3.25 STANDARDS FOR NEONATAL INTENSIVE CARE UNITS (NICUs)

3.25.1 Regional NICU – General Information

A. Regional NICU – Definition

1. For the purpose of the California Children’s Services (CCS) program, a Regional Neonatal Intensive Care Unit (NICU) shall be defined as a nursery within a CCS-approved Tertiary Hospital that has the capability of providing a full range of neonatal care services (intensive, intermediate, and continuing care as defined in Section 3.25.1/A.2.), including neonatal surgery, for severely ill neonates and infants. Regional NICUs shall provide support to Community and Intermediate NICUs that includes, but is not limited to, professional education and consultation.

2. Types of care provided to severely ill neonates in a Regional NICU shall be defined as follows:
   a. “Intensive care” is that care which is provided to neonates and infants who require:
      1) twelve hours or more of nursing care by a registered nurse per 24-hour period; and
      2) continuous cardiopulmonary monitoring; and
      3) other specialized care technology for their multisystem problems.
   b. “Intermediate care” is that care which is provided to neonates and infants who require:
      1) greater than or equal to eight hours, but less than 12 hours, of nursing care by a registered nurse per 24-hour period; and
      2) other medically-necessary support.
   c. “Continuing care” is that care which is provided to neonates and infants who require:
      1) greater than or equal to six hours, but less than eight hours, of nursing care by a registered nurse per 24-hour period; and
      2) may have previously received intermediate or intensive care but who no longer require intermediate or intensive care.
CHAPTER 3 - PROVIDER STANDARDS

Regional NICU – General Requirements and Procedure for CCS Program Approval

1. A hospital with an NICU wishing to participate in the CCS program as a Regional NICU for the purpose of providing care to sick infants shall be licensed by the Department of Health Services (DHS), Licensing and Certification Division, under California Code of Regulations (CCR), Title 22, Division 5, Chapter 1 as an:

a. acute general hospital, Article 1, Sections 70003, 70005; and

b. Intensive Care Newborn Nursery (ICNN), Article 6, Sections 70483 through 70489.

2. A Regional NICU

a. shall be located in a hospital approved by CCS as a Tertiary Hospital, as per Chapter 3.3.1, CCS Standards for Tertiary Hospitals; and

b. shall meet CCS Standards for Neonatal Surgery, as per Chapter 3.34, CCS Standards for Neonatal Surgery; and

c. shall only perform neonatal extracorporeal membrane oxygenation (ECMO) if approved by CCS as a Neonatal ECMO Center, as per Chapter 3.35, CCS Standards for Neonatal ECMO Centers.

3. A Regional NICU shall have Regional Cooperation Agreements as specified below:

a. A Regional NICU shall enter into written agreements, approved by the CCS program, with affiliated Community NICUs and/or Intermediate NICUs. All Regional Cooperation Agreements shall specify mutual responsibility for at least the following:

1) joint education and training of perinatal health professionals; and

2) joint development of guidelines for obtaining consultation by perinatal, neonatal, and other specialty disciplines as necessary; and

3) joint development of guidelines for maternal and neonatal patient referral and transport to and from each facility/NICU; and

4) joint identification, development and review of protocols, policies and procedures related to the care of the high-risk obstetric and neonatal patient, at least every two years; and

5) joint review of outcome data, based on CCS requirements, at least annually.
b. The Regional Cooperation Agreement shall be developed, negotiated, signed, and dated prior to CCS approval by at least the following persons from each hospital:

1) Hospital Administrator; and
2) Medical Director of the NICU; and
3) Medical Director, Maternal-Fetal Medicine, (hospitals without licensed perinatal beds are exempt from this requirement); and
4) Nurse Administrator.

It shall be the mutual responsibility of the Regional and the Community or Intermediate NICUs to review annually and recommend any modifications of said agreement to reflect the evaluation of outcome.

4. An NICU shall meet and maintain CCS Standards for Regional NICUs, as contained within this Chapter. All NICUs shall conform to the most current edition of the American Academy of Pediatrics and The American College of Obstetricians and Gynecologists (AAP/ACOG) Guidelines for Perinatal Care. Where there is a conflict with specific AAP/ACOG recommendations and CCS Standards, the CCS Standards for NICUs shall apply.

5. A hospital wishing to participate in the CCS program for the purpose of providing care to sick infants which meets NICU requirements, shall complete a CCS NICU application in duplicate and submit both copies to: Department of Health Services; Chief, Children's Medical Services Branch; California Children's Services Program; 714 P Street, Room 350; P.O. Box 942732; Sacramento, CA 94234-7320. Questions concerning the standards and the application process should be directed to the appropriate CMS Regional Office.

6 Review Process

a. Upon receipt, the NICU application will be reviewed by the appropriate CMS Regional Office. A site visit will be scheduled if the documentation submitted by the hospital appears to meet the CCS Standards for Regional NICUs.

b. The site review shall be conducted by a state CCS review team in accordance with established CCS procedures for site visits. The team shall consist of State staff augmented by consultant experts in the fields of neonatology, neonatal critical care nursing, and, as indicated, by other medical specialists.

c. Approval shall be based on compliance with CCS Standards for Regional NICUs and upon site review of NICU procedures, services provided, patient chart review the demonstration of community need and NICU patient outcome data.
Approval may be withheld if there is not a community need based on geographic considerations and a lack of sufficient caseload that is necessary to maintain proficiency in the care of critically ill neonates. The CCS program may consult with other divisions or branches within the DHS, such as the Maternal and Child Health Branch and/or Licensing and Certification Division and with other state and federal agencies to determine community need.

After the site visit, the following types of approval actions may be taken by the CCS program:

a. **Full approval** is granted when all CCS Standards for Regional NICUs are met.

b. **Provisional approval** may be granted when all CCS Standards for Regional NICUs appear to be met, however, additional documentation is required by the CCS program. This type of approval may not exceed one year.

c. **Conditional approval**, for a period not to exceed six months, may be granted when there are readily remediable discrepancies with program standards. The hospital must present a written plan for achieving compliance with program standards, and the plan must be approved by the CCS program. If the discrepancies are not corrected within the time frame specified by the CCS program, approval shall be terminated.

d. **Denial** is based upon failure of the hospital to meet CCS program standards.

A hospital shall be notified in writing of the decision regarding approval status within 90 days after the site visit. A hospital whose application has been denied may appeal the decision by submitting a letter in writing to the Chief, Children's Medical Services Branch, within 30 days of receipt of the notification of denial.

Annually, as determined by CMS, the hospital shall submit a list of staff who meet the qualifications as specified in the CCS Standards for Regional NICUs to: Department of Health Services; Children's Medical Services Branch; Attention: Center Desk; 714 P Street, Room 398; P.O. Box 942732; Sacramento, CA 94234-7320. This list shall be accompanied by a copy of the most current hospital license. Any changes in the professional staff or facility requirements mandated by these standards shall be reported to the State CMS Branch at the address in Section 3.25.1/B.5. above within 30 days of occurrence.

Periodic reviews of CCS-approved NICUs may be conducted on an annual basis or as deemed necessary by the CCS program. If an NICU does not meet CCS program requirements, the NICU may be subject to losing CCS approval.
C Regional NICU -- CCS Program Participation Requirements

1 Facilities providing services to CCS-eligible clients shall agree to abide by the laws, regulations, and policies of the CCS and Medi-Cal programs. Specifically, facilities shall agree to:

a. Refer all neonates/infants with potentially eligible CCS conditions to the CCS program for review of CCS program eligibility.

b. Assist families with the CCS referral and enrollment process by providing CCS application forms, phone numbers, and office locations.

c. Request prior authorization from the CCS program, as per Title 22, Section 42180

d. Notify the local CCS program office, in a timely manner, of specialized neonatal transport methods for potentially eligible neonates/infants to and from the facility/NICU.

e. Accept referral of CCS-eligible clients including Medi-Cal patients, whose services are authorized by CCS.

f. Serve CCS-eligible clients regardless of race, color, religion, national origin, or ancestry.

g. Bill client's private insurance, Medi-Cal or Medicare within six months of service in accordance with Medi-Cal and Medicare regulations regarding claims submission time frames or within 12 months for private insurance prior to billing CCS, including Medi-Cal or Medicare, if the client is eligible for such coverage.

h. Bill CCS within:

1) six months from the date of service if the client does not have third party insurance coverage; or

2) six months from the date of receipt of insurance payment/denial, including an explanation of benefits from the insurance carrier; or

3) twelve months from the date of service if insurance carrier fails to respond

Utilize electronic claims submission when available, upon CCS request.

Accept CCS payment for authorized services in accordance with state regulations as payment in full.

k. Provide copies of medical records, discharge summaries, and other information as requested by the CCS program within ten working days of request.
Provide annual reports as requested by the CCS program

m. Provide services in a manner that is family centered and culturally competent including the provision of translators and written materials.

n. Permit CCS staff to visit and monitor facilities to assure ongoing compliance with CCS standards.

o. Assist and cooperate with CCS staff in the on-site utilization review by CCS staff of services provided to CCS-eligible clients.

2. Failure to abide by the regulations and procedures governing the CCS program may result in the removal of the hospital from the list of CCS-approved facilities.

D. Regional NICU - Exclusions

Hospitals that are formally and involuntarily excluded from participation in programs of federal and state agencies shall automatically be excluded from participation in the CCS program.

2. A hospital may also be excluded by the CCS program because of, but not limited to, the following:

a. Failure to successfully complete the CCS approval process;

b. Inadequate and/or untimely addressing of deficiencies identified during a CCS site visit;

c. Loss of Joint Commission on Accreditation of Healthcare Organizations accreditation; or

d. Failure to abide by the laws, regulations, standards, and procedures governing the CCS program.

E. Regional NICU - Organization

1. There shall be a separate and identifiable administrative unit for the NICU

2. Medical care of the Regional NICU shall be under the direction of a medical director:

   a. Who shall meet the qualifications contained in Section 3.25.1/F.;

   b. Whose primary responsibility shall be the organization and supervision of the Regional NICU; and
c. Who shall not be the medical director of more than one NICU (Regional, Community or Intermediate) other than at the same contiguous medical building complex.

3. There shall be a Regional NICU nurse manager:
   a. Who shall have the responsibility on a 24-hour basis for the organization, management, supervision and quality of nursing practice and nursing care in the NICU;
   b. Who shall not be a nurse manager of more than one NICU other than at the same contiguous medical building complex; and
   c. Who shall meet the requirements contained in Section 3.25.1/F

4. The Regional NICU medical director and the Regional NICU nurse manager shall have joint responsibility for the development and review of an ongoing quality improvement program.

5. The Regional NICU medical director and the Regional NICU nurse manager shall have joint responsibility for development and review of a Policies and Procedures Manual for the NICU which addresses, at a minimum, patient admission, patient care, discharge and transfer criteria.

6. There shall be an identified NICU multidisciplinary team:
   a. Which shall have the responsibility for coordination of all aspects of patient care and
   b. Which shall consist of, at a minimum, a CCS-paneled neonatologist, a clinical nurse specialist, a respiratory care practitioner and a CCS-paneled medical social worker with current experience and practice in neonatal care and whose professional requirements are defined in Section 3.25.1/F. Optional members of the Regional NICU multidisciplinary team may include, but are not limited to, the following: CCS-paneled clinical registered dietitian, CCS-paneled occupational therapist and CCS-paneled physical therapist.

F Regional NICU - Professional Resources and Requirements

1 Regional NICU Physician Staff

1.1 Regional NICU Medical Director
   a. There shall be a full-time CCS-paneled neonatologist as the medical director:
      1) Who shall have overall responsibility for the quality of medical care for the infants admitted to the NICU; and
b. The responsibilities of the Regional NICU medical director shall include, but are not limited to, the following:

1) Participation in the development, review and assurance of the implementation of NICU policies and procedures as specified in Section 3.25.1/1.

2) Approval of, at a minimum, written criteria that defines the following:
   a) Which infants admitted to the NICU require care to be provided by a neonatologist; and
   b) Which infants require consultation by a neonatologist; and
   c) Which infants requiring intermediate or continuing care who may be managed by a CCS-paneled pediatrician who has evidence of current experience and practice in neonatal medicine and who meets the requirements defined in Section 3.25.1/F.1.3.e.

3) Supervision of quality control and quality assessment activities (including morbidity and mortality reviews).

4) Assuring NICU staff competency in resuscitation techniques.

5) Assuring ongoing NICU staff education.

6) Participation in NICU budget preparation.

7) Oversight of neonatal/infant transport to and from the NICU.

8) Assuring maintenance of NICU database and/or vital statistics.

c. The facility shall maintain written documentation of the qualifications and responsibilities of the Regional NICU medical director.
1.2 Regional NICU Neonatologist Staff

The Regional NICU medical director shall have two or more full-time equivalent associate neonatologists on staff:

a. Who shall be CCS-paneled neonatologists; and

b. Who shall share the clinical care responsibilities of the NICU; and

c. Who shall be certified by the American Board of Pediatrics and certified by the American Board of Pediatrics in the subspecialty of Neonatal-Perinatal Medicine; and

d. Associate neonatologists shall meet all board certification requirements within four years of becoming eligible to sit for the subspecialty examination; and

e. Who shall have evidence of current successful completion of the Neonatal Resuscitation Program course of the AAP and AHA.

1.3 Regional NICU Additional Physician Staff

a. A CCS-paneled pediatric cardiologist shall be on the hospital staff, on-call, and available on-site to the NICU in less than one hour.

b. At a minimum, the following CCS-paneled pediatric subspecialists with neonatal expertise shall be on the hospital staff and readily available for in-hospital consultation to the NICU on a 24-hour basis: neurologist and geneticist/dysmorphologist.

c. At a minimum, the following CCS-paneled pediatric subspecialists with neonatal expertise shall be readily available for consultation to the NICU: ophthalmologist, gastroenterologist, endocrinologist, nephrologist, pulmonologist, hematologist/oncologist, infectious disease specialist, and immunologist.

d. CCS-paneled surgeons (pediatric surgeon, neurosurgeon, orthopedic surgeon, otolaryngologist, urologist, cardiovascular surgeon and plastic surgeon), anesthesiologists with special expertise in neonatal anesthesia and radiologists shall be on hospital staff; shall meet the requirements contained in Chapter 3.34 of the CCS Standards for Neonatal Surgery and Chapter 3.3.1 of the CCS Standards for Tertiary Hospitals; and shall be available in-hospital for consultation to the NICU on a 24-hour basis.

e. CCS-paneled pediatricians may provide care to infants requiring intermediate and/or continuing care under the direct supervision of the Regional NICU medical director or CCS-paneled neonatologist. The CCS-paneled pediatrician shall:
1) be certified by the American Board of Pediatrics with evidence of current experience and practice in neonatal medicine; and

2) meet the continuing education requirements as specified in Section 3.25.1/K.; and

3) have evidence of current successful completion of the Neonatal Resuscitation Program course of the AAP and AHA.

2. Regional NICU Nurse Staff

Nurse staff titles or positions listed in CCS Standards may differ from those used in a facility. For the purpose of CCS Standards for NICUs, the facility is allowed to have an individual whose staff title is not the same as that used in the CCS Standards, however, the individual shall meet the requirements described below.

2.1 Regional NICU Nurse Manager

a. The Regional NICU nurse manager shall direct the nursing administrative operation of the NICU, as per Section 3.25.1/E.3. and shall:

1) be a registered nurse (R.N.) licensed by the State of California holding a master's degree in nursing; or

2) be a R.N. holding a bachelor's of science degree in nursing (BSN) and either a master's degree in a related field or certificate in nursing or health care administration from a nationally recognized accrediting organization; and

3) have at least three years of clinical nursing experience at least one of which shall have been in a facility with an NICU that is equivalent to a Regional or Community NICU.

b. The responsibilities of the Regional NICU nurse manager shall include, at a minimum, personnel, fiscal and materiel management, and coordination of the quality improvement program for the NICU.

c. The Regional NICU nurse manager shall directly supervise the nurse supervisor(s) for the NICU.

d. The facility shall maintain written documentation of the qualifications and responsibilities of the Regional NICU nurse manager.

e. The Regional NICU nurse manager shall have direct responsibility to the administrative director of nursing or individual holding an equivalent position.
2.2 Regional NICU Nurse Supervisor

a. The Regional NICU nurse supervisor shall directly supervise personnel and assure the quality of clinical nursing care of patients in the NICU at all times.

b. The Regional NICU nurse supervisor shall:

1) be a R.N. licensed by the State of California with a BSN;

2) have at least three years of clinical experience, one year of which shall have been in a facility with an NICU that is equivalent to a Regional or Community NICU;

3) have evidence of current successful completion of the Neonatal Resuscitation Program course of the AAP and AHA; and

4) have current certification in Neonatal Intensive Care Nursing from a nationally recognized accrediting organization, i.e., the National Certification Corporation (NCC).

c. The Regional NICU nurse supervisor shall have 24-hour responsibility for:

1) the direct supervision of all clinical personnel who provide patient care; and

2) the day-to-day coordination of and quality of clinical nursing care of patients in the NICU.

d. The facility shall maintain written documentation of the qualification and responsibilities of the Regional NICU nurse supervisor.

e. The Regional NICU nurse supervisor shall not be assigned direct patient care responsibilities.

2.3 Regional NICU Clinical Nurse Specialist

a. There shall be a minimum of one full-time equivalent clinical nurse specialist (CNS) for the Regional NICU.

b. The Regional NICU CNS shall:

1) be a R.N. licensed by the State of California;
2) be certified by the State Board of Registered Nursing as a CNS, as per the California Business and Professions Code, Chapter 6, Section 2838 of the Nursing Practice Act;

3) have at least three years of clinical experience in neonatal nursing care at least one of which shall have been in a facility with an NICU that is equivalent to a Regional or Community NICU;

4) have current certification in Neonatal Intensive Care Nursing from a nationally recognized accrediting organization, i.e. the NCC; and

5) have evidence of current successful completion of the Neonatal Resuscitation Program course of the AAP and AHA.

c. The Regional NICU CNS shall be responsible for:

1) directing the clinical nursing practice in the NICU;

2) coordination and assessment of critical care educational development and clinical competency of the nursing staff in the NICU; and for ensuring continued neonatal critical care nursing competency through educational programs for both the newly-hired and experienced nursing staff;

3) consultation with staff on complex neonatal critical care nursing issues

4) oversight of comprehensive parent and or primary caretaker education activities; and

5) ensuring the implementation of a coordinated and effective discharge planning program.

d. The facility shall maintain written documentation of the qualifications and responsibilities of the Regional NICU CNS.

2.4 Regional NICU Neonatal Nurse Practitioner (optional)

a. Neonatal nurse practitioners (NNPs) who provide care for infants in the NICU shall:

1) be a R.N. licensed by the State of California, as per CCR, Title 16, Division 14, Section 1482;

2) have evidence of current successful completion of the Neonatal Resuscitation Program course of the AAP and AHA; and

3) have completed the NNP program in accordance with CCR, Title 16, Division 14, Article 8, Sections 1480 through 1485.
b. The NNP shall provide medical and nursing care under the supervision of the medical director of the NICU or the CCS-paneled neonatologist and shall function in accordance with standardized procedures as per CCR, Title 16, Division 14, Article 7, Sections 1470 through 1474.

2.5 Regional NICU Charge Nurse

a. There shall be at least one Regional NICU charge nurse for each shift in the NICU who shall:

1) be a R.N. licensed by the State of California

2) have education, training, and demonstrated competency in neonatal critical care nursing;

3) demonstrate competency in the role of a charge nurse; and

4) have evidence of current successful completion of the Neonatal Resuscitation Program course of the AAP and AHA.

b. The responsibilities of the Regional NICU charge nurse during each shift shall include the following:

1) coordinating the patient care activities in the NICU; and

2) ensuring the delivery of quality patient care.

c. The facility shall maintain written documentation of the qualifications and responsibilities of the Regional NICU charge nurse.

2.6 Regional NICU Registered Nurses

a. R.N.s who are assigned direct patient care (intensive, intermediate, and continuing care) responsibilities in the Regional NICU shall:

1) be licensed by the State of California;

2) have education, training and demonstrated competency in neonatal critical care nursing; and

3) have evidence of current successful completion of the Neonatal Resuscitation Program course of the AAP and AHA.

b. R.N.s functioning in an expanded role shall do so in accordance with standardized procedures as per CCR, Title 16, Division 14, Article 7, Sections 1470 through 1474.
c. The facility shall maintain written documentation of the qualifications and responsibilities of the R.N. staff which shall include, at a minimum, the standards of competent performance of the R.N. staff providing care in the Regional NICU.

2.7 Regional NICU Licensed Vocational Nurses

a. Licensed vocational nurses (LVNs) who provide nursing care in the NICU shall only provide nursing care to infants requiring continuing care and shall:

1) be licensed by the State of California;
2) have demonstrated competency in neonatal critical care nursing;
3) have evidence of current successful completion of the AHA Basic Life Support (BLS) or equivalent course;
4) be limited to those responsibilities within their scope of practice, as per CCR, Title 16, Division 25, Chapter 1; and
5) be under the direction of a R.N.

b. The facility shall maintain written documentation of the qualifications and responsibilities of the LVN, which shall include only those responsibilities in accordance with their scope of practice, as per CCR, Title 16, Division 25, Chapter 1.

2.8 Regional NICU Unlicensed Assistive Personnel

a. Unlicensed Assistive Personnel, as defined by the State Board of Registered Nursing Position Statement, Unlicensed Assistive Personnel (September 1994), shall function in accordance with written policies and procedures which delineate the non-nursing task(s) the unlicensed assistive personnel is allowed to perform on infants requiring continuing care in the NICU under the direction of a R.N. These non-nursing tasks shall require no scientific knowledge and/or technical skill.

b. The unlicensed assistive personnel may be utilized only as assistive to licensed nursing personnel under the direction of a R.N.

3. Regional NICU Respiratory Care Practitioner

a. Respiratory care services shall be provided by respiratory care practitioners (RCPs) who are licensed by the State of California and who have additional training and experience in neonatal respiratory care. Additional training in neonatal respiratory care shall be demonstrated by the following:
1) Completion of a formal neonatal respiratory therapy course at an approved school of respiratory therapy that includes didactic and clinical course work; or

2) Completion of a minimum of 20 hours of didactic and four weeks of precepted neonatal clinical experience in a hospital-based course at a facility with an NICU equivalent to a Regional or Community NICU.

b. The facility shall maintain a written job description delineating the qualifications and duties of the RCP in the NICU which reflects the provision of practice in accordance with Business and Professions Code, Respiratory Care Practice Act, Chapter 8.3, Article 1, Section 3702 and CCR, Title 16, Division 13.6, Articles 1 through 8.

c. The RCP shall be responsible, at a minimum, for the monitoring and application of respiratory equipment.

d. There shall be an identified RCP with expertise in neonatal respiratory care practice available at all times to the NICU.

e. RCPs shall be assigned solely to the NICU when supportive ventilation is being provided and the staffing level shall be such that immediate availability of the RCP to the NICU is assured at all times.

f. There shall be a system in place for ensuring continuing clinical respiratory care competency through educational programs both for the newly-hired and experienced RCP staff in accordance with CCR, Title 16, Division 13.6, Article 5.

g. All RCPs providing services in the NICU shall have evidence of current successful completion of the Neonatal Resuscitation Program course of the AAP and AHA.

4. Regional NICU Medical Social Worker

a. Social work services shall be provided in the NICU by a CCS-paneled medical social worker (MSW) holding a master’s degree in social work who has expertise in psychosocial issues affecting the families of seriously ill neonates/infants.

b. For every 15 patients in the NICU, there shall be one full-time equivalent MSW.

c. The facility shall maintain a written job description defining the qualifications, responsibilities and functions of the MSW in the Regional NICU.

d. There shall be 24-hour coverage by a MSW for the Regional NICU.

e. There shall be a written agreement with CCS-approved Community and/or Intermediate NICUs with which the Regional NICU has a Regional Cooperation Agreement for providing telephone consultation from a MSW on a 24-hour basis, as specified in Section 3.25.1/H.12.
5. Regional NICU Pharmaceutical Services
   a. There shall be at least one licensed pharmacist holding a doctoral degree in 
      pharmacy (PharmD) with neonatal expertise available for consultation to Regional 
      NICU staff.
   b. Pharmacy staff and pharmaceutical services shall be available on a 24-hour basis 
      to the Regional NICU.
   c. Pharmacy staff shall provide neonatal unit doses including individual neonatal 
      intravenous and parenteral nutrition solutions, and neonatal nutritional products, in 
      clearly marked containers; and shall also provide continuous drug surveillance.
   d. Pharmaceutical services shall also meet the requirements contained in 
      Chapter 3.3.1 of the CCS Standards for Tertiary Hospitals.

6. Regional NICU Clinical Registered Dietitian
   a. Nutritional consultation to the Regional NICU shall be provided by a CCS-paneled 
      clinical registered dietitian who has clinical experience in pediatric and neonatal 
      nutritional services.
   b. The clinical registered dietitian shall meet the requirements contained in Chapter 
      3.3.1 of the CCS Standards for Tertiary Hospitals.
   c. There shall be a written agreement with CCS-approved Community and/or 
      Intermediate NICUs with which the Regional NICU has a Regional Cooperation 
      Agreement, for providing telephone consultation from a clinical registered dietitian 
      as specified in Section 3.25.1/H.

7. Regional NICU Occupational Therapy Staff
   There shall be a CCS-paneled occupational therapist available to the Regional NICU who 
   meets the requirements contained in Chapter 3.3.1 of the CCS Standards for Tertiary 
   Hospitals.

8. Regional NICU Physical Therapy Staff
   There shall be a CCS-paneled physical therapist available to the Regional NICU who 
   meets the requirements contained in Chapter 3.3.1 of the CCS Standards for Tertiary 
   Hospitals.
G. Regional NICU – Facilities and Equipment

The Regional NICU shall be a distinct, separate unit within the hospital

2. The Regional NICU shall meet the following bed requirements

a. There shall be at least 16 licensed ICNN beds for providing intensive, intermediate, and continuing care and:

   1) At least eight of the licensed beds shall meet all requirements pertaining to space (80 square feet per patient station), equipment, supplies, and physical environment for provision of intensive care as required in the ICNN regulations, CCR, Title 22, Division 5, Sections 70483 through 70489.

   2) There shall be at least eight beds in the Regional NICU providing intermediate and/or continuing care. These beds shall be licensed as required in Section 3.25.1/G.2.a.1) above or licensed under program flexibility, CCR, Title 22, Division 5, Article 4, Section 70307. Beds licensed under program flexibility shall not be used for intensive care and shall, at a minimum, have the following:

      a) fifty square feet for each patient station exclusive of space needed for storage, desks, counters, treatment rooms, etc.; and

      b) eight electrical outlets, two oxygen outlets, two compressed air outlets, and two suction outlets per patient station.

b. Beds in addition to the 16 required in Sections 3.25.1/G.2.a.1) and 2) which provide only continuing care and are licensed under program flexibility, CCR, Title 22, Division 5, Article 4, Section 70307, shall at a minimum, have the following:

   1) forty square feet for each patient station exclusive of space needed for storage, desks, counters, treatment rooms, etc.; and

   2) four electrical outlets, one oxygen outlet, one compressed air outlet and one suction outlet per patient station.

c. For the purpose of CCS Standards, program flexibility granted by Licensing and Certification for areas other than beds/patient stations, shall be superceded by the requirements in this document.

3. A Regional NICU shall have the following space/rooms available within, adjacent to, or in close proximity to the NICU:

   a. an on-call physician’s room/sleeping quarter;
b. a parent waiting room;

c. a separate room available for parent and infant interaction in privacy; and

d. a separate room for parent and physician/staff conferences, NICU multidisciplinary team conferences, case presentations, teaching/in-service education, and other staff meetings.

4. In addition to meeting the requirements contained in CCR, Title 22, Division 5, Article 6, Section 70487, Intensive Care Newborn Nursery Service Equipment and Supplies, a Regional NICU shall also have:

a. Beds licensed for intensive care, as required in the ICNN regulations, that meet the following requirements:

   1) monitoring equipment at each infant station in the NICU that have, at a minimum, the capability to monitor:

      a) heart rate and electrocardiogram (ECG);
      b) respiratory rate;
      c) temperature; and
      d) oxygen saturation and/or transcutaneous PaO2.

   2) individual infant monitoring equipment that have features including, at a minimum, the following:

      a) visible and audible high/low alarms for heart rate, respiratory rate, and all pressures;
      b) hard-copy capability for the rhythm strip;
      c) routine testing and maintenance of all monitors; and
      d) two pressure monitor channels.

b. Beds licensed for intermediate care, and are not used for intensive care, that meet the following requirements:

   1) monitoring equipment at the infant station in the NICU that have at a minimum the capability to monitor:

      a) heart rate and ECG;
      b) respiratory rate;
      c) temperature; and
d) oxygen saturation and/or transcutaneous PaO₂

2) individual infant monitoring equipment that have features including, at a minimum, the following:
   a) visible and audible high/low alarms for heart rate, respiratory rate, and pressures;
   b) routine testing and maintenance of all monitors; and
   c) one pressure monitoring channel per every two beds.

c. Beds licensed for continuing care, and are not used for intensive care or intermediate care, that meet the following requirements:

   1) monitoring equipment at the infant station in the NICU that have the capability to monitor:
      a) heart rate and ECG;
      b) respiratory rate; and
      c) oxygen saturation.

   2) individual infant monitoring equipment that have features including, but not limited to, the following:
      a) visible and audible high/low alarms for heart rate and respiratory rate and
      b) routine testing and maintenance of all monitors.

d. Equipment available for infants in the NICU that includes, but is not limited to, the following:

   1) emergency ("code" or "crash") cart with emergency drugs with size/weight appropriate neonatal unit doses and a defibrillator;

   2) neonatal surgical cut-down trays (including equipment for umbilical vessel catheterization, thoracostomy, chest and pericardial tube placement, peripheral vessel cutdown, and exchange transfusion);

   3) chest tube drainage, collection, water seal, and suction devices;

   4) incubators;

   5) radiant heat device;

   6) heart rate/respiratory rate/blood pressure monitors;
7) blood pressure transducers
8) automated noninvasive blood pressure apparatus;
9) pulse oximeter;
10) neonate scale(s), 10 kilogram;
11) 500 gram scale(s), with one gram increments;
12) infusion pumps (with microinfusion capability);
13) intravenous stands;
14) suction pressure regulators;
15) suction/drainage bottles;
16) vascular access equipment;
17) suction catheters in a range of sizes, (i.e. 10, 8, 6 French [Fr], and smaller);
18) feeding tubes # 5 and # 8 Fr;
19) nasogastric tubes # 10 Fr;
20) stethoscopes, infant size appropriate;
21) otoscopes and ophthalmoscopes;
22) neonate laryngoscope with # 0 and # 1 laryngoscope blades, spare batteries, and bulbs;
23) endotracheal tubes, sterile and disposable, sizes 2.5, 3.0, 3.5, 4.0 mm with malleable stylets;
24) oral airways;
25) portable surgical illumination/procedure lamp;
26) wall clocks with sweep second hand; and
27) portable transilluminator.

e. Equipment for infants available to the NICU that includes, but is not limited to, the following:

1) ECG machine;
2) central venous catheters, both temporary and permanent;
3) phototherapy lights;
4) refrigerators;
5) ice maker;
6) surgical tray stands;
7) supply carts;
8) blood warming apparatus;
9) heating mattresses;
10) electric breast pump; and
11) freezer for storage of breast milk.

f. Respiratory equipment for infants available in and/or to the NICU that includes, but is not limited to, the following:
1) oxygen-air blenders;
2) gas flow meters (oxygen and air);
3) continuous oxygen analyzers with alarms;
4) oxygen humidifier/nebulizer with heater;
5) oxygen temperature detectors with alarms;
6) oxygen hoods;
7) ventilation bag, 500 ml flow-through with adjustable pop-off valve capable of generating pressure of 40-50 mm Hg;
8) face masks in appropriate sizes for neonates;
9) mechanical ventilators;
10) CPAP capability either via ventilator or separate units;
11) aerosol medication administration equipment; and
12) chest physiotherapy and suctioning equipment.

5. Oxygen and compressed air, supplied from a central source, shall supply 50 pounds per square inch (psi) with an alarm system to warn of a critical reduction in line pressure. Reduction valves and blenders shall produce concentrations of oxygen from 21 percent to 100 percent at atmospheric pressure for head hoods and 50 psi for mechanical ventilators. Oxygen monitoring for inspired concentrations shall be available in the NICU.
6. Transport equipment with provisions for temperature control, ventilation, and cardiopulmonary monitoring shall be available for transport of infants within the hospital. Transport equipment shall meet the conditions in CCR, Title 22, Division 5, Article 6, Section 70487.

7. Diagnostic imaging procedures and consultation services necessary for the level of care provided shall be available on a 24-hour basis as specified in Chapter 3.3.1 of the CCS Standards for Tertiary Hospitals.

8. Laboratory services and consultation services necessary for the level of care provided shall be available on a 24-hour basis. There shall be the capability for a ten minute turnaround time for pH and blood gas determinations.

H. Regional NICU – Patient Care

1. CCS-eligible infants in the Regional NICU requiring intensive care shall be under the direct supervision of the Regional NICU medical director or CCS-paneled neonatologist.

2. A CCS-paneled pediatrician who meets the requirements contained in Section 3.25.1/F., in consultation with a neonatologist, may provide care to infants requiring intermediate or continuing care.

3. Infants requiring intensive care provided by a NNP shall have daily review, evaluation, and documentation of care by a CCS-paneled neonatologist. Infants requiring intermediate or continuing care provided by a NNP shall have daily review, evaluation, and documentation of care by a CCS-paneled neonatologist or CCS-paneled pediatrician.

4. A CCS-paneled neonatologist or CCS-paneled pediatrician shall review, evaluate, and document the clinical management of each infant, on-site, at least on a daily basis.

5. It shall be the responsibility of the CCS-paneled neonatologist to ensure that information is provided, on an ongoing basis, to referring physicians regarding their patients.

6. There shall be a CCS-paneled neonatologist on-call to the Regional NICU on a 24-hour basis who:

   a. shall be in the hospital or be no more than 30 minutes away from the NICU at any time; and

   b. shall not be on-call for more than one hospital at the same time; and

   c. shall be notified of new admissions and adverse changes in the status of neonates in a timely manner as described in Section 3.25.1/H.7 below.

7. A neonatologist, pediatrician in postdoctoral training in neonatal-perinatal subspecialty medicine, a NNP, and/or a physician who has completed more than two years of a
postgraduate pediatric residency training program with experience and training in neonatology shall be in-house and called:

a. to evaluate every infant on admission; and
b. whenever an unstable infant is in the NICU; and
c. when there is a major change in an infant's condition which requires a reevaluation

8. There shall be 24-hour in-house coverage by a professional staff member (physician, NNP, and/or R.N.):

a. who has evidence of current successful completion of the Neonatal Resuscitation Program course of the AAP and AHA; and
b. who is proficient in needle aspiration for pneumothorax and intubation for resuscitation.

9. Nurse staffing in the Regional NICU shall meet the requirements contained in CCR, Title 22, Division 5, Article 6, Section 70485; Section 3.25.1/F.2.; and shall also include the following:

a. The nurse supervisor or designee shall be present in the NICU at all times.
b. There shall be at least one nurse supervisor assigned to the NICU for every 30 full-time equivalent NICU positions or 50 NICU staff members to be supervised, whichever is less.
c. There shall be a R.N. assigned to each patient in the NICU.
d. There shall be no less than two R.N.s physically present in each area of care of the NICU at all times, when a patient is present.
e. A NNP assigned to the NICU may not be included in the calculation of nurse staff to infant ratio in the NICU.
f. There shall be no more than one LVN for every three R.N.s assigned to provide direct nursing care to infants requiring continuing care.

10. Unlicensed assistive personnel in the NICU may only be assigned non-nursing tasks to infants requiring continuing care and which require no scientific knowledge and/or technical skill.

11. RCP staffing shall be based on the level of required patient care as determined by the attending neonatologist or physician designee and shall consider the acuity of, and numbers of, patients in the NICU.
12. There shall be a MSW assigned to all patients upon admission to the NICU; and:
   a. A social work assessment shall be completed within two working days of admission.
   b. The social work assessment shall include an interview of at least one of the infant’s parents or primary caretaker(s). The parent(s) or primary caretaker(s) shall be included as early as possible in the decision-making process(es) relating to the care of their infant.
   c. A preliminary case service plan shall be developed with the parent(s) or primary caretaker(s) within five working days of admission to the NICU which shall include, but not be limited to, assessment of the following: significant family stress factors, environmental factors, mental health factors, and any other psychosocial factors, and how these factors in the family will be addressed.
   d. Social work progress notes shall be completed at least on a weekly basis, or more often as indicated, and shall include psychosocial data, significant changes in the infant’s family, updates and results of the implementation of the service plan and plans to continue contact with the family for ongoing support.
   e. MSW reports and notes shall be recorded in the infant's chart and shall be readily available to other NICU team members.
   f. The authorizing CCS program shall have access to social work reports in order to coordinate services.

13. The Regional NICU shall provide physician, nursing, social work and clinical registered dietitian consultation, on a 24-hour basis, to the CCS-approved Community and Intermediate NICUs with which the Regional NICU has a Regional Cooperation Agreement.

14. Physicians, nurses, medical social worker, and clinical registered dietitian shall be available for consultation to community practitioners and facilities who refer patients to the NICU.

15. There shall be, at a minimum, weekly NICU multidisciplinary team conferences (rounds).
   a. The NICU multidisciplinary team conference shall include representation from the NICU’s medical, nursing, medical social service, RCP staff, and other specialists, i.e., the clinical registered dietitian, occupational therapist and physical therapist, when appropriate.
   b. Minutes of these weekly team conferences which document attendance and discussion of plan(s) of care for the individual infants shall be included either in the infant’s chart or in a binder that shall be available for review by CCS program staff.
The Regional NICU medical director shall ensure, either directly or through written agreements with another NICU or agency, that a mechanism for neonatal transport exists.

a. The Regional NICU neonatal transport team program or the written neonatal transport agreement for the provision of transport services of infants by another NICU or agency shall be subject to CCS program approval. The neonatal transport agreement shall be updated and signed annually by the medical directors of NICUs involved in the agreement.

b. The medical director of the neonatal transport program shall be responsible for a written neonatal transport plan which shall include, but is not limited to, the following:

1) a summary of the neonatal transport training program; and

2) annual evaluation and documentation of competency in neonatal transport of the neonatal transport team members by the Regional NICU medical director or CCS-paneled neonatologist designee; and

3) requirement of a minimum number of preceptored neonatal transports for new neonatal transport team members; and

4) maintenance of written records of each neonatal transport completed shall be available for review by CCS program staff.

c. The NICU shall agree to accept, on a space and staff available basis, any infant requiring a level of care beyond that which can be provided by a hospital with which the NICU has transport agreements and/or by the Regional Perinatal Dispatch Center. All guidelines and reporting requirements of the Regional Perinatal Dispatch Center shall be followed.

The medical director of the NICU, or a CCS-paneled neonatologist designee providing the neonatal transport, shall be responsible for:

a. Selecting the method of transport to be used;

b. The medical care of infants during transport; and

c. Designating neonatal transport team members to be utilized for transport of unstable, potentially unstable and stable infants.

1) The transport team for unstable and potentially unstable infants shall:

a) Include a physician, a NNP, or a R.N. functioning in an expanded role under standardized procedures in accordance with CCR, Title 16, Division 14, Article 7, Sections 1470 through 1474 who:
shall have advanced skills which include, but are not limited to, endotracheal intubation, needle aspiration, and placement of an umbilical venous catheter; and

shall have evidence of current successful completion of the Neonatal Resuscitation Program course of the AAP and AHA and shall function in an expanded role under standardized procedures in accordance with CCR, Title 16, Division 14, Article 7, Sections 1470 through 1474.

b) Also include at least one other professional who may be a physician who has completed three or more years of a postgraduate pediatric residency training program, a NNP, a neonatal R.N. with advanced neonatal skills and/or an RCP. Transport team members shall be determined by the neonatologist. The composition of the team shall be balanced to provide all required skills.

c) The transport team shall be in attendance during the entire transport procedure.

2) A stable infant may be transported by a R.N. who has NICU experience and who shall have evidence of current successful completion of the Neonatal Resuscitation Program course of the AAP and AHA.

18. The Regional NICU shall participate in the California Newborn Hearing Screening Program (NHSP) and shall perform a hearing screening test on each infant receiving care in the NICU using protocols approved by DHS.

Regional NICU—General Policies and Procedures

1 There shall be a Regional NICU Policies and Procedures Manual which shall be:

a. Updated, reviewed, and signed at least on an annual basis by the medical director and nurse manager of the Regional NICU; and

b. Readily available in the NICU for all NICU staff.

2. The written Policies and Procedures Manual for the Regional NICU shall address/include, but not be limited to, the following:

a. Criteria delineating the clinical privileges granted to attending CCS-paneled physicians other than neonatologists. Criteria shall include definitions of:

1) those infants requiring intermediate or continuing care who may be managed by a CCS-paneled pediatrician; and
2) those infants requiring consultation by a neonatologist;

b. Criteria for admission of infants to the NICU;

c. Criteria for infant discharge from the NICU and infant transfer to/from the NICU;

d. Criteria for monitoring infants in the NICU;

e. Pain management and sedation for operative/medical procedures;

f. Criteria for NICU staff to provide neonatal resuscitation in the delivery room and written protocol for the provision of skilled neonatal resuscitation in the delivery room;

g. Mechanism for bioethical review of neonatal patients when indicated;

h. Mechanism for infection surveillance, prevention, and control in the NICU;

Discharge planning process which includes the roles of the designated coordinator for discharge planning and the NICU multidisciplinary team members with the parent or caretaker and the referring physician, primary care physician, and any specialized follow-up agency, including CCS Special Care Centers and the Early Start Program;

j. Parent visitation in the NICU;

k. Mechanism for the referral to the hospital’s child abuse and neglect team or Child Protective Services on a 24-hour basis;

A written plan that facilitates a family-centered and culturally competent approach to NICU care by the professional staff which includes, but is not limited to, the following:

1) A system that will encourage and provide for inclusion of the parent(s) or primary caretaker(s) in the decision-making process relating to the care and interventions of their infant as early as possible; and

2) A method for the parent(s) or primary caretaker(s) to provide input and feedback to the NICU multidisciplinary team members regarding their infant’s care and experiences in the NICU.

m. A system to ensure that all infants who are provided care in the NICU receive a hearing screening test prior to hospital discharge, in accordance with the California NHSP and as mandated by California Health and Safety Code, Section 123975.
A system to ensure that an ophthalmology examination is performed on infants at risk for retinopathy of prematurity, as defined by the most recent joint statement of the AAP, the American Association for Pediatric Ophthalmology and Strabismus, and the American Academy of Ophthalmology. The ophthalmology examination shall be performed by a CCS-paneled ophthalmologist with experience in the examination of preterm infants.

J. Regional NICU – Discharge Planning Program

Discharge of infants from a Regional NICU shall be the responsibility of the CCS-paneled neonatologist or CCS-paneled pediatrician responsible for the care of the infant. Discharge planning, at a minimum, shall include but not be limited to the following:

1. Designation of a coordinator for discharge planning who shall be responsible for:
   a. Ensuring collaboration between the NICU multidisciplinary team members and communication with the primary care physician, community agencies, CCS programs, CCS Special Care Centers, Medi-Cal In-Home Operations Unit, and the Early Start Program whose services may be required and/or related to the care needs of the infant after hospital discharge; and
   b. Ensuring that each infant discharged from the NICU shall have follow-up by a primary care physician and a program specialized in the follow-up care of the high-risk infant.

2. Identification of the responsibilities and involvement of the NICU multidisciplinary team members in discharge planning activities on an ongoing basis.

3. Ensuring culturally and linguistically appropriate written discharge information shall be given to the parent(s) or primary caretaker(s) participating in the infant’s care at the time of discharge and shall include, but not be limited to, the infant’s diagnoses, medications, follow-up appointments, including community agencies and High-Risk Infant Follow-up program appointments and instructions on any medical treatment(s) that will be given by the parent(s) or primary caretaker(s). A copy of this written discharge information shall be sent to the primary care physician and as applicable, agencies involved in providing follow-up care.

4. Ensuring that infants, determined by a neonatologist to be ready for discharge from a Regional NICU to a facility closer to the home of the parent or primary caretaker shall
   a. be transferred to a CCS-approved NICU for those who continue to require NICU care, or
   b. be transferred to a CCS-approved hospital appropriate for those who no longer require NICU care but require continued hospitalization for the CCS-eligible condition.
5. Provision for teaching the parent, legal guardian, and/or primary caretaker about the medical needs of the infant, including the use of necessary technology to support the infant in the community, when appropriate.

K. Regional NICU – Quality Assurance and Quality Improvement

1. There shall be an ongoing quality assurance program specific to patient care activities in the Regional NICU that is coordinated with the hospital’s overall quality assurance program.
   a. Documentation shall be maintained of the quality assurance and quality assessment activities provided.
   b. Documentation shall include utilization review and medical records review which shall be available for on-site review by CCS program staff.

2. There shall be morbidity and mortality conferences held at least quarterly to discuss neonatal care issues. These conferences shall be held conjointly with professionals in obstetrics and/or perinatal subspecialties.
   a. CCS encourages multidisciplinary participation, including primary care physicians, as well as participation by outside consultants on a regular basis.
   b. A hospital without licensed perinatal beds is exempt from having joint conferences but shall have neonatology staff morbidity and mortality conferences.
   c. Meeting agendas, lists of attendees, and minutes of such conferences shall be maintained and available for on-site review by CCS program staff.

3. There shall be a written plan that facilitates a family-centered and culturally competent approach to NICU care by the professional staff. This plan shall include, but not be limited to, a mechanism for the parent(s) or primary caretaker(s) to provide input and feedback to NICU multidisciplinary team members regarding their infant’s care and experiences in the NICU. This may be in the form of a patient/family satisfaction questionnaire.

4. There shall be a formalized method for the Regional NICU medical director to review and document, on an annual basis, professionals who are required to successfully complete the Neonatal Resuscitation Program course of the AAP and AHA as described in Section 3.25.1/F.

5. There shall be a formalized method for reviewing and documenting, on an annual basis, the skills of professionals responsible for 24-hour in-house coverage of the following:
   a. Neonatal resuscitation and intubation. This review shall be based on maintaining evidence of current successful completion of the Neonatal Resuscitation Program course of the AAP and AHA; and
b. needle aspiration for pneumothorax

6. There shall be annual reviews of the neonatal transport program and an evaluation of the members making up the neonatal transport team by the medical director of the NICU or CCS-paneled neonatologist designee.

7. Infant morbidity and mortality data concerning birth weight, survival, transfer, incidence of certain conditions, and other information as required, shall be compiled in a CCS-approved format and shall be submitted to the Chief, Children’s Medical Services Branch/CCS Program; 714 P Street, Room 350; P.O. Box 942732; Sacramento, CA 94234-7320; annually and are due on the first day of June for the data of the preceding calendar year.

8. Assurance of continuing education for staff providing services in the NICU shall include, at a minimum, the following:

a. There shall be a written plan for orientation of all newly-hired professionals who will be providing care in the NICU and an ongoing evaluation of the program. This written plan shall include the competencies required of the professional staff and documentation of successful demonstration of these competencies.

b. There shall be written plans for the continuing education of all professionals involved in neonatal care.

1) The continuing education program shall include, but is not limited to, a neonatal/perinatal in-service education program for all professionals, held at least monthly.

2) CCS-paneled pediatricians providing care to infants requiring intermediate or continuing care shall document a minimum of 36 hours of continuing education in neonatal medicine every three years.

c. The Regional NICU shall have in-house educational programs which are based on the standards of practice for all professionals responsible for providing care in the NICU as demonstrated by peer review journal articles and current professional reference books. These programs shall be provided as specified in the requirements for the Regional Cooperation Agreement, as per Section 3.25.1/B.3.

d. There shall be a method for monitoring attendance of all professionals involved in neonatal care at the monthly continuing education programs.

8. The latest editions of the following texts and documents shall be kept in the NICU

a. Red Book: Report of the Committee on Infectious Diseases, Committee on Infectious Diseases, American Academy of Pediatrics;
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b. *Guidelines for Perinatal Care*, American Academy of Pediatrics and The American College of Obstetricians and Gynecologists (AAP/ACOG);

c. Two current reference books pertaining to the care of the high risk infant;

d. One current reference book pertaining to critical care nursing of the high-risk infant;

e. CCS Manual of Procedures, Chapter 3.25, CCS Standards for Neonatal Intensive Care Units;

f. CCS Manual of Procedures, Chapter 3.34, CCS Standards for Neonatal Surgery;

g. CCS Manual of Procedures, Chapter, 3.35, CCS Standards for Neonatal Extracorporeal Membrane Oxygenation Centers;

h. CCS Manual of Procedures, Chapter 3.3, CCS Standards for Hospitals;

i. Current listing of CCS medically eligible conditions; and

An annually updated Policies and Procedures Manual of the Regional NICU.

L. **Regional NICU – High Risk Infant Follow-up Program**

1. The medical director of the Regional NICU shall have responsibility for ensuring that all high-risk infants discharged from the NICU are referred to an appropriate high-risk infant follow-up (HRIF) program.

2. There shall be an organized HRIF program in the NICU's facility or there shall be a written agreement for the provision of services provided in high risk infant follow-up programs by another hospital or agency, including High Risk Infant Follow-up Special Care Centers.

3. The HRIF program shall conform with the CCS high risk infant eligibility criteria and components of service, as per the CCS Manual of Procedures, Chapter 2.17.2, CCS Medical Eligibility Criteria.