Public Health and Health Planning Council

Codes, Regulations and Legislation Committee Meeting Agenda
February 9, 2023

(Immediately following the Special Establishment and Project Review Committee meeting scheduled to begin at 10:00 AM)

90 Church Street, Conference Rooms 4 A/B, NYC

Empire State Plaza, Concourse Level, Meeting Room 6, Albany

I. WELCOME AND INTRODUCTION

Thomas Holt, Chair of the Committee on Codes, Regulations and Legislation

II. REGULATIONS

For Adoption

22-21 Amendment of Section 23.1 of Title 10 NYCRR (Mpox to the List of Sexually Transmitted Diseases (STDs))

For Discussion

20-28 Amendment of Sections 12.2 & 405.21, and Parts 721, 754 & 795 of Title 10 NYCRR (Perinatal Services, Perinatal Regionalization, Birthing Centers and Maternity Birthing Centers)

III. ADJOURNMENT

******Agenda items may be called in an order that differs from above******

Pursuant to the authority vested in the Public Health and Health Planning Council and the Commissioner of Health by sections 225(4), 2304, 2305 and 2311 of the Public Health Law, Section 23.1 of Title 10 of the Official Compilation of Codes, Rules and Regulations of the State of New York is amended, to be effective upon publication of a Notice of Adoption in the State Register, to read as follows:

Group B of Section 23.1 is amended to read as follows:

Group B

Facilities referred to in section 23.2 of this Part must provide diagnosis and treatment, including prevention services, as provided in section 23.2(d) of this Part for the following STDs:

Human Papilloma Virus (HPV)

Genital Herpes Simplex

Human Immunodeficiency Virus (HIV)

<u>Mpox</u>

Regulatory Impact Statement

Statutory Authority:

Pursuant to sections 225(4), 2304, 2305 and 2311 of the Public Health Law (PHL), the Commissioner of Health and the Public Health and Health Planning Council have the authority to adopt regulations that list the sexually transmitted diseases (STDs) for which PHL Article 23 is applicable and, in particular, that establish requirements for local health departments (LHDs) concerning STD services.

Legislative Objectives:

PHL section 2311 requires the Commissioner of Health to promulgate a list of STDs. The purpose of Article 23 of the PHL, and its associated regulations, is to ensure that persons at risk for or diagnosed with an STD have access to diagnosis and treatment, including prevention services, thereby improving their health and public health in New York State. Additionally, providing STD diagnosis and treatment, including prevention services, is vital to protecting the health of newborn children whose mothers may have an STD.

Needs and Benefits:

This amendment adds mpox to Group B of the existing list of STDs. County LHDs already have an obligation to control the spread of mpox under PHL Article 6 communicable disease guidance. Consistent with such guidance, this regulation requires STD clinics operated by LHDs or providing services through contractual arrangements to provide diagnosis and treatment, including prevention services, to persons diagnosed or at risk for mpox, either directly or through

referral. Further, minors will be able to consent to their own mpox testing, prevention services (including vaccine), and treatment.

This amendment supports the Department's plan to control the current and future mpox outbreaks by connecting persons diagnosed with, exposed to, or at risk of mpox with testing, vaccine, treatment, and prevention services. Young people currently face barriers that can prevent or delay access to care, including denial and fear of their mpox infection, misinformation, mpox-related stigma, low self-esteem, lack of insurance, homelessness, substance use, mental health issues, and lack of adequate support systems. Because of these factors, many young people need the ability to consent to mpox diagnosis and treatment, including prevention services.

These regulations will help ensure that more young people have optimal health outcomes and do not transmit the virus to others. In addition, young people will have the ability to consent to mpox related preventive services, including those who have been exposed to STDs or who are at high risk for mpox. Under the amended regulation, such individuals will be able to obtain mpox vaccine so they can remain mpox negative. These amendments are necessary to provide appropriate health care rights and protections to minors and remove the barriers that can prevent or delay access to diagnosis and treatment, including prevention services.

Costs to Regulated Parties:

LHDs may diagnose patients for mpox by offering mpox testing. In regard to mpox treatment, including prevention services, some LHDs may experience up-front costs associated with providing treatment to additional individuals. However, these regulations do not mandate that an

LHD provide treatment directly. As with the other conditions already listed in Group B, LHDs may fulfill their obligation to provide mpox treatment by referring the patient to another provider; they are not required to pay for treatment.

Providing diagnosis and treatment, including mpox vaccine, to persons diagnosed or at risk for mpox may increase the use of mpox vaccine. It is anticipated that any increase in mpox vaccination will decrease the number of people who become mpox positive, thereby greatly decreasing the cost of providing care to individuals who are mpox positive. The mpox vaccine is provided by the federal government at no cost to the State.

Generally, LHDs and other providers that provide mpox treatment must seek to offset any costs by billing insurance for rendered services. At this time, treatment for mpox, including Tecovirimat (also known as TPOXX or ST-246), is provided under an expanded access Investigational New Drug (EA-IND) protocol, which allows for the use of TPOXX for primary or early empiric treatment of non-variola orthopoxvirus infections, including mpox, in adults and children of all ages. The treatment is provided at no cost.

Costs to State Government:

There are no direct costs to the State or the Department. The Department will continue to work with LHDs using existing resources to provide guidance regarding the control of communicable diseases using STD clinics and other methods as required by the PHL Article 6 State aid rules and these regulations.

Local Government Mandates:

As discussed above, these amendments will require STD clinics operated by LHDs to provide mpox diagnosis and treatment, including prevention services, either directly or by referral. LHDs are not, however, required to provide mpox treatment directly; they may refer patients to other providers for treatment.

Paperwork:

LHDs will be required to bill public and commercial third-party payers to the extent practicable to offset the costs of providing mpox treatment services.

Duplication:

There are no relevant rules or other legal requirements of the Federal or State governments that conflict with this rule. Like other STDs (syphilis, gonorrhea, etc.), since mpox will be listed on both the state communicable disease list and the STD list, two sets of Article 6 guidance documents for LHDs will apply to mpox.

Alternatives:

The alternative is to continue not to list mpox as an STD in New York. However, to advance the goal of controlling mpox outbreaks, mpox should be listed as an STD. This will not only reduce morbidity and mortality, but will also decrease health care costs statewide by lowering the prevalence of mpox and the cost of providing care to mpox-positive individuals.

Federal Standards:

There are no Federal standards in this area.

Compliance Schedule:

The amendment will take effect upon publication of a Notice of Adoption in the State Register.

The Department will assist affected entities in compliance efforts.

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Regulatory Flexibility Analysis
for Small Businesses and Local Governments

Effect of the Rule:

The proposed amendments to 10 NYCRR Part 23 will impact the 58 local health departments (LHDs) and the New York City Department of Health and Mental Hygiene, which are required to provide STD services as a condition of State Aid pursuant to Article 6 of the Public Health Law. In addition, local governments are responsible for the local share of the cost of the Medicaid program. The amendments will not impact small businesses (i.e., small private practices or clinics) any differently from other health care providers.

This mandate does not create new costs for local government. Currently, since mpox is listed as a communicable disease in 10 NYCRR §2.1, and since LHDs are responsible for controlling the spread of communicable diseases, LHDs are already required to treat mpox. Therefore, this regulation adding mpox to the list of STDs will not create any unfunded mandate for local government.

Increasing vaccination rates will decrease the number of mpox cases and will reduce Medicaid costs to care for Medicaid recipients with mpox, thereby reducing the local share of the cost of the Medicaid program. Since the vaccine is provided for free, this regulation implements a public health measure that will save money for local governments that are supported by property taxpayers.

Compliance Requirements:

Pursuant to these amendments, LHDs must provide mpox diagnosis and treatment, including prevention services, either directly in an STD clinic, or by making a written or electronic prescription or referral to another health care provider. Implementation of this rule will require recordkeeping and reporting by LHDs.

Professional Services:

Those LHDs that provide mpox treatment services directly or through contract may be required to ensure the development or updating of billing systems to comply with the obligation to seek payment from insurance providers to the extent practicable.

Compliance Costs:

LHDs diagnose patients for mpox by offering mpox testing. In regard to mpox treatment, including prevention services, some LHDs may experience up-front costs associated with providing treatment to additional individuals. However, these regulations do not mandate that an LHD provide treatment directly. As with the other conditions already listed in Group B, LHDs may fulfill their obligation to provide mpox treatment by referring the patient to another provider; they are not required to pay for treatment.

Providing diagnosis and treatment, including prevention services, to persons diagnosed or at risk for mpox may increase the use of mpox vaccine. It is anticipated that any increase in the use of prophylactic services will decrease the number of people who become mpox positive, thereby greatly reducing the cost of providing care to individuals who are mpox positive.

In addition, LHDs and other providers that provide mpox treatment must seek to offset any costs by billing insurance for rendered services to the extent practicable. Remaining costs may be eligible for reimbursement from other sources that fund mpox treatment in New York.

Economic and Technological Feasibility:

The requirement to seek insurance recovery and the availability of other funding sources make this requirement economically feasible. There are no new technology requirements. The Department will also provide technical advice and support as needed.

Minimizing Adverse Impact:

LHDs and other providers that provide mpox treatment must seek to offset any costs by billing insurance for rendered services. Remaining costs may be eligible for reimbursement from other sources that fund mpox treatment in New York.

Small Business and Local Government Participation:

Community stakeholders, representative of regions and businesses across New York State, have been engaged in the response to the mpox outbreak, including ensuring that minors have the right to consent to mpox treatment and prevention services. The recommendation to amend regulations to ensure minors have the right to consent to mpox treatment and prevention services has been supported by community stakeholders. The Department sought and received input from local health departments, including the New York City Department of Health and Mental Hygiene.

This regulation does not have the effect of imposing a mandate. Rather, it permits local governments to expand access to mpox vaccine, which will result in cost savings, because less money will need to be spent on treatment. LHDs are already providing mpox vaccine. The reason minors should be permitted to access mpox vaccine is that it will prevent minors from getting mpox, which furthers the Department's mission to decrease morbidity and mortality.

Cure Period:

Chapter 524 of the Law of 2011 requires agencies to include a "cure period" or other opportunity for ameliorative action to prevent the imposition of penalties on the party or parties subject to enforcement when developing a regulation or explain in the Regulatory Flexibility Analysis why one was not included. This regulation creates no new penalty or sanction. Hence, a cure period is not necessary.

Rural Area Flexibility Analysis

Types and Estimated Numbers of Rural Areas:

The proposed amendments to 10 NYCRR Part 23 will impact clinicians in rural areas no differently than throughout New York State.

Reporting, Recordkeeping and Other Compliance Requirements; and Professional Services:

This rule imposes no mandates upon entities in rural areas outside those entities noted in Article 23 of the Public Health Law. As stated, local health departments (LHDs) must provide mpox treatment, including prevention services, either directly in an STD clinic, or by making a written or electronic prescription or referral to another health care provider. Implementation of this rule will require recordkeeping and reporting by LHDs.

Costs:

Some clinicians may experience up-front costs associated with providing mpox treatment services, including prevention services, to additional individuals. However, these regulations do not mandate health care providers to provide mpox treatment services. Any provider that does provide mpox treatment for additional patients can offset any costs by billing for services rendered.

Minimizing Adverse Impact:

As discussed above, the ability to recover costs will minimize the impact of these regulations.

Rural Area Participation:

Community stakeholders, representative of regions and businesses across New York State, including those in rural areas, have been engaged in the response to the mpox outbreak, including ensuring that minors have the right to consent to mpox treatment and prevention services. The recommendation to amend regulations to ensure minors have the right to consent to mpox treatment and prevention services has been supported by community stakeholders in rural areas.

Statement in Lieu of
Job Impact Statement

No Job Impact Statement is required pursuant to section 201-a(2)(a) of the State Administrative Procedure Act. It is apparent, from the nature of the proposed amendments, that it will not have an adverse impact on jobs and employment opportunities.

SUMMARY OF EXPRESS TERMS

This regulation amends 10 NYCRR sections 12.2 and 405.21, and Parts 721, 754 and 795.

The amendments carry out the recommendations of the Department's perinatal regionalization expert panel. The Department's expert panel made recommendations for the perinatal system in New York State, which includes Regional Perinatal Centers (RPCs), Level III hospitals, Level II hospitals, Level I hospitals, and freestanding birth centers including midwifery-led birth centers.

The recommendations addressed the role of RPCs and affiliation agreements with RPCs, transfers, maternal services, neonatal services, behavioral health and substance use, subspecialists (obstetric and neonatal), and finance. The regulations align with current standards of practice as advised by the American Association of Birth Centers (AABC), American College of Gynecologists (ACOG), and American Academy of Pediatrics (AAP). Standards from the Commission for the Accreditation of Birth Centers (CABC) related to accreditation and clinical requirements were reviewed in relation to freestanding- and midwifery-led birth center standards, to assess the impact of accreditation. Operational requirements for accredited midwifery birth centers were added to maintain their involvement in the regional perinatal system, including affiliation and transfer agreements and data and quality improvement requirements. These requirements are identical to those of other freestanding birth centers.

The proposed regulations also reflect New York State's requirements for the establishment of midwifery led birth centers, which includes physical plant standards,

namely compliance with National Fire Protection Association (NFPA) 101 Life Safety Code, Facility Guidance Institute (FGI) requirements for Birth Centers, and ADA Standards for Accessible Design. These national standards are utilized by the Department of Health in Article 28 licensure, similar to those referenced by the CABC for accreditation. Regulations also remove Advanced Cardiac Life Support (ACLS) requirements for freestanding and midwifery birth centers, in line with current standards of practice. Additionally, the Department has outlined areas of flexibility to those national standards for birthing centers with a maximum of three birthing rooms (and a maximum of six rooms total, birthing and exam).

The proposed regulations add requirements to notify the Department within two days when Neonatal Intensive Care Unit (NICU) and/or maternity census exceeds the number of licensed beds.

The proposed regulations strengthen the role of RPCs in offering support to affiliates. The regulations will require RPCs to coordinate transfers among its affiliates. The role of the RPCs in quality improvement and data review ensures that identified problems are reported to and addressed by quality assurance committees. Quality improvement will be achieved through a systematic, formal application of continuous actions aimed at optimizing patient health and safety.

In addition, section 12.2 is amended to remove references to tetracycline or erythromycin eye preparation or a one percent solution of nitrate of silver, while still requiring eye prophylaxis to newborns to prevent purulent conjunctivitis in accordance with current standards of care.

Finally, updating regulatory language with the use of gender-neutral terminology will make the document more all-inclusive of persons receiving midwifery, obstetrical and neonatal health care services in New York.

Pursuant to the authority vested in the Public Health and Health Planning Council and the Commissioner of Health by section 2803 of the Public Health Law, Sections 12.2 and 405.21, and Parts 721 and 754 of Title 10 (Health) of the Official Compilation of Codes, Rules and Regulations of the State of New York are hereby amended, to be effective upon publication of a Notice of Adoption in the New York State Register:

Section 12.2 is amended read as follows:

Precautions to be observed for the prevention of purulent conjunctivitis of the newborn. It shall be the duty of the attending physician, licensed midwife, licensed nurse or other authorized provider in attendance at a [delivery] birth to place into the eyes of the [infant, on delivery] neonate upon birth, an agent effective for preventing purulent conjunctivitis of the [newborn such as tetracycline or erythromycin eye preparation or a one percent solution of nitrate of silver] neonate in accordance with current standards of care.

Section 405.21 is amended to read as follows:

Perinatal services.

(a) Applicability. This section shall apply to all general hospitals having [maternity] midwifery, obstetrical and [newborn] neonatal services and providing pregnancy-related care for [women] patients who are pregnant at any stage, parturient or within six weeks from [delivery] birth and for infants 28 days of age or less (i.e., neonate) or, regardless of age, who are less than 2,500 grams (5 1/2 pounds).

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

(1) Perinatal services shall mean those services provided in a particular hospital where, as a regular practice, [maternity] midwifery/obstetrical patients and [newborn infants] neonates 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] midwifery, obstetrical and [newborn] neonatal health care services, designed as set forth in [Part] this section and Parts 721, 754 and 795 of this Title, to ensure that [mothers] midwifery/obstetrical patients and [newborns] neonates receive the care they need in a timely, safe and effective manner.

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

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

(5) Single unit [maternity] midwifery, obstetrical or labor-delivery-[recrovery] recovery-postpartum model shall mean a model for family-centered [maternity] midwifery, obstetrical and [newborn] neonatal care in which labor, [delivery] birth, 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] patients.

(6) Rooming-in shall mean an arrangement which allows the [mother] postpartum patient and [her newborn infant] neonate to be cared for

together, so that the [mother may have access to her infant] neonate is accessible during all or a substantial part of the day and night, not limited to feeding times.

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

* * *

(9) Low [birth weight infant] birthweight neonate shall mean [an infant] a neonate weighing less than 2,500 grams (5 1/2 pounds) at birth. Very low birthweight neonate shall mean a neonate weighing less than 1,500 grams (3 pounds 5 ounces). Extremely low birthweight neonate shall mean a neonate weighing less than 1,000 grams (2 pounds 3 ounces).

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

(11) Neonatal intensive care unit ("NICU") shall mean a room at Level II, Level III and Regional Perinatal Center perinatal care services for housing [newborns] neonates, including premature [infants] and low [birth weight infants] birthweight neonates, who require specialized care and who are not suspected of nor diagnosed as having any communicable condition. A Level I hospital shall not provide NICU or other specialized care services to neonates.

(12) Observation nursery shall mean a room, physically separate from the normal newborn nursery, where [newborns] neonates, including premature and low birthweight neonates exposed to potential sources of infection,

and [newborns] neonates suspected of but not diagnosed as having any communicable condition may be observed, pending diagnosis.

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

* * *

(15) Level I perinatal care service shall mean [a comprehensive maternal] an obstetrical and [newborn] neonatal service as defined by Section 721.2([a]c) of this Title. Midwifery services may also be provided.

(16) Level II perinatal care service shall mean a comprehensive [maternal] obstetrical and [newborn] neonatal service as defined by Section 721.2([b]d) of this Title. Midwifery services may also be provided.

(17) Level III perinatal care service shall mean a comprehensive [maternal] obstetrical and [newborn] neonatal service as defined by Section 721.2([c]e) of this Title. Midwifery services may also be provided.

(18) Regional perinatal center ("RPC") shall mean a hospital [or hospitals] housing a Level III perinatal care service and providing additional services to perinatal affiliates within a regional perinatal network as defined by Sections 721.2([d]g) and 721.2(h) of this Title.

(19) Perinatal affiliates shall mean birth centers and Level I, Level II and Level III hospitals which belong to a regional perinatal network and have a current perinatal affiliation agreement as defined [in Part] by Parts 721, 754 and 795 of this Title as applicable.

(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] patient's usual residence following a normal uncomplicated pregnancy, as defined in sections 754.1 and 795.1 of this Title.

(21) Birthing room shall mean a hospital room designed as a homelike setting which serves as a combined [labor/delivery/recovery] labor/birthing/recovery room and where family members or other supporting persons may remain with [a woman] a patient 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 problems 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] in alignment with evidence-based practice and current standards of professional care.

(23) Definitions in section 721.2 of this Title shall apply to this section.

(c) General requirements.

(1) Hospitals providing 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 professional qualifications of the [obstetric] midwifery, obstetrical and [pediatric] neonatal staff;

* * *

(iii) 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];

(iv) protocols and resources available to stabilize and assess [infants] neonates for their need of neonatal intensive care; and

(v) the daily care of [maternity] midwifery/obstetrical patients and [infants] neonates in the perinatal service.

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

(i) a copy or abstract of the prenatal record, if existing, including [a maternal] a reproductive history and physical examination as well as [results] documentation of [maternal and fetal risk assessment, results of maternal] any HIV [, Hepatitis] testing under section 69-1.3(n) of this Title, prenatal hepatitis B [and] antigen test result, including the date of specimen collection, in accordance with Subpart 69-3 of this Title, syphilis and other sexually transmitted infection testing and treatment during the current pregnancy, Group B strep testing if done, and ongoing assessments of fetal growth and development and [maternal] patient health;

* * *

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

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

(i) [newborn] neonatal physical assessment, including but not limited to Apgar scores, presence or absence of three cord vessels, ability to feed, vital signs and accommodation to extrauterine life;

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

(iii) description of [maternal-newborn] patient-neonate interactions; [and]

(iv) orders for newborn screening tests, including [arrangements for] screening for hearing[.] and critical congenital heart defects;

(v) documentation of hepatitis B vaccination in accordance with subpart 69-3 of this Title; and

(vi) documentation of HIV prophylaxis and/or treatment under section 69-1.3(n) of this Title.

(4) The hospital shall ensure the transfer to the[newborn's] neonate's medical records of [a mother's] the midwifery/obstetrical patient's HIV test result under section 69-1.3(n) of this Title, hepatitis B antigen test result, including the date of specimen collection, in accordance with subpart 69-3 of this Title, and syphilis and other sexually transmitted infection test results, if [one exists] such results exist.

(5) The hospital shall maintain in a timely manner in the 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] birth, names of personnel present [in the delivery room] at birth, sex, weight and gestational age of [infant] neonate, location of [delivery] birth and outcome of [delivery] birth. Any [delivery] birth 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 perinatal service. In addition, the following requirements relating to the control of infection or other communicable conditions in the 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 [practioner] 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] a midwifery/obstetrical 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 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] neonates exposed to or showing signs of developing an infection or communicable condition. Such policies shall not unnecessarily restrict the [mother's] postpartum patient's access to [her infant; and] the neonate;

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

(v) the hospital shall adopt and implement written policies and procedures to address situations in which the labor-delivery/maternity unit and/or neonatal intensive care unit (NICU) census exceeds the number of licensed beds identified on the hospital's certificate of need. Level I, II and III birthing hospitals shall develop such policies in collaboration with their Regional Perinatal Center (RPC); RPCs shall also develop such policies. These policies and procedures must include at a minimum:

(*a*) notification to the Department within two (2) business days when the maternity and/or NICU census exceeds the number of licensed beds;

(*b*) prioritization of current patients who are stable to transfer to another affiliate hospital that is capable of providing appropriate care;

(*c*) documentation of consent to transfer midwifery/obstetrical patients, and consent from the birthing person, or their family if the birthing person is not able to give consent, to transfer neonatal patients;

(*d*) documentation of refusal and patient education efforts when consent to transfer is not given;

(*e*) policies to reduce the number of newly admitted patients, including those newly presenting for birth and those transferred from a lower level of care when there is an alternate and appropriate hospital that is available to admit the transferred patient.

(7) Preconception services. The hospital shall develop and implement written policies and procedures for preconception services either onsite or through referral arrangements. Services shall include but not be limited to family planning and reproductive health services, sexual health assessment, including partner HIV and sexually transmitted infection status, nutritional assessment and counseling, genetic screening and counseling, screening for depression and perinatal mood disorder, intimate partner violence, alcohol and substance use, tobacco use, and identification and treatment of medical conditions that could adversely affect the patient's health,

including a future pregnancy, and referral for identified supportive service needs.

(8) [Hospital prenatal] 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] pregnant people in the hospital service area. Such prenatal care activities shall encourage active participation by patients and families in their own plan of health care. Hospitals shall implement policies and procedures to address missed visits and patients lost to care. 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] patients 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] screening for depression and perinatal mood disorder, intimate partner violence, alcohol and substance use, tobacco use, provision of pregnancy complications

educational material as required by section 2803-w and subdivision 2 of section 266 of Public Health Law, 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, mental health and alcohol, substance, and tobacco cessation support services as needed;

(*f*) ongoing [maternal and fetal] risk assessment of the pregnant person and fetus;

(*g*) prebooking for [delivery] birth;

(*h*) providing HIV counseling and a clinical recommendation for testing to pregnant [women] patients as early in pregnancy as possible, and again in the third trimester, preferably between 34 and 36 weeks gestation, for all patients who test negative for HIV in early pregnancy. Counseling and/or testing, if accepted, shall be provided pursuant to Public Health Law Article 27-F and Part 63 of this Title. Information regarding the [woman's] patient's HIV counseling and HIV status must be transferred as part of [her] the medical history to the [labor and delivery site] birth center or birthing hospital. [Women] Patients with positive test results shall be referred to the necessary health and social services as soon as possible and within a clinically appropriate time. If no HIV test result is

documented in the health record of the patient, and the patient's HIV status during the current pregnancy is unknown, the hospital shall immediately arrange an expedited HIV test of the patient with the patient's consent. If the patient declines testing, the hospital shall arrange for expedited HIV antibody screening for the neonate, with results available as soon as practicable in accordance with current standards of care.

(ii) To perform the activities and provide the services in subparagraph (i) of this paragraph, the 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[;] and 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 and midwifery 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] patients which address [as] at a minimum the anatomy and physiology of pregnancy, labor and [delivery] birth, neonatal/infant care and feeding, breastfeeding, formula feeding if desired by the patient, parenting, nutrition, prenatal, neonatal, infant and childhood vaccines, the effects of smoking, alcohol and other drugs on the patient and fetus, signs of perinatal depression or perinatal mood and anxiety disorder, what to expect if transferred, [and]the newborn screening program with the distribution of newborn screening educational literature, and the newborn hearing screening program.

(iv) The hospital shall assure that each prebooked [woman] patient 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] birth, and postpartum services. The attending [practioner] practitioner shall:

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

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

(*c*) obtain from the [woman her] patient informed [choice of] consent for 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] transfer agreements with [free standing] birth centers in their service area, [upon request from such centers,] for the prompt admission of [women and newborns] patients and transfer of records of any birth center patients whose assessed condition necessitates admission to the level of perinatal service provided by such hospital.

* * *

(ii) Unless already performed at a [free-standing] birth center, [newborns] neonates 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 improvement activities, shall allow the RPC to review all [maternal] obstetrical and [/or newborn] neonatal transfers [from birth centers] between perinatal providers within its affiliate network to ensure [adequacy of] that perinatal providers are adequately assessing risk [assessment] and [care, that each transfer has been appropriately arranged] arranging for and [that] documenting the 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]10 of this Title, the hospital shall also perform quality improvement activities in accordance with its perinatal affiliation agreement. Continuous quality improvement practices shall be undertaken by the affiliate birth centers, hospitals and RPC, and, as facilitated by the RPC, in the affiliate region as a whole. Quality improvement shall be achieved through a systematic, formal application of continuous actions aimed at optimizing patient health and safety. These actions include, but are not limited to:

(i) accurate collection, submission and analysis of perinatal data;

(ii) review of sentinel cases and patterns of care;

(iii) identification of processes and practices for improvement;

(iv) planning and implementation of rapid cycle improvements; and

(v) ongoing review of policies and procedures to ensure alignment with current standards of professional practice.

(11) Functioning of perinatal services.

* * *

(ii) The perinatal service shall meet all requirements for level of perinatal care in accordance with Part 721 of this Title, and have available: services for the identification of high-risk [mothers]

obstetrical patients and fetuses, and 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 perinatal service shall:

(i) meet all requirements for level of perinatal care in accordance with Part 721 of this Title and have immediate access to the [hosiptal's] hospital's laboratory services including a 24-hour capability to provide blood group, Rh type and cross-matching, and basic emergency laboratory evaluations. The perinatal service shall establish protocols for massive transfusion. Either ABO Rh-specific or 0-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 perinatal service shall be performed on a timely basis.

(ii) ensure the availability at all times of expedited HIV testing, with results reported as soon as practical but no later than 12 hours after the pregnant or postpartum patient provides consent or, if consent is not provided, 12 hours after the birth of the neonate, in accordance with subpart 69-1 of this Title.

(13) Admissions.

(i) [Women] Patients in need of medical care and services pertaining to pregnancy, [delivery] birth and the puerperal period shall be

admitted to the [maternity] midwifery or obstetrical service. Such admission shall be consistent with section 405.9 of this Part and Part 721 of this Title.

* * *

(*b*) [A patient may be sent home without] The hospital must notify and obtain the [prior knowledge and] approval of [her] the patient's attending physician or licensed midwife before making the determination not to admit the patient.

(*c*) Patients who present to a perinatal service who may need care that is not available at that hospital shall be stabilized and transferred, in consultation with the RPC, and in accordance with Part 721 of this Title.

(ii) Admission of [non obstetric] non-pregnant patients.

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

(*b*) The following [non obstetric] non-pregnant patients shall not be admitted to the [maternity] obstetrical service:

* * *

(14) Voluntary acknowledgement of paternity for [a child born out of wedlock] certain children pursuant to section 4135-b of the Public Health Law.

* * *

(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] higher level perinatal hospitals.

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

* * *

(2) [Maternal] Obstetrical intensive care services.

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

(ii) Hospitals [which provide multiple levels of 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, including but not limited to critical care or intensive care services.

(iii) Evaluation of the patient's condition and need for 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 perinatal service. The hospital shall consult with the RPC as needed.

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

(v) An RPC shall:

(*a*) offer education and training to its perinatal affiliates [and associated birth centers]. Education and training shall be designed to update and enhance staff knowledge and familiarity with relevant procedures [and], technological advances, and current standards of professional practice;

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

(*c*) participate in case conferences with its perinatal affiliates [and associated birth centers] to determine whether any non-transferred cases including high-risk cases 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'] birth center and hospital 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] Hospitals shall develop and implement written policies and procedures that indicate the areas of responsibility of [both] medical, midwifery and nursing personnel as appropriate for normal, high-risk, and emergency deliveries. These policies and procedures 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] in the hospital are occupied. Level II and III facilities and RPCs shall implement written policies for the care of neonatal intensive care unit (NICU) patients, which may include back transports and transfers under the direction of the RPC when resources are at capacity.

(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] birth by [the father] a partner 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, but not limited to, serologic tests for blood group, Rh type, hepatitis B, syphilis and rubella titer and HIV test results;

(*1*) if the [woman's] patient's serology is positive, a cord blood serology shall be obtained. If the sample could not be taken prior to the pregnancy's end, the serology shall be taken at the time of termination of the pregnancy;

(*2*) the [woman] patient 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] birth or termination of pregnancy;

(*3*) For patients found to be hepatitis B surface antigen negative early in the pregnancy, the hospital shall repeat the hepatitis B surface antigen test upon

admission if the patient has identified risk factors for acquiring hepatitis B virus infection during the pregnancy or has developed clinical signs and symptoms of hepatitis infection since the previous test.

(*b*) an assessment of the [woman's] patient's HIV status and risk of syphilis infection or reinfection, and the provision of testing in accordance with Section 69-1.3([i]n) and subparts 69-2 and 69-3 of this Title;

(*c*) an admitting physical examination in accordance with current standards of professional practice which shall include at a minimum the [woman's] patient'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 [should be made. If there is suspected leakage of amniotic fluid or any unusual bleeding, the attending physician or licensed midwife] shall be [notified immediately before a pelvic examination is performed] made. When there are no complications or contraindications, qualified midwifery or nursing personnel may perform the initial pelvic examination to evaluate labor status and the imminence of [delivery] childbirth. The physician or licensed midwife responsible for the

[woman's] patient's care shall be informed of [her] the status, so that a decision can be made regarding further management; and

(*d*) interval assessments including physical and psychological status of the [woman] patient 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] their scope of practice according to State Education [law] Law who meets the hospital's criteria for privileging and credentialing practitioners in management of labor and [delivery] birth in accordance with the hospital's policies and procedures.

(*b*) [Pharmacological] Mechanical, pharmacological, or surgical induction or augmentation of labor may be initiated only after a qualified practitioner has evaluated the [woman] obstetric patient, determined that induction or augmentation is medically necessary for the obstetric patient [woman] or fetus, recorded the indication, obtained informed consent, including shared decision making as appropriate, for induction or augmentation of labor, and established a prospective plan of management acceptable to the [woman]obstetric patient. If the qualified practitioner initiating these procedures does not have privileges to perform cesarean [deliveries] birth, a physician who has

such privileges shall be contacted directly prior to initiation of the induction or augmentation and a determination made that he or she shall be available [within 30 minutes of determination of the need] to perform a [Cesarean delivery] cesarean birth within a timeframe appropriate to meet the needs of the patient. If the patient has had a previous cesarean [delivery] birth, a physician with cesarean privileges must be immediately available during pharmacological induction or augmentation of labor.

(*c*) [Pharmacological] Mechanical, 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] patient 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] practitioner 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] patient's needs.

* * *

(*e*) During the entire time of the labor induction or augmentation, the [woman] patient 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, and addressing complications that may result. 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] accordance with current standards of professional practice.

(iii) No attempt shall be made to delay birth of a [infant] neonate by physical restraint or anesthesia.

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

(v) The medical record shall be updated to note whenever the [woman's] patient'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] patient, and the [woman] patient agrees to such implementation.

(4) Delivery and Childbirth.

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

(*a*) regular evaluation of [maternal] the patient's health status in accordance with current standards of care, including but not limited to, patient blood pressure and pulse both during and after [delivery] birth; [and]

(*b*) fetal heart evaluation[.]; and

(*c*) accurate methodology to qualitatively and quantitatively assess blood loss.

* * *

(iv) Alternative arrangements for the organization of the 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] Parts 754 and 795 of this Title as appropriate.

(v) Immediate care of the [newborn] neonate. The practitioner who [delivers the baby] attends the birth of a neonate shall be responsible for the immediate [post-delivery] postpartum care of the [newborn] neonate until another qualified person assumes this duty. At all times, the [newborn] neonate shall be attended by a physician or licensed midwife and shall be under the care of a registered professional nurse in accordance with Parts 721 and 754 of this Title.

(*a*) Resuscitation of a distressed [newborn] neonate. The hospital shall develop and implement policies and procedures for the recognition and immediate resuscitation of a distressed [newborn] neonate, in accordance with Neonatal Resuscitation Program (NRP) guidelines. Level I and II perinatal care services shall accomplish this in consultation with, and with assistance of, the RPC with which the hospital has a perinatal affiliation agreement. The policies and procedures shall include the following elements:

* * *

(*2*) approval of these policies and procedures by the directors of [maternity] obstetrical and [newborn] neonatal services, anesthesia, pediatrics, nursing, midwifery, and by the medical staff;

(*3*) requirement for immediate availability of needed resuscitative equipment and personnel, in accordance with Part 721 of this Title;

(*4*) presence in the delivery or birthing room of a member of the professional staff specifically qualified in [newborn] neonatal resuscitation;

* * *

(*6*) procedures for the stabilization of the distressed [newborn] neonate; and

[(7) capability to perform endotracheal intubation and umbilical vessel catheterization. For a Level I

perinatal care service, the perinatal affiliation agreement with its designated RPC shall provide for staff training to develop current staff competence in these procedures; and]

([8]7) procedures for the preparation and transfer of the distressed [newborn] neonate to a [a Level III or RPC] higher level of care perinatal [care service] hospital when medically indicated.

(*b*) Ventilation of a distressed neonate. Ventilation of distressed patients shall include the following:

(*1*) Level I hospitals shall provide immediate resuscitation after birth as appropriate, stabilization, and assisted ventilation of patients until timely transfer to a higher level of care hospital;

(*2*) Level II hospitals shall implement standard short-term mechanical ventilation and airway maintenance. If it is determined that the neonate does not require transfer, the Level II hospital may retain the neonate for no more than a total of seven days on assisted ventilation or oxygen at 50% or greater, and must then transfer the neonate to a higher level of care hospital unless the RPC is consulted and agrees that the neonate's care is in accordance with current standards of professional

practice and remaining at the Level II hospital is in the best interests of the neonate.

(*3*) Level III hospitals and RPCs may provide long-term standard mechanical ventilation and complex ventilation techniques, such as high-frequency ventilation and extracorporeal membrane oxygenation (ECMO).

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

([*c*]*d*) The hospital shall conduct expedited HIV testing of a [newborn whose mother's] neonate when the midwifery or obstetric patient's HIV status is unknown at [delivery] birth in accordance with Section 69-1.3([l]n) of the Title and shall determine the need for, and ensure the provision of, HIV prophylaxis and/or treatment, in accordance with standards of care to prevent transmission to the infant;

(e) The hospital shall offer the universal dose of hepatitis B vaccine to all neonates without known medical contraindications, shall offer to vaccinate neonates whose birth parent has a positive or unknown hepatitis B surface

antigen test result, and shall provide a certificate of immunization, in accordance with Part 69 of this Title.

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

(*1*) The hospital shall ensure continuous identification of the [newborn infant] neonate during the entire period of [hospitalization] neonatal care including verification of identity after each separation and reunion of [mother] postpartum patient and [newborn] neonate. 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] neonate becomes separated from the [newborn] neonate.

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

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

(f) Postpartum care of [mother] midwifery or obstetric patient.

(1) Appropriate nursing care shall be available to the [mother] patient during the period of recovery after [delivery] birth. At all times after [delivery] birth, the [mother] patient shall have maximum access to the [the baby] neonate unless such access is medically contraindicated and recorded in the appropriate medical record.

([1]2) The [mother] postpartum patient shall be transferred to the postpartum area, if applicable, only after [her vital signs have] being 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]3) Postpartum monitoring shall be in accordance with current standards of professional practice and shall, at a minimum, include the following:

* * *

(iii) blood loss occurring during and after birth shall be estimated accurately;

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

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

([v]vi) the [father] partner or other support person(s) shall be allowed to remain with the [mother] midwifery or obstetric patient 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] patient or other patients;

([vi]vii) a physical assessment of the [mother] midwifery or obstetric patient shall be conducted in accordance with established protocols; and

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

([3]4) Education and orientation of the [mother] parent who is planning to raise the baby.

(i) [The] Unless the pregnant or postpartum patient has contraindications to breastfeeding, the hospital shall provide instruction and assistance to each [maternity] patient who has chosen to breastfeed and shall provide information on the advantages of breastfeeding [and possible impacts of not breastfeeding] to [women] patients who are undecided as to the feeding method for their [infants] neonates. At 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] shall be available at least one staff member qualified to assist and encourage [mothers] patients with breastfeeding;

(*b*) written policies and procedures shall be developed, updated, implemented and disseminated annually to staff providing [maternity] midwifery, obstetrical or [newborn] neonatal care to assist and encourage the [mother] patient to breastfeed, in the absence of contraindications, which shall include, but not be limited to:

* * *

(*2*) placement of the [newborn] neonate skin-to-skin for breastfeeding immediately following delivery, unless contraindicated;

(*3*) restriction of the [newborn's] neonate's supplemental feedings to those indicated by the medical condition of the [newborn] neonate or of the [mother] postpartum patient;

(*4*) provision for the[newborn] neonate to be fed on demand; and

(*5*) pacifiers or artificial nipples may be supplied by the hospital to breastfeeding [infants] neonates to decrease pain during procedures, or for specific medical reasons[, or upon the specific request of the mother]. Before providing a pacifier or artificial

nipple that has been requested by the [mother] patient, the hospital shall educate the [mother] patient on the possible impacts to the success of breastfeeding and discuss alternative methods for soothing [her infant] the neonate, and document such education;

(*6*) prohibition of the distribution of marketing materials, samples or gift packs that include breast milk substitutes, bottles, nipples, pacifiers, or coupons for any such items to pregnant [women, mothers] and postpartum patients or their families;

(*7*) prohibition of the use of educational materials that refer to proprietary product(s) or bear product logo(s), unless specific to the [mother's] patient's or [infant's] neonate's needs or condition; and

* * *

(*8)* sources for advice and information available to the [mother] patient following discharge; and

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

(ii) The hospital shall provide to the [mother] patient instructions in self-care and caring for [herself and her] the baby. Topics to be covered shall include but not be limited to: [to] self-care, nutrition,

breast examination, exercise, signs of perinatal depression, infant care including taking temperature, feeding, bathing, diapering, infant growth and development, neonatal, infant and childhood vaccines, and parent-infant relationships.

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

(iv) Each [maternity] midwifery or obstetric patient shall be offered a program of instruction and counseling in family planning and, 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.

(v) For postpartum patients and neonates with a pending expedited HIV test, breastfeeding shall not be initiated until confirmatory results are available and indicate a negative HIV status. Postpartum patients without a documented HIV-negative status during the current pregnancy shall be provided with lactation support during the time that expedited HIV testing is pending, to establish and maintain breastmilk supply and to avoid the risk of breast complications. A risk reduction plan shall be in place for pregnant or postpartum patients who are at significant risk for HIV acquisition to reduce the incidence of acute infection and subsequent transmission of HIV to their neonates.

([4]5) Visiting. The hospital shall develop and implement written policies and procedures regarding visiting that:

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

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

* * *

([5]6) Discharge planning. The discharge of [mother and newborn] patients 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] neonate and [mother] obstetric patient 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, consistent with current perinatal guidelines and recommendations, have been made for the [mother] postpartum patient and [newborn] neonate;

(iii) the [mother] patient has been informed of community services and benefits, including but not limited to, the Special Supplemental Nutrition Program for Women, Infants and Children (WIC), and shall make referrals to such community services as appropriate.

(iv) the [mother] patient 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] signs of perinatal depression, family planning, resumption of coitus and signs of common complications;

(v) the [mother] patient has been advised on what to do if any complication or emergency arises;

(vi) the [newborn] neonate has had a documented and complete physical examination and verification of a passage of stool and urine;

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

(viii) the [newborn] neonate is stable; sucking and swallowing abilities are normal. Routine medical evaluation of the neonate's status [at two to three days] in a timeframe that meets the needs of [age] the neonate and postpartum patient shall have been conducted or arranged. Newborn screening shall be conducted 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[.]; and

(ix) postpartum patients with HIV infection and neonates exposed or infected with HIV shall be provided with adequate supplies of antiretroviral medications for each patient. The postpartum patient

shall be instructed on proper storage, dosing and administration of such medication for all affected patients and shall be provided instructions on when and where to call for assistance as necessary. The hospital shall transmit a copy of the neonate's HIV test result to the responsible provider. For any neonate with a result indicating exposure to HIV, the hospital shall coordinate with the responsible provider to arrange appointments for follow-up care with a provider experienced with the treatment of pediatric HIV, case management and other social services as needed. The responsible provider shall also submit to the Department any specimens necessary to confirm the HIV infection status of the neonate or submit documentation of confirmatory test results from a laboratory permitted pursuant to section 574 of Public Health Law and subpart 69-1 of this Title.

(g) High-risk neonatal care.

(1) Each hospital providing Level I, II or III perinatal services shall enter into a perinatal affiliation agreement with its designed 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] higher level affiliate hospitals.

(i) The perinatal affiliation agreements and transfer agreements shall include provisions for standardized risk assessment of the obstetric patient and neonate, based on generally accepted standards of practice, stabilization and resuscitation of [newborns] obstetric and neonatal patients as necessary, newborn screening in accordance

with Part 69 of this Title, consultation, obstetric and neonatal patient transport, transfer of [maternal] obstetrical and [newborn] neonatal records and any other features needed to ensure prompt and efficient transport of [newborns] obstetric patients and neonates, that minimize risks and provide the [newborns] obstetric patients and neonates with needed services.

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

(iii) The perinatal affiliation agreements and transfer agreements shall provide for the return of the distressed [newborn] neonate to [the sending] a Level II or III hospital when the condition has been stabilized and return is medically appropriate. Level I hospitals shall not receive neonates from a higher level of care hospital. A Level I hospital may receive a postpartum patient when their condition has been stabilized and return is medically appropriate; such hospital should be closer to the patient's residence and be able to continue care including potential obstetrical emergencies.

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

(2) Placement in nurseries.

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

(ii) [Newborns] Neonates requiring specialized care shall be placed in a NICU and hospitals shall develop and implement protocols for all phases of treatment of such [newborns] neonates. [Newborns] Neonates who are delivered in perinatal care services that are not capable of providing all necessary care and services shall be transferred to [perinatal] higher level of care [services at] hospitals that can meet the [newborns'] patients' needs.

(h) Neonatal intensive care services.

* * *

(2) Decisions regarding the appropriate level of care and the need for transport of a neonate to a higher level of care shall be made in consultation with the hospital's RPC and shall be consistent with generally accepted standards of care and the hospital's perinatal affiliation agreement.

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

(i) Severely ill, injured or [handicapped infants] disabled neonates exhibiting life-threatening conditions shall be transferred to and/or treated at RPCs or other hospitals having Level III perinatal care

services after a consultation with [that service] the RPC has established that the [infant] neonate might benefit from such transfer.

(ii) Level III [perinatal care services] hospitals and RPCs shall 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] disabled neonates with life-threatening conditions. The committee:

(*a*) shall consist of such members of the medical staff, midwifery 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] parent is fully advised regarding the [infant's] neonate'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 a competent [parents] parent 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 the 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] neonate's best interest.

Section 721.1 is amended to read as follows:

Introduction.

(a) All birth centers, including midwifery birth centers and hospital-based perinatal care services shall participate in the statewide perinatal regionalization system. Such system shall coordinate perinatal care within a particular geographic [areas or among a group] region of perinatal affiliates.

(b) Each perinatal service within a general 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).

(c) The RPC shall be the source of perinatal clinical consultation, outreach and education, and quality improvement support within the group of perinatal affiliates. The RPC shall provide assistance when an affiliate facility's patient requires specialized services beyond the capacity of the RPC and its perinatal affiliates.

Section 721.2 is amended to read as follows:

Definitions.

(a) Birth center shall mean a diagnostic and treatment center organized to provide care to low-risk patients during pregnancy, labor and birth who require a stay of less than 24 hours after birth as defined in Part 754.1 of this Title.

(b) Midwifery birth center shall mean a facility licensed pursuant to Article 28 of the Public Health Law that is engaged principally in providing prenatal and obstetric care, and where such services are provided principally by midwives as defined in Part 795.1 of this Title.

(c) Hospital shall mean a physician-led birth center, midwifery birth center, or general hospital that provides perinatal care services as defined in this Part. General hospital shall mean a Level I, Level II, Level III, or RPC-designated perinatal care hospital excluding physician-led birth centers.

([a]d) Level I perinatal care service means a comprehensive [maternal and newborn] obstetrical and neonatal service provided by a hospital designated as such by the Department for normal low-risk [newborns] neonates and for [women] obstetrical patients 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. Midwifery care services may also be provided.

([b]e) Level II perinatal care means a comprehensive [maternal and newborn] obstetrical and neonatal service provided by a hospital designated as such by the Department which includes services for moderately high-risk [newborns] neonates greater than or equal to 37 and 0/7 weeks and for [women] obstetrical patients who have been assessed as having the potential or likelihood for a moderately complicated or high-risk [delivery] birth and/or bearing a fetus exhibiting the potential for unusual or high-risk development. Such services may also provide services to [women] patients requiring care normally provided at Level I perinatal care services.

([c]f) Level III perinatal care means a [maternal and newborn] obstetrical and neonatal service provided by a hospital designated as such by the Department and which includes services for [women and newborns] patients 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] patients requiring care normally provided at Level I and II perinatal care services.

([d]g) 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] and also [,] includes highly specialized services that may not be available at all Level III hospitals, and is designated as such by the Department. An RPC serves [a geographic area or a group of] perinatal affiliates within a regional perinatal network as defined in subdivision (h) of this section. It provides all aspects of comprehensive [maternal] obstetrical 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] coordination of obstetrical and neonatal transports, including coordination of transfers to the RPC as well as between affiliate facilities, outreach to affiliates to determine educational needs, education and training of [affiliate hospitals] affiliates, 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.]

(h) A Regional perinatal network shall include one RPC, at least one lower-level birthing hospital, and any birth centers within the geographic catchment area. Regional perinatal networks shall cover one or more contiguous geographic regions as determined by the Department and must include all birthing hospitals and centers within the designated region(s) unless otherwise agreed upon by the Department and all affected birthing hospitals and birth centers.

([e]i) Perinatal affiliation agreement shall mean a written fully executed agreement between a birth center, or Level I, II or III perinatal care hospital, and that [hospital's] facility'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, research 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]j) 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] an affiliate birth center and an affiliate Level I, II or III hospital, or two affiliate hospitals that provide different levels of care. Perinatal transfer agreements shall address the provision and/or coordination of all high-risk [maternal and newborn] obstetrical and neonatal 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.]

(k) Patient shall mean a pregnant, parturient or postpartum person, or a neonate receiving medical services.

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

Section 721.3 is amended to read as follows:

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;] 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, Part 754 of this Title for a birth center and Part 795 of this Title for a midwifery birth center;

(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] each hospital designated as a birth center, midwifery birth center, Level I, Level II, or Level III perinatal care hospital shall enter into a written perinatal affiliation agreement with an RPC;

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

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

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

(iii) RPCs shall provide no fewer than 4,000 high-risk [newborn] neonatal patient days annually, and no fewer than 400 high-risk [maternal] obstetrical patient days annually[.]; and

(iv) An RPC shall provide quality improvement services to a group of perinatal affiliates with a minimum total of 8,000 births annually [each year];

(4) the availability of appropriate medical, nursing, and other staffing as described in this Part, Part 754 of this Title for birth centers, or Part 795 of this Title for midwifery birth centers, 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]5) 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 site-specific operating certificate.

* * *

(4) Only those hospitals designated for a level of perinatal care shall provide pre-booked or pre-planned admission and care to midwifery, obstetrical and neonatal patients.

(5) Any hospital not designated to provide perinatal care that receives a laboring or birthing patient or neonate shall transfer such patient to the most appropriate perinatal care hospital, in collaboration with the nearest RPC.

(i) All perinatal hospitals shall admit obstetrical and neonatal patients for emergency services, in accordance with state and federal law.

(ii) All non-perinatal hospitals shall have policies and procedures for the stabilization and transfer of obstetrical and neonatal patients.

(6) Only those hospitals designated as a Level II, III or RPC level of care may maintain a neonatal intensive care unit (NICU) and provide care to obstetrical and neonatal patients in accordance with this Part. No hospital shall state or imply that it has the capability to provide care to obstetrical or neonatal patients outside the scope of perinatal designation, including advertising or promoting the ability to care for high risk obstetrical or neonatal patients, or neonates requiring special care.

(c) Redesignations.

* * *

[(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.]

(d) Criteria for Maintenance of Designation.

(1) Upon designation, a hospital shall:

(i) remain subject to the provisions of this Part and all other applicable requirements of this Part and of the Public Health Law related to hospitals;

(ii) notify the Department immediately in writing of any inability to meet the capabilities required by its current designation. Such notification must be made in writing to the Department by the hospital's chief administrative official.

(2) The Department or its designee may request documentation from the hospital in question, conduct one or more conference calls or site visits with appropriate staff, or engage in other activities to obtain information regarding the hospital's plan to come into compliance with requirements.

If the hospital in question is a birth center or Level I, II, or III facility, the Department may involve the hospitals' RPC at its discretion.

(3) Upon notification of the inability to meet requirements, or that the hospital is determined to be performing below the expected level of care, the Department may:

(i) request a corrective action plan from the hospital to address the identified issue(s) in accordance with Department requirements; and/or

(ii) require participation in specific Department- or RPC-led quality assurance and quality improvement activities as outlined in section 721.10 of this Part related to identified areas of concern.

(4) If a Level II or III hospital, or an RPC is unable to improve performance to meet or exceed the relevant requirements established in Part 721 of this Title, the Department may reduce the hospital's designation to a level appropriate for the services provided.

(5) Birth centers and Level I facilities unable to improve performance to meet or exceed the relevant requirements established in Parts 721, 754 and 795 of this Title may be required to participate in Department- and RPC-led quality improvement initiatives and other activities designed to improve the quality of care to at least minimum required levels.

(e) Reduction or Withdrawal of Designation. The Department may change a level of designation from the hospital if:

(1) The hospital fails to comply with SPDS or other reporting requirements and is unable to meet requirements as agreed to in the corrective action plan;

(2) The hospital fails to participate in quality improvement activities and provide evidence of internal quality improvement activities, when specific issues related to reducing maternal or neonatal morbidity and mortality have been identified by either the RPC or the Department; or

(3) The Department documents findings that indicate ongoing evidence that the hospital has not been able to provide the level of care expected for the hospital's designation level.

(f) Upon reduction of designation level, the hospital shall immediately notify affected parties, including emergency medical services, to ensure that obstetrical and neonatal patients are taken to appropriate designated perinatal hospitals, and within 30 days, provide to the Department a written plan describing the specific measures it has taken to notify affected parties, and its process for transfer of obstetrical and neonatal patients received. The facility shall ensure it has a transfer agreement with a perinatal hospital to ensure timely and safe transfer of obstetrical and neonatal patients.

Section 721.4 is amended to read as follows:

Patient care and 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] midwifery, obstetrical and neonatal patients.

(i) For patients needing a higher level of care, it shall consult with [a higher level hospital] its affiliated RPC 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] obstetrical patients with an anticipated [delivery] birth at [36] 35 weeks gestation or later and for healthy [newborns] neonates 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] neonates shall be delivered at higher level hospitals; if such [an infant] a neonate is born at a Level I perinatal care hospital, he/she shall be transferred promptly after birth.

(iv) [Women] Obstetrical patients 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] neonate may require immediate complex care, it shall be delivered at a Level III perinatal care hospital or an RPC whenever possible.

* * *

(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] obstetrical patients, fetuses and [newborns] neonates and moderately ill [women and newborns] obstetrical and neonatal patients who have problems that do not require highly specialized care; and

(ii) stabilize ill [women and newborns and women whose fetuses] patients and patients who are expected to need complex care, consult with [a higher level hospital] the RPC for care coordination 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] neonates with an anticipated [delivery] birth at [30] 32 weeks gestation or later and with an anticipated birthweight of [1,250] 1,500 grams or more.

(iv) Except in unusual circumstances, [infants] neonates 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] a neonate 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] patients who may require complex care.

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

(iii) [Women] Obstetrical patients 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] patients 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.

* * *

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

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

(2) at a Level II perinatal care hospital the ventilation of a distressed newborn shall be as described in paragraph (1) above and, in addition, standard short-term mechanical ventilation. A Level II perinatal care hospital may care for infants requiring mechanical ventilation and/or 50% or more oxygen for no more than four days. By the fourth day of a newborn's receipt of assisted ventilation or oxygen at 50% or more, the Level II hospital shall consult with its designated RPC regarding the status of the newborn and determine whether to transfer the newborn to a higher level

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

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

(c) Transfers.

(1)]

(b) 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] a Level II or III hospital for neonates, or for obstetrical patients the referring hospital or other hospital providing a lower level of care, shall be described in any transfer agreement negotiated between a birth center or Level I, II and III perinatal care hospitals, and in transfer provisions in the perinatal affiliation agreements between affiliate birth centers, Level I, II and III perinatal care hospitals and their RPCs.

[(2)](c) When a [newborn and/or mother] patient requires transfer, care shall be provided at an affiliate hospital providing the appropriate level of perinatal care which is, whenever feasible, accessible and convenient to the [mother's] patient's place of residence. When [mothers and their infants] patients 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] neonate to the sending hospital when the condition has been stabilized and return is medically appropriate.

(d) 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 parent's place of residence whenever feasible.

(e) Unless otherwise directed by the RPC, the transfer of midwifery/obstetrical and neonatal patients shall be to the nearest affiliate facility that has the capacity to provide appropriate care for the patient. Whenever possible, the surface travel time to reach the receiving hospital within the geographic affiliate network, under usual travel conditions, shall be no more than two hours. Transfers to a non-affiliate hospital must be coordinated by the RPC, and the patient must be transferred to the nearest non-affiliate hospital that has the capacity to provide appropriate care for the patient.

(f) Higher level hospitals shall, whenever feasible, transfer a stable neonatal patient back to a Level II or III level of care hospital that is closer to the parent's or parents' residence. Such back transfers shall require the receiving hospital to agree to admit the neonate and have sufficient clinical expertise and availability to continue care for the neonate during the convalescence period, including but not limited to, care related to thermoregulation, the neonate's ability for oral feeding,

and assessment and response to episodes of immature respiratory control. Such care shall be provided in accordance with current standards of practice.

(g) Higher level hospitals shall, whenever feasible, transfer a stable postpartum patient back to a lower level of care hospital that is closer to the patient's residence. Such back transfers shall require the receiving hospital to agree to admit the patient and have sufficient clinical expertise and availability to continue patient care during the convalescence period.

Section 721.5 is repealed and a new Section 721.5 is added to read as follows:

Requirements for the Designation of a Level I Perinatal Care Service Hospital

(a) Qualifications and Responsibilities of Chiefs of Services

(1) Qualifications

(i) Obstetrics. A board-certified or board-eligible obstetrician with admitting privileges at the hospital shall serve as the chief of obstetrics.

(ii) Pediatrics. A board-certified or board-eligible pediatrician with admitting privileges at the hospital shall serve as the chief of pediatric services.

(iii) Anesthesiology. A board-certified or board-eligible anesthesiologist with admitting privileges at the hospital shall serve as the chief of anesthesia services.

(iv) Midwifery. A midwife or nurse-midwife licensed in the state of New York, at minimum, with privileges at the hospital shall serve as the chief of midwifery services. Facilities that do not employ or utilize midwifery staff are exempt from this requirement.

(v) Nursing. Nursing leadership shall include, at minimum, a registered nurse with expertise in perinatal and neonatal care.

(2) Care Coordination. Care shall be coordinated jointly by the applicable chiefs of obstetrics, pediatrics and anesthesia, midwifery, and nursing leadership in collaboration with appropriate physicians/staff in the fields of midwifery and family medicine. For hospitals that do not have chiefs of service in all such areas, each discipline shall have effective input in care coordination.

(3) Responsibilities of Chiefs of Services.

(i) The coordinators of perinatal care at a Level I hospital shall be responsible for developing policy, maintaining standards of care, and collaborating and consulting with professional staff of hospitals providing higher level of care services in the region.

(ii) The chiefs of obstetrics, pediatrics, anesthesiology, and nursing leadership each shall have oversight of and be responsible for their respective services' quality improvement initiatives, including but not limited to participation in Department-led and RPC-led initiatives as defined by section 721.9 of this Part.

(iii) In hospitals that do not separate midwifery, obstetrical and/or neonatal services, one person may be given the responsibility for coordinating perinatal care.

(b) Qualifications and Responsibilities of Physicians and Other Licensed Midwifery, Obstetrical and Pediatric/Neonatal Practitioners.

(1) Staff and Equipment Required for All Births

(i) A physician or licensed midwife with appropriate training and expertise shall attend all births.

(ii) At least one additional person who is a current Neonatal Resuscitation Program (NRP) provider shall be present at every birth to attend to the neonate.

(iii) At least one person who is a current basic life support (BLS) provider shall be present at every birth to attend to the pregnant or postpartum patient.

(iv) At least one person who is an advanced cardiac life support (ACLS) provider shall be immediately available at every birth to attend to the pregnant or postpartum patient.

(v) An ultrasound machine shall be readily available to labor and delivery. A radiologist or obstetrician skilled in interpretation of ultrasound scans shall be available, either onsite or by telemedicine, within a timeframe appropriate to meet the patients' needs.

(vi) The Level I facility shall have ventilation and resuscitative equipment appropriate to the patients' age and weight immediately available for all deliveries. This includes equipment necessary to carry out neonatal resuscitation under current NRP guidelines. In addition to requirements in subparagraphs (ii) and (iii) of this paragraph, a current BLS, ACLS, and NRP provider must be immediately available onsite to labor and delivery.

(2) Physicians

(i) Obstetricians should be available for consultation 24 hours a day, onsite, by telephone or telemedicine. Such staff shall be available onsite within a timeframe appropriate to meet the patient's needs to address emergencies, including cesarean deliveries.

(ii) The expertise of the maternal-fetal medicine (MFM) board-certified obstetrician and care team of the RPC, as described in section 721.8(a)(2)(ii) of this Part, shall be engaged to provide consultation and support, as required by the Level I hospital.

(iii) The expertise of the neonatologist board-certified pediatrician and care team of the RPC, as described in section 721.8(a)(2)(iii) in this Part, shall be engaged to provide consultation and support, as required by the Level I hospital.

(iv) An anesthesiologist shall supervise or directly provide anesthesia care for all obstetrical and neonatal patients.

(3) Physician Assistants and Nurse Practitioners. A licensed Physician Assistant (PA) or Nurse Practitioner (NP) may assist in caring for patients throughout pregnancy, labor, birth, and postnatal care. Such staff shall be current BLS, ACLS, and NRP providers.

(c) Midwifery Staff

(1) Licensed midwives shall be continuously available onsite to provide care for patients at all stages of pregnancy during a normal, uncomplicated pregnancy.

(2) Midwives attending births shall be current BLS and NRP providers.

(3) Midwives shall have the ability to stabilize patients in distress, and transfer to an appropriate higher level of care facility for continued care, following consultation with the RPC.

(4) Midwifery staff shall co-manage the care of pregnant and birthing patients with obstetricians within obstetrician-led, midwifery-led, or shared models of care.

(d) Nursing Care

(1) Obstetrical and neonatal nursing care shall be provided under the direct supervision of a registered nurse. Licensed midwives who are also nurses (i.e., a licensed nurse-midwife) may be under the direct supervision of a registered nurse or other provider as determined by the birthing facility; licensed nurse-midwives may supervise other licensed midwives and nursing staff as determined by the birthing facility.

(2) Nursing leadership shall have expertise in perinatal nursing care, and the ability to stabilize and transfer high-risk patients.

(3) All obstetrical nursing personnel shall be qualified in interpretation of fetal heart rate monitoring and understand the physiology of labor and postpartum. All obstetrical and neonatal nursing personnel shall be qualified in assessment of the neonate and all aspects of routine monitoring and care, including education and support related to breastfeeding.

(4) All neonatal nursing personnel shall be current BLS and NRP providers; obstetrical nursing personnel shall be current BLS, ACLS, and NRP providers.

(5) Licensed practical nurses and other licensed patient care staff with demonstrated knowledge and clinical competence in the nursing care of pregnant patients and neonates during labor, birth, and the postpartum and neonatal periods may be assigned to perinatal services.

(e) Ancillary Services

(1) Alcohol and Substance Use Specialists

(i) As part of routine midwifery and obstetrical care, all patients shall receive a screening for alcohol, tobacco use and substance use, as well as physical, sexual and emotional abuse.

(ii) The Level I hospital shall have a pre-arranged system with a local institution or higher level of care affiliate hospital for alcohol/substance use and opioid replacement therapy, if necessary, to co-manage patients.

(iii) A qualified mental health professional with experience in alcohol and substance use shall be available for consultation, onsite, by phone or by telemedicine, and within a timeframe appropriate to meet the needs of the patients.

(iv) Neonates with the potential of having neonatal abstinence syndrome (NAS) or fetal alcohol spectrum disorder (FASD) shall be stabilized and monitored after birth. Transfer of neonates with NAS or FASD, along with the parent patient, to a higher level of care hospital is dependent on professional judgement and availability of resources at the Level I hospital.

(v) For patients who are currently receiving alcohol or substance use disorder services, the prenatal provider will collaborate with the

patient's alcohol or substance use service provider to co-manage care of pregnant and postpartum patients.

(vi) Patients identified as using tobacco products will be offered tobacco cessation support services and education as appropriate.

(2) Anesthesia Care

(i) The Level I hospital will provide labor analgesia and surgical anesthesia for the patients on a 24-hour basis.

(ii) The Level I hospital shall have the capability to perform cesarean birth in a timeframe appropriate to meet the patients' needs, including availability of anesthesia services, labor analgesia and surgical anesthesia.

(iii) Prior to birth, anesthesiology staff shall assure access to anesthesia consultation when indicated.

(3) Breastfeeding

(i) A certified lactation counselor (CLC) or an International Board-Certified Lactation Consultant (IBCLC) shall be responsible for the hospital's breastfeeding support program, as described in section 405.21(f)(4)(i) of this Title.

(ii) Staff shall be available to educate and assist patients during the antenatal and postpartum periods.

(4) Genetic Specialists. The Level I hospital shall provide access, through referral or consultation onsite, by telephone or telemedicine, to genetic screening, carrier testing, and genetic counseling for patients.

(5) Infection Control. Infection control personnel shall be responsible for surveillance of infections in patients, as well as for the development of an appropriate environmental control program.

(6) Laboratory Services. Personnel who are capable of determining blood type, cross-matching blood, and performing antibody testing shall be continuously available.

(7) Nutrition. A Certified Dietitian-Nutritionist shall be available through referral for consultation with patients during the prenatal, intrapartum and postpartum phase.

(8) Occupational and Physical Therapy. The Level I facility shall refer patients to an appropriate occupational or physical therapist.

(9) Pharmacists and Pharmacy Services

(i) A pharmacist shall be immediately available 24 hours a day for consultation.

(ii) A Level I hospital shall have immediate access to emergency obstetrical and pediatric medications 24 hours a day for labor, birth, and emergent care.

(iii) To ensure patient safety, pharmacy services shall incorporate the use of patient-specific identifiers.

(10) Radiology

(i) The Level I hospital shall have a radiologic technician or obstetrician skilled in interpretation of ultrasound scans available within a timeframe appropriate to meet the patients' needs, either onsite or by telemedicine.

(ii) When results are inconclusive, or an abnormality is detected that requires immediate neonatal care, patients shall be directed to a higher level of care affiliate hospital for further management including consultation by a radiologist or other qualified provider who can interpret results.

(11) Respiratory Therapy, Ventilation and Respiratory Support Services

(i) A Level I hospital shall have respiratory therapists in-house or on-call 24 hours a day and available within a timeframe to meet the patients' needs, with the ability to provide respiratory stabilization of the patient, and neonatal cardiorespiratory monitoring to stabilize, assess, or observe the neonate prior to transport.

(ii) Clinical or nursing staff who are NRP providers shall be available onsite 24 hours a day.

(12) Social Work, Psychosocial and Mental Health

(i) A Level I hospital shall assess all patients to determine availability of sufficient resources prior to or following birth.

(ii) A Level I hospital shall provide prenatal and postpartum screenings during prenatal and postpartum visits, and provide referrals as indicated. Patients who screen positive during prenatal screening for perinatal depression or perinatal mood disorder shall receive a consultation at a higher level of care facility or a local institution with a perinatal qualified mental health professional to determine an appropriate course of action.

(iii) If a patient is receiving mental health services, the Level I hospital shall collaborate with the patient's mental health service provider to co-manage care of the patient.

(iv) At least one qualified social worker who has experience with the socioeconomic and psychosocial problems of pregnant patients, ill neonates, and their families shall be assigned to the perinatal service.

(v) Additional qualified social workers sufficient to meet the needs of patients are required when there is a high volume of medical activity or psychosocial need.

(vi) At least one staff person with expertise in bereavement shall responsible for the hospital's bereavement activities, and shall be available to assess and meet the patients' needs and the needs of patient families.

(13) Speech-Language Pathology. Neonates demonstrating difficulty feeding and swallowing shall be referred to a licensed speech-language pathologist.

Section 721.6 is repealed and a new Section 721.6 is added to read as follows:

Requirements for the Designation of a Level II Perinatal Care Service Hospital.

(a) Qualifications and Responsibilities of Chiefs of Services

(1) Qualifications

(i) Obstetrics. A full-time board-certified obstetrician with admitting privileges shall serve as the chief of the obstetrical service.

(ii) Neonatology. A full-time board-certified pediatrician with subspecialty certification in neonatal medicine, or at a minimum successful neonatal medicine fellowship completion, with admitting privileges shall be the chief of neonatal care services.

(iii) Anesthesiology. A board-certified anesthesiologist shall be the chief of anesthesiology.

(iv) Midwifery. A midwife or nurse-midwife licensed in the state of New York, at minimum, with privileges at the hospital shall serve as the chief of midwifery services. Facilities that do not employ or utilize midwifery staff are exempt from this requirement.

(v) Nursing. Nursing leadership shall be, at minimum, a registered nurse with expertise in perinatal and neonatal care.

(2) Care coordination. The hospital's perinatal care services shall be coordinated jointly by the chiefs described in paragraph (1) of this subdivsion.

(3) Responsibilities of Chiefs of Services

(i) The chiefs of obstetrics, neonatology, anesthesiology, midwifery, and nursing leadership shall, in conjunction with the hospital administration and the chiefs of critical care, midwifery, family practice, and other patient care, shall develop policies concerning staffing, procedures, equipment, and supplies; maintaining standards of care; and planning, developing, and coordinating in-hospital professional education program.

(ii) The chiefs of obstetrics, neonatology, anesthesiology, midwifery, and nursing leadership each shall have oversight of and be

responsible for their respective services' quality improvement initiatives, including participation in Department-led and RPC-led initiatives as defined by section 721.9 of this Part.

(b) Qualifications and Responsibilities of Physicians and Other Licensed Midwifery, Obstetrical and Neonatal Practitioners

(1) Staff and Equipment Required for All Deliveries. Level II facilities shall meet the requirements described in section 721.5(b)(1) of this Part.

(2) Physicians. Care for moderately high-risk women and neonates shall be provided by appropriately qualified physicians.

(i) Obstetricians shall meet the requirements described in section 721.5(b)(2)(i) of this Part.

(ii) Maternal-fetal medicine (MFM). A board-certified maternal-fetal medicine specialist shall be available 24 hours a day, either onsite, by telephone, or by telemedicine, to provide consultation and support, and shall be available onsite when indicated within a timeframe appropriate to meet the patients' needs. In addition, the expertise of the MFM specialist and care team of the RPC, as described in section 721.8(a)(2)(ii) of this Part, shall be engaged to provide consultation and support, as required, by the Level II hospital.

(iii) Neonatology. A board-certified neonatologist shall be available on-site 24 hours a day within a timeframe appropriate to meet the patients' needs to provide needed services. A designated immediate response team shall be available, with at least two personnel who are current BLS, ACLS, and NRP providers.

(iv) Pediatrics. General pediatricians with the expertise to assume responsibility for acute care of patients, shall be available on-site 24 hours a day within a timeframe appropriate to meet the patients' needs to provide needed services.

(v) Radiology. The hospital staff shall also include a radiologist skilled in interpretation of ultrasound scans, available 24 hours a day.

(vi) Pathology. The hospital staff shall include a clinical pathologist, available 24 hours a day.

(vii) Medical and surgical subspecialists. Specialized adult and pediatric medical and surgical staff shall be available for consultation, either onsite, by phone, or by telemedicine. If such subspecialists are not available, the hospital shall consult with subspecialty staff from the RPC.

(3) Physician Assistants and Nurse Practitioners

(i) At a minimum, a Physician Assistant (PA) or Nurse Practitioner (NP) with expertise, as defined by the hospital or neonatologist shall be available onsite within a timeframe appropriate to meet the patients' needs, 24 hours a day.

(ii) A licensed PA or NP may assist in caring for patients throughout pregnancy, labor, birth, and postnatal care. Such staff shall be current BLS, ACLS, and NRP providers.

(c) Midwifery. Level II hospitals shall meet the qualifications described in section 721.5(c) of this Part.

(d) Nursing care. Level II hospital obstetrical and neonatal nursing care staff shall meet the qualifications described in section 721.5(d) of this Part. In addition:

(1) Direct patient care shall be provided by registered nurses (RNs) who have the education and experience in the care of moderately high-risk obstetrical and/or neonatal patients.

(2) All nurses caring for patients shall demonstrate competence in the observation and treatment of such patients, including cardiorespiratory monitoring.

(3) There shall be an appropriate and adequate number of nursing staff who are trained in breastfeeding support for patients, including neonates with special needs. Such staff shall be available within a timeframe to meet the patients' needs.

(e) Ancillary Services.

(1) Alcohol and Substance Use Specialists. The Level II hospital shall meet the requirements and qualifications as described in section 721.5(e)(1) of this Part. In addition, the Level II hospital shall have appropriately skilled staff and protocols in place for the treatment and management of infants with neonatal abstinence syndrome and/or fetal alcohol spectrum disorder.

(2) Anesthesia Care. The Level II hospital shall meet the requirements as described in section 721.5(e)(2) of this Part.

(3) Breastfeeding. The Level II hospital shall meet the requirements and qualifications as described in section 721.5(e)(3)(i) of this Part. In addition, staff shall be available 24 hours a day to educate and assist patients during the antenatal and postpartum periods.

(4) Genetic Specialists. The Level II hospital shall meet the requirements described in section 721.5(e)(4) of this Part.

(5) Infection Control. The Level II hospital shall meet the requirements described in section 721.5(e)(5) of this Part.

(6) Laboratory Services.

(i) Qualified personnel for laboratory services shall be available onsite 24 hours a day.

(ii) Blood bank services shall be maintained 24 hours a day, with all blood components available on an emergency basis, either on premises or by pre-arrangement with another hospital.

(7) Nutrition. At least one Certified Dietitian-Nutritionist who has special training in perinatal nutrition and can plan diets that meet the special needs of high-risk patients shall be available in a timeframe that meets the patient's needs.

(8) Occupational and Physical Therapy. At least one occupational or physical therapist with neonatal expertise shall be available for consultation in a timeframe to meet the patient's needs.

(9) Pharmacists and Pharmacy Services. The Level II hospital shall meet the requirements described in section 721.5(e)(9) of this Part. In addition:

(i) Hospital staff shall include personnel available on-site 24 hours a day who are qualified to compound and dispense specialized pharmaceutical services, appropriate to the patients' size and age, and consult with obstetrical and neonatal staff on medication administration.

(ii) The pharmacy shall have available total parenteral nutrition appropriate for patients, including neonates and infants.

(10) Radiology. The Level II hospital shall meet the requirements described in section 721.5(e)(10) of this Part. In addition:

(i) A pediatric radiologist shall be available for consultation, either onsite or by telemedicine, 24 hours a day.

(ii) Radiology services, including computed tomography with interpretation, shall be available onsite, 24 hours a day.

(iii) Whenever possible, radiology services shall be designed to accommodate patients with disability and/or patients who are severely obese. If such equipment is not available, the Level II hospital shall consult with the RPC to identify affiliate hospitals that can provide such services in a timeframe appropriate to meet the patients' needs.

(11) Respiratory Therapy, Ventilation, and Respiratory Support Services. The Level II hospital shall meet the requirements as described in section 721.5(e)(11) of this Part. In addition:

(i) Hospital staff shall include a designated, in-house credentialed person for neonatal resuscitation, available 24 hours a day. In addition, an advanced practice nurse or physician shall be available onsite 24 hours a day to provide ongoing care, manage airways of ventilated patients, and address emergencies.

(ii) Respiratory therapists, who are current BLS, ACLS, and NRP providers, can provide stabilization and respiratory support for the pregnant or postpartum patient and neonate. In addition, supplemental oxygen, assisted ventilation, and continuous positive pressure ventilation, including high flow nasal cannula, shall be

available for neonates. Such staff shall be continuously available onsite to provide ongoing care as well as to address emergencies.

(iii) Respiratory therapists, with the ability to provide conventional ventilation to neonates, shall be available onsite 24 hours a day.

(12) Social Work, Psychosocial, and Mental Health. The Level II hospital shall meet the requirements and qualifications as described in section 721.5(e)(12) of this Part.

(13) Speech-Language Pathology. A licensed speech-language pathologist with neonatal expertise, skilled in evaluation and management of neonatal feeding and swallowing disorders, shall be available for consultation, either onsite, by telephone, or telemedicine, in a timeframe appropriate to meet the patients' needs.

Section 721.7 is repealed and a new Section 721.7 is added to read as follows:

Requirements for the Designation of a Level III Perinatal Care Service Hospital.

(a) Qualifications and Responsibilities of Chiefs of Services

(1) Qualifications

(i) Obstetrics and maternal-fetal medicine. A full-time, board-certified obstetrician with admitting privileges and subspecialty certification in maternal-fetal medicine with shall be the chief of obstetrical services.

(ii) Neonatology. A full-time, board-certified pediatrician with admitting privileges and subspecialty certification in neonatal medicine shall be the chief of neonatal services.

(iii) Anesthesiology. A board-certified anesthesiologist shall be the chief of anesthesiology.

(iv) Midwifery. A midwife or nurse-midwife licensed in the state of New York, at minimum, with privileges at the hospital shall serve as the chief of midwifery services. Facilities that do not employ or utilize midwifery staff are exempt from this requirement.

(v) Nursing. Nursing leadership shall be at minimum a registered nurse with expertise in perinatal and neonatal care.

(2) Care coordination. The hospital's perinatal care services shall be coordinated by the chiefs described in paragraph (1) of this subdivision.

(3) Responsibilities of Chiefs of Services. Chiefs of services shall meet the responsibilities described in section 721.6(a)(3) of this Part.

(b) Qualifications and Responsibilities of Physicians and Other Licensed Obstetrical and Neonatal Practitioners

(1) Staff and equipment required for all deliveries. Level III hospitals shall meet the requirements described in section 721.5(b)(1) of this Part.

(2) Physicians. Care for high-risk patients shall be provided by appropriately qualified physicians.

(i) Obstetrics. The Level III hospital shall have a board-certified obstetrician with admitting privileges available onsite, 24 hours a day.

(ii) Maternal-fetal medicine.

(*a*) A board-certified maternal-fetal medicine specialist with admitting privileges shall be available 24 hours a day by telephone or telemedicine for consultation and management

and be onsite as needed and within a timeframe appropriate to meet patient's needs for patient care.

(*b*) Maternal-fetal medicine specialists who care for high-risk patients shall be a board-certified obstetrician with subspecialty certification in maternal-fetal medicine, or at a minimum will have successfully completed a fellowship in maternal-fetal medicine.

(*c*) A maternal-fetal medicine specialist may also be available for interpretation of ultrasound scans, as described in section 721.5(b)(1)(v) of this Part. Staff available for interpretation must be available in-house 24 hours a day.

(iii) Neonatology.

(*a*) A board-certified neonatologist with admitting privileges shall be available onsite 24 hours a day to provide needed services.

(*b*) Neonatologists who care for high-risk neonates shall have qualifications equivalent to those of the chief of neonatology, as described in subparagraph (ii) of paragraph (1) of subdivision (a) of this section, or at a minimum will have successfully completed a fellowship in neonatology.

(*c*) A neonatology fellow who is a board-certified pediatrician, may meet the requirements in place of nursing or physician assistants as described in paragraph (3) of subdivision (b) of this section. Such fellows must be credentialed by the

institution in all necessary procedures, and must also be current NRP providers.

(iv) Anesthesiology. A board-certified anesthesiologist with a maternal-fetal anesthesia team shall be available onsite 24-hours per day. The anesthesiology team shall provide labor analgesia and surgical anesthesia for the patient. Anesthesia care for neonatal and pediatric patients shall be provided or supervised by anesthesiologists with clinical privileges. Personnel with credentials in the administration of neonatal and pediatric deep sedation anesthesia shall be onsite 24 hours per day.

(v) Radiology.

(*a*) A board-certified or board-eligible radiologist shall be available 24 hours a day for consultation onsite or by telemedicine for patients at the Level III hospital in a timeframe appropriate to meet the patient's needs.

(*b*) A pediatric radiologist shall be available for consultation either onsite or by telemedicine in a timeframe appropriate to meet the patient's needs.

(vi) Pathology. Pathologists with special competence in placental, fetal, and neonatal disease shall be members of the Level III facility staff. A clinical pathologist shall be available 24 hours a day.

(vii) Medical and surgical subspecialties.

(*a*) Adult-trained medical subspecialists in the following fields shall be available onsite for consultation within a timeframe to meet the patient's needs: cardiology, critical care,

endocrinology, gastroenterology, hematology, immunology, infectious disease, nephrology, neurology, and pulmonology. In addition, general surgeons and surgical subspecialists in the following fields shall be available onsite for consultation and care within a timeframe appropriate to meet the patient's needs: cardiothoracic, neurosurgery, orthopedics, ophthalmology, otolaryngology, and urology.

(*b*) Pediatric subspecialists in the following fields shall be available onsite for consultation within a timeframe to meet the patient's needs: cardiology, critical care, endocrinology, gastroenterology, hematology, immunology, infectious disease, nephrology, neurology and pulmonology. In addition, general pediatric surgeons and surgical subspecialists in the following fields shall be available onsite for consultation and care within a timeframe to meet the patient's needs: cardiothoracic, neurosurgery, orthopedics, ophthalmology, otolaryngology, and urology.

(*c*) Adult and pediatric medical and surgical specialists and subspecialists shall be available onsite to collaborate with the Level III hospital's maternal-fetal medicine care team and neonatology care team.

(*d*) In the event of a medical and surgical subspecialist vacancy at a Level III birthing hospital, the hospital may consult the

Regional Perinatal Center's subspecialists to determine appropriate treatment and possible transfer.

(3) Physician Assistants and Nurse Practitioners.

(i) A Physician Assistant (PA), or Nurse Practitioner (NP) with neonatal expertise shall be available onsite at all times.

(ii) All PAs, NPs, and must be credentialed by the institution in all necessary procedures. These staff must also be current NRP providers.

(c) Midwifery. Level III hospitals shall meet the qualifications described in section 721.5(c) of this Part.

(d) Nursing care. Level III hospital obstetrical and neonatal nursing care staff shall meet the qualifications described in section 721.6(d) of this Part. In addition:

(1) Obstetrical and critical care (Intensive Care Unit and Critical Care Unit) RNs shall have special training and experience in management of patients with complex obstetrical illnesses and complications.

(2) An advance practice nurse (APN) shall be available to staff for consultation and support on nursing care issues. Licensed nurse-midwives may serve in this capacity as appropriate.

(3) Assessment and monitoring activities shall remain the responsibility of RN or APN staff in obstetrical or neonatal care, even when personnel with a mixture of skills are used.

(4) The Level III hospital shall have a nurse educator on staff to provide obstetrical and neonatal staff education.

(e) Ancillary Services.

(1) Alcohol and substance use specialists.

(i) The Level III hospital shall have a system of care for alcohol and substance use disorders, including opioid replacement therapy, to co-manage the patient(s).

(ii) If a patient is receiving alcohol or substance use services prior to admission, the prenatal provider shall collaborate with the patient's alcohol or substance use provider to co-manage care of the patient.

(iii) A qualified mental health professional with experience in alcohol and substance use, or a substance use specialist, shall be available onsite for consultation, within a timeframe to meet the patient needs.

(iv) The Level III hospital shall have appropriately skilled staff and protocols in place for the treatment and management of neonates with severe neonatal abstinence syndrome or fetal alcohol spectrum disorder.

(2) Anesthesia Care. The Level III hospital shall meet the requirements of section 721.6(e)(2) of this Part.

(3) Breastfeeding. The Level III hospital shall meet the requirements of section 721.6(e)(3) of this Part.

(4) Genetic specialists. Genetic counseling services shall be available for consultation onsite, by phone or telemedicine, including a certified genetic specialist with experience in managing metabolic and genetic disorders.

(5) Infection control. The Level III hospital shall meet the requirements described in section 721.5(e)(5) of this Part.

(6) Laboratory services. The Level III hospital shall meet the requirements described in section 721.6(e)(6)(i) of this Part. In addition, blood bank

services shall be maintained 24 hours a day, with all blood components available onsite.

(7) Nutrition.

(i) The Level III hospital must have at least one certified dietitian-nutritionist who has special training in perinatal nutrition and can plan diets that meet the special needs of high-risk antepartum and postpartum patients, in a timeframe to meet patient needs.

(ii) The Level III hospital must have at least one certified dietitian-nutritionist who has special training in parenteral and enteral nutrition of low birthweight (under 1,500g) and other high-risk neonates and infants.

(8) Occupational and physical therapy. At least one occupational therapist and one physical therapist with neonatal expertise shall be available onsite for consultation within a timeframe appropriate to meet the patient's needs.

(9) Pharmacists and pharmacy services. The Level III hospital shall meet the requirements as described in section 721.6(e)(9) of this Part. In addition, the Level III facility shall have pharmacists onsite 24 hours a day available to prepare and dispense specialized pharmaceutical services, including to neonates and infants.

(10) Radiology. The Level III hospital shall meet the requirements as described in section 721.6(e)(10) of this Part. In addition, radiology services, including basic interventional radiology, obstetrical echocardiography, computed tomography, magnetic resonance imaging, and nuclear medicine imaging shall be readily available 24 hours a day, with interpretation in a timeframe appropriate to meet the patients' needs.

(11) Respiratory therapy. The Level III hospital shall meet the requirements described in section 721.6(e)(11) of this Part. In addition:

(i) The ventilation of a distressed neonate shall include long-term standard conventional ventilation and complex ventilation techniques.

(ii) Respiratory therapists shall be available onsite 24 hours a day for immediate care of patients to provide assisted ventilation, including conventional and/or high-frequency ventilation and inhaled nitrous oxide or nitric oxide as appropriate and as needed.

(12) Social work, psychosocial and mental health.

(i) Patients who screen positive for perinatal mood disorder during prenatal screening or have a history of psychiatric/mental health conditions, shall be evaluated by a licensed, qualified mental health professional, including but not limited to a psychiatrist, psychologist, psychiatric NP, clinical social worker, or other mental health counselor with training in perinatal mental health. This evaluation may be conducted onsite or by telemedicine.

(ii) If a patient is receiving mental health services, the prenatal care provider shall collaborate with the patient's mental health provider to co-manage care of the patient prenatally and post-partum. The patient shall be screened to determine any new symptoms.

(13) Speech-language pathology. A speech-language pathologist with neonatal expertise, skilled in evaluation and management of neonatal feeding and swallowing disorders shall be available onsite for consultation, in a timeframe appropriate to meet the patients' needs.

Section 721.8 is repealed and a new Section 721.8 is added to read as follows:

Requirements for the Designation of a Regional Perinatal Center.

(a) Qualifications and Responsibilities of Chiefs of Services

(1) Qualifications

(i) Obstetrics. The chief of obstetrics shall be one of the following:

(*a*) A full-time, board-certified obstetrician with subspecialty certification in maternal-fetal medicine and admitting privileges; or

(*b*) A full-time board-certified obstetrician with critical care certification and admitting privileges.

(ii) Neonatology. A full-time, board-certified pediatrician with subspecialty certification in neonatal medicine and admitting privileges shall be the chief of neonatal services.

(iii) Anesthesiology. A board-certified anesthesiologist shall be the chief of anesthesiology.

(iv) Midwifery. A midwife or nurse-midwife licensed in the state of New York, at minimum, with privileges at the hospital shall serve as the chief of midwifery services. Facilities that do not employ or utilize midwifery staff are exempt from this requirement.

(v) Nursing. Nursing leadership shall be at minimum a registered nurse with expertise in perinatal and neonatal care.

(2) Care coordination.

(i) The hospital's perinatal care services shall be coordinated by the chiefs described in paragraph (1) of this subdivision, in order to

ensure provision of a comprehensive continuum of high-quality care to mothers and neonates.

(ii) The RPC shall have a maternal-fetal medicine care team, which shall have expertise to assume responsibility for patients who are in critical condition or have complex medical conditions. This includes co-management of ICU-admitted obstetrical patients. An MFM care team member with admitting privileges shall be available 24 hours a day for onsite consultation and management. The care team shall be led by a board-certified obstetrician with subspecialty certification in maternal-fetal medicine and with expertise in critical care obstetrics.

(iii) The RPC shall have a neonatal care team, which shall have expertise to assume responsibility for patients who are in critical condition or have complex medical conditions. A neonatal care team member with admitting privileges shall be available 24 hours a day for onsite consultation and management. The care team shall be led by a board-certified pediatrician with subspecialty certification in neonatology.

(3) Responsibilities of Chiefs of Services. Chiefs of services shall meet the responsibilities described in section 721.7(a)(3) of this Part. In addition, the chiefs of obstetrics, neonatology, and midwifery will 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

birth centers and Level I, Level II, and Level III perinatal care affiliate hospitals in the region.

(b) Qualifications and Responsibilities of Physicians and Other Licensed Obstetrical and Neonatal Practitioners.

(1) Staff and equipment required for all deliveries. RPCs shall meet the requirements described in section 721.5(b)(1) of this Part.

(2) Physicians. Care for high-risk patients shall be provided by appropriately qualified physicians. RPCs shall meet the requirements described in section 721.7(b)(2) of this Part.

(3) Physician Assistants and Nurse Practitioners. RPCs shall meet the requirements described in section 721.7(b)(3) of this Part. In addition, NPs and PAs may have additional responsibilities, such as maintaining clinical care during patient transfers, and conducting continuing education both at the RPC and at affiliate facilities.

(c) Midwifery. RPCs shall meet the requirements described in section 721.5(c) of this Part.

(d) Nursing care. RPC obstetrical and neonatal nursing care staff shall meet the requirements and qualifications described in section 721.7(d) of this Part. In addition, advanced practice registered nursing staff shall be responsible for outreach and education to registered nurses in obstetrics, neonatology and critical care within the RPC as well as in affiliate hospitals. Licensed nurse-midwives may serve in this capacity as appropriate, and may also provide education to registered nurses and licensed midwives in midwifery.

(e) Ancillary Personnel. RPCs shall meet all of the requirements described in section 721.7(e) of this Part. In addition, the RPC shall have access to in-patient

psychiatric consultative services. Such services shall also be available for consultation in person, by telephone or by telemedicine, to affiliate hospitals.

Section 721.9 is amended to read as follows:

Regional quality improvement activities.

(a) Quality of care reviews of affiliates. Each birth center and 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 section 721.10 of 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] assurance purposes as described in the affiliation agreement which [may] shall include, at a minimum:

* * *

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

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

(iv) appropriateness and timeliness of [maternal] perinatal and [newborn] neonatal 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] perinatal and [newborn] neonatal serious adverse events or occurrences that may include the following:

(*a*) [maternal] perinatal and [newborn] neonatal fatalities, including pathology and significant surgical specimens;

(*b*) [maternal] perinatal and [newborn] neonatal morbidity in circumstances other than those related to the natural course of disease or illness, including pathology and significant surgical specimens;

(*c*) [maternal and newborn] nosocomial infections; and

(*d*) [maternal] obstetrical and [newborn] neonatal 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]10 of this [Title] Part.

(b) Each RPC shall cooperate with the [department] Department in regular quality improvement reviews by the [department] 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] Department's quality of care review of the RPC shall include the elements set forth in section 721.9(a)(1) of this [Title] Part.

(2) The [department's] 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] Department by providing medical records and other relevant documents and information on a timely basis when requested.

(c) [Quality improvement] Professional education and outreach program. Each RPC shall provide professional education and training for physicians, midwives, nurses, and other staff at all birthing hospitals and centers in the [region or affiliate] region's affiliate network for which it provides quality of care review. The RPC may also provide such education to private practitioners, community-based providers and non-clinical providers as appropriate. Education and training shall be designed to update and enhance staff knowledge and familiarity with relevant procedures and technological advances and shall also enhance staff

knowledge of systemic and individual factors that may impact outcomes including but not limited to implicit bias, cultural humility, physiological impacts of racism, the importance of informed consent, including shared decision-making, during pregnancy through postpartum period, recognizing obstetric violence and neglect, providing trauma-informed patient care, honoring client autonomy and satisfaction, and understanding of the impact of policies and practices of the patients served by the facilities, including marginalized groups. RPCs may provide such education and training directly, through engagement with subject matter experts, and shall provide such training using modalities best suited for the topic and audience.

(d) Quality improvement initiatives. In addition to hospital-specific quality improvement initiatives defined by section 405.6 of this Title, each birth center, Level I, II or III facility and RPC may participate in applicable initiatives led by the Department to improve quality of midwifery, obstetrical, and neonatal care and patient outcomes. RPCs shall provide guidance to their affiliate facilities, in conjunction with the Department, on such initiatives.

Section 721.10 is amended to read as follows:

Perinatal affiliation agreements and transfer agreements.

(a) Each [hospital with a] birth center and Level I, II or III perinatal care service hospital shall enter into and comply with a perinatal affiliation agreement with an RPC. Each [hospital] birth center or Level I or II perinatal care service hospital may also enter into a transfer agreement with a [hospital with a] Level III perinatal care service hospital if such an agreement would result in an acceptable level of care and provide a more [convenient] accessible alternative for the patient

and the patient's family than transfer to an RPC. All such agreements and amendments to such agreements shall be made available to the [department] Department, upon request. The terms of such agreements shall be mutually agreed upon by the [affiliating hospitals] affiliate hospital and the RPC.

(b) RPCs are required to enter into a perinatal affiliation agreement with all birth centers and birthing hospitals within their geographic regions. Where the geographic regions overlap with one or more RPCs:

(1) the geographically closest RPC to a newly established birth center or birthing hospital is required to enter into a perinatal affiliation agreement; or

(2) another RPC that is geographically close to the new facility may enter into a perinatal affiliation agreement, provided that this must be agreed upon by both the RPC and new facility and approved by the department.

(3) The Department may review proposed affiliation agreements and make recommendations and directives related to establishing perinatal affiliation agreements under this section.

([b]c) 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] 90 days prior notice to the Department. If such a change results in an affiliation agreement with an RPC that does not serve the birthing hospital or center's geographic area, the birthing hospital or birth center, current RPC and proposed RPC must agree to such a change in affiliation; this new affiliation must still be geographically close and of similar travel time to the new RPC.

(d) Minimum requirements of affiliation agreements.

(1) Birth centers and Level I, II, and III perinatal care service hospitals. The affiliation agreement shall include, at minimum, the following provisions:

(i) allowance for the hospital to provide continuing care of patients with anticipated birthweight and gestational age as described in section 405.21 of this Title;

(ii) timely consultation on treatment plans for patients who develop or exhibit unanticipated conditions which may require transfer to a higher level of care;

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

(iv) RPC involvement in the development of written transfer agreements between perinatal affiliates including criteria regarding transport of patients;

(v) criteria, policies and procedures for transfer of patients, with appropriate consent, to the RPC or other affiliate hospitals, transfers of neonatal patients back to a Level II or III hospital that is closer to the parent's residence, and transfers of postpartum patients back to the sending hospitals;

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

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

(viii) assurances to provide the RPC with full access to medical records and quality assurance reports as described in section 721.9(a) of this Part, in accordance with applicable confidentiality laws;

(ix) the affiliate birth center and hospital shall take actions necessary to authorize participation by the RPC's representatives in the affiliate facility's quality assurance committee. For purposes of such participation, the RPC representative or representatives shall be deemed member(s) of the affiliate's quality assurance committee and shall maintain the confidentiality of all information obtained in such capacity. RPC representatives are subject to the confidentiality restrictions of Public Health Law Section 2805-m; and

(x) established policies which describe the process to resolve disputes between the RPC and affiliate hospital. Resolution of disputes or disagreements between the RPC and the affiliate hospital, 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 facilities shall follow the dispute resolution process outlined in their perinatal affiliation agreement. If the dispute is not resolved within 60 days, the parties must request review by the Department. The Department shall initiate compliance reviews at both sites, advise each hospital of its findings, and require corrective action, as indicated, to resolve the dispute. This process shall not interfere with the timely and proper care and transfer of patients.

(xi) The transfer and consultation criteria included in the affiliation and transfer agreements may 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.

(2) Regional Perinatal Centers. In addition to the minimum requirements described in paragraph (1) of subdivision (d) of this section, the RPC shall:

(i) maintain a prearranged system for the transfer of patients, antenatally or postpartum, to an appropriate level of care hospital. The system shall include consultation prior to all transfers of patients.

(ii) participate in at least quarterly scheduled meetings with each affiliate hospital to engage in quality improvement reviews and to facilitate Department-led quality improvement initiatives. At least one such meeting annually shall be onsite at the affiliate hospital, with additional onsite meetings at the discretion of the RPC or request of the affiliate hospital, based on mutually agreed-upon criteria identified in the affiliation agreement. Meetings may include reviewing information and data for quality improvement purposes.

(iii) The RPC shall be involved with the development of written agreements, such as transfer agreements, among lower-level perinatal affiliates. This may include criteria regarding transport of patients to assure all patients shall be transferred to the appropriate level hospital for medical care.

(e) Transfer Agreements.

(1) Transfer agreements between two affiliate hospitals that provide different levels of care shall include, at minimum, the following provisions:

(i) the maximum allowable surface travel time to reach a hospital that provides a higher level of care shall be two hours under usual weather and road conditions, and the receiving hospital shall be accessible and convenient to the patients' place of residence whenever possible;

(ii) mutually agreed-upon criteria for determining when consultation with the RPC and/or transfer is required;

(iii) procedures and responsibility for arranging transport, in consultation with the RPC;

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

(v) emergency transport shall depart from the transferring facility within thirty minutes of the request for transfer;

(vi) back transfer of neonates who no longer need a higher level of care but who need continuing care in a Level II or III hospital located near their home communities; such transfers shall take into consideration any relationships between the facilities,

reimbursement issues, and overcrowding of the NICU to prevent infectious disease outbreaks. Family and geographical preference for back transfer will be considered whenever possible within these contexts;

(vii) if a postpartum patient and their neonate need different levels of care, efforts shall be made to keep the patient dyad together; and

(viii) the higher-level hospital shall inform referring hospitals of the patient's status as well as major changes in status of transferred patients, with patient's consent or with parental or guardian consent in the case of neonatal transfers.

(2) Transfers from Birth Centers, Level I or Level II Perinatal Care Service Hospital.

(i) Transfer procedures shall be initiated immediately upon identification of risk for the patient(s). Transfer optimally shall occur in the antenatal period.

(ii) All referrals for inter-hospital transfer from the birth center or Level I facility shall be evaluated for patient acuity, physiologic stability, and the need for urgent, time sensitive diagnostic or therapeutic intervention.

(iii) Decisions regarding the appropriate level of care and need for transport shall be made consistent with generally accepted standards of care, the perinatal affiliation agreement, and through consultation with the RPC.

(iv) The method of transport shall be determined based on the region, level of acuity, availability of transport services, and weather

conditions. The transport unit shall have the appropriate equipment and qualified providers on board to handle obstetrical or neonatal emergencies. If such a unit is unavailable, the hospital shall coordinate with the RPC for appropriate transportation.

(3) Transfers from a Level III Perinatal Care Service Hospital. The Level III facility shall meet the requirements of paragraph (2) of subdivision (e) of this section. In addition, transfer agreements shall include critical transport decisions to:

(i) assess the patients' clinical status;

(ii) determine the medical care necessary before and during transport, especially determining what level of care will be necessary during transport;

(iii) assess the urgency of transport; and

(iv) provide options on the mode of transport.

(4) Role of the RPC in Transfer Coordination. The RPC shall meet the requirements of paragraph (3) of subdivision (e) of this section. In addition:

(i) be involved and provide consultation in establishing transfer agreements between affiliate facilities;

(ii) develop policies and procedures to address situations where multiple emergency transfers are needed and such policies shall be provided and enacted at all affiliate hospitals; and

(iii) determine the appropriate level of care when directing transfers based on patient acuity and for neonatal transfers, the receiving hospital's available NICU capacity. Additional factors, such as

organizational relationships between the transferring and receiving hospitals, insurance and payment issues, and family preference, shall also be considered secondary to patient care.

Section 754.1 is amended to read as follows:

Definitions.

(a) A birth center is a diagnostic and treatment center organized to provide care to low-risk patients during pregnancy, labor and [delivery] birth who require a stay of less than 24 hours after birth. Services are provided by a physician or licensed midwife to [women] a birthing person during a normal and an uncomplicated pregnancy, labor, birth and puerperium. Birth center services are based on a philosophy that promotes a family-centered approach to care and views pregnancy and [delivery] birth as a normal physiological process requiring limited technological and pharmacological support. The center services are designed to meet the specific needs of the population being served and promote optimum pregnancy outcomes. The licensed midwife or physician provides care for the low-risk [woman] patient during pregnancy and stays with [her] the patient during labor from the time of admission to the birth center through the immediate postpartum period providing continuous physical and emotional support, evaluating progress, facilitating family interaction and assisting the [woman] patient in labor and [delivery] birth. Nurse practitioners may provide prenatal and [post partum] postpartum care to [birthing] birth center patients. They may also provide supportive care during labor and [delivery] birth, but the attending provider for birth must be a physician or licensed midwife.

(b) A patient at low risk means a patient with a [normal] medical, mental health, surgical and [obstetrical] reproductive history, including alcohol, tobacco and substance use history, and a normal, uncomplicated prenatal course as determined by adequate prenatal care, and prospects for a normal uncomplicated birth. A [pregnant woman] patient, parturient patient, or [newborn] neonate shall be determined as low risk during the prenatal period, intrapartum and postpartum by the use of standardized criteria based on generally accepted standards of professional practice [such as those approved by the department's Prenatal/Perinatal Advisory Council Subcommittee on Birth Centers in Guidelines for Birth Centers in New York State].

754.2 is amended to read as follows:

Administrative Requirements. When [birthing] birth center services are provided the operator shall ensure that:

(a) only those [women] patients for whom a prenatal and intrapartum history, physical examination and laboratory screening procedures have demonstrated the expectation of a normal, uncomplicated course of pregnancy and labor are admitted and cared for at the birth center;

* * *

(d) a physician or licensed midwife reviews the content of the informed consent form with each [woman] patient, and a copy is given to the [woman] patient before signing;

(e) there is a transfer agreement with a Level I, II or III perinatal care service hospital[(s)], or a regional perinatal center (RPC) located within [20 minutes'] a transport time [from the birth center to the transfer hospital] less than two hours

under usual weather and road conditions for medical care of a [woman or an infant] patient when complications arise during the antepartum, intrapartum, postpartum or [newborn] neonatal period, written in accordance with [section] sections 400.9 and 721.10(d) of this Title;

(f) support and ancillary services such as mental health, alcohol and substance use, laboratory, radiology and family planning services not provided by the birth center are available by referral;

(g) the birth center services are available 24 hours a day for the admission of [women] patients, professional consultation and prompt response to inquiries;

(h) kitchen facilities are available to enable families to store and prepare food brought in for the laboring family; [and]

(i) the birth center takes action in accordance with the requirements of paragraph 405.21(c)(14) of this Title with respect to a voluntary acknowledgement of paternity [for a child born out of wedlock.]; and

(j) the birth center enters into an affiliation agreement with an RPC as defined in Part 721 of this Title. The affiliated RPC shall be the closest geographically located RPC provided, however, when two or more RPCs are approximately equal distance from the birth center, the birth center may use additional criteria to determine affiliation. Any requested change in affiliation to a new RPC must be submitted to the Department as described in section 721.10(b) of this Title.

Section 754.3 is amended to read as follows:

Service restrictions. The operator shall ensure that:

(a) only [women] patients assessed as being low-risk by application of risk assessment criteria during pregnancy, labor, birth and puerperium are admitted and cared for at the birth center;

* * *

(c) general and regional anesthesia are not administered at the center; [and]

(d) labor is not induced, inhibited, stimulated or augmented with pharmacological agents acting directly on the uterus during the first or second stages of labor[.]; and

(e) patients requiring services outside the scope of practice of the birth center shall be transferred to a higher level of care facility, in coordination and consultation with the birth center's affiliated RPC. If such transfer is required after birth, the birth center shall coordinate with the RPC to transfer both the postpartum patient and neonate(s) to the same receiving hospital.

Section 754.4 is amended to read as follows:

Hospital transfer procedures.

(a) There are written plans and procedures for the transfer of a [woman or an infant] patient to the obstetrical or pediatric services of the [transfer] receiving hospital(s) when complications arise of an emergency nature. Such plans and procedures shall include consultation and coordination with the RPC and arrangements for an ambulance service and, when appropriate, the escort of the patient to the admitting facility by a clinical staff member of the birth center.

(b) The operator, in collaboration with the transfer hospital(s), shall develop a list of indicators necessitating transfer and a written procedure for automatic acceptance

of such transfers by the transfer hospital. This information shall be incorporated into any written transfer agreements as described in section 721.10 of this Title.

* * *

(d) There shall be an established mechanism for jointly reviewing all transfer cases by the RPC, transfer hospital(s) and the birth center as part of the quality assurance program specified in section 754.9 of this Part.

Section 754.5 is amended to read as follows:

Medical director and medical consultants. The operator shall:

(a) appoint a medical director who:

* * *

(2) has [obstetrical] privileges that include admission and care of [maternity] patients at the hospital(s) used for transfer. In the absence of [obstetrical] such privileges at the transfer hospital(s), there must be formal arrangements for the provision of obstetrical care at the transfer hospital(s)[;] as described in section 721.10 of this Title;

* * *

(4) approves standardized criteria for admission screening and monitoring the risk status of each [mother] patient during pregnancy, labor, birth and postpartum; [and]

(5) has oversight and is responsible for quality improvement initiatives, including participation in Department-led and RPC-led initiatives as defined by section 721.9 of this Title; and

(6) oversees the establishment and implementation of an affiliation agreement with an RPC, as described in section 721.10 of this Title;

(b) appoint a consultant physician who:

(1) is a qualified specialist, as defined in section 700.2 of this Title, in pediatrics or family practice and who has pediatric privileges that include admission and care of [newborns] neonates at the transfer hospital(s). In the absence of pediatric privileges, there must be formal arrangements for the provision of pediatric care at the transfer hospital(s) as described in section 721.10 of this Title; and

* * *

Section 754.6 is amended to read as follows:

Clinical staff. The operator shall ensure that:

(a) a licensed midwife or an obstetrician or a family practitioner attends each [woman in labor] pregnant or laboring person from the time of admission, during labor, during the birth and through the immediate postpartum period. Such person shall be a current basic life support (BLS) and Neonatal Resuscitation Program (NRP) provider; providers may also be current advanced cardiac life support (ACLS) providers. Such attendance may be delegated only to another licensed midwife or physician;

(b) a second staff person is also present at each birth who:

* * *

(2) has specialized training in labor and [delivery] birth techniques and care of the [newborn] neonate, and is a current BLS and NRP provider; and

* * *

(c) if the center employs licensed midwives[,]:

(1) a licensed midwife is appointed as director of midwifery services who is responsible for the development of policies and procedures for such services[.];

(2) midwives attending births shall be current BLS and NRP providers and may be current ACLS providers; and

(3) midwives attending births shall have the ability to stabilize patients in distress and, if necessary, transfer to an appropriate higher level of care facility for continued care, following consultation with the RPC.

(d) If the center employs nursing staff, licensed nurse practitioners must be currently certified and registered, with the ability to prescribe medications. Nursing staff shall be current BLS and NRP providers, may be current ACLS providers, and may provide prenatal and postpartum care to birth center patients.

Section 754.7 is amended as follows:

Services for the care of [mothers] midwifery and [newborns] neonatal patients.

The operator shall ensure that the birth center provides at least the following:

(a) admission screenings to assure that only low risk [women] birthing persons are admitted to the birth center;

(b) active participation by [women] birthing persons and families in their own health care plan to include but not be limited to:

* * *

(2) attendance at prenatal education classes approved by the clinical staff which address, as a minimum, labor and [delivery] birth, infant care and feeding, parenting, nutrition, the effects of [smoking] tobacco and

nicotine, 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;

(c) prenatal and intrapartum care including:

* * *

(2) selection of pediatric services [by the woman] for follow-up care of the [infant] neonate;

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

(4) continuous risk assessment of the [woman] patient and fetus; and

(5) labor support and professional attendance at birth for the [mother] patient and [her] the patient's family;

(d) postpartum care including:

* * *

(2) a physical assessment of the [newborn] neonate with the required eye prophylaxis and vitamin K prophylaxis in accordance with section 12.2 of this Title and newborn screening tests in accordance with Part 69 of this Title;

(3) birth registration in accordance with [s]Section 4130 of the Public Health Law or in instances of a birth that requires registration in the City of New York, and any and all applicable laws associated with birth registration as set forth in the laws, codes and regulations of the City of New York;

(4) a physical assessment of the [mother] patient in accordance with established protocols including the evaluation of Rh status, need for Rh prophylaxis and the [mother's] patient's ability to feed the [infant] neonate prior to discharge from the birth center; and

(5) the transfer to the [newborn's] neonate's medical record of a [mother's] prenatal or postpartum patient's HIV test result, if one exists.

(e) discharge and follow-up including:

(1) [maternal and newborn] home visits the following day after discharge and upon the third day after discharge unless arrangements have been made for the [infant] neonate to be seen by his/her physician. The home visits may be performed by professional nursing staff from the birth center, if the facility is approved under article 36 of the Public Health Law, or through an arrangement with a certified or licensed home health agency, to include an assessment of the [mother-child] postpartum patient-neonate relationship, an evaluation of the nutritional status of the [infant] neonate and the physical and psychological status of the [mother] patient, performance of a hematocrit, rubella and hepatitis B vaccination and Rh prophylaxis, if indicated, and newborn screening blood collection in accordance with Part 69 of this Title;

* * *

(f) Ancillary services. The birth center, in coordination with the RPC, affiliate birthing hospitals and other community-based providers as appropriate, shall provide the following ancillary services to birth center patients, through referral, onsite, telephone or telemedicine as available and appropriate:

(1) Alcohol and substance abuse specialists:

(i) The birth center shall have a prearranged system for referral of patients with alcohol or substance use disorders to a higher level-of-care facility.

(ii) The birth center shall screen patients prior to admission for alcohol, tobacco and substance use during pregnancy, in addition to screening for physical, sexual and emotional abuse as part of routine midwifery care.

(iii) Patients who fall out of the scope of practice due to alcohol and substance use shall be referred for consultation with a qualified perinatal mental health professional to determine an appropriate course of action.

(iv) Patients identified as using tobacco or nicotine products shall be referred to appropriate tobacco cessation services and programs.

(2) Anesthesia care: Patients requiring services outside the scope of practice at the birth center, including anesthesia, shall be transferred to a higher level of care facility, in coordination with the RPC.

(3) Breastfeeding: A trained and qualified international board-certified lactation consultant or a certified lactation counselor shall be available to educate and assist patients to initiate breastfeeding in a timeframe appropriate to meet the needs of the patient.

(4) Genetic specialists: The birth center shall provide access to genetic screening, carrier testing, and genetic counseling for patients.

(5) Infection control: The birth center shall have policies and procedures for infection control in accordance with current standards of care.

(6) Laboratory services: The birth center shall have a prearranged plan for access to laboratory services for patients.

(7) Nutrition: The birth center shall have policies and procedures for nutrition support in accordance with current standards of care.

(8) Occupational and physical therapy: The birth center shall refer patients to an appropriate occupational or physical therapist in a timeframe appropriate to meet the needs of the patient.

(9) Pharmacy services: Any controlled drugs or medications prescribed, dispensed or administered in the birth center shall be properly stored and tracked.

(10) Radiology services: The birth center shall have a prearranged plan for access to imaging services such as ultrasonography. When results are inconclusive or an abnormality that requires immediate neonatal care is detected, patients shall be directed to a higher level of care facility for further management, including consultation by a radiologist or a qualified provider who can interpret results.

(11) Respiratory therapy: Birth center staff attending deliveries must be current NRP providers and shall be able to provide oxygen and utilize all necessary equipment to support resuscitation to maintain the airway of the patient(s).

(12) Social work, psychosocial and mental health:

(i) Patients shall be assessed to determine availability of sufficient resources prior to or following birth.

(ii) The birth center shall have a prearranged system for referral of patients with mental health conditions.

(iii) The birth center shall provide prenatal and postpartum screenings for perinatal depression and perinatal mood disorder during such visits, and provide referrals as indicated.

(iv) Patients who screen positive during prenatal or postpartum screening for perinatal depression or perinatal mood disorder shall be referred to a higher level-of-care facility or a local institution with a perinatal qualified mental health professional to determine an appropriate course of action.

(v) If a patient is receiving mental health services, the birth center provider shall collaborate with the patient's mental health service provider to co-manage care of the pregnant or postpartum patient.

(13) Speech-language pathology: Neonates demonstrating difficulty feeding and swallowing shall be referred to a licensed speech-language pathologist.

Section 754.8 is amended to read as follows:

Medical records. The operator shall ensure that, in addition to meeting the requirements in section 751.7 of this Title:

(a) The medical record for each [woman] patient admitted to the birth center shall contain the following information:

* * *

(2) [maternal] reproductive history, to include medical, surgical, gynecological and psychosocial history;

(3) shared decision making including informed consent for birth center services;

* * *

(5) periodic evaluations of [maternal] the patient's health;

* * *

(8) [newborn] neonatal physical assessment, including APGAR scores, [maternal-newborn] postpartum patient-neonate interaction, ability to feed, eye prophylaxis, vital signs and accommodation to extrauterine life;

* * *

(b) The medical record for each [newborn] neonate shall be cross-referenced with the [mother's] postpartum patient's medical record and contain the following information:

(1) copy of the [newborn] neonatal physical assessment;

* * *

(3) vaccination information, including the date, time, site(s) of administration, dosage, vaccine manufacturer and lot number for each vaccine; record of parental consent and parental receipt of relevant vaccine information sheets; or documentation of an exemption as described in Sections 69-3.9 and 69-3.10 of this Title;

(4) discharge summary with follow-up plans; and

[4] (5) home visit report.

Section 754.9 is amended to read as follows:

Quality assurance. In addition to meeting the requirements set forth in [section] sections 721.9 and 751.8 of this Title, the operator shall ensure that there is a review of all [mother and/or newborn] hospital patient transfers, with reasons for such transfers documented. Findings from these reviews shall be used in the development and revision of policies and in the consideration of renewing or granting staff privileges.

Section 754.10 is amended to read as follows:

Emergency care. The operator shall ensure that:

(a) emergency equipment and supplies approved by the medical director are available for use at all deliveries and include at least the following:

* * *

(4) oxygen and oxygen administration equipment appropriate for [mother and infant] the patient(s);

(5) airways and manual breathing bags appropriate for [mother and infant] the patient(s);

(6) suction machine and equipment appropriate for [mother and infant] the patient(s);

(7) infant laryngoscope and either endotracheal tubes or laryngeal mask airways; [and]

(8) medications and intravenous fluids with supplies and equipment for administration; and

(9) any additional equipment required for compliance with BLS and NRP guidelines;

(b) center staff are trained in resuscitation and other emergency procedures and are current BLS and NRP providers as previously described in this section; and

(c) a physician or registered professional nurse and another staff member, both trained in emergency procedures and current BLS and NRP providers, are on duty in the center when a [mother] patient is in the birth center.

Section 795.1 is amended to read as follows:

Definitions.

As used in this Part:

(a) A midwifery birth center means a facility licensed pursuant to Article 28 of the Public Health Law that is engaged principally in providing [prenatal and obstetric] midwifery care, and where such services are provided principally by midwives. The facility shall be organized to provide prenatal, child birth and postpartum care and primary preventive reproductive health care to patients at low risk. Services are provided by a midwife, licensed pursuant to Article 140 of the Education Law, to patients at low risk, during pregnancy, labor, [delivery,] birth, and who require only a stay of less than 24 hours after birth. Such services shall include newborn evaluation, resuscitation and referral. Midwifery birth center services are based on a philosophy that promotes a home-like setting and family-centered approach to care and views pregnancy and [delivery] birth as a normal physiological process requiring limited technological and pharmacological support. The center services are designed to meet the specific needs of the population being served and promote optimum pregnancy outcomes. The licensed midwife provides care for the low-risk patient during pregnancy and remains available to the patient during labor from the time of admission to the midwifery birth center through the immediate postpartum period, providing continuous physical and emotional support, evaluating progress, facilitating family

interaction and assisting the patient in labor and [delivery] birth. Other health care providers can provide prenatal and postpartum care to midwifery birth center patients. They may also provide supportive care during labor and [delivery] birth, but the attending provider for birth must be a licensed midwife.

(b) A patient at low risk means a patient [who has:] with a [normal] medical, mental health, surgical, and [obstetrical] reproductive history, including alcohol, tobacco and substance use history, and [;] a normal, uncomplicated pregnancy as determined by adequate prenatal care; and prospects for a normal, uncomplicated gestation and birth. Risk shall be determined using standardized criteria based on generally accepted standards of professional practice.

* * *

Section 795.2 is amended to read as follows:

Administrative requirements. The operator shall ensure that:

(a) only patients [at] for whom a prenatal and intrapartum history, physical examination and laboratory screening procedures demonstrate the expectation of a low risk, uncomplicated course of pregnancy and labor are admitted and cared for at the midwifery birth center;

* * *

(e) there is a transfer agreement with one or more Level I, II or III perinatal [center] care service hospital, or a regional perinatal center (RPC) as defined in section 721 of this Title, for medical care of patients when complications arise antepartum, intrapartum, or postpartum and that meets the following requirements:

(1) compliance with [section] sections 400.9 and 721.10(d) of this Title;

(2) the surface travel time to reach a receiving perinatal hospital within the geographic affiliate network is less than two hours under usual weather and road conditions; and

* * *

(f) support and ancillary services such as mental health, alcohol and substance use services, laboratory, radiology and imaging, and family planning services not provided by the midwifery birth center are available by referral;

* * *

(i) the midwifery birth center acts in accordance with the requirements of section 405.21(c)(14) of this Title with respect to a voluntary acknowledgement of paternity [for a child born out of wedlock];

[(j) the midwifery birth center refers patients for genetic screening, carrier testing, and genetic counseling as needed;

(k) the midwifery birth center refers patients requiring physical or occupational therapy to an appropriate therapist as needed; and]

(j) the midwifery birth center provides ancillary services, directly or through referral, as described in section 795.7(f) of this Title;

[(l)](k)] the needs of infants demonstrating difficulty feeding and swallowing are addressed to ensure the infant is healthy and developing properly, including referral to a lactation consultant or licensed speech and language pathologist as needed[.]; and

(l) the midwifery birth center shall enter into an affiliation agreement with an RPC as defined in section 721.2 of this Title, for the provision of professional education and outreach, quality improvement and transfer coordination, and that meets the

requirements described in section 721.10 of this Title. The RPC must be the closest geographically located facility; when two or more RPCs are approximately equal distance from the midwifery birth center, the midwifery birth center may use additional criteria to determine affiliation. Any requested change in affiliation to a new RPC must be submitted to the Department as described in section 721.10(c) of this Title.

Section 795.3 is amended to read as follows:

Service restrictions. The operator shall ensure that:

* * *

(c) general and regional anesthesia are not administered at the center; [and]

(d) labor is not induced, inhibited, stimulated or augmented with pharmacological agents acting directly on the uterus during the first or second stages of labor[.]; and

(e) patients requiring services outside the scope of practice of the midwifery birth center, as described in this section, shall be transferred to a higher level of care birthing hospital, in coordination and consultation with the affiliated RPC. If such transfer is required after birth, the midwifery birth center shall coordinate with the RPC to transfer both the postpartum patient and neonate(s) to the same receiving hospital.

Section 795.4 is amended to read as follows:

Midwifery birth center transfer procedures.

(a) The midwifery birth center shall maintain the capability to evaluate, stabilize and transfer patients other than patients at low risk, including newborns. The

midwifery birth center shall refer or transfer patients for any health care services that fall outside the scope of midwifery birth center resources and risk criteria at any point during the course of care. The midwifery birth center shall [initiate] consult and coordinate with the affiliated RPC to transfer patients when risks are identified, including when there is prolonged labor, fetal distress, or a need for spinal or epidural anesthesia, or when there may be an operative or cesarean birth.

(b) Midwifery birth centers shall have written plans and procedures for the transfer of patients to the obstetrical or pediatric services of the receiving hospital(s) when complications arise. Such plans and procedures shall include consultation and coordination with the RPC and arrangements for an ambulance service and, when necessary, accompanying the patient in the ambulance with a clinical staff member of the midwifery birth center.

(c) The operator, in consultation with the [receiving hospital(s)] affiliate RPC, shall develop a list of indicators necessitating transfer and a written procedure for automatic acceptance of such transfers by the receiving hospital, which shall include transfer of patients when neonatal abstinence syndrome or fetal alcohol syndrome is evident or suspected. This information shall be incorporated into any written transfer agreements as described in section 721.10 of this Title.

* * *

(e) The operator shall establish a mechanism for jointly reviewing all transfer cases by the receiving hospital(s), the affiliate RPC, and the midwifery birth center as part of the quality assurance program specified in section 795.9 of this Part.

Section 795.5 is amended to read as follows:

Midwifery birth center director and medical consultants. The operator shall appoint a midwifery birth center director who:

* * *

(f) has oversight of and responsibility for quality improvement initiatives, including participation in Department-led and RPC-led initiatives as defined by section 721.9 of this Title;

(g) oversees the establishment and implementation of an affiliation agreement with an RPC, as defined in section 721.10 of this Title;

(h) may appoint a consultant physician who:

(1) is a qualified specialist, as defined in section 700.2 of this Title, in pediatrics or family practice and who has pediatric privileges that include admission and care of [newborns] neonate at the receiving hospital(s). In the absence of pediatric privileges, there must be formal arrangements included in the transfer agreement for the provision of pediatric care at the receiving hospital(s); and

* * *

([g]i) ensures that the midwifery birth center has:

* * *

(2) collaborative relationships with pediatricians and other medical specialists needed to meet patients' needs, including with at least one pediatrician who has pediatric privileges that include admission and care of [newborns] neonates at the receiving hospital(s). In the absence of pediatric privileges, there shall be arrangements for the provision of pediatric care at the receiving hospital(s); and

(3) transfer agreements with one or more perinatal [centers] care hospitals which are geographically close, affiliated with the midwifery birth center's RPC, and licensed under Article 28 of the Public Health Law to provide:

(i) obstetrics through a licensed physician having obstetrical privileges at such perinatal [center] care hospital;

* * *

([h]j) has standardized criteria for admission screening and monitoring risk.

Section 795.6 is amended to read as follows:

Clinical staff. The operator shall ensure that:

(a) a licensed midwife attends each patient from the time of admission, during labor, during the birth and through the immediate postpartum period, and that such practitioner [maintains current certification by the American Academy of Pediatrics as a] is a current basic life support (BLS) and Neonatal Resuscitation Program (NRP) provider;

(b) a second trained staff person is also present at each birth who:

* * *

(4) maintains current status as a BLS and NRP provider;

(c) trained and qualified staff are available to educate and assist patients to initiate breastfeeding;

(d) at least two [people] staff members who [attend patients during labor, delivery and postpartum are currently certified NRP, Basic Life Support (BLS)] are current BLS and NRP providers shall be immediately available at all times and [Advanced Cardiac Life Support (ACLS) providers and are] able to provide

oxygen to patients, and operate all equipment necessary to maintain airways for the [patient and infant.] patients; and

(e) if the midwifery birth center employs nursing staff, licensed nurse practitioners must be currently certified and registered, with the ability to prescribe medications. Nursing staff shall be current BLS and NRP providers, may be current Advanced Cardiac Life Support (ACLS) providers, and may provide prenatal and postpartum care to patients.

Section 795.7 is amended to read as follows:

Services for the care of patients. All patients shall be assessed to determine availability of sufficient resources prior to and following [delivery] birth. The operator shall ensure that the midwifery birth center provides at least the following:

* * *

(b) active participation by patients and families in their own plan of health care, which shall include but not be limited to:

* * *

(2) access to prenatal education classes approved by the clinical staff which address, at a minimum, labor and [delivery] birth, infant care and feeding, parenting, nutrition, the effects of [smoking] tobacco and nicotine, alcohol and other drugs on fetal development and on the newborn patient, signs of [postpartum] perinatal mood and anxiety disorders and perinatal depression, what to expect if transferred, and the newborn screening program, including hearing screening, with the provision and distribution of newborn screening educational literature;

(c) prenatal and intrapartum care including:

* * *

(2) selection of pediatric services by the patient for follow-up care of the [infant] neonate;

* * *

(6) consultation with perinatal qualified mental health professionals to determine the appropriate course of action for patients who screen positive during the prenatal screening for perinatal depression or perinatal mood and anxiety disorder or who have other mental health conditions;

(7) a system for screening patients prior to admission for alcohol[/] and substance use during pregnancy and for prior physical, sexual and emotional abuse, as part of routine obstetric care, and for referral of patients as appropriate to a higher-level facility; and

* * *

(d) postpartum care including:

* * *

(2) a physical assessment of the newborn with the required eye prophylaxis and vitamin K prophylaxis in accordance with sections 12.2 and 12.3 of this Title and newborn screening tests in accordance with Part 69 of this Title;

(3) birth registration in accordance with [s]Section 4130 of the Public Health Law or in instances of a birth that requires registration in the City of New York, and any and all applicable laws associated with birth registration as set forth in the laws, codes and regulations of the City of New York;

(4) a physical assessment of the patient in accordance with established protocols including the evaluation of Rh status, need for Rh prophylaxis and the patient's ability to feed the [infant] neonate prior to discharge from the center; and

(5) the transfer to the [newborn's] neonate's medical record of a patient's HIV test result, if one exists; and

(e) discharge and follow-up including:

(1) a program for discharge and follow-up of the [patient and infant] patients in their home for the immediate postpartum period unless arrangements have been made for the [infant] neonate to be seen by another health care provider. The home visits may be performed by licensed professional nursing staff from the midwifery birth center, if the facility is approved under article 36 of the Public Health Law, or through an agreement with a certified or licensed home health agency, to include an assessment of the parent-child relationship, an evaluation of the nutritional status of the [infant] neonate and the physical and psychological status of the postpartum patient, performance of a hematocrit, rubella and Hepatitis B vaccination if not already provided, and Rh prophylaxis, if indicated, and newborn screening blood collection in accordance with Part 69 of this Title;

* * *

(4) arrangements for follow-up visits at the midwifery birth center within a six-week period following the birth[.]; and

(f) ancillary services: the midwifery birth center, in coordination with the RPC, affiliate birthing hospitals and other community-based providers as appropriate, shall provide the following ancillary services to patients, through referral or direct onsite, telephone or telemedicine provision as available and appropriate:

(1) Alcohol and substance abuse specialists:

(i) The midwifery birth center shall have a prearranged system for referral of patients with alcohol or substance use disorders to a higher level-of-care facility or community-based provider.

(ii) The midwifery birth center shall screen patients prior to admission for alcohol, tobacco and substance use during pregnancy, in addition to screening for physical, sexual and emotional abuse as part of routine midwifery care.

(iii) Patients who fall out of the scope of practice due to alcohol and substance use shall be referred for consultation with a qualified perinatal mental health professional to determine an appropriate course of action.

(iv) Patients identified as using tobacco or nicotine products shall be referred to appropriate tobacco cessation services and programs.

(2) Anesthesia care: Patients requiring services outside the scope of practice at the midwifery birth center, including anesthesia, shall be transferred to a higher level of care facility, in coordination with the RPC.

(3) Breastfeeding: A trained and qualified international board-certified lactation consultant or a certified lactation counselor shall be available to

educate and assist patients to initiate breastfeeding in a timeframe appropriate to meet the needs of the patient.

(4) Genetic specialists: The midwifery birth center shall provide access to genetic screening, carrier testing, and genetic counseling for patients.

(5) Infection control: The midwifery birth center shall have policies and procedures for infection control in accordance with current standards of care.

(6) Laboratory services: The midwifery birth center shall have a prearranged plan for access to laboratory services for patients.

(7) Nutrition: The midwifery birth center shall have policies and procedures for nutrition support in accordance with current standards of care.

(8) Occupational and physical therapy: The midwifery birth center shall refer patients to an appropriate occupational or physical therapist in a timeframe appropriate to meet the needs of the patient.

(9) Pharmacy services: Any controlled drugs or medications prescribed, dispensed or administered in the midwifery birth center shall be properly stored and tracked.

(10) Radiology services: The midwifery birth center shall have a prearranged plan for access to imaging services such as ultrasonography. When results are inconclusive or an abnormality that requires immediate neonatal care is detected, patients shall be directed to a higher level of care facility for further management, including consultation by a radiologist or a qualified provider who can interpret results.

(11) Respiratory therapy: Midwifery birth center staff attending deliveries must be current BLS and NRP providers and shall be able to provide oxygen

and utilize all necessary equipment to support resuscitation to maintain the airway of the patient(s).

(12) Social work, psychosocial and mental health:

(i) Patients shall be assessed to determine availability of sufficient resources prior to or following birth.

(ii) The midwifery birth center shall have a prearranged system for referral of patients with mental health conditions.

(iii) The midwifery birth center shall provide prenatal and postpartum screenings for perinatal depression and perinatal mood and anxiety disorder during such visits, and provide referrals as indicated.

(iv) Patients who screen positive during prenatal or postpartum screening for perinatal depression or perinatal mood and anxiety disorder shall be referred to a higher level-of-care facility or a local institution with a perinatal qualified mental health professional to determine an appropriate course of action.

(v) If a patient is receiving mental health services, the birth center provider shall collaborate with the patient's mental health service provider to co-manage care of the pregnant or postpartum patient.

(13) Speech-language pathology: Neonates demonstrating difficulty feeding and swallowing shall be referred to a licensed speech-language pathologist.

Section 795.8 is amended to read as follows:

Medical records. The operator shall ensure that, in addition to meeting the requirements in section 751.7 of this Title:

(a) The medical record for each patient shall contain the following information:

* * *

(2) patient history, to include medical, surgical, [gynecological] reproductive, and psychosocial history;

* * *

(8) newborn patient physical assessment, including APGAR scores, [maternal-newborn] parent-neonate or surrogate-neonate interaction, ability to feed, eye prophylaxis, vitamin K prophylaxis, vital signs and accommodation to extrauterine life;

* * *

(b) The medical record for each newborn shall be cross-referenced with the patient's medical record and contain the following information:

(1) copy of the [newborn] neonatal physical assessment

* * *

(3) [discharge summary with follow-up plans; and] vaccine information, including the date, time, site(s) of administration, dosage, vaccine manufacturer and lot number of for each vaccine, record of parental consent and parental receipt of relevant vaccine information sheets, or documentation of medical or religious exemption as described in sections 69-3.9 and 69-3.10 of this Title;

(4) discharge summary with follow-up plans; and

([4]5) home visit report.

Section 795.9 is amended to read as follows:

Quality assurance. In addition to meeting the requirements set forth in [section] sections 721.9 and 795.8 of this Title, the operator shall ensure that there is a review of all pregnant and postpartum patients and/or [newborn] neonatal hospital transfers, with reasons for such transfers documented. Findings from these reviews shall be used by the operator and midwifery birth center director in the development and revision of policies and in the consideration of renewing or granting staff privileges.

Section 795.10 is amended to read as follows:

Emergency care. The midwifery birth center shall have the capability and equipment to provide care to patients at low risk and a readiness at all times to meet any unexpected needs of patients within the center, and to facilitate transport to an acute care setting when necessary. The midwifery birth center shall stabilize and transfer patients, in consultation with the birth center's RPC, to an appropriate [general] perinatal care hospital for continued care when medically indicated. Staff [with required current course completion status in] who are current NRP, and BLS [, and ACLS] shall be immediately available and shall have immediate access to all necessary equipment in accordance with these certifications to initiate resuscitation of patients. The midwifery birth center must have availability of adequate numbers of qualified professionals with competence and ability to stabilize and transfer high-risk patients. The operator shall ensure that at a minimum:

(a) emergency equipment and supplies approved by the midwifery birth center director are available for use for resuscitation of [both adult and neonate] all patients and include at least the following:

* * *

(3) [infant] neonatal transport equipment;

(4) oxygen and oxygen administration equipment for the midwifery patient and [infant] neonate;

(5) airways and manual breathing bags for the midwifery patient and [infant] neonate;

(6) suction machine and equipment for the midwifery patient and [infant] neonate;

(7) adult and [infant] neonatal laryngoscope and endotracheal tubes or neonatal laryngeal mask airways; [and]

(8) medications and intravenous fluids with supplies and equipment for administration; and

(9) any additional equipment required for compliance with BLS and NRP guidelines;

(b) center staff are current BLS and NRP providers and are certified in [NRP, BLS, and ACLS resuscitation and] other emergency procedures; and

(c) a licensed midwife, and one other staff member, both [trained] current BLS and NRP providers and are certified in [NRP, BLS, and ACLS] other emergency procedures, are on duty in the center when patients are in the midwifery birth center.

Section 795.11 is repealed and a new Section 795.11 is added to read as follows:

Midwifery birth center operational standards and accreditation.

(a) Minimum operational standards of a midwifery birth center require compliance with sections 400.2 through 400.7, 400.9, and 400.10, sections 751.5 through 751.10, and Part

795 of this Title and require utilization of evidence-based standards for midwifery birth centers published by a national standards body selected by the Department and published on the Department's website.

(b) Additional operational requirements for New York State midwifery birth centers shall include affiliation agreements with designated Regional Perinatal Centers; patient transfer agreements with those facilities and/or other designated birthing hospitals; and the implementation of quality improvement protocols related to their integration with a regional perinatal care system, as described in sections 795.2, 795.4, and 795.9 of this Part, respectively.

(c) The Department may, at its sole discretion, accept as evidence of

(i) the intent and capability to comply with minimum operational standards, or

(ii) ongoing compliance with minimum operational standards in this subdivision, accreditation by an accreditation agency that the Department has determined has standards sufficient to assure the Department that midwifery birth centers so accredited are in compliance with such minimum operational standards.

(d) The Department may enter into collaborative agreements with one or more accreditation agencies to provide that such an agency’s accreditation survey can be used in lieu of a survey by the Department. As part of such collaborative agreements, an accreditation agency may, at the Department’s discretion, investigate complaints received by the Department related to care and services provided by a midwifery birth center.

(1) Notwithstanding any such collaborative agreements, the Department reserves the right to survey any midwifery birth center for compliance

with the evidence-based standards established pursuant to this section. A list of accreditation agencies with which the Department has a collaborative agreement will be posted on the Department's website.

(2) Except as otherwise prohibited by law, all survey reports, complaint investigation results, plans of correction, interim self-evaluation reports, certificates of accreditation, notices of noncompliance, or any other document, provided to the Department by an accreditation agency, pursuant to a collaborative agreement with the Department, shall be subject to public disclosure.

(e) The midwifery birth center shall notify the Department in writing within seven days of failure to be accredited, re-accredited or the loss of accreditation by the accreditation agency.

Section 795.12 is amended to read as follows:

Application for establishment.

(a) An application to the Public Health and Health Planning Council (Council) for establishment of a midwifery birth center, as required by law, shall be in writing on forms provided by the Department and executed by the chief executive officer or other officer duly authorized by the proposed operator. [An original and eight copies] The application shall be [filed with the Coucil] submitted electronically through the [project management unit] New York State Electronic Certificate of Need (NYSECON) system or its replacement. The Project Management Unit in the Department's central office in Albany[, which] shall transmit [one] an

electronic copy of the application to the health systems agency, if any, having geographic jurisdiction.

(b) Applications to the Council shall contain information and data with reference to:

(1) the [public need] number of projected births over time for [the existence of] the proposed midwifery birth center at the time and place and under the circumstances proposed;

(2) the character, experience, competency and standing in the community of the proposed incorporators, directors, stockholders, sponsors, individual operators, members, or partners;

(3) the [financial resources and sources of future revenue] capability of the applicant to fund any acquisition, renovations, and construction costs for the midwifery birth center to be operated by the applicant;

(4) the fitness and adequacy of the premises and equipment to be used by the applicant for the proposed midwifery birth center [; and], which includes, but is not limited to:

(i) compliance with Part 711 of this Title which sets forth the minimum construction and physical environment standards applicable to all health facilities subject to Department of Health oversight and pursuant to Article 28 of the Public Health Law;

(*a*) As required by NFPA 101 *Life Safety Code,* only birth centers occupied by fewer than four patients at any one time, not including infants, shall be classified as "Business Occupancies" and must comply with Chapter 38, "New Business Occupancies" or Chapter 39, "Existing Business Occupancies" of NFPA 101 *Life Safety Code*;

(*b*) compliance with The Facility Guidelines Institute, *Guidelines for Design and Construction of Outpatient Facilities*, Chapter 2.4, "Specific Requirements for Birth Centers,";

(*c*) compliance with *2010 ADA Standards for Accessible Design*;

(*1*) The local authority having jurisdiction for accessibility requirements, which includes New York State or New York City Building Code and/or local codes, may conflict with the Department's accessibility requirements, in those situations the most stringent requirement governs pursuant to Department regulations in section 711 of this Title;

(ii) due to their limited size, birth centers with a maximum of 3 birthing rooms (a maximum of 6 rooms total birthing and exam rooms), have minimum physical environment standards that allow for greater flexibility, including:

(*a*) waiting area is not required;

(*b*) staff lounge is not required, provisions for personal storage for staff remains a requirement;

(*c*) separate toilet rooms, containing a toilet and hand washing sink, for staff and public are not required, may provide shared staff/public toilet room;

(*d*) reduced number of required electrical receptacles in birthing rooms;

(*e*) 44” width of corridors are not required with an occupant load of less than 50, minimum corridor widths required is 36”;

(*f*) exam rooms shall be a minimum of 80 sq. ft clear floor area and demonstrate clearances and accessibility; at the Department’s discretion, a minimum of 72 sq. ft. clear floor area may be permitted for existing construction, if the applicant demonstrates clearances and accessibility;

(*g*) birthing rooms shall be a minimum of 120 sq. ft. clear floor area and demonstrate clearances, space for newborn care, and accessibility;

(*h*) environmental services room may be shared with other tenants that are business occupants only (this would exclude ambulatory health care settings, hospitals, and nursing homes) on the same floor. Only cleaning supplies may be stored in this room/area and it must be located near birth center space; and

(*i*) ventilation per ASHRAE Standard 170 is not required

(iii) Where an applicant is unable to meet a requirement in this paragraph, such application shall include a detailed explanation, including proposed alternatives, regarding the identified requirement, for the Department and/or the Council's consideration.

REGULATORY IMPACT STATEMENT

Statutory Authority:

The Department of Health (Department) and the Public Health and Health Planning Council (PHHPC) are authorized under Section 2803 of the Public Health Law to regulate health care facilities, including general hospitals and birth centers.

Legislative Objectives:

The legislative objectives of PHL Article 28 include the protection of the health of the residents of the State by assuring the efficient provision and proper utilization of health services, of the highest quality at a reasonable cost.

Needs and Benefits:

It has been over 20 years since standards for New York's regionalized perinatal system have been updated. Significant changes have occurred to standards for perinatal care, hospital systems and health care. In addition, maternal mortality rates are high in New York State, with significantly higher rates for Black women compared to other racial and ethnic groups, and must be addressed.

To improve perinatal care in New York State, the Department identified the current standards for perinatal care from the American College of Obstetricians and Gynecologists (ACOG) and American Academy of Pediatrics (AAP) *Guidelines for Perinatal Care* (8th Edition), the ACOG's *Obstetric Care Consensus – Levels of Maternity Care (2019)*, the standards and indicators of the American Association of Birth Centers (AABC; 2017) and the Commission for Accreditation of Birth Centers (CABC;

2020), and a literature review. The Department also convened a 49-member expert panel to make recommendations for the perinatal system in New York State, which includes freestanding birth centers, Level I hospitals, Level II hospitals, Level III hospitals, and Regional Perinatal Centers (RPCs), as described in 10 NYCRR Part 721. Freestanding birth centers with physician medical directors are regulated under 10 NYCRR Part 754. Midwifery birth centers are regulated under 10 NYCRR 795.

The expert panel met three times in September and November of 2017 and in May 2018, with subcommittees meeting to address more complex topics requiring in-depth discussion. The subcommittees discussed the role of RPCs, affiliation agreements with RPCs, transfers, maternal services, neonatal services, behavioral health and substance use, subspecialists (obstetric and neonatal), and financials. The subcommittees' recommendations were brought to the full expert panel for review and approval.

The expert panel made extensive recommendations concerning perinatal regionalization in New York, including recommendations for freestanding birth centers and midwifery birth centers. These recommendations have been incorporated into these regulations, and are broadly described as follows:

The requirement to provide eye prophylaxis for newborns, to prevent purulent conjunctivitis, is updated to align with current practice. This will protect the neonates from aseptic neonatal conjunctivitis that is induced by silver nitrate solution, previously used at birth for prophylaxis of infectious conjunctivitis. This update also removes reference to treatments no longer considered as standard practice.

The regulations align the appropriate gestational age and birthweight with current standards of practice as advised by experts in perinatology including AABC, AAP and ACOG.

The proposed regulations will add requirements to notify the Department within two days when the Neonatal Intensive Care Unit (NICU) and/or maternity census exceeds the licensed number of beds on the site's Certificate of Need (CON). This allows the Department to work with the facility and in the case of a lower-level birthing hospital, their RPC, to reduce overcrowding. Overcrowding is a significant risk factor associated with nosocomial outbreaks (i.e., Methicillin-resistant Staphylococcus aureus (MRSA), Gram-negative bacteria, or fungal infections) in NICUs. These infections may be debilitating or fatal to already immunocompromised NICU patients with multiple risk factors.

The proposed regulations strengthen the RPC's role in offering support to affiliates, including coordination of RPC and affiliate staff education on implicit bias, cultural competency, and the impact of these areas on patient care. This will help address social disparities in perinatal treatment and outcome in New York.

The regulations will require RPCs to coordinate neonatal transports between affiliates, and to coordinate maternal transports both between affiliates and from affiliates to the RPC. This change will ensure that the appropriate level of care, including the need for transport of a neonate or midwifery/obstetrical patient to a higher level of care, is consistent with generally accepted standards and with the hospital's perinatal affiliation agreement.

The role of the RPCs in quality improvement and data review will be to monitor the quality and appropriateness of patient care provided by its affiliates and to ensure that identified problems are reported to the quality assurance committee together with recommendations for corrective action. Quality improvement shall be achieved through a systematic, formal application of continuous actions aimed at optimizing patient health and safety.

The regulations will require RPCs to establish affiliation agreements with any freestanding and midwifery birth centers, and to provide appropriate supportive and consultation services similar to those provided to lower-level affiliate birthing hospitals. Additionally, regulations related to accreditation and establishment of midwifery birth centers have been added to address regulatory items noted in the Midwifery Birth Center Accreditation Act (Public Health Law § 2803(11)).

Finally, updating regulatory language with the use of gender-neutral terminology will make the regulations more inclusive of all persons receiving midwifery, obstetrical and neonatal health care services in New York and will align the language with New York State policies.

COSTS:

Costs to Private Regulated Parties:

Under these regulations, there are no costs to hospitals specific to the voluntary designation process. Hospitals may incur costs associated with hiring of perinatal clinical staff. According to the Bureau of Labor Statistics (BOLS), the New York State average salaries (May 2020) are as follows: registered nurse ($89,760), obstetrician/gynecologist ($214,490), pediatrician ($170,720), and nurse-midwives ($125,780). BOLS does not provide salary estimates for specialty and subspecialty clinicians (e.g., maternal-fetal medicine specialists, neonatologists).

Additional costs may be incurred related to establishing systems for maternal transport between affiliate hospitals; costs related to purchasing equipment and construction to meet the new requirements. Costs will likely be significantly higher if a hospital seeks to become designated at a higher level of care than their current level.

Costs for existing birth centers are anticipated to be relatively minimal. Costs may include purchasing of equipment and training costs to meet regulatory requirements (e.g., basic life support and Neonatal Resuscitation Program® training and associated equipment requirements). Costs for newly established birth centers, including midwifery birth centers, are anticipated to be similar to those incurred without adoption of these regulations. Costs will vary depending on the specifics of the physical premises.

For all currently designated birthing hospitals, the requirement to review and update policies and procedures is expected to be accomplished with existing staff, imposing little or no additional cost.

Designated RPCs are already required to perform a significant proportion of the proposed requirements. Obstetrical transfer coordination, as well as neonatal transfer support between lower-level affiliates, may result in increased need for staff to coordinate transfers and provide stabilization and ongoing care during transportation to a receiving hospital.

Costs to State and Local Governments:

No additional costs to state and local governments are anticipated, with the exception of eleven NYC Health and Hospital Corporation and 2 State University of New York perinatal hospitals. These entities may incur additional costs as described above.

Costs to the Department of Health:

No additional costs to the Department of Health are anticipated. Costs for designation, hospital surveying and hospital site visits are funded by the federal Title V Maternal and Child Health Services Block Grant. Existing staff will be utilized for ongoing oversite, contract management, site visits, quality improvement initiatives and other services to monitor compliance with these provisions.

Local Government Mandates:

There are no specific mandates that impact local governments.

Paperwork:

Hospitals may need to develop or revise written policies and procedures, including obstetrical and neonatal transfer and referral protocols for ancillary services. Additionally, hospitals will likely need to revise affiliation agreements with an RPC and hospitals that choose to establish a transfer agreement with another non-RPC affiliate will need to develop or revise such agreements.

Birthing hospitals seeking to increase the number of maternity and/or neonatal intensive care beds on their operating certificate will need to apply through the Department's Certificate of Need process; this requirement and the application process are not impacted directly by these regulations.

Midwifery birth centers seeking accreditation through a third-party recognized establishment organization will be required to adhere to the requirements of those organizations, and provide documentation of proof of accreditation to the Department. Midwifery birth centers seeking establishment through the Department's Certificate of

Need process will need to submit the required documents for consideration by the Department and the Public Health and Health Planning Council. In adherence with the Midwifery Birth Center Accreditation Act (see Public Health Law § 2803(11)), the Department is promulgating this regulation to meet the requirements of the Law; additional efforts related to reducing the burden of establishment and the Certificate of Need process that can be accomplished administratively are in development.

Duplication:

These regulations will not duplicate State or federal rules.

Alternatives:

There are multiple professional medical organizations (ACOG, AAP, AABC; Society of Maternal-Fetal Medicine) that establish standards of care for perinatal patients specific to each organization's membership. Current guidelines from these organizations were used to establish comprehensive regulations for service delivery.

Leaving the regulations unchanged from 2005 would subject birthing hospitals and their patients to outdated standards that would be contrary to good medical practice. These regulatory changes ensure that perinatal care is provided with the most up-to-date standards.

Federal Standards:

The United States Department of Health and Human Services, and its' constituent agencies, do not currently have standards for perinatal regionalization systems. Any requirements of the regulations are based on recommendations of national healthcare provider organizations not affiliated with the federal government.

Compliance Schedule:

These regulations will go into effect upon a Notice of Adoption in the New York State Register. Hospitals seeking perinatal designation will need to meet all relevant requirements at the time of designation request.

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REGULATORY FLEXIBILITY ANALYSIS

FOR SMALL BUSINESSES AND LOCAL GOVERNMENTS

Effect of Rule:

These regulations will apply to all birthing hospitals that currently have a perinatal designation. The regulation will apply to all currently operating birth centers regulated under 10 NYCRR 754. Freestanding birth centers, as well as midwifery birth centers (regulated under 10 NYCRR 795) are likely to qualify as small businesses with fewer than 100 FTE. Birthing hospitals are unlikely to qualify as a small business. Any hospitals seeking to become newly designated, as well as newly established birth centers and midwifery birth centers would be subject to these regulations.

Currently there are 11 perinatal hospitals operated by New York City Health and Hospitals Corporation (NYCHHC) and 2 perinatal hospitals operated by the State University of New York (SUNY).

Compliance Requirements:

There are no additional programs, services, duties, or responsibilities imposed by this rule upon any county, city, town, village, school district, fire district or any other special district. Hospitals would only need to comply with these regulations if they perform maternity services outside of emergency rooms in accordance with the federal Emergency Medical Treatment and Labor Act. The Department reviews compliance with all applicable sections of 10 NYCRR 721 based on the birthing hospital's current level of designation or the level of designation which a new or upgrading hospital seeks to obtain. This is done through the designation process, as well as through various mechanisms and

programs within the Department, and includes hospital attestations, surveys, remote and/or on-site visits, and complaint investigations.

Freestanding birth centers under 10 NYCRR 754 and midwifery birth centers under 10 NYCRR 795 may be small businesses. As noted above, there are three operating freestanding birth centers and two centers in various stages of pre-licensure; there are currently no midwifery birth centers. They are regulated in a similar manner to Level I perinatal hospitals. Birth centers will be affiliated with an RPC, and they will have transfer agreements and quality assurance activities that are coordinated on a regional basis. Midwifery birth centers under 10 NYCRR 795 who choose to become accredited through a recognized accrediting organization will be required to comply with all requirements of accreditation and maintenance of accreditation, and will need to submit proof of accreditation to the Department as a condition of establishment.

Professional Services:

These regulations are not expected to require any additional use of professional services.

Compliance Costs:

Under these regulations, there are no costs to hospitals specific to the voluntary designation process. Hospitals may incur costs associated with hiring of perinatal clinical staff. According to the Bureau of Labor Statistics (BOLS), the New York State average salaries (May 2020) are as follows: registered nurse ($89,760), obstetrician/gynecologist ($214,490), pediatrician ($170,720), and nurse-midwives ($125,780). BOLS does not provide salary estimates for specialty and subspecialty clinicians (e.g., maternal-fetal medicine specialists, neonatologists).

Additional costs may be incurred related to establishing systems for maternal transport between affiliate hospitals, costs related to purchasing equipment, and construction to meet the requirements. Costs will likely be significantly higher if a hospital seeks to become designated at a higher level of care than their current level.

Costs for existing birth centers are anticipated to be relatively minimal. Cost may include purchasing of equipment and training costs to meet requirements (e.g., basic life support and Neonatal Resuscitation Program® training and associated equipment requirements). Costs for newly established birth centers, including midwifery birth centers, are anticipated to be similar to those incurred without adoption of these regulations. Costs will vary depending on the specifics of the physical premises.

For all currently designated perinatal centers, the requirement to review and update policies and procedures is expected to be accomplished with existing staff, imposing little or no additional cost.

Designated RPCs are already required to perform a significant proportion of the requirements the regulations. Obstetrical transfer coordination, as well as neonatal transfer support between lower-level affiliates, may result in increased need for staff to coordinate transfers and provide stabilization and ongoing care during transportation to a receiving hospital.

There are no anticipated costs to local and state agencies, with the exception of 11 NYCHHC and 2 SUNY perinatal hospitals, which may incur additional costs as described above.

Economic and Technological Feasibility:

These regulations are economically and technically feasible.

Minimizing Adverse Impact:

The Department has considered how best to ensure that these recommendations create minimal disruption to the perinatal regionalization system, in coordination with the expert panel. With the advice of the expert panel, the proposed regulations take into consideration the balance between patient need for advanced cardiac life support and existing capacity within hospital systems that may not be assigned specifically to obstetrics or labor and delivery.

The Department periodically communicated with birthing hospitals and birth centers about the intent to reform the perinatal care, perinatal regionalization, and birth center regulations. This included formal and informal communication with all levels of perinatal care and departments affiliated with perinatal services. Additionally, following passing of the Midwifery Birth Center Accreditation Act, the Department engaged with midwifery stakeholders and advocates, including representatives of state and national midwifery organizations, to discuss the proposed regulations with a focus on accreditation and establishment. Following these discussions, the regulations were further revised to clarify requirements and reduce burdensome requirements while still supporting the integration of midwifery birth centers into the perinatal regionalization system and ensuring compliance with national life and safety standards.

Upon adoption of these regulations, the Department will begin the process of redesignating hospitals in accordance with the new provisions. Hospitals that wish to be redesignated, including those seeking to maintain their current level of designation, will complete a comprehensive assessment of perinatal and ancillary services. A proportion of Level I and II hospitals, as well as all Level III and RPC hospitals, will receive a site visit to ensure compliance. Any deficiencies found during such checks may result in a

corrective action plan to ensure that the hospital is making progress towards meeting all requirements. Facilities that receive a corrective action plan will be given an appropriate timeframe to come into compliance with regulation; this will be dependent on situations and the potential impact to direct patient care. The Department may issue provisional designations if a hospital demonstrates a good faith effort to meet new or updated requirements within a timely fashion.

Small Business and Local Government Participation:

The Department has conducted outreach to the affected parties, including representatives from state midwifery and birth center professional organizations. Representatives from the New York State Association of Licensed Midwives (NYSALM) were involved in the expert panel that developed recommendations for all levels of perinatal care. Additionally, discussions with representatives from the New York State Birth Center Association (NYSBCA) were held related to the proposed regulations related to midwifery practice and birth center operations. Outreach was also conducted with midwives not representing leadership of NYSALM or NYSBCA. Midwifery practices, as well as freestanding birth centers are typically small private practices that operate within a wide variety of communities (urban, suburban and rural). The Department also had conversations with the Commission for the Accreditation of Birth Centers (CABC), which represents birth centers that are traditionally small businesses and/or rurally located, as well as leadership of the American College of Nurse-Midwives (ACNM) which represents the nurse-midwifery profession.

Local government was not involved as a category of stakeholders, although representatives from NYCHHC and SUNY perinatal hospitals were on the expert panel as well. These regulations do not have an anticipated impact on local government outside

of perinatal care settings. Finally, the Department discussed the feasibility and current capacity of emergency medical services as they relate to availability of advanced cardiac life support (ACLS) and obstetric and neonatal transportation, particularly at rural and suburban locations.

RURAL AREA FLEXIBILITY ANALYSIS

Types and Estimated Numbers of Rural Areas:

This rule applies uniformly throughout the state, including rural areas. Rural areas are defined as counties with a population less than 200,000 and counties with a population of 200,000 or greater that have towns with population densities of 150 persons or fewer per square mile. The following 43 counties have a population of less than 200,000 based upon the United States Census estimated county populations for 2010 (https://www.census.gov/quickfacts/).

Allegany County	Hamilton County	Schuyler County
Cattaraugus County	Herkimer County	Seneca County
Cayuga County	Jefferson County	St. Lawrence County
Chautauqua County	Lewis County	Steuben County
Chemung County	Livingston County	Sullivan County
Chenango County	Madison County	Tioga County
Clinton County	Montgomery County	Tompkins County
Columbia County	Ontario County	Ulster County
Cortland County	Orleans County	Warren County
Delaware County	Oswego County	Washington County
Essex County	Otsego County	Wayne County
Franklin County	Putnam County	Wyoming County
Fulton County	Rensselaer County	Yates County
Genesee County	Schenectady County	
Greene County	Schoharie County	

The following counties have a population of 200,000 or greater and towns with population densities of 150 persons or fewer per square mile. Data is based upon the United States Census estimated county populations for 2010.

Albany County	Monroe County	Orange County
Broome County	Niagara County	Saratoga County
Dutchess County	Oneida County	Suffolk County
Erie County	Onondaga County	

Compliance Requirements:

Health care facilities in rural areas providing perinatal services will be subject to the same requirements as regulated entities in non-rural areas. Perinatal hospitals and birth centers will be affiliated with a Regional Perinatal Center (RPC), and hospitals will have transfer agreements and quality assurance activities that are coordinated on a regional basis.

Professional Services:

These regulations are not expected to require any additional use of professional services.

Compliance Costs:

Under these regulations, there are no costs to hospitals specific to the voluntary designation process. Hospitals may incur costs associated with hiring of perinatal clinical staff. According to the Bureau of Labor Statistics (BOLS), the New York State average salaries (May 2020) are as follows: registered nurse ($89,760), obstetrician/gynecologist ($214,490), pediatrician ($170,720), and nurse-midwives ($125,780). BOLS does not provide salary estimates for specialty and subspecialty clinicians (e.g., maternal-fetal medicine specialists, neonatologists).

Additional costs may be incurred related to establishing systems for maternal transport between affiliate hospitals, costs related to purchasing equipment, and construction to meet the requirements. Costs will likely be significantly higher if a hospital seeks to become designated at a higher level of care than their current level.

Costs for existing birth centers are anticipated to be relatively minimal. Cost may include purchasing of equipment and training costs to meet requirements (e.g., basic life

support, advanced cardiac life support, and Neonatal Resuscitation Program® training and associated equipment requirements). Costs for newly established birth centers, including midwifery birth centers, are anticipated to be similar to those incurred without adoption of these regulations. Costs will vary depending on the specifics of the physical premises.

For all currently designated perinatal centers, the requirement to review and update policies and procedures is expected to be accomplished with existing staff, imposing little or no additional cost.

Designated RPCs are already required to perform a significant proportion of the requirements. Obstetrical transfer coordination, as well as neonatal transfer support between lower-level affiliates, may result in increased need for staff to coordinate transfers and provide stabilization and ongoing care during transportation to a receiving hospital.

There are no anticipated costs to local and state agencies, with the exception of the 11 NYCHHC and 2 SUNY perinatal hospitals, which may incur additional costs as described above.

Minimizing Adverse Impact:

The Department has considered how best to ensure that these recommendations create minimal disruption to the perinatal regionalization system, in coordination with the expert panel. With the advice of the expert panel, the proposed regulations take into consideration the balance between patient need for advanced cardiac life support and existing capacity within birth centers and birthing hospitals that may not be assigned specifically to obstetrics or labor and delivery.

The Department periodically communicated with birthing hospitals and birth centers about the intent to reform the perinatal care, perinatal regionalization, and birth center regulations. This included formal and informal communication with all levels of perinatal care and departments affiliated with perinatal services.

Upon adoption of these regulations, the Department will begin the process of redesignating hospitals in accordance with the new provisions. Hospitals that wish to be redesignated, including those seeking to maintain their current level of designation, will complete a comprehensive assessment of perinatal and ancillary services. A proportion of Level I and II hospitals, as well as all Level III and RPC hospitals, will receive a site visit to ensure compliance. Any deficiencies found during such checks may result in a corrective action plan to ensure that the hospital is making progress towards meeting all requirements. Facilities that receive a corrective action plan will be given an appropriate timeframe to come into compliance with regulation; this will be dependent on situations and the potential impact to direct patient care. The Department may issue provisional designations if a hospital demonstrates a good faith effort to meet new or updated requirements within a timely fashion.

Rural Area Input:

The Department has conducted outreach to the affected parties. Staff from rural and community hospitals (typically Level I hospitals), as well as representatives from the fields of nursing and midwifery were involved in the development of recommendations. Additionally, the Department involved lower level (I, II and III) facilities, as well as RPCs in discussions around the role of the RPC and affiliation agreements, particularly the role of the RPC in obstetrical and neonatal transport in rural areas that may not have

adequate emergency medical services for around-the-clock availability. The Department held multiple discussions with experts and representatives from health care plans (Medicaid and private) and emergency medical services to obtain feedback and gain information on appropriate services and feasibility of these regulations. The Department also had conversations with the Commission for the Accreditation of Birth Centers (CABC), which represents birth centers that are traditionally small businesses and/or rurally located, and the American College of Nurse-Midwives representing the nurse-midwifery profession. Finally, midwives representing both urban and rural private practice were consulted on issues related to midwifery practice in birthing hospitals and birth centers.

JOB IMPACT STATEMENT

No job impact statement is required pursuant to section 201-a(2)(a) of the State Administrative Procedure Act. No adverse impact on jobs and employment opportunities is expected as a result of these regulations. As a result of these regulations, hospitals and birth centers may need to increase staffing through new hires; this is particularly true for hospitals which choose to redesignate at a higher level of care. Additionally, newly established birth centers and midwifery birth centers may increase staffing through new hires.