request is approved, Connecticut Children's will implement a hybrid staffing model where perfusionists and nurses run and monitor the ECMO circuit under the direction of the designated ECMO attending physician. With this model, Connecticut Children's would be able to provide 24/7 in-house coverage from staff scheduled to cover "ECMO Call".

Benefits of the hybrid model include:

- An in-house member of the team would always be available to set up and initiate ECMO, and to monitor and operate the ECMO circuit for the entire run. The current model sometimes requires the use of per diem staff to perform these functions. The hybrid staffing model permits the use of a consistent team; this approach will lead to an optimally successful program.
- All team members will have pediatric expertise, which mitigates the risks associated with advanced technology. The consistent team offered by the in-house hybrid model permits the review of each case with all team members after the ECMO run has completed.
- 24/7 in-house coverage permits Connecticut Children's to operate an emergency ECMO response team that could use ECMO to provide emergency resuscitation services.

Concerns if the change is not implemented

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

1. *A perfusionist-only model is not the norm.* Of the 26 children's hospitals ECMO programs that Connecticut Children's surveyed in 2009, only one used a perfusionist-only model. In contrast, 24 of the programs (92%) used nurses, respiratory therapists or both on their ECMO teams.
2. *Our ECMO program will be stronger if all team members are in-house staff.* An in-house member of the team would always be available to set up and initiate ECMO, and to monitor and operate the ECMO circuit for the entire run. The current model sometimes requires the use of per diem staff to perform these functions. The hybrid staffing model permits the use of a consistent team; this approach will lead to an optimally successful program. All team members will have pediatric expertise, which mitigates the risks associated with advanced technology. The consistent team offered by the in-house hybrid model permits the review of each case with all team members after the ECMO run has completed.
3. *A perfusionist-only model is not necessary to operate a high quality program.* The Extracorporeal Life Support Organization supports the use of Nurses as ECMO Specialists.
4. *The hybrid model that we propose will be more cost effective than the alternative.* We currently employ more than enough nurses who possess the required credentials and have an interest in pursuing ECMO training to fully staff our proposed hybrid model. Using per diem perfusionists to fill these ECMO Specialist slots would add unnecessary costs to our program.
5. *A consistent team where all members have specific pediatric expertise will be superior to what is currently permitted.* Approving our requested expansion to the scope of practice for Nursing will actually result in an increase in the education and certification standards by permitting Connecticut Children's to use an ECMO team where each member has specific training in pediatrics. Very few perfusionists in Connecticut have specific training in pediatrics, which is essential to providing the high-quality family-centered care that our patients deserve.

3. The impact on public access to health care

Approval of this request would allow access to a stronger ECMO program at Connecticut Children's.

- A scope of practice change for Nursing would allow Connecticut Children's to operate an optimally designed "best in class" ECMO program at the state's only facility dedicated exclusively to children.
 - An in-house member of the team would always be available to set up and initiate ECMO, and to monitor and operate the ECMO circuit for the entire run. The current model sometimes requires the use of outside per diem staff to perform these functions.
 - The hybrid staffing model permits the use of a consistent pediatric expert team.
 - All team members will have pediatric expertise, which mitigates the risks associated with caring for children with advanced technology.
 - The consistent team offered by the in-house hybrid model permits the expeditious review of each case with all team members after the ECMO run has completed.

Approval of this request would permit access to enhanced resuscitation services at Connecticut Children's.

- Connecticut Children's would have the opportunity to offer an emergency ECMO response team (eCPR) that could use ECMO to provide emergency resuscitation services.

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

State law –Connecticut General Statutes, Sec. 20-87a

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.

This scope of practice request is in line with current national thinking about the nursing profession. The *Institute of Medicine's* 2010 report on *The Future of Nursing* advocates that nurses **should practice to the full extent of their education and training**. Clearly provision of ECMO care would fall within this practice.

Connecticut Children's is also pursuing Magnet Status, which emphasizes the importance of nurses delivering excellent patient outcomes, having a high level of job satisfaction, being involved in the decision-making in patient care delivery, and being rewarded for advancing in nursing practice. Magnet institutions foster an environment of open communication between nursing and other members of the health care team, and require an appropriate, safe personnel mix to attain the best patient outcomes.

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

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

The Department of Public Health oversees the licensure of Nurses under the statutory authority of the Nursing Practice Act, CGS, Sec. 20-87a.

Advanced Practice Registered Nurses Licensure Requirements from the DPH web site:
<http://www.ct.gov/dph/cwp/view.asp?a=3121&q=389398>

Registered Nurses Licensure Requirements from the DPH web site:
<http://www.ct.gov/dph/cwp/view.asp?a=3121&q=389432>

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

The only known scope of practice change for Nursing in the past five years was implemented by Public Act 10-117 § 18 which allows a registered nurse to execute orders issued by a licensed physician assistant, podiatrist, or optometrist as long as the orders do not exceed the scope of practice of the nurse or ordering practitioner. The law allows a registered nurse to provide medical care under the direction of a licensed physician, dentist, or advanced practice registered nurse.

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

Connecticut Children's relationship with its core group of salaried perfusionists as well as its two employed pediatric perfusionists will remain unchanged. The addition of nursing staff to the ECMO team may eliminate the need for outside per diem perfusionists. The full care team available to patients utilizing Connecticut Children's ECMO services will continue to include neonatologists, cardiologists, intensivists, surgeons, perfusionists, nurses, nutritionists, pharmacists and respiratory therapists.

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

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

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

Of the 26 children's hospitals ECMO programs that Connecticut Children's surveyed in 2009, only one used a perfusionist-only model. In contrast, 24 of the programs (92%) used nurses, respiratory therapists or both on their ECMO teams.

Survey Results: Independent Children's Hospitals' ECMO Programs

ECMO teams permit respiratory therapists and/or nurses	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 Los Angeles (CA) 4. Children's Hospital of Orange County (CA) 5. Lucile Packard Children's Hospital at Stanford (CA) 6. Rady Children's Hospital - San Diego (CA) 7. The Children's Hospital (CO) 8. Children's National Medical Center (DC) 9. Miami Children's Hospital (FL) 10. Children's Health Care of Atlanta (GA) 11. Children's Memorial Hospital (IL) 12. Children's Hospital New Orleans (LA) 13. Children's Hospital Boston (MA)* 14. Children's Hospital of Michigan* 15. Children's Hospitals and Clinics of Minnesota (MN) 16. Children's Hospital & Medical Center (NE) 17. Nationwide Children's Hospital (OH) 18. Children's Hospital of Philadelphia (PA) 19. Children's Hospital of Pittsburgh (PA) 20. LeBonheur Children's Medical Center (TN) 21. Children's Medical Center Dallas (TX) 22. Cook Children's Medical Center (TX) 23. Primary Children's Medical Center (UT) 24. Children's Hospital of Wisconsin (WI) 	<ol style="list-style-type: none"> 1. Children's Medical Center of Akron (OH)

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

This request should not affect other professions because Connecticut Children's will still utilize in-house perfusionists and those who are part of its core clinical group. The inclusion of nurses simply provides 24/7 coverage by in-house staff, reducing or eliminating the need to utilize per diem perfusionists. The full care team available to patients utilizing Connecticut Children's ECMO services will continue to include neonatologists, cardiologists, intensivists, surgeons, perfusionists, nurses, nutritionists, pharmacists and respiratory therapists.

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. 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.

The *Institute of Medicine's* 2010 report on *The Future of Nursing* advocates that nurses should practice to the full extent of their education and training. The report recommends that nurses "achieve higher levels of education and training through an improved education system that promotes seamless academic progression and that nurses should be full partners, with physicians and other health care professionals, in redesigning health care in the United States". The IOM advocates that removing scope of practice barriers is a key strategy for achieving these goals.