STATE OF FLORIDA

DEPARTMENT OF HEALTH (DOH)

CHILDREN’S MEDICAL SERVICES (CMS)

REGIONAL PERINATAL INTENSIVE CARE CENTERS (RPICC) PROGRAM

EXTRACORPOREAL LIFE SUPPORT (ECLS) FOR NEONATES:

CONTRAST STANDARDS

I. DEFINITIONS - GENERAL

A. “ECLS” - (Extracorporeal Life Support also known as Extracorporeal Membrane Oxygenation or ECMO) - A method for provision of cardiac or pulmonary support with a system including a pump, membrane oxygenator, and heat exchanger with additional system monitoring devices used to provide rescue therapy for selected neonates who have failed to respond or improve with maximal conventional neonatal intensive care support including, but not limited to, ventilation and inhaled nitric oxide administration (iNO), and who meet institutionally specific diagnostic and acuity criteria required for this therapy. Such services are provided in designated Level III neonatal intensive care units.

B. “Level III neonatal intensive care unit ECLS bed” - A patient care station with the capability of providing neonatal intensive care services and extracorporeal life support to critically ill neonates meeting medical criteria required for their therapy, and which is staffed to provide 24 hours of ECLS specialist care per neonate per day and to simultaneously provide 12 to 24 hours or more of nursing care per day depending on the acuity of the neonate. There is the capability of delivering total intensive care to newborns requiring ECLS including, but not limited to, veno-arterial or veno-venous cannulation, continuous cardiopulmonary bypass with a membrane oxygenator and servo-controlled pumps with heat exchanger(s); as well as, total respiratory support, supplemental parenteral alimentation, continuous electronic monitoring of vital signs, prolonged vascular cannulation, maintenance of prolonged anticoagulation and monitoring thereof. Such care is customarily provided at all times with a minimum ratio of one ECLS technical specialist and 1:1 or 1:2 nurse to patient ratio for the critical care of infants requiring neonatal ECLS.

C. “Neonatal ECLS candidate” - An infant less than 29 days of age who meets current institutional medical criteria recommended for the initiation of ECLS.

D. “Neonatologist” - A CMS approved RPICC neonatologist, as provided in chapter 64C-6, Florida Administrative Code, (F.A.C.), who is certified, or who meets the requirements for certification, by an appropriate board in the area of neonatal-perinatal medicine.

E. “Pediatric Cardiologist” - A CMS approved pediatric cardiologist, as provided in chapter 64C-6, F.A.C., who is certified, or who meets the requirements for certification, by an appropriate board in the area of pediatric cardiology.

F. “Pediatric Surgeon” - A CMS approved pediatric surgeon, as provided in chapter 64C-6, F.A.C., who is certified, or who meets the requirements for certification, by an appropriate board in the area of surgery with a certificate of special competence in pediatric surgery.
G. “Pediatric Cardiovascular Surgeon” - A CMS approved pediatric cardiovascular surgeon, as provided in chapter 64C-6, F.A.C., who is certified, or who meets the requirements for certification, by an appropriate board in the area of cardiovascular surgery with demonstrated competence in pediatric cardiovascular surgery.

H. “Regional Perinatal Intensive Care Centers (RPICC)” - Specialized units within hospitals specifically designed to provide a full range of health services to women with high risk pregnancies and a full range of newborn intensive care services which have been designated by the Department of Health (DOH), and which meet the standards as set forth in chapter 64C-6, F.A.C., for facilities, staffing and services.

I. “Regional Perinatal Intensive Care Centers providing ECLS Services” - Regional Perinatal Intensive Care Centers as defined above that have been evaluated and approved for the provision of Extracorporeal Life Support by the Children's Medical Services Program. Such facilities meet the standards as set forth in this document for facilities, staffing and services as defined herein.

J. “RPICC ECLS Program Patient” - A neonatal patient who meets patient eligibility criteria as provided in chapter 64C-6, F.A.C., and meets medical criteria recommended for the initiation of ECLS.

II. ECLS STANDARDS

A. The RPICC Program provides services in designated hospitals through two interrelated components:

1. Neonatal, including Level II and III neonatal intensive care services.

2. Obstetrical.

B. General Requirements - The CMS RPICC ECLS standards, based on Extracorporeal Life Support Organization (ELSO) guidelines, set forth in this section pertain specifically to ECLS programs in designated RPICC facilities.

1. Neonatal ECLS services shall be located in RPICCs with an Agency for Health Care Administration (AHCA) licensed tertiary level Neonatal Intensive Care Unit (NICU).

2. CMS RPICCs providing ECLS services must support a minimum of twelve (12) ECLS patients (neonatal and pediatric) per center per year for consideration as a CMS RPICC ECLS contract provider. ECLS programs that do not serve a minimum of 12 patients per year will be reviewed by the Deputy Secretary of CMS with the statewide neonatal consultant to determine whether to continue ECLS contract services.

3. CMS RPICCs providing ECLS services are encouraged to actively participate in ELSO, including the Central Registry of patients receiving ECLS in order to provide outcome measures referable to national standards and performance. RPICCs providing ECLS services shall share ELSO center comparative data at the time of annual program review.

C. Facilities and Location
1. An individual RPICC provider may request the addition of ECLS services to its contract with the Department. The CMS Central Office shall make a determination of the need for the establishment of ECLS services within a RPICC facility in the geographic area. Upon review of available information, this determination shall be based, in part, upon the following factors:

   a. Projection of anticipated need utilizing medical criteria for ECLS services as defined by current medical practice to include as a minimum review of projected utilization requirements referable to the “Guidelines for Neonatal ECLS Centers” as published and amended by the Extracorporeal Life Support Organization (ELSO).

   b. Survey existing utilization of RPICC ECLS providers.

   c. The neonatal mortality rate in the proposed service region.

   d. The accessibility of patients in need of ECLS services to established RPICC services and the neonatal referral rate to the requesting institution.

   e. Current alternative medical and technologic developments that would either increase or decrease the need for proposed services and the potential for collaboration with existing programs.

2. Upon determination of the need for ECLS services within a geographic region, the CMS Central Office shall review the RPICC facilities within the geographic area to determine which, if any, should be considered to provide RPICC ECLS services.

3. On-site review of the hospital will be made by CMS Central Office staff and the RPICC program neonatal medical consultant to ascertain the extent to which the hospital facilities, personnel, staffing, and services will comply with the standards set forth herein. Based upon this review, a recommendation will be made to the Deputy Secretary for appropriate contract amendment as an RPICC providing ECLS services.

4. Institutions designated as RPICCs providing ECLS services must meet all standards for facilities, personnel, staffing, and services as set forth herein, as of the date of designation, and further shall commit to maintaining compliance as a minimum, with “Guidelines for Neonatal ECLS Centers” as published and amended from time to time by the Extracorporeal Life Support Organization (ELSO).

D. CMS Quality Assurance

1. Monitoring for the purposes of quality assurance shall be the function of the CMS Central Office with advice and consultation from the RPICC medical consultants at the time of RPICC program review on at least an annual basis.

2. Failure to meet CMS RPICC ECLS standards may result in a contract amendment to remove CMS RPICC ECLS services.
F. Reporting

1. The RPICC Coordinator of the neonatal program component and the center data specialist are responsible for assuring that all patient demographic, medical, and fiscal data have been entered into the RPICC data system. Each RPICC providing ECLS services must commit to enrollment and assure the continuing follow-up of ECLS patients, as “infants at risk for developmental delay” in Early Steps, Florida’s Early Intervention System for Infants and Toddlers and Their Families, which is administered by the Department of Health, Children’s Medical Services.

2. Each RPICC providing ECLS services will report neonatal morbidity of ECLS patients in a format as designated by CMS.

3. The Directors of the Neonatal ECLS Program in the RPICC shall submit an annual summary report in the format required by the CMS Central Office. Appropriate ELSO reports will also be utilized in the reporting process.

G. Budget Allocation

1. Operating funds for CMS RPICC Program oversight, including ECLS services, are provided by appropriation from the State General Revenue fund.

2. The Department, in accordance with Department Contract and Grants Management rules and regulations, shall include the ECLS standards attachment in RPICC contracts with each center for the provision of perinatal intensive care services that include ECLS physician and hospital services. Required services shall be additionally identified in all contracts with the Department of Health, Children’s Medical Services for RPICC ECLS services.

3. Reimbursement of any center professional services for RPICC program patients shall be disbursed by the Medicaid Program for Medicaid recipient patients based on current Neonatal Care Group (NCG) methodology utilizing the pricing methodology approved by the Health Insurance Portability and Accountability Act (HIPAA) and Current Procedural Terminology (CPT) codes for reimbursement in accordance with the Florida Medicaid Program memorandum of October 1, 2003. Such NCG physician provider reimbursement shall include both medical and surgical reimbursement with the exception that charges for ECLS cannulation (CPT code 36822 - AMA CPT 2001) may be additionally charged by the cannulating surgeon.

4. Funds shall be used for transportation services for RPICC ECLS Program patients as provided through departmental RPICC contracts.

III. STANDARDS - SPECIFIC

Standards for ECLS Component - Level III Neonatal Intensive Care Unit (NICU) - the following standards pertain to the facilities, services, and population to be served under the neonatal component for Level III neonatal intensive care ECLS services in RPICC facilities designated for the provision of ECLS by the Department of Health.
A. Personnel

1. Physicians
   
a. The Director of the RPICC ECLS Program shall be a designated CMS approved neonatologist or CMS approved pediatric surgeon, who shall be responsible for the overall operation of the Center.

b. Each center shall have a CMS approved pediatric surgeon available at all times.

c. Each center shall have a CMS approved pediatric cardiologist available at all times.

d. Each RPICC Level III neonatal intensive care ECLS Center shall have twenty-four (24) hour, seven (7) days per week in-house coverage by either a CMS approved neonatologist, or an advanced resident physician enrolled in a fully accredited Neonatal Perinatal Medicine training program. The in-house physician shall be responsible for patient care, for communication with physicians in other hospitals, to provide consultation with regard to the need for ECLS services for patients, and for supervision of transportation services. If in-house coverage is provided by a neonatology advanced resident physician, proof of supervision by a CMS approved neonatologist and availability of the neonatologist within one hour with continuing evidence of assignment for backup by a CMS approved neonatologist is required. Patients will not be placed on ECLS without written documentation of direct, timely, and personal interaction with the on-call CMS approved neonatologist prior to cannulation and during the provision of ECLS.

e. In addition to the in-house CMS approved neonatologist, an ECLS trained physician shall provide 24 hour on call medical coverage for the ECLS patient. The physician may be a CMS approved neonatologist or CMS approved pediatric surgeon. Advanced subspecialty resident physicians enrolled for training in Accreditation Council for Graduate Medical Education (ACGME) approved programs may participate in patient care under the supervision of a CMS approved neonatologist who has training and experience in ECLS services.

2. ECLS Coordinator
   
a. An ECLS Coordinator shall be responsible for organizing and assuring the quality of care provided to ECLS patients in the RPICC Level III neonatal intensive care ECLS Center. The ECLS Coordinator shall possess the following minimum training and functional experience:

   (1) A nurse registered by the State of Florida, as defined in chapter 464, Florida Statutes, (F.S.), with training in both neonatal or pediatric intensive care nursing and the provision of ECLS services, or;

   (2) A registered respiratory therapist who is currently registered in Florida in accordance with part V, chapter 468, F.S., and has a minimum of 1 year
of Level III neonatal or pediatric intensive care experience and training in the provision of ECLS services, or;

(3) A certified clinical perfusionist with at least 1 year of Level III neonatal experience or completion of an approved program of training in neonatal care.

3. Nurses

a. Registered nurses, as defined in chapter 464, F.S., with neonatal intensive care nursing experience shall provide bedside patient care in accordance with the RPICC standards set forth in chapter 64C-6, F.A.C.

b. A designated nurse to patient care ratio of 1:1 or 1:2 shall be assigned to the ECLS patient at all times.

c. Additional nursing personnel may be required for:

   (1) Care of the unstable infants.

   (2) Initiation of ECLS services.

d. The Director of Nursing or designee for the Level III neonatal intensive care center shall:

   (1) Supervise neonatal nursing.

   (2) Assure appropriate staffing, ECLS education and training programs and assignments.

4. ECLS Clinical or Technical Specialist(s)

The ECLS Clinical or Technical Specialists must have a strong intensive care background (1 year of neonatal or pediatric intensive care experience preferred) and have attained at least one of the following:

a. Successful completion of an approved course of nursing and registration by the State of Florida, as defined in chapter 464, F.S., with training in the provision of ECLS services; or,

b. Successful completion of an accredited school of respiratory therapy (2-4 years) and achievement of a passing score on the Registry exam given by the National Board of Respiratory Care (NBRC) and registration in Florida in accordance with part V., chapter 468, F.S.; or,

c. Successful completion of an accredited school of perfusion and national certification through the American Board of Cardiovascular perfusion (ABCP); or,
d. Physicians trained in ECLS who have successfully completed institutional training requirements for the clinical specialists.

5. Respiratory Therapist

a. At least one certified Respiratory Therapist who has been trained in the ventilator management of ECLS patients shall be available in the NICU at all times.

b. One therapist for each unstable infant is recommended; one therapist trained as an ECLS respiratory therapy specialist is recommended for each two infants on ECLS. The therapist may provide, concomitantly other patient respiratory care services in the NICU so long as the respiratory care needs of the ECLS patient are not compromised.

6. Additional Personnel

a. Additional support personnel from the permanent hospital and medical staff shall be available on a 24 hour per day on-call basis and available to the hospital within 1 hour of an urgent request for assistance.

(1) Physicians who are CMS approved providers or other medical personnel who routinely care for neonates from the following disciplines:

(a) Pediatric Cardiology.

(b) Pediatric Cardiovascular Surgery.

(c) Pediatric Surgery.

(d) Cardiovascular Perfusion.

(e) Anesthesiology with credentialed expertise in the care of neonates

(f) Pediatric Neurology.

(g) Neurosurgery.

(h) Pediatric Radiology.

(i) Genetics.

(j) Pediatric Nephrology.

(k) Registered Nurses.

(l) Respiratory Therapists.
(2) Biomedical Engineer.

b. The following consultants skilled in neonatal care from the permanent medical staff shall be available upon request:

(1) Pediatric Social Services.

(2) Developmental Specialist.

(3) Occupational Therapy.

(4) Physical Therapy.

(5) Psychology and Counseling Services.

(6) Pastoral Care.

B. Additional Programs

1. A fully trained neonatal and perinatal transport team must be available 24 hours daily meeting the requirements of chapter 64C-6, F.A.C., and chapter 64E-2, F.A.C., as amended.

2. Staff, from the CMS Early Steps, Florida’s Early Intervention System for Infants and Toddlers, must be actively involved in the assessment, intervention, and long-term follow-up of the ECLS patient.

C. Area and Equipment

1. In RPICCC facilities designated with ECLS Programs, each patient station in the RPICCC Level III neonatal intensive care unit utilized for the provision of ECLS services shall have as a minimum:

   a. 100 square feet per infant.

   b. Not less than 2 wall mounted suction outlets equipped with an alarm to signal loss of vacuum.

   c. Not less than 16 electrical outlets including provision for emergency operation and a non-interruptible backup power source for all monitoring equipment.

   d. Not less than 2 oxygen outlets and an equal number of compressed air outlets with adequate provision for mixing of these gases.

   e. Provision for administration and monitoring in line of nitric oxide (NO) administration
f. Conventional and High Frequency Oscillatory Ventilator (HFOV) or High Frequency Jet Ventilator (HFJV).

g. Radiant warmer.

h. Oxygen saturation monitor.

i. One resuscitation bag and mask.

j. Cardio-respiratory monitor.

k. Continuous on-line pressure, temperature and oxygen concentration monitoring.

l. Two or more infusion pumps.

m. One servo-controlled roller pump with a system for servoregulation to balance venous drainage rate from the patient and blood return to the patient.

n. An appropriate blood heat exchanger and warming unit with inline monitoring and alarm system.

o. Circuit pressure monitors.

p. Backup battery power source for roller pump.

q. Appropriate disposable materials including membrane oxygenator, tubing packs, and connectors, all suitable for prolonged extracorporeal support.

r. Appropriate devices to measure activated clotting time with appropriate supplies at the bedside.

s. Devices to regulate the blending of carbon dioxide and oxygen for the membrane oxygenator.

t. Availability of devices capable of measuring continuous arterial or venous oxygenation or saturation of the patient. (In-line SvO2 monitor).

u. The following equipment must be readily available in the unit providing ECLS:

(1) Not less than one backup ECLS system and supplies for all current components.

(2) Adequate lighting to support surgical interventions.

(3) Surgical instrument set for revision of cannulae or exploration for bleeding complications.
2. Each RPICC Level III neonatal intensive care unit with approved ECLS services shall have the following support facilities with staff available on a 24-hour basis:

a. Blood banking, blood gas, and laboratory capabilities meeting RPICC program standards, chapter 64C-6, F.A.C.

b. Radiographic support including cranial ultrasound, Computed Axial Tomography (CAT) Scan and Magnetic Resonance Imaging (MRI) to be available in the post decannulation phase as medically necessary.

c. An approved CMS Class III Pediatric Cardiovascular Surgical facility in compliance with standards promulgated in chapter 64C, F.A.C., which includes:

   (1) Cardiovascular operating room facilities available 24 hours per day with cardiopulmonary bypass capabilities located within the hospital performing ECLS.

   (2) Readily accessible echocardiography, EKG with printout capability, and a defibrillator.

D. Staff Training and Continuing Education.

1. Each RPICC Level III neonatal intensive care unit with approved ECLS services will have a well-defined program for staff training, certification, and re-certification. This program should include: didactic lectures, laboratory training with the ECLS equipment, bedside training, and a defined system for testing proficiency of the team members.

2. Each member of the ECLS team shall have successfully completed this program.

3. All members must pass the “ELSO” examination in addition to in-house training as above.

4. A well-defined program for staff continuing education as specified by ELSO and active team members must outline emergency drill training on a routine basis with records documenting participation.

5. It is recommended that team members not involved in ECLS pump management for three or more months should be required to go through a re-certification process as defined by the ECLS program.

E. Patient Eligibility

1. Eligibility for the RPICC ECLS program shall be limited to neonates admitted to the RPICC Level III neonatal intensive care unit with approved ECLS services. All neonates who meet the established medical criteria as defined in chapter 64C-6, F.A.C., and, in addition, meet the specified medical criteria for ECLS services, upon direct referral by the attending physician, must be admitted to the RPICC Level III neonatal intensive care unit with approved ECLS services, regardless of geographic origin in Florida or financial
eligibility. The only valid grounds for refusal of admission shall be the lack of availability of a functional ECLS bed. Admission to an ECLS program does not constitute acceptance of a patient for eligibility under the RPICC Program.

2. All neonates admitted to an ECLS program shall be evaluated for RPICC program eligibility. Only those patients who meet both the medical and financial criteria as defined in chapter 64C-6, F.A.C., and the specific ECLS criteria, shall be eligible for the RPICC Program.

3. Demographic, medical, and fiscal data shall be collected on all RPICC Program patients and entered into the RPICC data system.

F. Selection Criteria.

1. ECLS is indicated for selected newborns with severe, acute cardiac or respiratory failure that have failed to respond to conventional medical management.

2. Each approved ECLS program in a RPICC will develop and annually review and revise institutional criteria for ECLS therapy, including indications and contraindications.

3. The institutional criteria of each ECLS program will be renewed annually, concurrent with RPICC site visits, by the CMS RPICC neonatal consultant, or a designee of the Deputy Secretary of CMS.

4. It is recognized that the medical criteria for ECLS will be dynamic and are subject to change. Current diagnoses that appear to be appropriate for consideration of the initiation of ECLS include:

   a. Meconium aspiration syndrome.

   b. Aspiration syndromes other than meconium.

   c. Persistence of fetal circulation (primary pulmonary hypertension).

   d. Disorders with a component of pulmonary hypertension such as but not limited to: sepsis, severe pneumonia, selected patients with severe respiratory distress syndrome where conventional therapy has been ineffective.

   e. Congenital diaphragmatic hernia.

   f. Congenital massive pulmonary cysts.

   g. Selected patients with pulmonary hypoplasia.

   h. Non-immune hydrops.

   i. Congenital heart disease in the post operative period with conditions such as
pulmonary vasoactive crisis, cardiogenic shock, or low cardiac output when there has been a satisfactory anatomic repair.

j. As an adjunct to a CMS approved cardiovascular surgery program for neonates.

k. As an adjunct to a CMS approved organ transplant program for neonates (lung and cardiac).

l. Preoperative and postoperative support for patients with congenital heart disease with pulmonary hypertension.

5. It is also recognized that additional medical and surgical criteria for ECLS as an adjunct to approved CMS Cardiovascular Surgery programs are dynamic and subject to change. Current cardiovascular programs that may have a need for ECLS in the support of preoperative and postoperative conditions include management of low output states prior to and following cardiac surgery, preoperative management of patients identified for cardiac transplantation who deteriorate while awaiting donor organs, and postoperative support to allow a cardiac graft time to function. Due to the dynamic character of advances in congenital heart surgery and transplantation for neonates, an exhaustive list of conditions cannot be given at this time. There may be areas of overlap outside the customary definition of the neonatal period.

6. Only a neonate whose attending physician is a CMS approved neonatologist in an RPICC ECLS program is eligible for the RPICC Program. In those institutions where there is joint responsibility for the care of ECLS patients by CMS consultant neonatologists and CMS approved pediatric surgeons, the neonate may be considered for eligibility under the RPICC Program for ECLS services.

G. Services.

1. Physician Services - The patient record must contain written comments on the patient’s treatment and condition by the CMS approved neonatologist or the CMS approved pediatric surgeon, as applicable, or a CMS approved cardiologist, a CMS approved cardiovascular surgeon, or a resident physician’s or fellow’s note co-signed by the CMS approved neonatologist documenting the neonatologist’s or pediatric surgeon’s continuing involvement in the care of the neonate.

2. ECLS Technical Services - the ECLS technical specialist working in the RPICC ECLS Center shall have knowledge and skills in the following:

a. Direct care to the ECLS patient, post-cannulation, including drawing of blood samples, administration of medications and fluids, checking of the circuit, monitoring heat exchanger temperature, maintenance of heparin infusions, analysis of activated coagulation time (ACT) level, collection of data, and adjustment of gas and pump flow per ECLS protocol.

b. Maintains detailed and complete documentation specific to the ECLS patient.

c. Maintains patency of the cannula while the neonate is undergoing ECLS
treatment.

d. If the technical specialist is a nurse, demonstrates expertise in neonatal nursing, including psychosocial aspects of care, technical skills and primary nursing.

e. Has knowledge of neonatal medication, ventilator management and care, routine laboratory values, knowledge of blood products and blood administration, and knowledge of neonatal medication and monitoring in the neonatal patient.

3. Ancillary Services - Each Level III neonatal intensive care unit with approved ECLS services shall meet all applicable laboratory and x-ray services, nutrition services, respiratory therapy services and social services requirements as specified in chapter 64C-6, F.A.C.

4. Transport Services - Each RPICC ECLS Center shall provide or arrange for, but not necessarily be financially responsible for, 24-hour transport of neonates in need of ECLS services within the RPICC ECLS program.

5. RPICC neonates requiring ECLS services must be referred to a CMS RPICC ECLS program.

H. RPICC ECLS Quality Assurance.

1. A well defined system shall be instituted for assuring that formal meetings of key ECLS team members occur on a routine basis to review all cases, equipment needs, administrative needs, and other pertinent issues. Minutes to these meetings shall be available for review. Quality management records must be available for review upon request to on-site reviewers.

2. A prompt review of any major complication or death will be held both with ECLS team members and with the responsible Morbidity and Mortality Committee in the hospital. These reviews may be conducted simultaneously or separately.

3. Formal clinical-pathological case reviews with a multi-disciplinary approach shall be regularly conducted (as outlined by the Joint Commission for Accreditation of Health Care Organizations [JCAHO] regulations).

4. An annual data report, utilizing the program’s collated report of data submitted to the ELSO Neonatal ECLS Registry, shall be available for quality assurance review.

5. Records documenting maintenance of equipment should be kept and maintained current (as per JCAHO regulations).

6. Each RPICC neonatal intensive care ECLS program will periodically, but at least annually, provide the CMS Central Office with a detailed report of all patients undergoing ECLS at the RPICC at the time of the on-site visit or when requested. This report shall include, as a minimum: patient initials, age, sex, survival vs. mortality, diagnosis and appropriate ancillary diagnoses, and current ECLS criteria for patient selection. In
addition, each center shall participate in the ELSO Neonatal ECLS Registry.

7. Each center will assure that coordination is made with the CMS Early Steps Program to ensure access to evaluation and the provision of intervention services for each RPICC Program neonate who receives ECLS services.