

Setting Up Your Agreements

Hospitals caring for mothers and babies can enter into a range of transferring and/or receiving agreements to assure that their clients have access to services appropriate to their needs. For example, the Regional Cooperation Agreement is a requirement for CCS-approved hospitals and should cover a range of institutional needs, including transfer/transport, outreach education and data review and program evaluation. Outreach education agreements, though not mandated by CCS or Title 22, reinforce the interhospital cooperation among perinatal care providers (AAP, Fifth Edition) to help assure quality of care. A third type of contractual arrangement, transfer/transport agreements, are mandated by Title 22 and cover interhospital transport for unavailable services at the hospital currently treating the patient. The major focus of transfer/transport agreements is to provide for safe, efficient, legal facilitation of patient movement from a transferring facility to a receiving facility. It should be noted that all facilities that have Intermediate and Community NICUs **MUST** have Regional Cooperation Agreements with one Regional level NICU. Refer to the *Perinatal Services Guidelines for Care: A Compilation of Current Standards, Update 2004 (Regional Perinatal Programs of California)* for the current ACOG/AAP, Title 22 and CCS requirements. All Regional level NICUs must have Regional Cooperation Agreements with Community and/or Intermediate NICUs.

Steps to Take

The following ten steps are a suggested process for determining your institutional needs and designing the optimal agreements to facilitate the provision of the highest level of perinatal care:

- Step 1: Acquaint yourself with the various kinds of agreements.
- Step 2: Do a self-assessment of your facility and its needs.
 - a. Review the standards.
 - b. Determine where you fit.
 - c. Consult your Regional Perinatal Program and/or the CCS/CMS (Children's Medical Services) Regional Office for assistance. See Appendices, RPPC Program Directors Roster and Children's Medical Services Roster.
 - d. Interview the CCS approved Regional NICUs with which you might partner.
- Step 3: Identify potential partners by considering the following factors:
 - a. Geographic distance from your facility.
 - b. Where do you currently send most of your babies that are transported out?
 - c. Which CCS approved Regional NICU offers the services you need?
 - d. Availability of sub-specialists.
 - e. With which NICU do you share medical staff?
- Step 4: Identify which agreements are needed by your facility.
- Step 5: Review the sample agreements in this section.
- Step 6: Determine fiscal and staffing resources that will be needed (see sample contract, cost estimate and budget justification in this section, Attachments C - G).
- Step 7: Select and adapt appropriate agreements.
- Step 8: Do joint planning with identified partner facilities to develop policies and procedures and set up timeline for review.
- Step 9: Sign and execute your agreement and send to CCS with your application.
- Step 10: Implement the agreement (See sample Tracking Form in this section).

A more in depth discussion of each step follows.

Step 1: Acquaint yourself with the various kinds of agreements

Transfer/Transport Agreements

Formal transport agreements between hospitals are developed to outline and clarify procedures for transport and responsibilities for patient care. Specific tasks of both the transferring and the receiving hospitals must be clearly delineated, especially with regard to which institution assumes responsibility for patient(s) care at specified times in the transfer process. A sample Transfer Agreement is included in Section 4, Attachment A.

There are regulations and standards that govern the development and implementation of Transport Agreements in the state of California. Each transport system must comply with the standards and regulations set forth by local, state and federal agencies. As an example, Title 22: Licensing and Certification of Health Facilities, Home Health Agencies, Clinics and Referral Agencies states, “A perinatal unit shall provide formal arrangements for consultation and/or transfer of an infant to an intensive care newborn nursery, or a mother to a hospital with the necessary services, for problems beyond the capability of the perinatal unit” [Title 22, 70547 (a)(4)].

There are three types of perinatal patient transport (AAP, 2002):

1. **Maternal transport** – A pregnant woman is transferred during the antepartum or intrapartum period for special care of the woman, the neonate or both
2. **Neonatal transport** -
 - A team is sent from the receiving hospital to the referring hospital to evaluate and stabilize the neonate at the referring hospital and then transfers the neonate to the referring hospital
 - A team is sent from the referring hospital with a neonate who is being transferred to another hospital for specialized or intensive care
 - A team is sent from one hospital to the referring hospital to evaluate and stabilize the neonate and then transfer the neonate to a third hospital (necessitated by bed or specialized care availability)
3. **Return transport** – A woman or her neonate, after receiving intensive or specialized care at a receiving center, is returned to the referring hospital or to a local hospital for continuing care after the acute problems that required the transfer have been resolved.

Standard – Transfer/Transport Agreements

The Title 22 regulations provide for the receiving Intensive Care Newborn Nursery to make available:

1. Consultation service to referring perinatal and neonatal units

2. Infant transport systems between perinatal and neonatal units and the Intensive Care Newborn Nursery
3. Continuing education for multidisciplinary staff of both the perinatal unit and neonatal and the Intensive Care Newborn Nursery
4. Review and evaluation of services offered at the perinatal and neonatal unit
5. Written policies and procedures to cover the aforementioned.

In addition they should:

1. Provide 24-hour service
2. Provide a continuum of care by various providers at the level of care dictated by the patient's condition and risk factors
3. Include a receiving center that assures high risk patients receive the appropriate level of care
4. Include a dispatch center to coordinate transport of patients between facilities
5. Include an appropriately equipped transport vehicle

Title 22 emphasizes the need for maintaining working relationships between referring perinatal units and Intensive Newborn Nurseries. The receiving unit has the task of providing joint staff conferences and continuing education for the multidisciplinary specialties, as indicated above.

Transfer/Transport Agreement Components

To assure optimal care for high risk patients, these components must be a part of a regional referral program:

1. Formal transport agreements between participating hospitals
2. Risk identification and assessment of problems that are expected to benefit from consultation and transport
3. Assessment of the perinatal and neonatal capabilities and determination of conditions necessitating consultation, referral or transfer by the medical staff of each participating hospital
4. Resource management
5. Adequate financial and personnel support
6. A reliable, accurate and comprehensive communication system between participating hospitals
7. Determination of responsibility for each of these functions

Signatures – Signers on the agreements are the same staff authorized to enter into contracts for the institution.

Agreement Partners – Partners to the agreement are perinatal units without Intensive Care Newborn Nurseries or units with neonatal intensive care units that do not have a full complement of services available for neonates and those institutions offering a higher level of care with Intensive Care Newborn Nurseries.

Outreach Education Agreements

Critical to the appropriate use of a regional referral program is a provision to educate the public and users about its capabilities. AAP emphasizes the need for both referring and receiving

hospitals to educate the public regarding services available at both kinds of institutions to assure that each level of care is sought and utilized appropriately.

Standard – Outreach Education Agreements

Outreach consultation and education should reinforce cooperation between all individuals involved in the interhospital care of perinatal patients by: (*AAP/ACOG Guidelines for Perinatal Care, 5th Edition*)

1. Receiving hospitals providing to transferring hospital information regarding their clinical capabilities
2. Receiving hospital ensuring that providers are aware of specialized resources available through the perinatal care network
3. Receiving hospital informs primary care providers of changes that occur in indications for consultation and referral of high-risk perinatal patients and for stabilization of their infants
4. Receiving hospital should provide continuing education and information to transferring providers and staff about current treatment modalities for high-risk situations

Effective outreach programs improve care capabilities of transferring hospitals and may allow for some patients to either be retained, or, if transferred, to be back-transferred earlier in their recovery course.

Outreach Education Program Components

Joint education and training of perinatal and neonatal health professionals is a requirement of the CCS RCA. An Outreach Agreement is included in the RCA and a separate agreement is not required. In fulfillment of the RCA a hospital may enter into an outreach agreement. Optional components may include:

1. Provision of medical in-service education with CME credits

Joint selection of topics to include but not limited to:

- Medical education lectures
- Electronic fetal monitoring strip reviews
- Case presentation and discussion
- Technical skill development

2. Provision of nursing in-service education and CEU credits

Joint selection of topics to include but not limited to:

- Nursing education lectures
- Electronic Fetal Monitoring strip reviews
- Case presentations and discussion
- Technical skill development

(See sample list of potential neonatal, obstetrical and pediatric nursing education topics that may be used to meet the affiliate hospital's identified educational needs as part of an outreach consultation and education agreement in Section 5, Attachment C)

There are hospitals in California that are not required to have a RCA but may choose to have one.

Regional Cooperation Agreements

The Regional Cooperation Agreement (RCA) as set forth by the California Children's Services (CCS) delineates responsibilities for both the referring hospital partner in the RCA and the receiving hospital. California Children's Services (CCS) requires all CCS Approved NICUs to enter into Regional Cooperation Agreements (RCAs) with appropriate level facilities in order to guarantee that appropriate outreach consultation and education occurs (*California Children's Services Manual of Procedures, Chapters 3.25.1, 3.25.2, 3.25.3, Issued 1/1/99*).

RCA Standard – Joint Responsibilities

California Children's Services requires that the CCS Approved Regional NICU, along with its RCA partner hospital, have joint responsibility for determining education needs and providing the education and training of staff. Further, there is a joint responsibility for development of perinatal, neonatal and other multidisciplinary specialty consultation guidelines along with maternal, neonatal and transport referral guidelines. Multidisciplinary telephone consultation requirements include nursing, social work, nutrition and medical specialties to be available on a 24-hour basis as set forth in the CCS Manual of Procedures, Chapter 3.25.1/H.13.

CCS regulations further require that both RCA partners have a responsibility for identification, development and review (at least every two years with approval from the receiving center required) of high-risk obstetric/neonatal protocols as well as policies and procedures. Additionally, there will be joint annual review of outcome data, based on CCS. This provides the basis for the annual RCA review for recommendations that can improve quality of care based on outcome and need.

Regional CCS NICU Responsibilities

The Regional CCS NICU has the responsibility for developing, negotiating and obtaining signatures for the RCA.

RCA Signatures – Signers are to include, at least, the following: hospital administrator, NICU medical director, Maternal Fetal Medicine Director (except for hospitals that are exclusively children's hospitals) and the nurse administrator. Signers may include representatives from the contracting department of the hospitals.

RCA Negotiators – RCAs should be negotiated between:

1. Regional Neonatologist, and the Medical Director of the referring (or sending) NICU and the nurse administrator
2. All of 1 plus Contracting Administrators
3. Regional nurse administrator and the sending Neonatologist
4. All of 1-3 plus Contracting Administrators
5. Regional Contracting Administrators and referring (or sending) Contracting Administrators

Agreements negotiated between other than the Medical Directors of the NICUs involved, administration and nursing (i.e. the persons providing the services specified in the RCA) have proven suboptimal. Other negotiators have resulted in deficient services delivered to contracting Intermediate and Community NICUs.

Community CCS NICU Responsibilities

The Community CCS NICU has the responsibility for requesting a RCA, developing, negotiating and obtaining signatures for the RCA.

RCA Signatures – Signers are to include, at least, the following: hospital administrator, NICU medical director, Maternal Fetal Medicine Director (except for hospitals that are exclusively children’s hospitals) and the nurse administrator. Signers may include representatives from the contracting department of the hospitals.

RCA Negotiators – RCAs should be negotiated between:

1. Regional Neonatologist, and the Medical Director of the referring (or sending) NICU and the nurse administrator
2. All of 1 plus Contracting Administrators
3. Regional nurse administrator and the sending Neonatologist
4. All of 1-3 plus Contracting Administrators
5. Regional Contracting Administrators and referring (or sending) Contracting Administrators

Intermediate CCS NICU Responsibilities

The Intermediate CCS NICU has the responsibility for requesting a RCA, developing, negotiating and having the RCA signed.

RCA Signatures – Signers are to include, at least, the following: hospital administrator, NICU medical director, Maternal Fetal Medicine Director (except for hospitals that are exclusively children’s hospitals) and the nurse administrator. Signers may include representatives from the contracting department of the hospitals.

RCA Negotiators – RCAs should be negotiated between:

1. Regional Neonatologist, and the Medical Director of the referring (or sending) NICU and the nurse administrator
2. All of 1 plus Contracting Administrators
3. Regional nurse administrator and the sending Neonatologist
4. All of 1-3 plus Contracting Administrators
5. Regional Contracting Administrators and referring (or sending) Contracting Administrators

Summary of Agreements for Perinatal Care

1. Basic/ Level I/ undesignated CCS (variously named by various references)
 - a. Responsibilities – have transfer/transport agreements with hospitals to whom the most maternal and neonatal patients are sent
 - b. Expectations of receiving hospital – most transported patients will be sent to them
2. CCS approved – Intermediate or Community NICU/ Level II
 - a. Responsibilities – to have entered into a full RCA with a CCS designated Regional NICU to which most mothers and babies are transported
 - b. Expectation of receiving hospital
 - Determine jointly with referring hospital staff education/training needs

- Jointly develop and review at least every two years perinatal, neonatal and other multidisciplinary specialty consultation guidelines as well as maternal, neonatal and transport referral guidelines.
- 3. CCS approved - Tertiary or Regional level NICU/ Level III
 - a. Responsibilities – to have entered into a full RCA with at least one hospital from which most mothers and babies are transported
 - b. Expectation of receiving hospital – determine jointly with referring hospital staff education/training needs
 - Jointly develop and review at least every two years perinatal, neonatal and other multidisciplinary specialty consultation guidelines as well as maternal, neonatal and transport referral guideline
 - Jointly review outcome data annually with specific process delineated in the RCA as to how this will occur

When the RCA language is approved by both the referring and the receiving CCS neonatal unit it should be signed by all appropriate parties and submitted to CCS with the application filing.

Step 2: Do a self-assessment of your facility and its needs

- A. Review the standards.
- B. Determine where you fit.
- C. Consult your CCS/CMS (Children’s Medical Services) Regional Office nurse consultant for assistance. Additional assistance is available from your Regional Perinatal Program.
- D. Interview the CCS Regional level NICU with which you might partner.

Step 3: Identify potential partners.

Consider the following factors in selecting partners:

- 1. Geographic distance from your facility.
- 2. Where do you currently send most of your babies that are transported out?
- 3. Which Regional CCS facility offers the services you need?
- 4. Availability of sub-specialists.

Step 4: Identify which agreements are needed by your facility.

Step 5: Review the sample agreements in this section.

Commonly Asked Questions

1. **Do I have to have a transfer/transport agreement with every hospital to which I send mothers or babies.**

ANSWER: Yes.

2. **How does a hospital initiate a RCA agreement?**

ANSWER: Contact the hospital in your region to which you transport the largest number of mothers and babies. If you require technical assistance in maneuvering the RCA process, contact your CCS/CMS (Children’s Medical Services) Regional Office nurse consultant. The Regional Perinatal Program office in your region can also assist you (See RPPC Program Roster in Section 8).

3. **How do I know what kinds of services to request?**

ANSWER: You can contact the CCS Regional office for requirements for CCS agreements. The contact person at the receiving CCS NICU will help you assess your needs. It may even involve a visit to your hospital to meet with you and your staff to help you and your staff determine what services you need.

4. **What kinds of agreements are there?**

ANSWER: Consult the table below for the kinds of agreements and the provisions of each.

Agreement	Provisions
1. Transfer/transport agreements	Contracts covering referrals via transport/transfer
2. Outreach education	Contracts for provision of staff education/training
3. RCA	Staff education/training Specialty/subspecialty/multidisciplinary consultation Transport/transfer agreements Joint policy/procedure development Joint outcome data review

5. **What happens to my RCA once it is signed?**

ANSWER: Submit a copy to CCS with the application to be filed.

6. **What if CCS does not approve the RCA or the application or both?**

ANSWER: CCS may grant provisional or conditional approval. In this case they will provide samples of remediation strategies and a timeline within which the changes are to be made. If CCS has serious concerns, it may be necessary to start again in the application process.

7. **If we have provisional approval and fail to meet CCS deadlines, what happens?**

ANSWER: Provisional approval may be extended or downgraded to conditional approval. Conditional approval is time limited. If specified conditions to be met within

this level of approval are not met within a specified time frame, then conditional approval may be removed.

8. Can one referring hospital have a Transfer Agreement with more than one receiving hospital?

ANSWER: Yes.

9. Can one referring hospital have a RCA with more than one Regional or Community NICU?

ANSWER: Yes.

10. Does a referring hospital HAVE to have a RCA with a CCS Regional or Community NICU in order to be in compliance with Title 22 Licensing and Certification regulations?

ANSWER: No. They only have to have a RCA if they are approved as a CCS Intermediate, Community or Regional NICU.

11. Can a transfer agreement between a CCS-approved referring hospital and a CCS-approved receiving hospital substitute for a fully executed RCA?

ANSWER: No. Transfer agreements only address the transfer component specified by CCS in their standards related to the content of a RCA. The other issues regarding education and training, development of multidisciplinary consultation guidelines, joint identification, development and review of protocols, policies and procedures and review of outcome data, and annual evaluation of the agreement are not routine components of a standard transfer agreement.

A CCS-approved NICU must have a RCA. In addition, there may be multiple agreements for specialty education, NRP certification, BSL, preceptorships, etc. between an approved CCS NICU and other contracting entities.

Standard AAP Regional level NICU Responsibilities

AAP stipulates that outreach education should reinforce collaboration and cooperation among those involved in the hospital-to-hospital transport and care of perinatal patients. Regional NICUs are charged with providing all referral hospitals with information about transport team response times, clinical capabilities and the specialized care resources available within the referral network. The referring hospital should be kept apprised of changes in the clinical course of the referred patient requiring consultations and altering care. This communication allows for retaining or back transporting clients as their course of care improves.

Step 6: Determine fiscal and staffing resources that will be needed (see samples included in this section)

Billing for Services Rendered

It is reasonable and appropriate for the facility providing the RCA services (e.g. the Regional level NICU) to charge the facility receiving the services (the affiliate hospital) the cost of providing that service. Expenses to consider when determining what constitutes the actual cost of providing Outreach Consultation and Education services include, but are not limited to, the following:

1. Hourly rate to hire staff to provide contractual services Rates will vary based on the credentials of the speakers (e.g. MD vs. RN vs. other ancillary staff)
2. Preparation time required for speaker to develop consultation/educational activities
3. Speaker travel time to and from the affiliate hospital site
4. Speaker travel expenses including airfare, mileage, parking, local transportation (e.g. shuttle, taxi) and lodging, if applicable
5. CME/CEU documentation expenses
6. Preparation of consultation/educational materials (e.g. handouts, PowerPoint presentations, and expenses related to photocopying, medical record procurement/delivery, postage and telephone consultation)
7. Affiliate fees vs. non-affiliate fees

Step 7: Select and adapt appropriate agreements

Step 8: Do joint planning with identified partner facilities to develop policies and procedures and set up timeline for review

Step 9: Sign and execute your agreement and send to CCS with your application

Step 10: Implement the agreement (See sample Tracking Form included in this section)

RCA Tracking

A system for consistently tracking the responsibilities embodied in the RCA will be put into place by the CCS receiving institution. The sample Tracking Form is a spreadsheet designed for this purpose on page 34 of this section.

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Letter for Developing Regional Cooperation Agreement

Dear _____:

We appreciate your facility's interest in developing a Regional Cooperation Agreement with _____ (your hospital) _____. The most recent California Children's Services (CCS) regulations of 1999 state that Community and Intermediate neonatal intensive care units enter into Regional Cooperation Agreements with a designated CCS Approved Regional NICU. If your facility does not have CCS status as a Community or Intermediate NICU, we are still able to provide your perinatal and neonatal departments with a Regional Cooperation Agreement to address your specific scope of practice.

Enclosed you will find information on the available Regional Cooperation Agreement option with _____ (your hospital) _____, depending on your CCS status or your specific needs.

In order to provide you with the best Regional Cooperation Agreement possible, I will be contacting you by phone after this letter to discuss any questions or revisions you may have.

It has been our pleasure to provide you with a relationship with our CCS Approved Regional NICU. _____, is the _____ (insert your hospital data/description here). Example: "...largest CCS Approved Regional NICU in Northern California. More than 1,000 infants are admitted each year to our NICU, a licensed 55 bed, tertiary care center. We have 6 board certified Neonatologists who are on site 24 hours a day. Our nursing staff of 150 is certified in the Neonatal Resuscitation Program and most are certified in advanced life support. Our specially trained Transport Team is available around the clock to bring infants and children from other hospitals to the Children's Center to receive the area's highest level of specialized intensive care services.")_____.

I look forward to talking with you soon. If you would like to contact me, please call me at _____.

Sincerely,

(your name)

(your title)

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Tertiary Care Center

Master Affiliation Agreement With Applicable Sub-Agreement(s)

I. INTRODUCTION

- A. _____, a California nonprofit public benefit corporation dba _____ (the “Center”), functions as a California Children’s Services (CCS) approved Tertiary Hospital for perinatal, neonatal, and pediatric services. The Center is also designated as a Pediatric Critical Care Center (PCCC) by the _____ Emergency Medical Services Agency and provides pediatric critical care services for the Northern region of the State of California. As a CCS and PCCC designated Tertiary Hospital, the Center provides a full range of medical and surgical services for critically ill premature and full term neonates and critically ill or injured infants and children.
- B. Affiliate Hospitals, defined hereunder, may require specific perinatal, neonatal, or pediatric support services from the Center in order to care for critically ill premature or full term neonates and critically ill or injured infants and children. In order to do so, CCS requires Affiliate Hospitals to enter an affiliation agreement with a tertiary hospital like the Center.
- C. Affiliate Hospitals may enter this Master Affiliation Agreement with the Center and meet CCS requirements to affiliate with a tertiary hospital to provide care to critically ill neonates, infants and children. This Master Affiliate Agreement contains four sub-agreements, each of which addresses the rights and responsibilities of the parties under the specific sub-agreement entered. The specific sub-agreement entered will depend on the type of services or support required by Affiliate Hospital.
- D. The four (4) sub-agreements contained within the Master Affiliation Agreement are designated as follows:
1. Neonatal, Pediatric and/or Maternal Transfer &Transport Sub-Agreement;
 2. Clinical Preceptorship Sub-Agreement;
 3. Education Sub-Agreement;
 4. Regional Cooperation Agreement Sub-Agreement;
- E. In addition to the four Sub-Agreements listed above, this Master Affiliation Agreement contains provisions which pertain to each and every Sub-Agreement executed. The provisions of this Master Agreement and only the specifically endorsed and executed Sub-Agreement(s), contained in Appendices A through D, comprise the entire agreement between the parties.
- F. The Center has agreed to enter into this Master Affiliation Agreement with _____, hereinafter known as the “Affiliate Hospital”. Affiliate Hospital hereby endorses the following Sub-Agreement for the following purpose:

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- Appendix A: Neonatal, Pediatric and/or Maternal Transfer & Transport Sub-Agreement A;
- Appendix B: Clinical Preceptorship Sub-Agreement B;
- Appendix C: Education Sub-Agreement C;
- Appendix D: Regional Cooperation Agreement Sub-Agreement D;

By signature below, Affiliate Hospital designates and executes the following Sub-Agreement, and agrees to be bound to the terms and provisions in this Master Affiliation Agreement and the executed Sub-Agreement. Provisions under other Sub-Agreements **not** endorsed and executed by Affiliate Hospital do not apply.

Affiliate Hospital

_____ (name)

hereby endorses and executes

Sub-Agreement(s) _____,

Title(s) of the Sub-Agreement(s)

Initial and date: _____

II. DEFINITIONS.

A. Center. _____ is a CCS approved Tertiary Hospital with the capability of providing a full range of neonatal and pediatric care services (intensive, intermediate, and continuing care) as defined in Section 3.25 1/A.2 of the CCS requirements.

B. Tertiary Hospital. A Tertiary Hospital is a hospital that is licensed by the Department of Health Services (CDHS), Licensing and Certification Division, under California Code of Regulations (CCR), Title 22, Division 5, Chapter 1, and is approved by CCS by meeting its program requirements.

C. Affiliate Hospital. The Affiliate Hospital is each individual hospital that associates with the Center by execution of the Master Affiliation Agreement and relevant Sub-Agreement.

D. Regional Cooperative Agreement. The Regional Cooperative Agreement is an agreement required by CCS standards, and necessitates cooperation between _____ and Affiliate Hospital to mutually negotiate and develop a Regional Cooperative Agreement that specifies mutual responsibility for professional education, methods to evaluate outcomes, and methods to modify provisions to reflect the evaluation of outcomes. The Regional Cooperative Agreement also serves as a Letter of Agreement for a Tertiary Center Affiliation between a Community PICU or Pediatrics and a CCS Approved Tertiary PICU.

E. Affiliate. _____ Affiliate is defined as any corporate entity of _____, a California nonprofit public benefit corporation.

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III. GENERAL PROVISIONS OF THE MASTER AFFILIATION AGREEMENT AND DESIGNATED SUB-AGREEMENT (S).

A. **Compliance with Rules and Laws.** Affiliate Hospital shall at all times comply with all applicable standards and recommendations of the Joint Commission on Accreditation of Healthcare Organizations, and all applicable federal, state and local laws, rules and regulations.

B. **Compliance Program.** Center and Affiliate Hospital represent that they have a compliance program that meets recommendations of the Office of Inspector General of the Department of Health Services. At the request of the Center, Affiliate Hospital will cooperate with any of the Center's compliance activities or specific recommendations or requirements relating to services provided under the Tertiary Care Center Affiliation Agreement.

C. **Insurance.** Each party shall maintain professional liability insurance in the minimum amounts of \$1,000,000 per occurrence/\$3,000,000 annual aggregate from an insurance company acceptable to the other party. If such insurance is on a "claims-made" basis, and such coverage is later terminated, or converted to an "occurrence" coverage (or vice versa), each party shall also acquire "prior acts" or "tail" coverage (as applicable), in the above amounts, covering all periods that this Agreement is or has been in force. Each party shall provide the other party with written evidence of such insurance upon other party's request.

D. **Use of Hospital Facilities.** Any facilities, equipment, supplies, or personnel provided by the Center shall be used by Affiliate Hospital solely to provide services under this Agreement and shall not be used for any other purpose whatsoever.

E. **Expenses.** Affiliate Hospital shall not incur any expense or financial obligation on behalf of the Center without the Center's prior written consent, which consent shall be in the Center's sole and absolute discretion. Affiliate Hospital shall be solely responsible for the all compensation attributable to any employees, subcontractors, or physicians engaged by Affiliate Hospital.

F. **Anti-Referral Laws.** Nothing in this Agreement, nor any other written or oral agreement, nor any consideration in connection with this Agreement, contemplates or requires or is intended to induce or influence the admission or referral of any patient to or the generation of any business for the Center. This Agreement is not intended to influence Affiliate Hospital's judgment in choosing the medical facility appropriate for the proper care and treatment of their patients, or restrict in any way Affiliate Hospital from establishing agreements with any other healthcare facility.

G. **EMTALA Provisions.** The Center and Affiliate Hospital shall comply with the Emergency Medical Treatment and Active Labor Act ("EMTALA"), also known as the "anti-dumping" law or "COBRA" (since it was part of the Consolidated Budget Reconciliation Act of 1985) and the implementing regulations dated June 22, 1994, as amended, and require all Medicare participating hospitals with an emergency department to provide appropriate medical screening examinations within the capability of the hospital's Emergency Departments, including ancillary services routinely available to the Emergency Departments to anyone who

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comes to the Emergency Department and on whose behalf a request is made for examination or treatment for a medical condition within the meaning of EMTALA;

EMTALA dictates that this medical screening examination cannot be conditioned upon the individual's ability to pay for services, and it cannot be delayed while the Affiliate Hospital investigates or inquires about the individual's ability to pay;

EMTALA requires that the Affiliate Hospital maintains a written list of physicians who are on call for duty to perform the initial screening examination and to provide treatment necessary to stabilize an individual with an emergency medical condition, and the Affiliate Hospital must maintain this list for five (5) years;

H. Nondiscrimination. Affiliate Hospital shall provide services to all patients requiring emergency care who present to the Affiliate Hospital without regard for payor classification or discrimination based upon indigent, Medicare, Medi-Cal, or any third party payor status.

I. Term and Termination.

1. Term. The term of this Agreement shall be one year commencing on the date of this Agreement, unless terminated earlier pursuant to **Section I.2.** hereof.

2. Early Termination

a. Immediate Termination by The Center. Either party may terminate this Agreement immediately by written notice to the other party upon the occurrence of any of the following events:

- (1) The occurrence of an event causing or likely to cause a failure by the other party to meet hospital qualification requirements of federal, state, or accreditation laws, regulations, or standards.
- (2) Loss of the Center's CCS approved Tertiary Service status, or sale or closure of the Center at which the Tertiary Service is located.

b. Material Breach. Subject to the immediate termination rights of Center set forth in Section **I.2.(a)**, either party shall have the right to terminate this Master Affiliation Agreement and designated Sub-Agreement upon a material breach of any terms or conditions of this Agreement by the other party, provided such breach continues uncured for 15 days after receipt by the breaching party of written notice of such breach from the non-breaching party. The parties hereto expressly acknowledge and agree that material breach includes, but is not limited to, any act or omission by Affiliate Hospital that jeopardizes the quality of care provided to patients.

c. Legal Jeopardy. If either party obtains a written opinion of legal counsel stating that, in the event of an audit or investigation, this Agreement is likely to be challenged by any governmental agency as illegal or improper or resulting in fines,

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penalties or exclusion from the Medicare or Medi-Cal programs, or in the case of the Center, loss of tax-exempt status or its ability to obtain tax-exempt financing, that party may terminate this Agreement by providing written notice, including a copy of such opinion, to the other party. Within ten days of such notice, the parties shall meet and confer to discuss mutually acceptable means of restructuring the relationship to eliminate the legal concern. In the event that the parties are unable to reach agreement on new terms within twenty days of their meeting, this Agreement shall automatically terminate.

d. **Without Cause Termination.** Either party may elect to terminate this Agreement, without cause, upon 30 days' written notice to the other party.

3. **Effect of Expiration or Termination.**

a. **Termination of Obligations.** Except as otherwise provided in this Section I.3.(a), upon expiration or other termination of this Agreement, the parties shall be relieved and released from any further duties and obligations under this Agreement.

b. **Pre-Termination Services.** Affiliate Hospital shall pay the Center any unpaid payment(s) due for any period prior to the termination date, with such monthly payment prorated on a daily basis if the termination date occurs on a day other than the last day of a month.

c. **Liability for Breach.** A termination by any party as a result of a material breach by the other party shall not be an exclusive remedy, and the non-breaching party shall be entitled to pursue other remedies for such breach available at law or in equity.

d. **Survival.** The provisions of Section III, paragraphs B, C, D, J, K, and N shall survive termination of this Agreement.

J. **Access to Books and Records.**

1. **Access.** Affiliate Hospital shall maintain and make available all necessary books, documents and records in order to assure that the Center will be able to meet all requirements for participation and payment associated with public and private third party payment programs, including but not limited to matters covered by Section 1861(v)(1)(I) of the Social Security Act, as amended. With respect to said Section 1861(v)(1)(I), Group agrees as follows:

(a) Until the expiration of four (4) years after the furnishing of such services, Affiliate Hospital shall, upon written request, make available to the Secretary of the Department of Health and Human Services (the "Secretary"), the Secretary's duly-authorized representative, the Comptroller General, or the Comptroller General's duly-authorized representative, such books, documents and records as may be necessary to certify the nature and extent of the costs of such services; and

(b) If any such services are performed by way of subcontract with a

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value or cost of \$10,000 or more over a twelve-month period, such subcontract shall contain, and Affiliate Hospital shall enforce, a clause to the same effect as subparagraph (1) immediately above.

2. **Limits.** The availability of Affiliate Hospital's books, documents, and records shall be subject at all times to all applicable legal requirements, including, without limitation, such criteria and procedures for seeking and obtaining access that may be promulgated by the Secretary by regulation.

K. **Confidentiality.**

1. **Center Information.** Affiliate Hospital recognizes and acknowledges that, by virtue of entering into this Master Affiliation Agreement and applicable Sub-Agreement, and coordinating services the Center hereunder, Affiliate Hospital may have access to certain information of the Center that is confidential and constitutes valuable, special and unique property of the Center. Affiliate Hospital agrees that it will not at any time, either during or subsequent to the term of this Master Affiliation Agreement with applicable Sub-Agreement, disclose to others, use, copy or permit to be copied, without the Center's express prior written consent, except pursuant to Affiliate Hospital's duties hereunder, any confidential or proprietary information of the Center, including, but not limited to, information which concerns the Center's patients, costs, prices and treatment methods at any time used, developed or made by the Center, and which is not otherwise available to the public.

2. **Terms of this Agreement.** Except for disclosure to Affiliate Hospital's legal counsel, accountant or financial advisors, Affiliate Hospital shall not disclose the terms of this Agreement to any person who is not a party or signatory to this Agreement, unless disclosure thereof is required by law or otherwise authorized by this Master Agreement and corresponding Sub-Agreement or consented to in writing by the Center.

3. **Patient Information.** Affiliate Hospital and Center shall not disclose to any third party, except where permitted or required by law or where such disclosure is expressly approved by the Center or Affiliate Hospital in writing, any patient or medical record information regarding the Center or Affiliate Hospital or the Center's or Affiliate Hospital's patients, and the Center and Affiliate Hospital shall comply with all federal and state laws and regulations, and all rules, regulations, and policies of the Center and Affiliate Hospital and their Medical Staff, regarding the confidentiality of such information, including, but not limited to, the Health Insurance Portability and Accountability Act (HIPAA) (45 C.F.R. Part 160, et seq.) and the Confidentiality of Alcohol and Drug Abuse Patient Records regulations (42 C.F.R. Part 2), as amended from time to time.

L. **Dispute Resolution.** In the event that any dispute arises between Affiliate Hospital and the Center arising out of or related to the validity, interpretation, enforcement or performance of this Master Affiliation Agreement and corresponding Sub-Agreement, or otherwise arising out of the relationship between the parties or the termination of that relationship, either party may by written notice call a meeting regarding such dispute to be attended by an executive officer of each party who has the authority to negotiate and bind that party to a resolution. At the meeting, the parties shall attempt in good faith to resolve the dispute. If the dispute cannot be resolved

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within forty-five (45) days from the date of the initial notice, and if any party wishes to pursue the dispute, the dispute shall be submitted to binding arbitration in accordance with the commercial rules of the American Arbitration Association. The decision of a single arbitrator shall be final and binding and shall be fully enforceable in any court having jurisdiction and venue over the parties. The arbitrator shall have no power to ignore or vary the terms of this Master Affiliation Agreement and corresponding Sub-Agreement and shall be bound by controlling law. The cost of such arbitration shall be shared equally by the Center and Affiliate Hospital. Each party shall bear its own legal expenses.

M. Notices. Any notices or other communications permitted or required by this Master Affiliation Agreement and applicable Sub-Agreement shall be deemed made on the day personally delivered in writing or three days after mailed by certified mail (or first class mail), postage prepaid, to the other party at the address set forth below or to such other persons and addresses as either party may designate in writing:

If to the Center:

With a copy to:

If to Affiliate Hospital:

N. Independent Contractor. No relationship of employer and employee is created by this Agreement. In performing the rights and duties identified in this Agreement, the parties are acting as independent contractors. Each party shall be responsible for its own salaries, payroll, taxes, withholdings, insurance, and other benefits of any kind. In no event shall either party have or exercise control over the manner in which the other party provides professional service to other services required by this Agreement.

O. Indemnification.

1. Center agrees to indemnify, defend and hold harmless Affiliate Hospital, its officers, employees, Participants and agents from any and all claims, demands, liabilities, expenses (including reasonable attorney's fees), or losses arising out of acts or omissions of Center, its officers, employees, or agents, in connection with any activity referred to in this Agreement, but only in proportion to and to the extent that such claims, demands, liabilities, expenses or losses result from the negligent, wrongful, or intentional acts or omissions of Center, its officers, employees, or agents.

2. Affiliate Hospital agrees to indemnify, defend and hold harmless Center, its officers, employees, Participants and agents from any and all claims, demands, liabilities,

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expenses (including reasonable attorney's fees) or losses arising out of acts or omissions of Affiliate Hospitals, its officers, employees, Participants or agents, in connection with any activity referred to in this Agreement, but only in proportion to and to the extent that such liabilities, expenses, or losses result from the negligent, wrongful, or intentional acts or omissions of Affiliate Hospital, its officers, employees, Participants or agents.

P. Finance. Affiliate Hospital shall pay Center for the specific clinical or education program which the Affiliate Hospital requests are provided to its Participants. The fees for the specific clinical program are designated under the applicable Sub-Agreement. This includes Pediatric Clinical Preceptorship, Pediatric Intensive Care Clinical Preceptorship, Labor and Delivery Clinical Preceptorship, Maternal Clinical Preceptorships, OB Scrub Technician Program Clinical Preceptorship and Neonatal Clinical Preceptorships and/or an education program.

Q. Miscellaneous.

1. No Waiver. No waiver of a breach of any provision of this Master Affiliation Agreement or corresponding Sub-Agreement shall be construed to be a waiver of any breach of any other provision.

2. Severability. The invalidity or unenforceability of any provision of this Master Affiliation Agreement or corresponding Sub-Agreement shall not affect the validity or enforceability of any other provision.

3. Assignability. The rights and obligations of each party under this Master Affiliation Agreement or corresponding Sub-Agreement shall inure to the benefit of the parties and to their respective successors and permitted assigns. Neither party may assign any of its rights and obligations under this Agreement without obtaining the prior written consent of the other party.

4. Use of Names and Logos. Neither party shall be permitted to use the other's name, logo or corporate identity for any purpose without the prior written consent of the party whose name, logo or corporate identity is to be used.

5. No Third Party Rights. The parties do not intend the benefits of this Master Affiliation Agreement or corresponding Sub-Agreement to inure to any third person not a signatory to this Agreement. Notwithstanding anything contained herein, or any conduct or course of conduct by any party to this Agreement, before or after signing this Agreement, this Agreement shall not be construed as creating any right, claim or cause of action against either party by any person or entity not a party to this Agreement.

6. Governing Law. This Agreement shall be governed by and construed and enforced in accordance with the laws of the State of California.

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7. **Counterparts.** This Master Affiliation Agreement and corresponding Sub-Agreement may be executed in any number of counterparts, each of which shall be deemed an original and all of which together shall constitute one and the same instrument.

8. **Entire Agreement.** This Master Affiliation Agreement and corresponding Sub-Agreement(s) _____ (designate in the space provided) constitutes the entire agreement of the parties with respect to the subject matter hereof.

9. **Amendments.** Amendments to this Master Affiliation Agreement or corresponding Sub-Agreement shall be made only in writing duly executed by both parties hereto.

10. **Force Majeure.** If either party is unable to perform its duties under this Master Affiliation Agreement or corresponding Sub-Agreement due to strikes, lock-outs, labor disputes, governmental restrictions, fire or other casualty, emergency, closure of the facility or department, etc., or any other cause beyond the reasonable control of the party, such non-performing party shall be excused the performance by the other party, and shall not be in breach of this Agreement, for a period equal to any such prevention, delay or stoppage. Notwithstanding this provision, a party may terminate this Master Affiliation Agreement and corresponding Sub-Agreement immediately upon written notice if such events continue for 30 days.

11. **Status of Participants.** It is understood that each party is responsible only for the actions of its respective officers, agents, Participants, and employees; that Affiliate Hospital Participants are not employees of Center; and that Center does not assume liability under any law or otherwise on account of any act of any Affiliate Hospital Participant in performing services, receiving training or traveling to or from site or other activities carried on in furtherance of this Agreement.

12. **Attorney's Fees.** If any legal action or proceeding is brought to enforce or interpret this Agreement, the prevailing party shall be entitled to recover from the other party all reasonable costs, including but not limited to reasonable costs and attorney's fees, including such fees and costs as may be incurred in enforcing a judgment or order entered in any arbitration or legal action. Any judgment or order entered in such action shall contain a specific provision providing for the recover of such attorney's fees and costs.

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IV. Signature Page. By their signatures below, each of the following represent that they have authority to execute this Agreement and to bind the party on whose behalf their execution is made.

Affiliate Hospital:

The Center:

Hospital Administrator

Tertiary Hospital Administrator

Medical Director NICU

Medical Director, Regional NICU

Medical Director, OB/Perinatal

Medical Director, OB/Perinatal

Medical Director, Pediatrics

Medical Director, Tertiary PICU

Nursing Administrator

Chief Nurse Executive

Date:

Date:

Address:_____

Address:_____

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Attachment C

Regional Cooperation Agreement – Addendum For CCS Undesignated Hospital

For hospitals without California Children’s Services (CCS) involvement.

Optional responsibilities:

1. Review of education and training plans/programs for perinatal and neonatal health professionals in the area of stabilization of high-risk obstetric patients and infants. This joint review shall be completed annually.
2. Review of policies, procedures and protocols related to the care of high-risk obstetric and neonatal patients. This review shall be jointly completed at least every two years.
3. Joint review of developed data elements to provide quality review of newborn data through conference call and/or written evaluation. These data elements will include: volume of births, birth weights of infants, criteria for maternal and newborn transport, outcomes of maternal and neonatal transports. Other data elements may be mutually developed according to specific needs. This review will be done annually.
4. Review of guidelines for obtaining consultation by perinatal, neonatal, and other specialty disciplines as applicable and as necessary.

The addendum is in effect from _____ to _____.

The fee for providing services specified within the Regional Cooperation Agreement (Undesignated) Addendum will be \$_____.

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Attachment D

Sample removed; please use Attachment E on page 31.

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Attachment E

Regional Cooperation Agreement – Addendum For CCS Community Designated NICU

For hospitals that have California Children's Services (CCS) designation as a Community NICU.

Includes responsibilities set forth for Regional level NICUs by the CCS Standards in the following areas:

1. CCS Regional level NICU and Affiliate Hospital will jointly identify and develop education and training plan and/or program for perinatal, neonatal, and pediatric (if applicable) health professionals. CCS Regional level NICU will serve as a resource to Affiliate Hospital for education and training of personnel and for identification of areas for performance improvement. This will include additional clinical nurse preceptorship agreement and/or education agreement.
2. CCS Regional level NICU and Affiliate Hospital will jointly identify and develop policies, procedures and protocols related to the care of high-risk obstetric, neonatal, and pediatric patients (if applicable). Policies, procedures and protocols shall be jointly reviewed at least every two years.
3. CCS Regional level NICU and Affiliate Hospital will jointly review California Perinatal Quality Care Collaborative (CPQCC) data set required by CCS and may include other data elements as mutually identified. This will be done on an annual basis and may make modifications to the Addendum to reflect evaluation of the review. (If Pediatric data is reviewed, mutually agreed upon data set will be reviewed.)
4. CCS Regional level NICU and Affiliate Hospital will jointly develop guidelines for maternal and neonatal (pediatric, if applicable) patient referral and transports to an appropriate Tertiary or CCS Regional level NICU. With respect to transport from Affiliate Hospital to an appropriate Tertiary or CCS Regional level NICU, the following shall apply:
 - a. Patients in need of complex medical services that are beyond the scope of Affiliate Hospital to provide, as determined by the Affiliate Hospital Pediatric Medical Director, shall be referred to an appropriate CCS approved Tertiary or CCS Regional level NICU. Selection of this CCS Regional level NICU will be based upon geographical proximity of Hospital and sub-specialist availability.
 - b. Patients in need of invasive cardiac procedures, both diagnostic and therapeutic, shall be similarly transferred to a CCS-approved Cardiac Center.
5. CCS Regional level NICU and Affiliate Hospital will jointly develop guidelines for obtaining consultation by perinatal, neonatal, pediatric (if applicable) and other specialty disciplines, as applicable and as necessary. Specialty consultation will be provided to the Affiliate Hospital under CCS Standards.

The addendum is in effect from _____ to _____.

The fee for providing services specified within the Regional Cooperation Agreement (Community) Addendum will be \$_____.

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Attachment F

REGIONAL COOPERATION AGREEMENT COST ESTIMATES AND BUDGET JUSTIFICATION

Contract Hospitals: MD - \$/hour, including travel time
RN/RT/LCSW/RD - \$/hour, including travel time
RN/RT/MSW/RD/PT/OT Preceptorships - \$/week (40 clinical hrs)

Non-Contract Hospitals: MD - \$/hour, including travel time
RN/RT/LCSW/RD - \$/hour, including travel time
RN/RT/MSW/RD/PT/OT Preceptorships - \$/week

Personnel Costs: Personnel costs include, but are not limited to, the following:

1. Chart review
2. Literature review
3. Preparation of PM&M minutes, suitable for JCAHO documentation
4. Handout preparation
5. Transport follow-up and communication
6. Additional data collection/analysis
7. Coordination of schedules, content selection, personnel, etc.

An additional ___% charge is added to cover the expense of materials and non-professional services, including, but not limited to, the following:

1. Travel expenses
2. Document preparation
3. Photocopying
4. Preparation of educational materials (e.g., PowerPoint presentations, handouts, etc.)
5. Medical record procurement/delivery
6. Postage
7. Telephone consultation

Additional services included at no charge include the following:

1. 24-hour Maternal/Fetal, Neonatal, and Pediatric Critical Medicine telephone consultation.
2. Assistance with communication and patient service problem-solving for referred or transported patients.
3. Transport agreements to meet JCAHO and government agency standards, such as CCS.
4. Consultation and review by Program staff on policies, procedures, facilities and staffing issues.
5. Access to Program Resource Library including AV materials, literature searches, policy and procedures samples.
6. Nursing continuing education credits for all programs and preceptorships.

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Attachment G

EDUCATION/CONSULTATION CONTRACT

Contract Budget Justification*

Contract Hospital

	<u>Cost to Contract Hospital</u>
1. Quarterly (4) Perinatal Morbidity and Mortality Conferences MFN/Neo/RN 1.5 hours PM&M @ \$500/hour = \$750 X 4 = \$3000 1 hour travel @ \$500/hour = \$500 X 4 = \$2000	\$5,000
2. Quarterly (4) EFM Strip Reviews MFN only 1 hour @ \$200/hour = \$200 X 4 = \$800 1 hour travel @ \$200/hour = \$200 X 4 = \$800	\$1,600
3. 40 hours of nursing education RN only 44 hours @ \$100/hour = \$4,000 1 hour travel @ \$100/hour = \$100 X 9 = \$900	\$4,900
4. 14 Nursing Journal Clubs RN only 2 hours @ \$100/hr = \$200 X 14 = \$2,800 1 hour travel @ \$100/hour = \$100 X 14 = \$1,400	\$4,200
5. RN/RT Preceptorships (40 clinical hours each) 6 RNs @ \$500/40 clinical hours = 6 X \$500 = \$3000 4 RTs @ \$500/40 clinical hours = 4 X \$500 = \$2000	\$5000
Sub-Total	\$20,700
18% Administrative Cost	\$ 3,726
Total	\$24,426

*(For illustration purposes, assume MDs are paid \$200/hr, RNs are paid \$100/hr, and preceptorships cost \$500/40 hours. These rates apply to contract hospitals, and will be higher for non-contract hospitals)

