**Title: Section 721.1 - Introduction**

Effective Date: Wednesday, September 14, 2005

Section 721.1 Introduction

(a) All hospital-based perinatal care services shall participate in the statewide perinatal regionalization system. Such system shall coordinate perinatal care within particular geographic areas or among a group of perinatal affiliates.

(b) Each perinatal service within a hospital shall be designated by the Department as providing Level I perinatal care, Level II perinatal care, Level III perinatal care or, the hospital shall be designated as a Regional Perinatal Center (RPC).

**Section 721.2 - Definitions**

Section 721.2 Definitions

(a) Level I perinatal care service means a comprehensive maternal and newborn service provided by a hospital designated as such by the department for normal low-risk newborns and for women who have been assessed as having a normal, low-risk pregnancy and having a fetus which has been assessed as developing normally and without apparent complications.

(b) Level II perinatal care means a comprehensive maternal and newborn service provided by a hospital designated as such by the department which includes services for moderately high-risk newborns and for women who have been assessed as having the potential or likelihood for a moderately complicated or high-risk delivery and/or bearing a fetus exhibiting the potential for unusual or high-risk development. Such services may also provide services to women requiring care normally provided at Level I perinatal care services.

(c) Level III perinatal care means a comprehensive maternal and newborn service provided by a hospital designated as such by the department and which includes services for women and newborns who have been assessed as high-risk patients and/or are bearing high-risk fetuses , who will require a high level of specialized care. Such programs may also provide services to women and newborns requiring care normally provided at Level I and II perinatal care services.

(d) Regional Perinatal Center (RPC) means a hospital or hospitals housing a perinatal care service which meets the standards for a Level III perinatal care service but which also, includes highly specialized services that may not be available at all Level III hospitals, and designated as such by the department. An RPC serves a geographic area or a group of perinatal affiliates. It provides all aspects of comprehensive maternal and neonatal care, and its functions and responsibilities also include efforts to coordinate and improve quality of perinatal care among its affiliates, attending level consultation regarding patient transfer and clinical management, transport of high-risk patients, outreach to affiliates to determine educational needs, education and training of affiliate hospitals, data collection, evaluation and analysis within that region. If two or more hospitals jointly sponsor an RPC, they must define in a written agreement between or among the hospitals comprising the RPC how the aforementioned functions and responsibilities will be carried out.

(e) Perinatal affiliation agreement shall mean a written fully executed agreement between a Level I, II or III perinatal care hospital, and that hospital's designated RPC. A perinatal affiliation agreement shall include provisions for, at a minimum:

(1) criteria, policies and procedures for transfer of patients, with appropriate consent, to the RPC and from the RPC back to the sending hospital.

(2) criteria and process for attending level subspecialty consultation on a 24-hour basis, including types of consultation processes (i.e., via telephone, telemedicine or in-house consults) acceptable for each subspecialty;

(3) participation in the statewide perinatal data system (SPDS) including the provision of the confidentiality and protection of all data obtained through the SPDS;

(4) cooperation in outreach, education, training and data collection activities; and

(5) authority for one geographically accessible RPC representative or representatives to participate in the affiliate hospital's quality assurance committee and other reviews of the quality of perinatal care provided by the affiliate and to provide recommendations for quality improvement of perinatal services. Each RPC and each affiliate hospital shall take actions necessary, including but not limited to, entering into a perinatal affiliation agreement, to authorize such participation by the RPC's representatives in the affiliate hospital's quality assurance committee and for purposes of such participation, the RPC representative or representatives shall be deemed member(s) of the affiliate's quality assurance committee, shall maintain the confidentiality of all information obtained in such capacity and are subject to the confidentiality restrictions of Public Health Law Section 2805-m.

(6) RPC involvement in the development of written agreements among perinatal affiliates including criteria regarding transport of women and newborns;

(7) timely consultation on treatment plans for women and neonates who develop or exhibit unanticipated conditions which may require transfer to a higher level of care; and,

(8) resolution of disputes or disagreements between the RPC and the perinatal affiliate, including disagreements regarding interpretation of affiliation agreement criteria for consultation and/or transfer. In cases of disputes or disagreement between an affiliate and its RPC, the affiliate and the RPC shall follow the dispute resolution process outlined in their perinatal affiliation agreement. If the dispute is not resolved within sixty days, the parties must request review by the department. The department shall initiate compliance reviews at both sites, advise each facility of its findings, and require corrective action, as indicated, to resolve the dispute. This process shall not interfere with the timely and proper transfer of mothers and newborns.

(f) Transfer agreement shall mean a written agreement between a Level I or II perinatal service and a Level III hospital for the transfer of patients requiring Level III care. Perinatal transfer agreements shall address the provision and/or coordination of all high-risk maternal and newborn transports. The agreements shall reflect the following:

(1) the maximum allowable surface travel time to reach a Level III or RPC hospital shall be two hours under usual weather and road conditions, and the receiving hospital shall be accessible and convenient to the mother's place of residence whenever possible;

(2) mutually agreed criteria for determining when consultation and/or transfer is required;

(3) procedures and responsibility for arranging transport;

(4) requirement for 24-hour availability of appropriately qualified RPC medical staff to respond to calls from affiliates;

(5) policies for obtaining patient or parent/guardian consent for patient transfer and to exchange medical information;

(6) procedures for making arrangements for transfer to another hospital if the receiving hospital is unable to accept the transfer due to capacity/bed limitations;

(7) a provision that an emergency transport shall depart within thirty minutes of the request for transfer;

(8) provisions for the back transfer of newborns who no longer need Level III or RPC care but who need continuing care in a hospital located near their home communities shall be part of the perinatal affiliation and/or transfer agreements between two hospitals; and

(9) higher level hospitals shall inform referring hospitals of major changes in status of transferred patients, with patient's consent or with parental or guardian consent in the case of newborn transfers.

(g) Definitions contained in section 405.21(b) of this Title shall apply to this Part.

**Section 721.3 - Perinatal Designation of Hospitals**

Section 721.3 Perinatal designation of hospitals.

(a) Perinatal services will be designated by the Commissioner based on the following:

(1) each hospital designated as a Level I, Level II or Level III hospital shall enter a written perinatal affiliation agreement with an RPC;

(2) the level of care currently provided by the hospital shall meet the definition, standards and criterion set forth in this Part for a Level I, Level II, Level III perinatal service or RPC;

(3) for level II, Level III and RPCs, the number of births and intensity of neonatal care at the hospital during the previous full calendar year must meet the following minimum volume standards.

(i) a Level II perinatal care hospital shall provide no fewer than 1,200 high-risk newborn patient days annually, and no fewer than 150 high-risk maternal patient days annually;

(ii) a Level III perinatal care hospital shall provide no fewer than 2,000 high-risk newborn patient days annually, and no fewer than 250 high-risk maternal patient days annually;

(iii) RPCs shall provide no fewer than 4,000 high-risk newborn patient days annually, and no fewer than 400 high-risk maternal patient days annually. An RPC shall provide quality improvement services to a group of perinatal affiliates with a minimum total of 8,000 births each year;

(4) the availability of appropriate medical, nursing, and other staffing as described in this Part supportive of the perinatal service at the hospital; and

(5) surface travel time for transfers. The surface travel time to reach a Level II hospital, a Level III hospital, or an RPC within the geographic area or affiliative perinatal network, under usual travel conditions shall be no more than two hours. Transfer decisions must be based on the appropriate level of perinatal care required, and care shall be provided at a hospital offering the appropriate level of care which is accessible and convenient to the mother's place of residence whenever feasible.

(6) the geographic distribution of designated hospitals throughout the state to ensure access to appropriate levels of care throughout the state; and,

(7) such other additional information as the Commissioner may require to make the designation.

(b) Designation process.

(1) Each hospital certified to provide perinatal services shall complete a designation survey by the department and verify specific data about its maternal and newborn discharges. The department shall assess the results of the survey and data in order to assign a designation. The department may require an on-site review of services at a hospital before making a designation, in which case the hospital shall participate and cooperate in the review and provide any additional information requested. A hospital shall receive its designation only after this process is complete and the department has obtained and considered all relevant information to its satisfaction.

(2) The perinatal designation of a hospital shall appear on the hospital's operating certificate.

(3) Perinatal designation on the maternity information leaflet. The hospital's perinatal designation and a brief definition of the Level shall be included in the maternity information leaflet distributed to each prospective maternity patient, pursuant to public health law section 2803-j (1).

(c) Redesignations.

(1) A hospital may apply to change its designation no sooner than one year following its most recent designation.

(2) The department may initiate a review and monitor compliance with the definitions, standards and criteria set forth in this Part by perinatal services and RPCs at any time.

(3) The department may change a designation if it finds that a hospital perinatal service or RPC no longer meets the definition, standards and criterion for its current designation.

(4) Maintenance of minimum volume standards. To ensure that service capability and staff competence are maintained for Level II, Level III, or an RPC, a hospital which fails to meet minimum volume standards and is seeking to maintain its designation, or applying for another designation, shall present evidence that the annual minimum volume standards will be achieved within one year following the decision to allow the hospital to remain at the present level of designation or the initiation of the new designation. Minimum volume standards may be waived by the department if the department determines that a waiver will improve access while maintaining high quality care.

**Section 721.4 - Patient Care and Patient Transfers**

Section 721.4 Patient care and patient transfers.

(a) Each hospital providing perinatal care services shall provide patient care based on the individual needs of the patient and in accordance with the following criteria.

(1) A Level I perinatal care service hospital shall evaluate and stabilize all women and neonates.

(i) For patients needing a higher level of care, it shall consult with a higher level hospital and arrange for timely transfer to a Level III perinatal care service hospital or an RPC that provides the appropriate level of perinatal care.

(ii) For healthy women with an anticipated delivery at 36 weeks gestation or later and for healthy newborns with a birthweight of 2,500 grams or more, it shall provide continuing care until their discharge.

(iii) Except in unusual circumstances, smaller and more premature infants shall be delivered at higher level hospitals; if such an infant is born at a Level I perinatal care hospital, he/she shall be transferred promptly after birth.

(iv) Women and neonates who have relatively minor problems that do not require advanced laboratory, radiologic, or consultation services may remain in the Level I perinatal care hospital.

(v) When it is known that the newborn may require immediate complex care, it shall be delivered at a Level III perinatal care hospital or an RPC whenever possible.

(vi) Level I perinatal care hospitals shall also provide care for convalescing babies who have been transferred from Level II, Level III and RPC perinatal care hospitals.

(2) A Level II perinatal care services hospital shall:

(i) provide the Level I perinatal care services described in paragraph (1) above and be capable of providing care for moderately high-risk women, fetuses and newborns and moderately ill women and newborns who have problems that do not require highly specialized care; and

(ii) stabilize ill women and newborns and women whose fetuses are expected to need complex care, consult with a higher level hospital and arrange for timely transfer to a hospital that provides the appropriate level of perinatal care.

(iii) Level II perinatal care hospitals are qualified to deliver infants with an anticipated delivery at 30 weeks gestation or later and with an anticipated birthweight of 1,250 grams or more.

(iv) Except in unusual circumstances, infants smaller and more premature than is described at subparagraph (iii) of this paragraph shall be delivered at Level III hospitals or RPCs. If an infant who is smaller or a lower gestational age than described in subparagraph (iii) of this paragraph is born at the Level II hospital, he/she shall be transferred promptly after birth.

(3) A Level III perinatal care services hospital shall:

(i) provide Level I and Level II perinatal care services described in paragraphs (1) and (2) of this subdivision and shall care for women, fetuses, and newborns who may require complex care.

(ii) stabilize ill women and newborns prior to transfer, including women whose newborns are expected to need the most complex care, consult with its designated RPC, and transfer if appropriate.

(iii) Women in unstable medical and/or obstetric situations shall be cared for at a Level III hospital or an RPC.

(4) Regional Perinatal Care Centers (RPC) shall provide Level I, Level II and Level III perinatal care services described in paragraphs (1), (2), and (3) of this subdivision and shall also care for women, fetuses, and newborns who require highly specialized services not available at the Level III care hospital, such as sophisticated ventilation techniques (e.g., high-frequency ventilation and extracorporeal membrane oxygenation), cardiac surgery or neurosurgery.

(5) The transfer and consultation criterion included in the affiliation and transfer agreements can be customized to reflect the RPC’s knowledge and the capabilities of each affiliate hospital. Any variation in transfer of patients to a higher level perinatal care service hospital as specified in this Section must be in accordance with generally accepted standards of professional practice and criteria established in the affiliation agreement with each hospital's respective RPC.

(b) Ventilation for distressed newborns. Resuscitation and ventilation of neonates who require cardiorespiratory assistance shall be performed at each Level of perinatal care and in the following ways:

(1) at a Level I perinatal care services hospital the ventilation of distressed newborns shall be immediate resuscitation after birth as appropriate, stabilization, and assisted ventilation of newborns until timely transfer to a hospital that provides a higher level of perinatal care;

(2) at a Level II perinatal care hospital the ventilation of a distressed newborn shall be as described in paragraph (1) above and, in addition, standard short-term mechanical ventilation. A Level II perinatal care hospital may care for infants requiring mechanical ventilation and/or 50% or more oxygen for no more than four days. By the fourth day of a newborn's receipt of

assisted ventilation or oxygen at 50% or more, the Level II hospital shall consult with its designated RPC regarding the status of the newborn and determine whether to transfer the newborn to a higher level hospital. If after such consultation the neonate stays at the Level II hospital, that hospital may retain the neonate for no more than a total of seven days on assisted ventilation or oxygen at 50% and must then transfer the neonate to a Level III hospital or to an RPC unless the hospital's RPC is consulted and agrees that the neonate's care is appropriate and in accordance with current standards of professional practice and remaining at the Level II hospital is in the best interests of the neonate.

(3) at Level III perinatal care services hospitals and RPCs the ventilation of a distressed newborn shall be as described in paragraphs (1) and (2) of this subdivision and, in addition, may also include long-term standard mechanical ventilation and complex ventilation techniques, such as high-frequency ventilation and extracorporeal membrane oxygenation (ECMO).

(c) Transfers.

(1) All patient care and transfers shall be in accordance with generally accepted professional standards and be consistent with section 405.21(g) and this Part. Requirements for consultation and for transfer to a higher level of perinatal care and transfer back to the referring hospital or other hospital providing a lower level of care, shall be described in any transfer agreement negotiated between Level I, II and III perinatal care hospitals, and in transfer provisions in the perinatal affiliation agreements between Level I, II and III perinatal care hospitals and their RPCs.

(2) When a newborn and/or mother requires transfer, care shall be provided at a hospital providing the appropriate level of perinatal care which is, whenever feasible, accessible and convenient to the mother's place of residence. When mothers and their infants need different levels of care, efforts shall be made to keep the mother-newborn dyad together. Level III hospitals and RPCs shall return a newborn to the sending hospital when the condition has been stabilized and return is medically appropriate.

**Section 721.5 - Responsibilities and Qualifications of Chiefs of Services At Each Designated Level**

Section 721.5 Responsibilities and qualifications of chiefs of services at each designated level. The qualifications and responsibilities for each designated level shall be as follows:

(a) Level I perinatal care service. Care shall be coordinated jointly by the chiefs of obstetrics, pediatrics, family practice, nursing, anesthesia, and midwifery. For facilities that do not have chiefs of service in all such areas, each discipline shall have effective input in care coordination. The coordinators of perinatal care at a Level I perinatal care services hospital shall be responsible for developing policy, maintaining standards of care, and collaborating and consulting with professional staff of hospitals providing Level II and Level III perinatal care services and RPC perinatal care in the region. In hospitals that do not separate maternity and newborn services, one person may be given the responsibility for coordinating perinatal care;

(b) Level II perinatal care service. A board-certified obstetrician with special interest, experience, and expertise in maternal-fetal medicine shall be the chief of the obstetric service at a Level II care hospital. A full-time board-certified pediatrician with subspecialty certification in neonatal medicine or at a minimum has successfully completed a fellowship in neonatal medicine shall be the chief of the neonatal care services. These physicians shall jointly coordinate the hospital's perinatal care services and, in conjunction with the chiefs of anesthesiology, nursing, midwifery, and family practice, and other patient care and administration staff, shall develop policies concerning staffing, procedures, equipment, and supplies; maintaining standards of care; and planning, developing, and coordinating in-hospital professional educational programs;

(c) Level III perinatal care services. The chief of the maternal-fetal medicine service at a hospital providing Level III perinatal care shall be a full-time, board-certified obstetrician with interest, experience and special competence in maternal-fetal medicine; subspecialty certification in maternal-fetal medicine is recommended. The director of a newborn intensive care service at a Level III hospital shall be a full-time, board-certified pediatrician with subspecialty certification in neonatal medicine. These physicians shall jointly coordinate the hospital's perinatal care services in order to ensure provision of a comprehensive continuum of high quality care to mothers and newborns. In conjunction with the chiefs of anesthesiology, nursing, midwifery, and family practice, and other patient care and administrative staff, these physicians shall be responsible for developing policies concerning staffing, procedures, equipment, and supplies; maintaining standards of care; and planning, developing, and coordinating in-hospital professional educational programs;

(d) RPC care. The chief of the maternal-fetal medicine service at an RPC shall be a full-time, board-certified obstetrician with subspecialty certification in maternal-fetal medicine. The chief of a newborn intensive care service at an RPC shall be a full-time, board-certified pediatrician with subspecialty certification in neonatal medicine. These physicians shall jointly coordinate perinatal care services in order to ensure provision of a comprehensive continuum of high quality care to mothers and newborns. In conjunction with the chiefs of anesthesiology , nursing, midwifery, and family practice, and other patient care and administration staff, these physicians shall be responsible for developing policies concerning staffing, procedures, equipment, and supplies; maintaining standards of care; and planning, developing, and coordinating in-hospital professional educational programs. The chiefs of maternal-fetal medicine and neonatology will also be responsible for providing outreach and professional education programs, participating in the evaluation and improvement of perinatal care in the region, and coordinating the services provided at their hospital with those provided at Level I, Level II and Level III care hospitals in the region.

**Section 721.6 - Qualification and Responsibilities of Physicians and Other Licensed Obstetrical Practitioners At Each Designated Level of Care**

Section 721.6 Qualifications and responsibilities of physicians and other licensed obstetrical practitioners at each designated level of care. The qualifications and responsibilities of licensed obstetrical practitioners at each designated level of care shall be:

(a) Level I perinatal care: A physician or licensed midwife with appropriate training and expertise shall attend all deliveries. At least one person capable of initiating neonatal resuscitation shall be present at every delivery. An ultrasound machine shall be readily available to labor and delivery. A radiologist or obstetrician skilled in interpretation of ultrasound scans shall be available within a timeframe appropriate to meet the patient's needs;

(b) Level II perinatal care: A physician or licensed midwife with appropriate training and expertise shall attend all deliveries. At least one person capable of initiating neonatal resuscitation shall be present at every delivery. An ultrasound machine shall be readily available to labor and delivery. A radiologist or obstetrician skilled in interpretation of ultrasound scans shall be available 24 hours a day within a timeframe appropriate to meet the patient's needs. Portable, neonatal-appropriate equipment and appropriately trained personnel to administer the service must be available within a timeframe appropriate to meet the patient's needs. Care for moderately high-risk women and neonates shall be provided by appropriately qualified physicians. General pediatricians and general obstetricians with the expertise to assume responsibility for acute care for infants and women, shall be immediately available within 20 minutes, 24 hours a day to provide needed services. The chief of obstetric anesthesia services shall be board-certified in anesthesia and shall have training and experience in obstetric anesthesia. A neonatologist shall be available on-site within 20 minutes 24 hours a day to provide needed services. The hospital staff shall also include a radiologist skilled in interpretation of ultrasound scans, a clinical pathologist , personnel qualified to administer specialized pharmaceutical services to newborns, and a designated, in-house credentialed person for neonatal resuscitation, all of whom shall be available 24 hours a day. Personnel with credentials to administer obstetric anesthesia shall be readily available. Specialized adult and pediatric medical and surgical consultation shall be readily available;

(c) Level III and RPC perinatal care: A physician or licensed midwife with appropriate training and expertise shall attend all deliveries. At least one person capable of initiating neonatal resuscitation shall be present at every delivery. An ultrasound machine shall be readily available to labor and delivery. A radiologist, obstetrician or maternal-fetal medicine specialist skilled in interpretation of ultrasound scans shall be available in-house 24 hours a day. Portable, neonatal-appropriate equipment and appropriately trained personnel to administer the service must be available within a timeframe appropriate to meet the patient's needs. Maternal-fetal medicine specialists and neonatologists who care for high-risk mothers and newborns in the Level III or RPC hospital shall have qualifications equivalent to those of the chief of their service as described in section 721.5(c) and (d) of this Title or at a minimum will have successfully completed a fellowship in maternal fetal medicine or in neonatal medicine, whichever is appropriate. A maternal-fetal medicine specialist and a neonatologist shall be available on-site within 20 minutes 24 hours a day to provide needed services. Obstetric and neonatal diagnostic imaging, provided by radiologists with special expertise in diagnosis of maternal and neonatal disease and its complications, shall be available 24 hours a day. Pediatric and adult subspecialists in cardiology, neurology, hematology, genetics, nephrology, metabolism, endocrinology, gastroenterology, nutrition, radiology, infectious diseases, pulmonology, immunology, and pharmacology shall be available for consultation. In addition, pediatric surgeons and pediatric surgical subspecialists, e.g., cardiovascular, neurological, orthopedic, ophthalmologic, urologic, and otolaryngological surgeons, shall be available for consultation and care. Pathologists with special competence in placental, fetal, and neonatal disease shall be members of the Level III or regional perinatal center staff. A clinical pathologist shall be available 24 hours a day. A board-certified anesthesiologist with special training or experience in maternal-fetal anesthesia shall be in charge of obstetric anesthesia services at a Level III or regional perinatal center facility, and personnel with credentials in the administration of obstetric anesthesia shall be available for all deliveries. Personnel with credentials in the administration of neonatal and pediatric anesthesia shall be readily available as needed. Personnel qualified to prepare, dispense and administer specialized pharmaceutical services to newborns shall be available 24 hours a day.

**Section 721.7 - Nursing Care**

Section 721.7 Nursing Care. In addition to providing nursing care that meets generally accepted professional standards, hospitals shall meet the following additional nursing requirements at each designated level of care.

(a) Level I perinatal care service hospital. Maternal and newborn nursing care shall be provided under the direct supervision of a registered nurse. All obstetric nursing personnel shall be qualified in interpretation of fetal heart rate monitoring and understand the physiology of labor. All newborn nursing personnel shall be qualified in assessment of the newborn and all aspects of routine monitoring and care, including education and support related to breastfeeding.

(b) Level II care hospital. In addition to the qualifications described in subdivision (a) of this section, direct patient care shall be provided by registered nurses who have education and experience in the care of moderately high-risk women and/or newborns. All nurses caring for ill women or newborns shall demonstrate competence in the observation and treatment of such patients, including cardiorespiratory monitoring. Registered nurses in a Level II perinatal care hospital shall be able to: monitor and support the stability of cardiopulmonary, neurologic, metabolic, and thermal functions; assist with special procedures such as lumbar puncture, endotracheal intubation, and umbilical catheterization; and perform emergency resuscitation.

(c) Level III perinatal care hospital. Responsibilities of registered nurses shall include those defined in subdivisions (a) and (b) of this section. In addition, registered nurses in the Level III perinatal care hospital shall have specialty certification or advanced training and experience in the nursing management of high-risk women, neonates and their families. They shall also be experienced in caring for unstable women and neonates with multi-organ system problems and in specialized care technology. An advanced practice nurse shall be available to the staff for consultation and support on nursing care issues. Assessment and monitoring activities shall remain the responsibility of a registered nurse or advanced practice nurse in obstetric-neonatal nursing, even when personnel with a mixture of skills are used.

(d) RPC. Responsibilities of registered nurses shall include those defined in subdivisions (a), (b), and (c) of this section. In addition, nurses with special training shall participate in regional perinatal center responsibilities such as outreach, training, education and support.

**Section 721.8 - Ancillary Personnel**

Section 721.8 Ancillary personnel. The ancillary personnel requirements for each designated level are as follows:

(a) All designated Level I, II, III perinatal care services and RPCs shall have:

(1) an organized plan of action that includes personnel and equipment for identification and immediate resuscitation of newborns and mothers requiring cardiorespiratory assistance;

(2) personnel who are capable of determining blood type, cross-matching blood, and performing antibody testing and who are available on a 24-hour basis;

(3) infection control personnel responsible for surveillance of infections in women and neonates, as well as for the development of an appropriate environmental control program;

(4) a radiologic technician available 24 hours a day to perform imaging;

(5) at least one staff member with expertise in lactation and breastfeeding management responsible for the hospital's breastfeeding support program, as described in section 405.21(f)(3)(i) of this Title;

(6) at least one staff member with expertise in bereavement responsible for the hospital's bereavement activities, including a systematic approach to ensuring that individuals in need receive such services;

(7) at least one qualified social worker available who has experience with the socioeconomic and psychosocial problems of pregnant women, ill neonates, and their families assigned to the perinatal service. Additional qualified social workers sufficient to meet the needs of women and newborns are required when there is a high volume of medical activity or psychosocial need; and,

(8) licensed practical nurses and other licensed patient care staff with demonstrated knowledge and clinical competence in the nursing care of women, fetuses, and newborns during labor, delivery, and the postpartum and neonatal periods.

(9) The need for other support personnel shall depend on the intensity and level of sophistication of the other support services provided and shall be sufficient to meet the needs of the patients.

(b) Additional requirements for Level II, Level III perinatal care services and RPC designation:

(1) at least one occupational or physical therapist with neonatal expertise;

(2) at least one registered dietician/nutritionist who has special training in perinatal nutrition and can plan diets that meet the special needs of high-risk women and neonates;

(3) appropriate and adequate numbers of the nursing staff who are trained in breastfeeding support for mothers and infants with special needs;

(4) qualified personnel for support services, such as laboratory studies, radiologic studies, and ultrasound examinations, who are available 24 hours a day; and

(5) respiratory therapists or nurses with special training who can manage the mechanical ventilation of neonates with cardiopulmonary disease.

**Section 721.9 - Regional Quality Improvement Activities**

Section 721.9 Regional quality improvement activities.

(a) Quality of care reviews of affiliates. Each hospital with a Level I, Level II or Level III perinatal care service shall enter into and comply with a perinatal affiliation agreement as defined in this Part with an RPC in its geographic area or network of perinatal affiliates. RPC representatives shall participate in the affiliate hospital's quality assurance committee and other reviews of the quality of perinatal care provided by the affiliate and in the provision of recommendations for quality improvement of perinatal services. Each RPC and each affiliate hospital shall take actions necessary, including but not limited to entering into a perinatal affiliation agreement, to authorize such participation by the RPC's representatives in the affiliate hospital's quality assurance committee and for purposes of such participation, the RPC representative or representatives shall be deemed members of the affiliate's quality assurance committee. RPC representatives may only access confidential patient information for quality improvement purposes through their roles on the affiliate hospitals’ quality assurance committees as set forth in the affiliation agreements and these regulations. Members of hospitals’ quality assurance committees must maintain the confidentiality of patient information and are subject to the confidentiality restrictions of Public Health Law Section 2805-m.

(1) The RPC representative(s) shall participate in the review of information and data for quality improvement purposes as described in the affiliation agreement which may include:

(i) statistical data from the statewide perinatal data system or equivalent data available from other sources;

(ii) the affiliate hospital's quality improvement program, policies, and procedures;

(iii) care provided by medical, nursing, and other health care practitioners associated with the perinatal service;

(iv) appropriateness and timeliness of maternal and newborn referrals and transfers and of patients retained at the affiliate hospital who met criteria for transfer to a higher level of care; and

(v) maternal and newborn serious adverse events or occurrences that may include the following:

(a) maternal and newborn fatalities;

(b) maternal and newborn morbidity in circumstances other than those related to the natural course of disease or illness;

(c) maternal and newborn nosocomial infections;

(d) maternal and newborn high-risk procedures; or

(vi) pathology related to all deaths and significant surgical specimens.

(2) The hospital shall implement quality improvement recommendations by its RPC. In the event of a disagreement related to a recommendation, the hospital and the RPC shall follow the dispute resolution process outlined in their perinatal affiliation agreement and section 721.2 of this Title.

(b) Each RPC shall cooperate with the department in regular quality improvement reviews by the department of the RPC's perinatal care, the RPC's internal quality improvement activities, and the services it provides to its perinatal affiliates:

(1) The department's quality of care review of the RPC shall include the elements set forth in section 721.9(a)(1) of this Title.

(2) The department's quality improvement review of an RPC shall include review of the quality of the services it has provided to its perinatal affiliates.

(3) The RPC shall cooperate with the department by providing medical records and other relevant documents and information on a timely basis when requested.

(c) Quality improvement outreach program. Each RPC shall provide professional education and training for physicians, nurses, and other staff at all hospitals in the region or affiliative network for which it provides quality of care review. Education and training shall be designed to update and enhance staff knowledge and familiarity with relevant procedures and technological advances.

**Section 721.10 - Perinatal Affiliation Agreements and Transfer Agreements**

Section 721.10 Perinatal affiliation agreements and transfer agreements.

(a) Each hospital with a Level I, II or III perinatal care service shall enter into and comply with a perinatal affiliation agreement with an RPC. Each hospital with a Level I or II perinatal care service may also enter into a transfer agreement with a hospital with a Level III perinatal care service if such an agreement would result in an acceptable level of care and provide a more convenient alternative than transfer to an RPC. All such agreements and amendments to such agreements shall be made available to the department, upon request. The terms of such agreements shall be mutually agreed upon by the affiliating hospitals.

(b) Changes in the identity of the RPC with which a hospital has a perinatal affiliation agreement may not be made more frequently than once annually. Such changes shall require 30 days prior notice to the department.