Pursuant to the authority vested in the State Hospital Review and Planning Council and the Commissioner of Health by sections 2500, 2800, 2803(2), 2803-j, 2805-j and 2805-m of the Public Health Law, provisions of section 405.21; section 407.14; section 711.4(d)(21); and section 711.4(e)(10) of Title 10 (Health) of the Official Compilation of Codes, Rules and Regulations of the State of New York are hereby amended, sections 708.2(b)(6) and 708.5(f) are repealed, and a new Part 721 is added to be effective upon publication of a Notice of Adoption in the New York State Register to read as follows:

The table of contents for Part 405 is amended to read as follows:

PART 405
HOSPITALS-MINIMUM STANDARDS

Sec.

* * *

405.21 [Maternity and newborn] Perinatal services.

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Section 405.21 of Part 405 of Title 10 is amended to read as follow:

Section 405.21 [Maternity and newborn] Perinatal services.

(a) Applicability. This section shall apply to all general hospitals having maternity and newborn services [or premature infant services] and [caring] providing pregnancy-related care for women who are pregnant at any stage, parturient or within six weeks from delivery and for infants 28 days of age or less or, regardless of age, who are less than 2,500 grams (5 ½ pounds).

(b) Definitions. For the purposes of this section:

(1) [Maternity and newborn] Perinatal services shall mean those services provided in a particular hospital where, as a regular practice, maternity patients and newborn infants receive care on a continuum ranging from preconception services to care during all stages of pregnancy, parturition, postpartum and neonatal care.

(2) Perinatal regionalization system shall mean the statewide organization of maternal and newborn health care services, designed as set forth in Part 721 of this Title, to ensure that mothers and newborns receive the care they need in a timely, safe and effective manner.

[(2)](3) Labor room shall mean a room for parturient patients in labor, distinct from patient bedrooms and from operating or delivery rooms.

[(3)](4) Delivery room shall mean a room distinct from patient bedrooms and set apart for the delivery of parturient patients.

[(4)](5) Single unit maternity or labor-delivery-recovery-postpartum model shall mean a model for family-centered maternity and newborn care [such as a cybele cluster,] in which labor, delivery, nursery and postpartum care are all provided in a single room and movable equipment is introduced and withdrawn from the room as required to provide services and care to the mother and neonate.

[(5)](6) Rooming-in shall mean an arrangement which allows the mother and her newborn infant to be cared for together, so that the mother may have access to her infant during all or a substantial part of the day and night, not limited to feeding times.

[(6)](7) Newborns shall mean all infants 28 days of age or less.

[(7)](8) Premature infant shall mean an infant whose gestational age at birth calculated from the first day of the last menstrual period or using another reliable method for patients with an unreliable history, is less than 37 completed weeks or 258 completed days.

[(8)](9) Low birth weight infant shall mean an infant weighing less than 2,500 grams (5½ pounds) [or less] at birth.

[(9)](10) [Well-infant]Normal newborn nursery shall mean a room for housing newborns who do not need intensive care and are not suspected of nor diagnosed as having any communicable condition.

[10)](11) [Special care nursery] Neonatal intensive care unit ("NICU") shall mean a room at Level II [and], Level III and Regional Perinatal Center perinatal care [programs] services for housing newborns, including premature infants and low birth weight infants, who require [extraordinary] specialized care and who are not suspected of nor diagnosed as having any communicable condition.

[(11)](12) Observation nursery shall mean a room, physically separate from the [well-infant] normal newborn nursery, where newborns exposed to potential sources of infection and newborns suspected of but not diagnosed as having any communicable condition may be observed, pending diagnosis.

[(12)](13) Isolation nursery shall mean a room, physically separate from other nurseries, for the isolation of newborns diagnosed as having any communicable condition.

[(13)](14) Family planning shall mean the planning and spacing of children by medically acceptable methods to achieve pregnancy, or prevent unintended pregnancy.

[(14)](15) Level I perinatal care [program] service shall mean a comprehensive maternal and newborn service [services program provided by a hospital designated as such by the department 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. A woman at low risk means a woman with a normal, medical surgical and

obstetrical history and a normal uncomplicated prenatal course as determined by adequate prenatal care, and prospects for a normal, uncomplicated birth] as defined by Section 721.2(a) of this Title.

[(15)](16) Level II perinatal care [program] service shall mean a comprehensive maternal and newborn service [services program provided by a hospital designated as such by the department for women who have been assessed as having the potential or likelihood for a complicated or high-risk delivery and/or bearing a fetus exhibiting the potential for unusual or high-risk development who may require an intermediate or intensive level of specialized care services. Such programs may also provide services to women requiring care normally provided at Level I programs] as defined by Section 721.2(b) of this Title.

[(16)](17) Level III perinatal care [program] service shall mean a comprehensive maternal and newborn service [services program provided by a hospital designated as such by the department, provided by a tertiary care hospital for women who have been assessed as high-risk patients and/or are bearing high-risk fetuses as determined by a standardized risk assessment tool, who will require the highest level of specialized care. Such programs may also provide services to women requiring care normally provided at Level I and II programs] as defined by Section 721.2(c) of this Title.

[(17)](18) Regional perinatal [care] center ("RPC") shall mean a [facility] hospital or hospitals housing a Level III perinatal care [program and designated as such by the department, serving a given designated region which provides all aspects of maternal and neonatal care and whose functions and responsibilities also include education, evaluation and data collection within that region] service as defined in Section 721.2(d) of this Title.

(19) Perinatal affiliates shall mean Level I, Level II and Level III hospitals which have a

current perinatal affiliation agreement as defined in Part 721 of this Title.

[(18)](20) Birth center shall mean a place, other than a traditional hospital childbirth unit or birthing room, where births are planned to occur away from the mother's usual residence following a normal uncomplicated pregnancy.

[(19)](21) Birthing room shall mean a hospital room designed as a homelike setting which serves as a combined labor/delivery/recovery room and where family members or other supporting persons may remain with a woman as much as possible throughout the childbirth process.

(22) Quality improvement shall mean improvement of the quality of care provided by the RPC or affiliate hospitals through initiatives and analyses designed to identify and then address potential problem areas in care in its own hospital or in affiliated hospitals, or in the region as a whole, through review of either sentinel cases or patterns of care.

(c) General requirements.

(1) Hospitals providing [maternity and newborn] perinatal services shall provide such services in accordance with current standards of professional practice. Written policies and procedures shall be developed and implemented which address the following:

(i) [the hospital shall develop and implement written policies and procedures for the maternity and newborn service which shall include, but shall not be restricted to,] the professional qualifications of [its] the hospital's obstetric and pediatric staff;

(ii) [the hospital shall develop and implement written policies and procedures designating] the requirements for consultation with a qualified specialist when required by specific medical conditions;

(iii) [the hospital shall develop and implement written policies and procedures for] the

establishment and implementation of rooming-in at the option of each patient unless the establishment or implementation of such program for that patient is medically contraindicated or unless the hospital does not have sufficient facilities to accommodate all such requests; [and]

(iv) protocols and resources available to stabilize and assess newborns for their need of neonatal intensive care; and

[(iv)] (v) [the hospital shall develop and implement written policies and procedures for] the daily care of maternity patients and infants [which shall be implemented by the staff] in the [maternity and newborn] perinatal service.

(2) Medical record for each maternity patient. The medical record for each maternity patient admitted to the [maternity] perinatal service shall be maintained in accordance with section 405.10 of this Part and shall also include the following:

(i) a copy or abstract of the prenatal record, if existing, including a maternal history and physical examination as well as results of maternal and fetal risk assessment, results of maternal HIV, Hepatitis B and Group B strep testing if done, and ongoing assessments of fetal growth and development and maternal health;

(ii) the results of a current physical examination performed by staff granted privileges to perform such examination that meets the requirements of section 405.9(b)(11) of this Part; and

(iii) labor and birth information, including records of fetal monitoring and postpartum assessment.

(3) Medical record for each newborn. The medical record for each newborn shall be cross-referenced with the mother's medical record and contain the following additional information:

(i) newborn physical assessment, including Apgar scores, presence or absence of three

cord vessels, [description of maternal-newborn interaction], ability to feed, [eye prophylaxis], vital signs and accommodation to extrauterine life; [and]

(ii) newborn care, including the administration of eye prophylaxis and vitamin K;

(iii) description of maternal-newborn interaction; and

[(ii)] (iv) orders for newborn screening tests, including arrangements for screening for hearing.

(4) The hospital shall ensure the transfer to the newborn's medical records of a mother's HIV test result, if one exists.

(5) The hospital shall maintain in a timely manner in the [maternity and newborn] perinatal service area, a register of births, in which shall be recorded the name of each patient admitted, date of admission, date and time of birth, type of delivery, names of personnel present in the delivery room [physicians, nurse-midwives, assistants and anesthetists], sex, weight, and gestational age of infant, location of delivery and [fetal] outcome of delivery. Any delivery for which the institution is responsible for filing a birth certificate shall be listed in this register.

(6) Control of infection or other communicable condition. The provisions of section 405.11 of this Part shall apply to the [maternity and newborn] perinatal service. In addition, the following requirements relating to the control of infection or other communicable conditions in the [maternity and newborn] perinatal service shall be met:

(i) each patient admitted to the labor-delivery unit shall be screened for signs of, or exposure to, infection. Those with suspected or confirmed communicable conditions shall be reported to the responsible attending practitioner and the infection control officer for observation or isolation as required;

(ii) isolation precautions shall be carried out for patients in labor with confirmed or

suspected infection. There shall be at least one room readily available for the use of a maternity patient requiring isolation. The hospital shall implement safe and effective isolation precautions to prevent the spread of infection and assign professional and other staff in the [maternity and newborn] perinatal service in a manner that will prevent the spread of infection. Written policies and procedures shall be developed and implemented reflecting such isolation precautions;

(iii) the hospital shall adopt and implement written policies and procedures governing the placement in observation or isolation nurseries of infants exposed to or showing signs of developing an infection or communicable condition. Such policies shall not unnecessarily restrict the mother's access to her infant; and

(iv) infection control measures shall be instituted to protect infants when the care and treatment of infants [encompasses] requires common surfaces.

(7) Preconception services. The hospital shall develop and implement written policies and procedures for [the provision of] preconception services either onsite or through referral arrangements. [Available services] Services shall include but not be limited to family planning, nutritional assessment and counseling, [and] genetic screening and counseling, and identification and treatment of medical conditions that could adversely affect a future pregnancy.

(8) Hospital prenatal care activities.

(i) The hospital shall participate in and shall provide or arrange for effective prenatal care activities including conducting effective community outreach programs either directly or in collaboration with community-based providers and practitioners who provide prenatal care and services to women in the hospital service area. Activities and services of a prenatal care program shall include but not be limited to the following:

(a) active promotion of prenatal care for pregnant women during the first trimester of

pregnancy and making services available to patients seeking initial care during each trimester;

(b) the initial prenatal care visit shall include a complete history, physical examination, pelvic examination, laboratory screening, initiation of patient education, screening for nutritional status, nutrition counseling and use of a standardized prenatal risk assessment tool;

(c) arrangements for repeat visits for follow-up prenatal care and education;

(d) nutrition counseling;

(e) psychosocial support services as needed;

(f) ongoing maternal and fetal risk assessment;

(g) prebooking for delivery; and

(h) providing HIV counseling and a clinical recommendation for [recommending voluntary] testing to pregnant women. Counseling and/or testing, if accepted, shall be provided pursuant to Public Health Law Article 27-F. Information regarding the woman's HIV counseling and HIV status must be transferred as part of her medical history to the labor and delivery site. Women with positive test results shall be referred to the necessary health and social services within a clinically appropriate time.

(ii) To perform the activities and provide the services in subparagraph (i) of this paragraph, the [maternity and newborn] perinatal service shall accommodate and coordinate services with primary care providers as follows:

(a) the hospital shall develop a memorandum of understanding with each diagnostic and treatment center, prenatal care provider who is not a member of the medical staff, and prenatal care assistance program in the hospital service area. These memoranda shall establish protocols for the provision of prenatal care, testing, prebooking arrangements, timely transfer of records, and other necessary services; and

(b) the hospital shall require as a condition of continuing medical staff membership that medical staff members provide to maternity patients under their care prenatal care, prebooking arrangements, testing, timely transfer of records and other necessary services. Written policies and procedures implementing this requirement shall be developed.

(iii) Hospitals shall assure the availability of prenatal childbirth education classes for all prebooked women which address at a minimum the anatomy and physiology of pregnancy, labor and delivery, infant care and feeding, breastfeeding, parenting, nutrition, the effects of smoking, alcohol and other drugs on the fetus, what to expect if transferred, and the newborn screening program with the distribution of newborn screening educational literature.

(iv) The hospital shall assure that each prebooked woman receives the hospital's maternity information leaflet as described in PHL section 2803-j, which includes a written description of available options for labor, delivery and postpartum services. The attending practitioner shall:

(a) advise the woman of options for treatment, care and technological support that are expected to be available at the time of labor and delivery, together with the advantages and disadvantages of each option;

(b) answer fully any questions the woman may have regarding the options available; and

(c) obtain from the woman her informed choice of mode of treatment, care and technological support that are expected to be necessary.

(9) Hospitals in consultation with the medical staff shall develop memoranda of understanding with free-standing birth centers in their service area, upon request from such centers, for the prompt admission of women and newborns and transfer of records of any birth center patients whose assessed condition necessitates admission to the level of [maternity

services] perinatal service provided by such hospital.

(i) Such transfer shall be accomplished in accordance with the provisions of sections 754.2(e) and 754.4 of this Title.

(ii) Unless already performed at a free-standing birth center, newborns transferred to a hospital shall have newborn screening performed at the hospital in accordance with Part 69 of this Title.

(iii) The hospital, as part of its quality [assurance] improvement activities, shall review all maternal and/or newborn transfers from birth centers to ensure adequacy of risk assessment and care, that each transfer has been appropriately arranged, and that reasons for the transfer have been documented clearly.

(10) Quality improvement activities. In addition to the quality assurance provisions of section 405.6 of this Part, the hospital shall, in conjunction with the medical staff and the nursing staff, monitor the quality and appropriateness of patient care and ensure that identified problems are reported to the quality assurance committee together with recommendations for corrective action. In accordance with section 721.9 of this Title, the hospital shall also perform quality improvement activities in accordance with its perinatal affiliation agreement.

(11) Functioning of [maternity and newborn] perinatal services. (i) Inpatient [maternity and newborn] perinatal services shall be operated as closed units with limited access to unnecessary hospital traffic.

(ii) The [maternity and newborn] perinatal service shall have available: services for the identification of high-risk mothers and fetuses, continuous electronic fetal monitoring, Cesarean delivery capabilities within 30 minutes of determination of need for such procedure, anesthesia services available on a 24-hour basis, radiology and ultrasound examination, with at least one

ultrasound machine immediately available for use by the labor and delivery service.

(12) Laboratory services. The [maternity and newborn] perinatal service shall have immediate access to the hospital's laboratory services including a 24-hour capability to provide blood group, Rh type and cross-matching, and basic emergency laboratory evaluations. Either ABO Rh-specific or O-Rh-negative blood and fresh frozen plasma shall be available at the facility at all times. Such other procedures as may be required by the [maternity and newborn] perinatal service shall be performed on a timely basis.

(13) Admissions.

(i) Women in need of medical care and services pertaining to pregnancy, delivery and the puerperal period shall be admitted to the maternity [and newborn] service. Such admission shall be consistent with section 405.9 of this Part.

(a) Each patient shall be attended by a licensed and currently registered obstetrician, family practitioner or [certified nurse-] licensed midwife who will be responsible for the patient's care.

(b) A patient may not be sent home without the prior knowledge and approval of her attending physician or [certified nurse] licensed midwife.

(ii) Admission of non-obstetric patients.

(a) The hospital shall develop and implement written policies and procedures for the admission of non-obstetric female patients to the [maternity and newborn] perinatal service area. The hospital shall ensure that obstetric patients take precedence over non-obstetric patients and that the safety and physical and psychological well-being of obstetric patients are not jeopardized.

(b) The following non-obstetric patients shall not be admitted to the maternity service:

[(1) patients with any known malignancy;

(2) patients requiring radiotherapy] (1) patients undergoing radiation therapy while they retain radioactive materials that have been administered for, or that result from, such treatment; and

[(3)] (2) patients in an acute, infectious state or with signs and symptoms which may denote infection.

(c) If an acute or chronic infection or any other condition which would have contraindicated admission to the [maternity and newborn] perinatal service is found during surgery or during any other period of hospitalization, the patient shall be removed from the [maternity and newborn] perinatal service area.

(14) Voluntary acknowledgment of paternity for a child born out of wedlock.

(i) If a child is born to an unmarried woman and the putative father is readily identifiable to the responsible hospital staff and available, the hospital shall:

(a) provide to the child's mother and putative father documents and oral and written instructions and information necessary for such mother and father to complete [a notarized] an acknowledgment of paternity form in compliance with section 4135-b of the Public Health Law and section 111-k of the Social Services Law; and

(b) [provide to the mother and putative father, prior to the execution of the acknowledgment of paternity, written information as required by section 111-k (1) of the Social Services Law concerning the legal consequences of signing a voluntary acknowledgment of paternity; and

(c)] file the executed acknowledgment of paternity with the registrar at the same time at which the certificate of live birth is filed, if possible.

(ii) The hospital shall not be required to seek out or otherwise locate a putative father who is not readily identifiable or available.

(15) Hospitals with a perinatal care service shall participate in the perinatal regionalization system in accordance with their level of care designations under Part 721 of this Title.

(16) Each hospital providing Level I, II or III perinatal care services shall enter into a perinatal affiliation agreement with its designated RPC in accordance with Part 721 of this Title. Level I and II hospitals may also enter into transfer agreements in accordance with Part 721 with Level III hospitals.

(d) High-risk antepartum services at Level II [and], Level III and RPC perinatal [care programs] services.

(1) Level II [and], Level III and/or RPC perinatal [care programs]services shall develop and implement written policies and procedures to indicate where pregnant patients with obstetric, medical, or surgical complications are to be assigned to provide for their continuous observation and care.

(2) Maternal [special] intensive care services.

(i) Hospitals providing Level I or II perinatal care [programs] services shall develop, enter into and implement written agreements with hospitals providing Level III and RPC perinatal care [programs] services for the transfer of obstetric patients whose physical conditions are evaluated as needing such higher level of care.

(ii) Hospitals which provide multiple levels of [maternal special] perinatal care services shall develop and implement written protocols and procedures for the in-house transfer of patients who are evaluated as requiring a level of care other than the level being provided in the

area where the patient is currently located.

(iii) Evaluation of the patient's condition and need for [special] intensive care services shall be conducted in accordance with standardized risk assessment criteria based on generally accepted standards of practice which shall be adopted in writing and implemented uniformly throughout the [maternity] perinatal service.

(iv) [Perinatal care programs. Hospitals] Level II, Level III and RPC perinatal care services shall [(a)] maintain a nursing staff that is appropriately trained and adequate in size to provide specialized care to distressed mothers and infants. The number of patient care staff on duty during any shift shall reflect the volume and nature of patient services being provided during that shift [; and].

[(b) a regional perinatal care center] (v) An RPC shall:

[(1)](a) offer education and training to [all hospitals] its perinatal affiliates and associated birth centers [in the region which provide maternity and newborn services]. Education and training shall be designed to update and enhance staff knowledge and familiarity with relevant procedures and technological advances;

[(2)](b) review, in conjunction with its perinatal affiliates, all cases of patients transferred to [the regional center] a higher level of care to determine whether such transfers were appropriate and accomplished according to established transfer agreements; and

[(3)](c) participate in case conferences with [hospitals] its perinatal affiliates and associated birth centers [in the region] to determine whether any non-transferred high-risk cases [which resulted in a poor pregnancy outcome] were handled appropriately and whether the transfer guidelines were adequate to address such circumstances.

(d) For purposes of participation in such activities, the RPC representative or

representatives shall be deemed member(s) of the perinatal 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.

(e) Intrapartum services.

(1) The hospital shall develop and implement written policies and procedures that indicate the areas of responsibility of both medical and nursing personnel for normal, high-risk, and emergency deliveries. These policies and procedures [should] shall be reviewed yearly and made available to all staff. There also shall be written policies for the care of pregnant patients when all antepartum and postpartum beds are occupied.

(2) Written policies and procedures shall be developed and implemented governing restrictions of entry to the closed labor and delivery unit, and the hospital shall ensure that, unless medically contraindicated, the patient may choose to be accompanied during labor and delivery by the father and/or other supportive person(s) who can provide emotional comfort and encouragement. Any such contraindications shall be noted in the medical record.

(3) Evaluation and preparation.

(i) In conjunction with the required updated history and physical exam, the hospital shall provide for the following:

(a) laboratory data including serologic tests for blood group, Rh type, syphilis and rubella titer;

(1) if the woman's serology is positive, a cord blood serology shall be obtained. If the

sample [has not been] could not be taken prior to the pregnancy's end [and the pregnancy terminates as a result of an emergency], the serology shall be taken at the time of termination of the pregnancy;

(2) the woman shall be evaluated for the risk of sensitization to Rho (D) antigen and if the use of Rh immune globulin is indicated, an appropriate dosage thereof shall be administered to her as soon as possible within 72 hours after delivery or termination of pregnancy;

(b) an assessment of the woman's HIV status and the provision of testing in accordance with Section 69-1.3(l) of this Title;

[(b)] (c) an admitting physical examination which shall include the woman's blood pressure, pulse and temperature, the fetal heart rate, the frequency, duration and evaluation of the quality of the uterine contractions, and which shall be recorded in the patient's medical record. An evaluation of any complications shall be made. If there is suspected leakage of amniotic fluid or any unusual bleeding, the attending physician or [certified nurse-] licensed midwife shall be notified immediately before a pelvic examination is performed. When there are no complications or contraindications, qualified nursing personnel may perform the initial pelvic examination to evaluate labor status and the imminence of delivery. The physician or [certified nurse-] licensed midwife responsible for the woman's care shall be informed of her status, so that a decision can be made regarding further management; and

[(c)] (d) [an] interval assessments including physical and psychological status of the woman and fetal status.

(ii) Pharmacological or surgical induction or augmentation of labor.

(a) Qualified practitioner as referred to in this section shall mean a practitioner functioning within his or her scope of practice according to State Education Law who meets the

hospital's criteria for privileging and credentialing practitioners in management of labor and delivery in accordance with the hospital's policies and procedures.

(b) [Chemical]Pharmacological or surgical induction or augmentation of labor may be initiated only after a [physician] qualified practitioner has evaluated the woman, determined that induction or augmentation is medically necessary for the woman or fetus, recorded the indication, obtained informed consent for induction or augmentation of labor, and established a prospective plan of management acceptable to the woman. If the [physician] qualified practitioner initiating these procedures does not have privileges to perform cesarean deliveries, a physician who has such privileges shall be contacted directly prior to [infusion of the oxytoxic agent, or other substance] initiation of the induction or augmentation [used to induce or augment labor] and a determination made that he or she shall be available within 30 minutes of determination of the need to perform a Cesarean delivery. If the patient has had a previous cesarean delivery, a physician with cesarean privileges must be immediately available during pharmacological induction or augmentation of labor.

(c) Pharmacological or surgical induction or augmentation shall be initiated by a qualified practitioner. A qualified practitioner shall initiate the induction or augmentation and shall remain with the woman for a period of time sufficient to ensure that the procedure or medication has been well-tolerated and has caused no adverse reaction. A physician capable of managing any reasonably foreseeable complications from the induction or augmentation of labor shall be available within a timeframe appropriate to the woman's needs.

(d) For pharmacological induction or augmentation of labor, the [(a) The] hospital shall develop and implement a written protocol for the preparation and administration of [an] the [oxytoxic] oxytocic agent and/or other substances used to induce or augment labor.

[(b) The attending, or another physician who has assumed responsibility for the patient's care, shall initiate the infusion of the oxytoxic agent, or other substance used to induce or augment labor, and remain with the woman for a period of time sufficient to ensure that the drug is well tolerated and has caused no adverse reactions.

(c) During the entire time of the infusion of the oxytoxic agent, or other substance used to induce or augment labor, the attending, or another physician who has assumed responsibility for the patient's care, shall be available within 10 minutes to manage any complications that may arise.

(d)] (e) During the entire time of the [infusion of the oxytoxic agent, or other substance used to induce or augment labor] labor induction or augmentation, the woman shall be monitored by staff who are trained and competent in both the monitoring of fetal heart rate and uterine contractions and interpretation of such monitoring. The monitoring shall be by either electronic fetal monitoring or auscultation. Where auscultation is used in lieu of electronic fetal monitoring, it shall be performed no less frequently than every 15 minutes during the first stage of labor and every five minutes during the second stage of labor.

(iii) No attempt shall be made to delay birth of an infant by physical restraint or anesthesia.

(iv) Each maternity patient, when present in a labor, delivery, birthing room or birth center shall be under the care of a registered professional nurse [immediately] available [to attend to her needs] in accordance with the patient's needs.

(v) The medical record shall be updated to note whenever the woman's choice of position for labor, use of drugs or technological support devices or mode of treatment and care cannot be honored due to medical contraindications. Standing orders for drugs or technological support

devices may only be implemented after the nature and consequences of the intervention have been explained to the woman, and the woman agrees to such implementation.

(4) Delivery.

(i) Hospitals shall develop and implement policies and procedures for the delivery room that shall require at least the following:

(a) regular evaluation of maternal blood pressure and pulse both during and after delivery; and

(b) fetal heart evaluation.

(ii) Section 405.13 of this Part concerning anesthesia services shall apply to the clinical [maternity and newborn] perinatal service. The anesthetist shall be informed in advance if complications with the delivery are anticipated.

(iii) The [maternity and newborn] perinatal service and the medical staff shall designate in writing those situations which require consultation with and/or transfer of responsibility from a [certified nurse-] licensed midwife or a family practice physician to an obstetrician.

(iv) Alternative arrangements for the organization of the [maternity] perinatal service, including but not limited to birthing rooms, birth centers or single unit maternity models, shall conform to pertinent requirements of this section and Parts 711 and 712 of this Title. Birth centers shall also conform to the patient care provisions of Part 754 of this Title.

(v) Immediate care of the newborn. The practitioner who delivers the baby shall be responsible for the immediate post-delivery care of the newborn until another qualified person assumes this duty. At all times, the newborn shall be attended by a [licensed] physician or [certified nurse-] licensed midwife and shall be under the care of a registered professional nurse.

(a) Resuscitation of a distressed newborn. The hospital shall develop and implement

policies and procedures for the recognition and immediate [skillful] resuscitation of a distressed newborn. Level I and II perinatal care [programs] services shall accomplish this in consultation with, and with assistance of, [the Level III perinatal care program] the RPC with which the [facility] hospital has a [transfer] perinatal affiliation agreement. The policies and procedures shall include the following elements:

(1) the designation of a physician to assume primary responsibility for the establishment of standards of care, review of practices, maintenance of appropriate drugs and training of personnel;

(2) approval of these policies and procedures by the directors of maternity and newborn services, anesthesia, pediatrics, nursing and by the medical staff;

(3) requirement for immediate availability of needed resuscitative equipment and personnel;

(4) presence in the delivery room of a member of the professional staff specifically qualified in newborn resuscitation;

(5) capability to provide short-term respiratory support including bag and mask ventilation;

(6) procedures for the stabilization of the distressed newborn;

(7) capability to perform endotracheal intubation and umbilical vessel catheterization. For a Level I perinatal care [programs] service, the [transfer agreements] perinatal affiliation agreement with [Level III perinatal care programs] its designated RPC shall provide for staff training to [ensure] develop current staff competence in these procedures[. These agreements shall also specify those situations that require immediate transfer rather than onsite performance of these procedures]; and

(8) procedures for the preparation and transfer of the distressed newborn to a Level III or RPC perinatal care [program] service when medically indicated.

(b) The hospital shall administer eye prophylaxis and vitamin K in accordance with sections 12.2 and 12.3 of this Title, [and] test for phenylketonuria and other diseases and provide or arrange for newborn hearing in accordance with Part 69 of this Title.

(c) The hospital shall conduct expedited HIV testing of a newborn whose mother's HIV status is unknown at delivery in accordance with Section 69-1.3(l) of this Title;

[(c)] (d) A professional staff person in attendance at a delivery shall ensure the proper identification of a newborn before it leaves the room where the delivery has occurred.

(1) The hospital shall ensure continuous identification of the newborn infant during the entire period of hospitalization, including verification of identity after each separation and reunion of mother and newborn. In addition to the development and implementation of written policies and procedures for continuous identification, further policies and procedures shall set forth steps to be taken when the means of identification which has been placed on the newborn becomes separated from the newborn.

(2) Newborns born of different mothers shall not be present at the same time in the room where delivery/recovery takes place, unless each has previously been identified by the methods prescribed in this clause.

[(d)] (e) Circumcision, which shall be an elective procedure, shall not be performed during the newborn stabilization period after birth.

(f) Postpartum care of mother. [Each maternity patient shall be under the immediate care of a registered professional nurse] Appropriate nursing care shall be available to the mother during the period of recovery after delivery. At all times after delivery, the mother shall have

maximum access to her baby unless such access is medically contraindicated and recorded in the appropriate medical record.

(1) The mother shall be transferred to the postpartum area only after her vital signs have stabilized. The hospital shall adopt and implement policies and procedures for identifying any postpartum complications that arise and informing the responsible practitioner who shall manage complications.

(2) Postpartum monitoring shall include the following:

(i) vital signs shall be recorded on a regular basis;

(ii) fluid intake and output shall be recorded. The uterine fundus shall be frequently examined to determine if it is well contracted and whether there is excessive bleeding;

(iii) the patient's practitioner shall be notified of any unusual findings;

(iv) nursing personnel qualified to recognize postpartum emergencies and problems shall be immediately available to the patient;

(v) the father or other support person shall be allowed to remain with the mother during the recovery period unless medically contraindicated or unless the nursing staff determines that the continued presence of the individual would interfere with the continuing care of the mother or other patients;

(vi) a physical assessment of the mother shall be conducted in accordance with established protocols; and

(vii) unless medically contraindicated or unacceptable to the mother, the newborn shall remain with the mother who shall provide a preferred source of body warmth for the newborn. During this period the newborn shall be closely observed for any abnormal signs and breastfeeding shall be encouraged.

(3) Education and orientation of the mother who is planning to raise the baby.

(i) The hospital shall provide instruction and assistance to each maternity patient who has chosen to breastfeed and shall provide information on the advantages and disadvantages of breastfeeding to women who are undecided as to the feeding method for their infants. As a minimum:

(a) the hospital shall designate at least one person who is thoroughly trained in breastfeeding physiology and management to be responsible for ensuring the implementation of an effective breastfeeding program. At all times, there should be available at least one staff member qualified to assist and encourage mothers with breastfeeding;

(b) written policies and procedures shall be developed and implemented to assist and encourage the mother to breastfeed which shall include, but not be limited to:

(1) prohibition of the application of standing orders for antilactation drugs;

(2) placement of the newborn for breastfeeding immediately following delivery, unless contraindicated;

(3) restriction of the newborn's supplemental feedings to those indicated by the medical condition of the newborn or of the mother;

(4) provision for the newborn to be fed on demand; and

(5) [restriction on] provision for distribution of discharge packs of infant formula [to an individual order] only upon a specific order by the attending practitioner or at the request of the mother;

(c) the hospital shall provide an education program as soon after admission as possible which shall include but not be limited to:

(1) the importance of scheduling follow-up care with a pediatric care provider within the

timeframe following discharge as directed by the discharging pediatric care provider.

[(1)](2) the nutritional and physiological aspects of human milk;

[(2)](3) the normal process for establishing lactation, including care of breasts, common problems associated with breastfeeding and frequency of feeding;

[(3)](4) dietary requirements for breastfeeding;

[(4)](5) diseases and medication or other substances which may have an effect on breastfeeding;

[(5)](6) sanitary procedures to follow in collecting and storing human milk; and

[(6)](7) sources for advice and information available to the mother following discharge; and

(d) for mothers who have chosen formula feeding or for whom breastfeeding is medically contraindicated, hospitals shall provide training in formula preparation and feeding techniques.

(ii) The hospital shall provide to the mother instructions in caring for herself and her baby. Topics to be covered shall include but not be limited to: self-care, nutrition, breast examination, exercise, infant care including taking temperature, feeding, bathing, diapering, infant growth and development and parent-infant relationships.

(iii) The hospital shall determine that the maternity patient can perform basic self-care and infant care techniques prior to discharge or make arrangements for post-discharge instruction.

(iv) Each maternity patient shall be offered a program of instruction and counseling in family planning and, [arrangements for family planning services shall be made if desired by the patient.] if requested by the patient, the hospital shall provide the patient with a list, compiled by the department and made available to the hospital, of providers offering the services requested.

(4) Visiting. The hospital shall develop and implement written policies and procedures regarding visiting that:

(i) do not unreasonably restrict fathers or other primary support person(s) from visitation to the mother during the recovery period;

(ii) promote family bonding by allowing regular visitation for the newborn's siblings in a manner consistent with safety and infection control; and

(iii) permit visitations by other family members and friends in a manner consistent with efficient hospital operation and acceptable standards of care.

(5) Discharge planning. The discharge of mother and newborn shall be performed in accordance with section 405.9 of this Part. In addition, prior to discharge, the hospital shall determine that:

(i) sources of nutrition for the infant and mother will be available and sufficient, and if this is not confirmed, the attending practitioner and an appropriate social services agency shall be notified;

(ii) follow-up medical arrangements for mother and infant have been made;

(iii) the mother has been instructed regarding normal postpartum events, care of breasts and perineum, care of the urinary bladder, amounts of activity allowed, diet, exercise, emotional response, family planning, resumption of coitus, and signs of common complications;

(iv) the mother has been advised on what to do if any complication or emergency arises;

(v) the newborn has [been examined for:

(a) possible dislocation of hips;

(b) both femoral pulses;

(c) vision capability; and

(d) passage of stools and urine] had a documented and complete physical examination and verification of a passage of stool and urine;

(vi) the means of identification of mother and newborn are matched. If the newborn is discharged in the care of someone other than the mother, the hospital shall ensure that the person or persons are entitled to the custody of the newborn; and

(vii) the newborn is stable; sucking and swallowing abilities are normal. Routine medical evaluation of the neonate's status at two[-] to three days of age shall have been conducted or arranged as well as newborn screening at time of discharge, provided discharge is greater than 24 hours after the birth, or between the third and fifth day of life, whichever occurs first, in accordance with Part 69 of this Title.

(g) High-risk neonatal [Neonatal] care. [(1) Hospitals providing Level I and II perinatal care programs shall enter into memoranda of agreement with Level III perinatal care programs for the transfer of distressed newborns requiring such higher level of care.]

(1) Each hospital providing Level I, II or III perinatal care services shall enter into a perinatal affiliation agreement with its designated RPC in accordance with Part 721 of this Title. Level I and II hospitals may also enter into transfer agreements in accordance with Part 721 with Level III hospitals.

(i) The [memoranda of agreement] perinatal affiliation agreements and transfer agreements shall include provisions for standardized risk assessment based on generally accepted standards of practice, stabilization and resuscitation of newborns as necessary, newborn screening in accordance with Part 69 of this Title, consultation, patient transport, transfer of maternal and newborn records, and any other features needed to ensure prompt and efficient transport of newborns, which minimize risks and provides the newborn with needed services.

(ii) Unless medically contraindicated, mothers shall be permitted to accompany distressed newborns to receiving [Level III] perinatal care facilities.

(iii) The [memoranda of agreement] perinatal affiliation agreements and transfer agreements shall provide for the return of the distressed newborn to the sending hospital when the condition has been stabilized and return is medically appropriate.

(iv) If transfer necessitates separating the mother and newborn, [Mothers] mothers who have chosen to breastfeed should be encouraged to maintain lactation, and breast milk should be available to the newborn.

(2) Placement in nurseries.

(i) Healthy newborns shall be placed in a [well-infant] normal newborn nursery. If a newborn in a [well-infant] normal newborn nursery is removed temporarily from the [maternity and newborn] perinatal service for any reason, the newborn may be returned to the [well-infant] normal newborn nursery only if infection control measures established by the hospital have been followed.

(ii) Newborns requiring [extraordinary] specialized care shall be placed in a [special care nursery] NICU and hospitals shall develop and implement protocols for all phases of treatment of such newborns. Newborns [requiring extraordinary care] who are delivered in [Level 1] perinatal care [programs] services that are not capable of providing all necessary care and services shall be transferred to [Level III] perinatal care [programs] services at hospitals that can meet the newborns' needs.

(h) [Neonatal special care services provided by Level II and III perinatal care facilities.

(1) Level III perinatal care facilities which provide neonatal special care services and are designated as regional perinatal care centers shall provide care and services in accord with the

patient care provisions of section 708.5(f)(3) of this Title.] Neonatal intensive care services.

(1) Neonatal intensive care services shall be provided by Level II, Level III and RPC perinatal care hospitals.

(2) [Level II and III perinatal care facilities providing intensive and/or intermediate neonatal care but not designated as regional perinatal care centers shall provide care and services in accord with the patient care provisions of section 708.5(f)(4) and (5) of this Title.] Decisions regarding the appropriate level of care and the need for transport of a neonate to a higher level of care shall be made consistent with generally accepted standards of care and the hospital's perinatal affiliation agreement.

(3) Treatment of severely ill, injured, or handicapped infants with life-threatening conditions.

(i) Severely ill, injured or handicapped infants exhibiting life-threatening conditions shall be transferred to and/or treated at RPCs or other hospitals having Level III perinatal care [programs] services after consultation with that [program] service has established that the infant might benefit from such transfer.

(ii) Level III perinatal care [programs] services and RPCs shall [establish an infant] consult with the hospital's bioethical review committee which shall assist the service and provide guidance to staff and families in the resolution of issues affecting the care, support and treatment of severely ill, injured, or handicapped infants with life-threatening conditions. The committee:

(a) shall consist of such members of the medical staff, nursing staff, social work staff and administration as designated by the governing body and such other community-based individuals with experience in bioethical matters as may be chosen by the governing body;

(b) shall operate in accordance with written policies and procedures developed by the

hospital. Such policies shall establish the protocols for organization and functioning of the committee and scope of responsibility for specified cases as well as development of general review policies governing bioethical matters. The hospital shall:

(1) ensure that the parents are fully advised regarding the infant's condition, prognosis, options for treatment, likely outcomes of such treatment and options, if any, for the discontinuance of heroic life- maintenance efforts; and

(2) ensure that any decision by competent parents to continue life-sustaining efforts is implemented by the hospital; and

(c) shall, in conjunction with the attending physician(s), child protective services, the medical staff, and governing body, recommend that the hospital obtain an appropriate court order to undertake a course of treatment, in all cases when in the judgment of the committee:

(1) the parents do not have the capacity to make a decision; or

(2) the parents' decision on a course of action is manifestly against the infant's best interest.

Section 407.14 of Part 407 of Title 10 is amended to read as follows:

Section 407.14 Optional services. A Primary Care Hospital (PCH) may offer additional special services, for which it is able to provide appropriate technical and human resources, in order to respond to community need or to assure quality in the delivery of services. Optional services may include but are not limited to ambulatory surgery, inpatient surgery under anesthesia, full range laboratory services, full range imaging services, radiation oncology and nuclear medicine, full range pharmacy services, physical medicine and rehabilitation services, respiratory care services, [maternity and newborn] perinatal services, mental health services,

blood bank/transfusion services, or special care services. Such services may only be provided if approved by the Commissioner of Health pursuant to sections 407.2(a) and 407.3(c) of this Part and the applicable provisions of Part 710 of this Title.

Paragraph (6) of subdivision (b) of section 708.2 of Part 708 of Title 10 is repealed in its entirety and RESERVED.

Subdivision (f) of section 708.5 of Part 708 Title 10 is repealed in its entirety and RESERVED.

Paragraph (21) of subdivision (d) of section 711.4 of Part 711 of Title 10 is amended to read as follows:

(21) Hospitals having [a maternity and newborn service] perinatal services shall provide a maternity patient nursing unit, an obstetrical suite, and a nursery unit, located so as to prevent traffic through them to any other part of the hospital. They shall be completely separate from all other clinical services, including the gynecological service. The requirement for these functions shall be the same as the minimum requirements for other nursing units required by this section.

Paragraph (10) of subdivision (e) of section 711.4 of Part 711 of Title 10 is amended to read as follows:

(10) A standby formula room, immediately available, with space for preparation of infant feedings and for reception and washing of equipment shall be provided. It shall have no direct access to a nursery or nursery accessory room. Such formula room, equipment and supplies, when not in use, may be designated for other clean purposes, with the approval of the full-time health officer, may be located on the [maternity and newborn] perinatal service floor, or

elsewhere in the hospital, and shall include the following:

A new Part 721 is added to Title 10 to read as follows:

Part 721

Perinatal Regionalization System

Sec.

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

(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.

(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.

(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 <u>assisted</u> 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. 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 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. 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. 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.

(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.

(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.