

SUMMARY OF EXPRESS TERMS

This regulation amends Title 10 of the New York Codes, Rules and Regulations to add a new Article 10 to the State Hospital Code and a new Part 795 – Midwifery Birth Centers.

The new Part 795 defines midwifery birth center and sets standards for such birth centers aligned with national evidence-based standards. Part 795 allows midwifery birth centers to demonstrate compliance with these regulations by obtaining accreditation from an accrediting organization approved by the Department, in lieu of routine surveillance by the Department.

Part 795 requires a midwifery birth center to have a center director, who may be a midwife. The center director may appoint a consulting physician and must have collaborative relationships as required by the Education Law and this regulation.

Part 795 sets standards for staffing at midwifery birth centers and requires at least two staff members with training and skills in resuscitation; one for the patient giving birth and one for the post-delivery neonate, to be present at every birth.

Part 795 requires midwifery birth centers to have quality assurance programs and plans for emergency care, including transfer when indicated.

Pursuant to the authority vested in the Public Health and Health Planning Council, and subject to the approval of the Commissioner of Health, by sections 2801 and 2803(11) of the Public Health Law, sections 69-8.1, 69-10.1, 400.9, and 405.21 of Title 10 (Health) of the Official Compilation of Codes, Rules and Regulations of the State of New York are amended, and Subchapter C of Chapter V of Title 10 (Health) of the Official Compilation of Codes, Rules and Regulations of the State of New York is amended by adding a new Article 10, to be effective upon publication of a Notice of Adoption in the New York State Register, to read as follows:

Subdivision (d) of section 69-8.1 is amended to read as follows:

(d) institution caring for infants (facility) means all general hospitals having maternity and infant services or premature infant services as defined in section 405.21 of this Title, [and] primary care hospitals and critical access hospitals as defined in section 407.1 of this Title, [and] birthing centers as defined in section 754.1 of this Title, and midwifery birth centers as defined in section 795.1 of this Title.

Subdivision (r) of section 69-10.1 is amended to read as follows:

(r) “Hospital” means a general hospital or a maternity hospital, including a birthing center located is a general hospital or a maternity hospital, [or] a birthing center operating as a diagnostic and treatment center, or a midwifery birth center, as defined by section 2801 or the public health law.

Paragraph (2) of subdivision (b) of section 400.9 is amended to read as follows:

(2) include in such agreement reasonable assurance that there will be transfer of the patient or resident whenever deemed medically appropriate and mutually agreed upon by the physician responsible for the medical care in the referring facility, or by the midwife responsible for the medical care in the case of a referring midwifery birth center, and by the physician who will become responsible for the medical care in the receiving facility, or, in the case of a certified home health agency, by the physician who will become responsible for the medical care when such patient or resident is to receive services from the certified home health agency;

Subparagraph (i) of paragraph (9) of subdivision (c) section 405.21 is amended to read as follows:

(i) Such transfer shall be accomplished in accordance with the provisions of sections 754.2(e) [and], 754.4, 795.2(e) and 795.4 of this Title.

A new Article 10 is added to read as follows:

Article 10 – Midwifery Birth Centers

Part 795 Midwifery Birth Centers

§ 795.1 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 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, 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 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. 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, but the attending provider for birth must be a licensed midwife.

(b) *A patient at low risk* means a patient who has: a normal medical, surgical, and obstetrical history; 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.

(c) The *Department* means the New York State Department of Health.

§ 795.2 Administrative requirements. The operator shall ensure that:

- (a) only patients at low risk are admitted and cared for at the midwifery birth center;
- (b) written policies, procedures and standard risk assessment criteria for determining low-risk pregnancies based upon generally accepted standards of practice are developed and implemented;
- (c) written policies, procedures and protocols for the management of care are implemented pursuant to generally accepted standards of practice and in accordance with midwifery birth center philosophy;
- (d) a record is made of all informed consent, including shared decision making, that indicates concurrence from both caregiver and patient parties;
- (e) there is a transfer agreement with one or more perinatal centers for medical care of patients when complications arise antepartum, intrapartum, or postpartum and that meets the following requirements:
 - (1) compliance with section 400.9 of this Title;
 - (2) the surface travel time to reach a receiving perinatal hospital is less than two hours under usual weather and road conditions; and
 - (3) the receiving hospital is accessible and convenient to the patient's place of residence whenever possible;
- (f) support services such as laboratory, radiology and imaging, and family planning services not provided by the midwifery birth center are available by referral;
- (g) the midwifery birth center services are available 24 hours a day for the admission of 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;

- (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
- (l) 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.

§ 795.3 Service restrictions. The operator shall ensure that:

- (a) only patients at low risk are admitted and cared for at the midwifery birth center;
- (b) surgical procedures are limited to those which may be performed during and after an uncomplicated childbirth, such as episiotomy and repair. Other surgical procedures, including forceps and vacuum extraction are not permitted;
- (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.

§ 795.4 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 transfer 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 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), 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.
 - (d) The operator shall implement a system to ensure that a copy of the medical record accompanies the patient upon transfer to the hospital.
 - (e) The operator shall establish a mechanism for jointly reviewing all transfer cases by the receiving hospital(s) and the midwifery birth center as part of the quality assurance program specified in section 795.9 of this Part.

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

- (a) is a licensed midwife or physician;

- (b) maintains documentation of collaborative relationships required under Section 6951 of the Education Law;
- (c) approves all policies, procedures and protocols for the management of care;
- (d) approves standardized criteria for admission screening and monitoring risk status during pregnancy, labor, birth and postpartum;
- (e) is available for consultation and referral or has made arrangements with a qualified physician for these services;
- (f) 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 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
 - (2) is available for consultation and referral;
- (g) ensures that the midwifery birth center has:
 - (1) collaborative relationships with one or more licensed physicians who are board certified as obstetrician-gynecologists by a national certifying body, who practice obstetrics, and who have obstetric privileges at one or more general hospitals licensed under Article 28 of the Public Health Law;
 - (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 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 perinatal centers licensed under Article 28 of the Public Health Law to provide:
 - (i) obstetrics through a licensed physician having obstetrical privileges at such perinatal center;
 - (ii) consultation, collaborative management and referral to address the health status and risks of the provider's patients; and
 - (iii) emergency medical coverage for patients; and
- (h) has standardized criteria for admission screening and monitoring risk.

§ 795.6 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 Neonatal Resuscitation Program (NRP) provider;
- (b) a second trained staff person is also present at each birth who:
 - (1) is under the supervision of the licensed midwife;
 - (2) has specialized training in labor and delivery techniques and care of the midwifery birth center patient;
 - (3) receives planned and ongoing training as needed to perform assigned duties effectively; and
 - (4) maintains current status as a NRP provider;

- (c) trained and qualified staff are available to educate and assist patients to initiate breastfeeding; and
- (d) at least two people who attend patients during labor, delivery and postpartum are currently certified NRP, Basic Life Support (BLS), and Advanced Cardiac Life Support (ACLS) providers and are able to provide oxygen and all equipment necessary to maintain airways for the patient and infant.

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

- (a) admission screenings to ensure that only patients at low risk are admitted to the midwifery birth center;
- (b) active participation by patients and families in their own plan of health care, which shall include but not be limited to:
 - (1) orientation to the midwifery birth center services and its philosophy and goals preceding registration; and
 - (2) access to prenatal education classes approved by the clinical staff which address, at a minimum, labor and delivery, infant care and feeding, parenting, nutrition, the effects of smoking, alcohol and other drugs on fetal development and on the newborn patient, signs of postpartum 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:

- (1) a plan of care developed according to accepted professional standards;
- (2) selection of pediatric services by the patient for follow-up care of the infant;
- (3) providing HIV counseling and recommending voluntary testing to pregnant 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 patient's HIV counseling and HIV status must be transferred as part of the patient's medical history to the labor and delivery site. 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 all patients;
- (5) labor support and professional attendance at birth for the patient and the patient's family;
- (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 depression or perinatal mood disorder or who have other mental health conditions;
- (7) a system for screening patients prior to admission for alcohol/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
- (8) a system for directing patients to appropriate health care providers for further diagnosis and treatment, including consultation by a radiologist or

qualified provider who can interpret imaging results when results are inconclusive or an abnormality is detected that requires immediate care;

(d) postpartum care including:

- (1) care in the midwifery birth center to be provided for a minimum of four hours and a maximum of 24 hours after the third stage of labor is complete;
- (2) a physical assessment of the newborn with the required eye 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 section 4130 of the Public Health Law;
- (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 prior to discharge from the center; and
- (5) the transfer to the newborn'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 in their home for the immediate postpartum period unless arrangements have been made for the infant 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 and the physical and psychological status of the patient, performance of a hematocrit, rubella vaccination and Rh prophylaxis, if indicated, and newborn screening blood collection in accordance with Part 69 of this Title;

- (2) assurance of immediate and ongoing pediatric care;
- (3) provision of family planning counseling or arrangements for such services, if desired by the patient; and
- (4) arrangements for follow-up visits at the midwifery birth center within a six-week period following the birth.

§ 795.8 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:
 - (1) results of physical and risk assessments;
 - (2) patient history, to include medical, surgical, gynecological and psychosocial history;
 - (3) record of informed consent, including shared decision making, for midwifery birth center services;
 - (4) ongoing assessments of fetal growth and development;
 - (5) periodic evaluations of patient health;
 - (6) results of laboratory tests;
 - (7) labor and birth information;

- (8) newborn patient physical assessment, including APGAR scores, maternal-newborn interaction, ability to feed, eye prophylaxis, vital signs and accommodation to extrauterine life;
 - (9) postpartum assessment;
 - (10) discharge and follow-up plans;
 - (11) home visit reports;
 - (12) midwifery birth center follow-up visit report; and
 - (13) documentation of family planning counseling and the arrangements made for family planning services, if any.
- (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 physical assessment;
 - (2) results from newborn screening tests;
 - (3) discharge summary with follow-up plans; and
 - (4) home visit report.

§ 795.9 Quality assurance. In addition to meeting the requirements set forth in section 795.8 of this Title, the operator shall ensure that there is a review of all pregnant and postpartum patients and/or newborn 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.

§ 795.10 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 to an appropriate general hospital for continued care when medically indicated. Staff with required current course completion status in NRP, BLS, and ACLS shall be 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 patients and include at least the following:
 - (1) intravenous therapy equipment;
 - (2) infant warmer;
 - (3) infant transport equipment;
 - (4) oxygen and oxygen administration equipment for patient and infant;
 - (5) airways and manual breathing bags for patient and infant;
 - (6) suction machine and equipment for patient and infant;
 - (7) adult and infant laryngoscope and endotracheal tubes; and
 - (8) medications and intravenous fluids with supplies and equipment for administration;
- (b) center staff are certified in NRP, BLS, and ACLS resuscitation and other emergency procedures; and

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

§ 795.11 Midwifery birth center accreditation.

- (a) Midwifery birth centers must comply with sections 400.2 through 400.7, 400.9, and 400.10, and sections 751.5 through 751.10 of this Title and must comply with evidence-based standards for midwifery birth centers published by a national standards body selected by the Department and published on the Department's website. The Department may accept, as evidence of compliance with minimum operational standards in this subdivision, accreditation by an accreditation agency that the Department has determined has accrediting standards sufficient to assure the Department that midwifery birth centers so accredited are in compliance with such minimum operational standards. 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. 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.

- (b) 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.
- (c) 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.

§ 795.12 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 shall be filed with the Council through the project management unit in the Department's central office in Albany, which shall transmit one copy to the health systems agency having geographic jurisdiction.
- (b) Applications to the Council shall contain information and data with reference to:
 - (1) the public need 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 or partners;
 - (3) the financial resources and sources of future revenue of 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
- (5) such additional pertinent information and documents necessary for the Council's consideration, as determined by the Department.

REGULATORY IMPACT STATEMENT

Statutory Authority:

Chapter 397 of the Laws of 2016 amended the definition of hospital in section 2801 of the Public Health Law to add midwifery birth centers under the supervision of a midwife, and added a new subdivision 11 to section 2801 to give the New York State Department of Health (the Department) specific authority to establish regulations relating to the establishment, construction, and operation of midwifery birth centers, in consultation with representatives of midwives, midwifery birth centers, and general hospitals providing obstetric services.

The 2016 law supplemented the authority of the Department and the Public Health and Health Planning Council (PHHPC) under section 2803 of the Public Health Law to regulate health care facilities, including birth centers.

Legislative Objectives:

Chapter 397 of the Laws of 2016 was intended to remove barriers that restrict the establishment of freestanding birth centers led by licensed midwives and to permit the Department to determine, with consultation, which Article 28 certificate-of-need requirements are appropriate and reasonable for the scope of services provided by midwifery birth centers. Education Law requirements governing the practice of midwifery will continue to apply to all midwives, regardless of the practice setting.

Needs and Benefits:

There are currently only three freestanding birth centers in New York. All of these are directed by physicians. This regulation -- which encourages the creation of midwife-led centers -- will foster the growth of birth centers throughout New York.

Evidence shows that midwifery birth centers can offer high-quality, cost-effective maternity and neonatal care. Research indicates that freestanding birth centers operated by midwives tend to have low cesarean-section rates, fewer labor inductions, and successful parent bonding and breastfeeding without prolonged separation. Midwife-led birth centers promote wellness-based birth over technology and interventions. They consistently earn high patient satisfaction from women seeking a welcoming environment without restrictions on the presence of supportive staff, friends, and family members. They can provide more cost-effective maternity and neonatal care with outcomes that are comparable to births in other settings. Midwifery birth centers can play a vital part in serving the needs of mothers and families in New York State.

This regulation implements Chapter 397 of the Laws of 2016 by creating a new Part 795 authorizing midwifery birth centers. Under these regulations, the midwifery birth center director may be a licensed midwife or a physician, provided that they maintain documentation of collaborative relationships required under Section 6951 of the Education Law.

These regulations allow midwifery birth centers to meet national standards set by a standards-setting agency selected by the Department in lieu of meeting some provisions of the State Hospital Code. This regulation also allows accreditation of midwifery birth centers in lieu of surveillance by the Department, although the Department retains the authority to inspect midwifery birth centers at its discretion. An accreditation agency can

ensure high quality of care consistent with Department regulations and nationally recognized standards in a manner that is flexible and imposes less of a resource and cost burden on the Department.

A physician-led birth center that is a diagnostic and treatment center and is regulated under 10 NYCRR Part 754 must have a transfer agreement with a perinatal hospital located within 20 minutes' transport time from the birth center to the receiving hospital. Under this regulation, for a midwifery birth center, the surface travel time to reach a receiving perinatal hospital must be less than two hours under usual weather and road conditions. This will allow birth centers to be established in rural areas that would otherwise not have access to this type of care.

This regulation requires that the medical record for each patient at a midwifery birth center must contain a record of informed consent, including shared decision making, for birth center services. Public Health Law §2805-d, which generally requires a patient's informed consent when receiving health care services, is applicable to midwifery birth centers.

COSTS:

Costs to Private Regulated Parties:

According to a national accreditation organization for midwifery birth centers, the Commission on the Accreditation of Birth Centers, typical fee structures for birth centers are as follows: a new birth center would be charged an initial registration fee of 4,000 dollars and a follow-up visit fee, one year later of 3,300 dollars. After that, a 250 dollar-per-month fee is assessed during the lifetime of the accreditation. All of these costs are

subject to change. Foundation grants may be available to potentially cover half of the costs for the initial and follow-up visit.

Costs to State and Local Governments:

The Department does not anticipate that any birth centers will be operated by State or local government.

Local ordinances would be enforced at midwifery birth centers in a comparable manner to any other local businesses.

Costs to the Department of Health:

There will be no additional costs to the Department, as systems already exist to approve and regulate birth centers and, as proposed, the services of the national standards setting body and accreditation would fulfill many obligations typically fulfilled by the Department.

Local Government Mandates:

The proposed regulations impose no new mandates on any county, city, town or village government.

Paperwork:

To become a new birth center, including a midwifery birth center, an applicant will need to follow certificate of need process as required by Public Health Law Article 28. This regulation does not create new reporting requirements.

Duplication:

There are no duplicative or conflicting rules.

Alternatives:

One alternative would be for the State to not allow accreditation of birth centers by a nationally recognized organization as evidence of compliance with minimum operational and construction standards. However, this alternative was rejected as inefficient and unnecessary.

Another alternative was to require midwifery birth centers to meet the exact same requirements as physician-led birth centers, other than allowing the center to be directed by a midwife. This alternative was rejected, because the Department believes that the Legislature intended and the public interest would best be served by the Department creating a regulatory framework that facilitates the establishment of distinct midwifery birth centers.

Federal Standards:

The proposed regulation does not exceed any minimum standards of the Federal government.

Compliance Schedule:

The proposed regulation will take effect upon a Notice of Adoption in the New York State Register.

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REGULATORY FLEXIBILITY ANALYSIS FOR SMALL BUSINESSES AND LOCAL GOVERNMENTS

Effect of Rule:

The proposed regulations will apply to midwifery birth centers in New York State. This proposal will not impact local governments or small businesses unless they operate such facilities. Many of the midwifery birth centers will be small businesses under the definition in the State Administrative Procedure Act (SAPA). In such case, the flexibility afforded by the regulations is expected to minimize delays and any costs of compliance as described below.

Compliance Requirements:

Pursuant to this rule, midwifery birth centers that are small businesses will be required to maintain appropriate documentation of professional credentialing and agreements between the birth center and other receiving medical facilities.

These regulations utilize the approach of allowing accreditation instead of traditional surveillance. This is intended to allow for oversight to be performed by accrediting organizations with specific experience measuring standards of compliance for midwifery birth centers. Small businesses may be required to enter into a contractual relationship with an accrediting organization.

Professional Services:

This proposal is not expected to require any additional use of professional services.

Compliance Costs:

According to a national accreditation organization for midwifery birth centers, the Commission on the Accreditation of Birth Centers, typical fee structures for birth centers are as follows: a new birth center would be charged an initial registration fee of 4,000 dollars and a follow-up visit fee, one year later of 3,300 dollars. After that, a 250 dollar-per-month fee is assessed during the lifetime of the accreditation. All of these costs are subject to change and will vary by size of birth center. Foundation grants may be available to potentially cover half of the costs for the initial and follow-up visit.

Economic and Technological Feasibility:

This proposal is economically and technically feasible, as these regulations would enable the establishment of midwifery birth centers and do not impose requirements on existing birth centers.

Minimizing Adverse Impact:

No adverse impact is anticipated, as these regulations would enable the establishment of midwifery birth centers and do not impose requirements on existing birth centers.

Small Business and Local Government Participation:

The Department convened a 49-member expert panel to make recommendations for the perinatal system in New York State, which includes freestanding birth centers, Level 1 hospitals, Level II hospitals, Level III hospitals, and Regional Perinatal Centers (RPCs), as described in 10 NYCRR Part 721. Regulated parties will also have an opportunity to submit comments during the notice and comment period.

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 (<http://quickfacts.census.gov>).

Allegany County	Greene County	Schoharie County
Cattaraugus County	Hamilton County	Schuyler County
Cayuga County	Herkimer County	Seneca County
Chautauqua County	Jefferson County	St. Lawrence County
Chemung County	Lewis County	Steuben County
Chenango County	Livingston County	Sullivan County
Clinton County	Madison County	Tioga County
Columbia County	Montgomery County	Tompkins County
Cortland County	Ontario County	Ulster County
Delaware County	Orleans County	Warren County
Essex County	Oswego County	Washington County
Franklin County	Otsego County	Wayne County
Fulton County	Putnam County	Wyoming County
Genesee County	Rensselaer County	Yates County
	Schenectady 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	

There are no birth centers currently operating in rural areas.

Reporting, Recordkeeping, Other Compliance Requirements and Professional Services:

Pursuant to this rule, midwifery birth centers will be required to maintain appropriate documentation of professional credentialing and agreements between the birth center and other receiving medical facilities.

These regulations utilize the approach of allowing accreditation instead of traditional surveillance. This is intended to allow for oversight to be performed by accrediting organizations with specific experience measuring standards of compliance for midwifery birth centers. Birth centers may be required to enter into contractual relationships with these accrediting organizations.

Professional services such as midwives and other health care practitioners will be needed to operate a midwifery birth center. It is also anticipated that staff will be needed to maintain the center and provide for a setting that is safe from biological or environmental hazards.

Costs:

According to a national accreditation organization for midwifery birth centers, the Commission on the Accreditation of Birth Centers, typical fee structures for birth centers are as follows: a new birth center would be charged an initial registration fee of 4,000 dollars and a follow-up visit fee, one year later of 3,300 dollars. After that, a 250 dollar-per-month fee is assessed during the lifetime of the accreditation. All of these costs are subject to change and will vary by size of birth center. Foundation grants may be available to potentially cover half of the costs for the initial and follow-up visit. These costs would be the same in a rural or non-rural area.

Minimizing Adverse Impact:

It is intended that midwifery birth centers will meet some of the needs of rural communities to provide birth services in the absence of a nearby hospital. The Department has added a standard within this rule allowing for midwifery birth centers to operate in any area of the state as long as the center is located within a two-hour road travel radius of a potential receiving hospital. This provision was specifically designed to allow for the possibility that a birth center could open in a rural community.

Allowing accreditation will minimize any adverse impact associated with the Department's surveillance process and will help to allow these centers to operate in rural communities.

Rural Area Participation:

The Department held meetings to seek input from practitioners in rural settings. The Department conducted outreach with state and national professional associations of midwifery birth centers, as well as representatives of midwives, midwifery birth centers, and general hospitals. This included practitioners practicing and intending to practice in rural settings. The proposed regulation will have a 60-day public comment period.

JOB IMPACT STATEMENT

A Job Impact Statement for these amendments is not being submitted because it is apparent from the nature and purposes of the amendments that they will not have a substantial adverse impact on jobs and/or employment opportunities.

SUMMARY OF ASSESSMENT OF PUBLIC COMMENT

The new 10 NYCRR Part 795 defines midwifery birth center and sets standards for such birth centers that are aligned with national evidence-based standards. Part 795 allows midwifery birth centers to demonstrate compliance with these regulations by obtaining accreditation from an accrediting organization approved by the New York State Department of Health (the Department), in lieu of routine surveillance by the Department.

Following the assessment of public comment, the Department has determined that no substantive changes to the regulations were necessary, and no additional requirements were added as a result of the comments received. Commenters included accrediting organizations, local governmental agencies, advocacy groups, birth center organizations, licensed midwives and other members of the general public. Several comments supported the need for ongoing collaboration between midwifery birth centers and hospitals. The Department responded to a large number of comments received in the areas of licensure, accreditation standards, transfer time frames, reporting requirements and services for the care of patients pre-term, at the time of delivery, and follow-up during the post-partum period.

The Department remains committed to support the establishment of midwifery birth centers as provided in these regulations, which align with and support healthy outcomes using national evidence-based standards of care delivery.

ASSESSMENT OF PUBLIC COMMENT

The New York State Department of Health (the Department) received comments from fifteen entities and individuals regarding the proposed amendments to Title 10 of the New York Codes, Rules and Regulations and the addition of Part 795, Midwifery Birth Centers. The comments and the Department's responses are summarized below.

§ 795.1 Definitions:

Comment: One commenter argued that midwives and midwifery birth centers do not provide “obstetric” care as stated in the definition of “midwifery birth center” in § 795.1(a), as obstetric care includes and implies many procedures and interventions that are not appropriate for midwifery birth centers and are not within the midwife's scope of practice.

Response: The definition of “midwifery birth center” in the regulation aligns with the definition in Public Health Law § 2801(11). The Department made no changes to the regulation in response to this comment.

Comment: Several commenters requested a revision of the regulation's definition of “midwifery birth center” in § 795.1(a), to clarify the meaning of the definition's requirement that a midwife “stays with the patient during labor.” In a hospital, the attending provider is not required to stay with the patient at all times, from admission until childbirth; instead, another trained staff person, such as a nurse, could monitor and assess the patient during labor. The commenters suggested that the same requirement should apply to midwifery birth centers. The commenters further recommended that other

licensed practitioners, in addition to midwives, be permitted to serve as an attending practitioner, if allowed by their scope of practice.

Response: The Department intended the regulation to require that a midwife “stays with” a patient by “providing continuous physical and emotional support, evaluating progress, facilitating family interaction and assisting the patient in labor and delivery.” The regulation was not intended to necessarily require a midwife to be in the same room as a patient at all times. The Department made a technical amendment to the final rule to clarify that the licensed midwife “remains available to the patient during labor.” The full revised sentences reads: “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.”

The regulation does not prohibit other licensed practitioners from attending.

Comment: A commenter requested that the regulation be amended to use the word “client” instead of “patient,” as the word “patient” could imply that a person has an illness, whereas pregnancy is a normal physiological process, not an illness.

Response: The Department appreciates that the colloquial use of the word “patient” could imply that a person has an illness. However, the regulation’s definition of “midwifery birth center” makes clear that services are based on a philosophy that views pregnancy and delivery as a normal physiological process. The regulation uses the word “patient” for consistency with other regulations governing health care facilities. The Department made no changes to the regulation in response to this comment.

Comment: One commenter recommended that the Department clarify the definition of “patient at low risk” in §795.1(b) to incorporate concepts from the American College of Obstetricians and Gynecologists’ publication, Levels Of Maternal Care. That document states that midwifery birth centers provide “peripartum care of low-risk women with uncomplicated singleton term pregnancies with a vertex presentation who are expected to have an uncomplicated birth.”

Response: Under § 795.11, midwifery birth centers will be required to comply with evidence-based standards for midwifery birth centers published by a national standards body. The Department expects that under such standards eligibility criteria would include, among other things, assessment of gestational age, singleton pregnancy, and cephalic presentation. The Department agrees that these are the types of criteria based on generally accepted standards of professional practice that can be used to determine risk. The Department made no changes to the regulation in response to this comment.

Comment: A commenter objected to the use of the word “normal” in the definition of “patient at low risk” in § 795.1(b), because a patient could be at low risk even where some aspect of the patient’s history is not “normal.”

Response: The Department believes that the use of the word “normal” clarifies the meaning of “patient at low risk.” The Department made no changes to the regulation in response to this comment.

§ 795.2 Administrative requirements:

Comment: Two commenters stated that the requirement in § 795.2(e) for midwifery birth centers to enter transfer “agreements” implies a need for a written document, and that midwifery birth centers are not always able to obtain a written agreement even when

appropriate transfer procedures are in place. The term transfer “arrangement” was recommended as an alternative. The commenter also recommended that transfer arrangements be permitted without any restrictions on transfer time or distance.

Response: The Department will work with accrediting organizations to develop transfer agreement templates to aid in the process of developing transfer agreements. The regulation’s two-hour travel time limit on transfers is necessary, because even when a patient is at low risk, serious complications may occur. The Department made no changes to the regulation in response to this comment.

Comment: Commenters requested that subdivisions (j) and (k) of § 795.2 be amended to specify that referrals for genetic screening, carrier testing, genetic counseling, physical therapy, or occupational therapy are required only “as needed,” as not all patients require these services.

Response: The Department made a technical amendment to the final rule to clarify that referrals to these types of services providers should be made only “as needed.”

Comment: Several commenters requested an amendment to § 795.2(1) to clarify that infants demonstrating difficulty feeding and swallowing could be referred to a lactation consultant rather than solely a speech and language pathologist, as implied by the proposed rule.

Response: The proposed rule only required referral to a speech and language pathologist “as needed” and would have also allowed a referral to a lactation consultant. The Department made a technical amendment to clarify that an infant demonstrating difficulty feeding may be referred to a lactation consultant as well as a speech and language pathologist.

Comment: One commenter recommended that the regulation require midwifery birth centers to report adverse events.

Response: Under § 795.11, midwifery birth centers must comply with 10 NYCRR §751.10 (adverse event reporting), the same adverse event reporting requirements that apply to physician-led birth centers. The Department made no changes to the regulation in response to this comment.

Comment: One commenter requested that each midwifery birth center develop a list of indicators necessitating transfer in consultation with the receiving hospital(s), using a collaborative approach to ensure shared decision making.

Response: The Department appreciates the comment and will reiterate in guidance that when midwifery birth centers develop lists of indicators for transfer, as required by the regulation, such lists will be developed collaboratively to ensure shared decision making. The Department made no changes to the regulation in response to this comment.

Comment: One commenter expressed concern that, although some accreditation organizations have robust complaint review process, some processes exclude certain types of complaint from review, such as those alleging criminal acts or license violations.

Response: The Department will work with accrediting organizations to address their complaint review process. Regardless, as health care facilities, complaints concerning midwifery birth centers can be made to the Department's Office of Primary Care and Health Systems Management. The Department made no changes to the regulation in response to this comment.

§ 795.4 Midwifery birth center transfer procedures:

Comment: One commenter stated that the various regulatory cross-references in the proposed midwifery birth center regulations include conflicting transfer timeframes.

Response: The Department respectfully disagrees, as the regulations set a clear limit on transfers of two-hours under normal weather and road conditions. The Department made no changes to the regulation in response to this comment.

Comment: Several commenters expressed concern that the requirement in § 795.4(a) that transfer be initiated where there is “prolonged labor” is subjective and unclear. The phrase “dysfunctional labor” was recommended as an alternative.

Response: The Departments considers that the widely used term “prolonged labor,” also known as failure to progress, occurs when labor lasts for approximately 20 hours or more for a first-time birth, and 14 hours or more if the patient has previously given birth. The Department made no changes to the regulation in response to this comment.

Comment: A commenter suggested that § 795.4(a) be amended, asserting that the requirement that a midwifery birth center maintain the ability to evaluate and transfer patients “other than patients at low risk, including newborns” is confusing, unnecessary and could be misinterpreted. The commenter stated that a low risk patient could quickly become high risk, and that a midwifery birth center should have the capacity to stabilize and transfer all patients.

Response: The current regulation clearly requires that midwifery birth centers have the capability to transfer patients who were low risk if they become high risk. The Department made no changes to the regulation in response to this comment.

Comment: A commenter requested confirmation that a transfer from a midwifery birth center could be to a Level 1 hospital as defined in 10 NYCRR §721.2(a).

Response: A midwifery birth center could transfer a patient to a Level 1 hospital. If a higher level of care was needed the patient could also be transferred to a higher-level hospital. The Department made no changes to the regulation in response to this comment.

Comment: A commenter suggested that the regulation be amended to specify that reasons for transferring a patient need not be limited to those outlined in § 795.4. The commenter further recommended that the terms “fetal heart rate abnormalities” or “fetal intolerance of labor” be used in place of the term “fetal distress.”

Response: The Department will provide additional guidance as necessary concerning the parameters for transfer. The Department made no changes to the regulation in response to this comment.

Comment: A commenter expressed concern with the use of the terms “evident” and “suspected” to describe neonatal abstinence syndrome and fetal alcohol syndrome in § 795.4(c).

Response: Consistent with other public health laws and regulations, this provision requires health care providers to make an evidence-based diagnosis of a case, or suspected case, of neonatal abstinence syndrome or fetal alcohol syndrome. The Department made no changes to the regulation in response to this comment.

Comment: Several commenters stated that the requirement, in § 795.4(e), for a joint review of transfer cases by receiving hospitals was unfeasible, as midwifery birth centers are not able to require another facility to establish a review process.

Response: Section 405.21(c)(9)(i) is amended by this regulation to require the receiving hospital to comply with the new § 795.4. Thus, the receiving hospital is required to participate in joint reviews with midwifery birth centers. The joint reviews will support the quality assurance and improvement processes necessary to lower the risk of negative outcomes experienced by patients. The Department made no changes to the regulation in response to these comments.

§ 795.5 Midwifery birth center director and medical consultants:

Comment: A commenter suggested that Regional Perinatal Centers should be required to enter into transfer agreements with midwifery birth centers in their region, and to help facilitate collaborative transfer arrangements between midwifery birth centers and other appropriate acute care transfer facilities in that region.

Response: The Department believes that the requirements for transfer agreements are adequately addressed in §§ 400.9, 795.2, and 795.5(g)(3). The Department made no changes to the regulation in response to this comment.

Comment: One organization supported the requirements for the midwifery birth center to have a collaborative relationship with one or more licensed physicians who are board certified as obstetrician-gynecologists and have obstetric privileges at one or more general hospitals. The commenter stated that this is critically important to ensure that women experience quality and coordinated maternal care. The commenter further stated that although midwives are adept in routine, low-risk deliveries, the role of a collaborating physician is critical in cases where a low-risk birth unexpectedly develops into an emergent, adverse situation that can only be handled by a highly trained obstetrician-gynecologist.

Response: These comments in support are noted by the Department. No changes were made to the regulation in response to this comment.

§795.6 Clinical staff:

Comment: One commenter recommended that the regulation include provisions for mothers who have chosen formula feeding or for whom breastfeeding is medically contraindicated, in addition to the regulation's requirement that midwifery birth centers make trained staff available to assist patients to initiate breastfeeding. Staff to provide individual training in formula preparation and feeding technique would support all patients, regardless of their choices regarding breastfeeding.

Response: The Department agrees that breastfeeding is a choice, and midwifery birth centers should support parents who have chosen formula feeding or for whom breastfeeding is medically contraindicated. The Department made no changes to the regulation in response to this comment.

Comment: One commenter indicated that the regulation's requirement that at least two staff who attend patients during labor should be certified in advanced cardiac life support is costly and overly burdensome.

Response: This requirement is intended to support healthy outcomes for all births. The Department made no changes to the regulation in response to this comment.

§795.7 Services for the care of patients:

Comment: One commenter suggested that §795.7 should be revised to reflect the fact that prospective patients may lack family members.

Response: Although in some instances a prospective patient may lack family members, this does not impact the requirements of these regulations. The Department made no changes to the regulation in response to this comment.

Comment: Several commenters expressed concern that the proposed regulation could be read to require that all patients attend childbirth classes, but that prenatal education classes may not be appropriate for some patients, and some patients may choose not to attend prenatal education classes. The regulations should be amended to reflect patient choice.

Response: The regulation requires that operators ensure that midwifery birth centers make prenatal education available. It does not mandate that patients participate in those classes, if they choose not to.

Comment: A commenter noted that perinatal education classes can be offered in many ways and that midwifery birth centers should provide “access to” perinatal education classes without requiring “attendance at” such classes.

Response: The Department made a technical amendment to the final regulation to make clear that the midwifery birth center is only required to provide access to the prenatal education classes.

Comment: A commenter organization suggested the regulation should specify that the midwifery birth centers are only required to provide consultation with perinatal qualified mental health professionals “as needed.” The commenter claimed that a midwifery birth center may be able to provide appropriate services to patients who screen positive during prenatal screening for depression or perinatal mood disorder or who have other mental

health conditions, without consulting perinatal qualified mental health professionals outside the midwifery birth center.

Response: The Department agrees that a midwifery birth center may be able to use its own perinatal qualified mental health professionals to fulfill the requirements of §795.7(c)(6). The Department made no changes to the regulation in response to this comment.

Comment: One commenter suggested that, in § 795.7(d)(1), the restriction on postpartum care to “a maximum of 24 hours after the third stage of labor is complete” should be a recommendation rather than a regulatory mandate.

Response: The regulations apply the same restrictions on postpartum care as currently apply to physician-led birth centers. In the Department’s view, this approach strikes an appropriate balance between the responsibility of the midwifery birth center and follow-up as needed by a facility licensed under Public Health Law (PHL) Article 36. The Department made no changes to the regulation in response to this comment.

Comment: One commenter requested that the regulation include birth registration requirements specific to the New York City Health Code.

Response: The birth registration requirements applicable to midwifery birth centers are consistent with those currently in place for physician-led birth centers, and are adequate to ensure that midwifery birth centers comply with birth registration requirements. The Department made no changes to the regulation in response to this comment.

Comment: One commenter suggested amending PHL § 4130 (birth registration requirements) so that it does not use the outdated term “nurse-midwife.”

Response: This comment is outside of the scope of these regulations. The Department made no changes to the regulation in response to this comment.

Comment: A commenter requested that specialized training in postpartum and newborn home visits be considered when approving midwifery birth centers for home visits under § 795.7(e), in recognition that early postpartum visits are key to healthy transition for mother and newborn.

Response: The regulation adequately addresses the minimum requirements for discharge and follow-up. The Department made no changes to the regulation in response to this comment.

Comment: One commenter suggested that postpartum care follow-up, specified in § 795.7(e), should include the offering of immunizations required by PHL §2164, as well as testing for immunity to measles due to the recent measles outbreak.

Response: The requirements in the regulations that midwifery birth centers provide follow-up that includes ongoing pediatric care, and offering specific vaccinations if indicated, are adequate and are consistent with other regulations of health care facilities that provide perinatal services. The Department made no changes to the regulation in response to this comment.

§795.10 Emergency care:

Comment: One commenter asked whether the term “transport,” as used in the regulation, mean moving from one geographical place to another and that “transfer” indicates handing off responsibility for the care of the patient from one provider to another.

Response: The Department agrees that the regulation’s use of “transfer” and “transport” have slightly different meanings, as described above. The Department made no changes to the regulation in response to this comment.

Comment: One commenter stated that the requirement that midwifery birth center emergency equipment and supplies include adult and infant laryngoscope and endotracheal tubes is inappropriate, as adult intubation is not within the scope of practice for midwifery birth centers. In the event of an adult arrest, midwifery birth center providers should only do basic CPR with bag and mask ventilation and would initiate emergency medical coverage procedures.

Response: Although the Department expects such equipment to be available, all licensed and or certified personnel are required to adhere to the relevant scope of practice requirements governing such license or certification. The Department made no changes to the regulation in response to this comment.

§ 795.11 Midwifery birth center accreditation:

Comment: A comment was received regarding this regulation’s reference, in § 795.11(a), to 10 NYCRR §400.2, which requires health care facilities to “comply with all pertinent Federal laws and regulations enacted pursuant thereto, applicable State law, including the Public Health Law and the Mental Hygiene Law and codes, rules, and regulations having general application.” The commenter stated that this provision was vague and requested more guidance about how a midwifery birth center could comply with this.

Response: This provision serves as a general reminder that, midwifery birth centers are subject to all applicable Federal and State laws, as are all health care facilities. The Department made no changes to the regulation in response to this comment.

Comment: One commenter strongly supported the requirement in § 795.11 that midwifery birth centers be accredited by a national accreditation body. Accreditation by national accrediting organizations with expertise in birth centers will help to ensure women receive safe, high-quality care in these newly established centers.

Response: These comments in support are noted by the Department. No changes were made to the regulation in response to this comment.

Comment: Several commenters argued that these regulations are not consistent with accreditation standards of accrediting organizations. Concern was expressed that the Department would require a midwifery birth center applicant to navigate competing requirements.

Response: These regulations do not conflict with accrediting organization standards. At present, one accreditation organization, the Commission on the Accreditation of Birth Centers, has indicated their interest in acting as an accreditation agency. The Department has determined that the Commission on the Accreditation of Birth Centers uses standards that are sufficient to assure the Department that MBCs comply with minimum operational standards. The Department will provide additional guidance as necessary. The Department made no changes to the regulation in response to this comment.

Comment: A commission on the accreditation of birth centers supported the absence of a requirement that the regulations do not require accreditation organizations to have Centers for Medicare & Medicaid Services “deeming status.”

Response: These comments in support are noted by the Department. The Department made no changes to the regulation in response to this comment.

Comment: An accreditation organization indicated that it does not currently offer the level of transparency required by § 795.11(b), which mandates public disclosure of all survey reports, complaint investigations, notices of non-compliance and other documentation, although it is exploring ways to enhance their transparency.

Response: The transparency required by this regulation is consistent with current practice, is essential for the protection of the public, and supports public confidence in the oversight of a new type of health care facility. The Department made no changes to the regulation in response to this comment.

§ 795.12 Application for establishment:

Comment: A commenter requested clarification as to whether accreditation by an accreditation organization will be accepted as meeting licensure requirements, or if a midwifery birth center must also apply to the Department for licensure.

Response: Under this regulation, midwifery birth centers will be a type of health care facility (or “hospital” under PHL § 2801) that must be established under 10 NYCRR Subchapter C, the State Hospital Code. Section 795.12 provides the requirements for establishment, including an application to the Public Health and Health Planning Council. After a midwifery birth center is established and issued an operating certificate, it may,

under § 795.11, be accredited in lieu of being surveyed by the Department. The Department made no changes to the regulation in response to this comment.

Comment: One commenter asked whether the Department intends to amend the regulations after the Perinatal Regionalization Expert Panel recommendations are implemented.

Response: The Perinatal Regionalization Expert Panel recommendations will be considered separately, as they are outside the scope of this regulations. Like all regulations, these regulations may be amended in the future. The Department made no changes to the regulation in response to this comment.

Comment: One commenter suggested that all birth centers should be incorporated more clearly into the perinatal regionalization system within New York State.

Response: The extent to which midwifery birth centers should be incorporated into the current perinatal regionalization system will be considered separately, if amendments are necessary based on the recommendations of the Perinatal Regionalization Expert Panel. The Department made no changes to the regulation in response to this comment.

Comment: One commenter asked questions concerning the process for approval and monitoring of training for advanced home health aides under 10 NYCRR §700.2(b)(54).

Response: This comment falls outside the scope of this regulation. The Department made no changes to the regulation in response to this comment.

Comment: A commenter requested clarification as to the reason for adding a reference to midwifery birth center transfers in 10 NYCRR § 400.9, which addresses hospital transfer protocols.

Response: 10 NYCRR § 400.9 required that both the physician at the receiving facility and the “physician responsible for the medical care in the referring facility” agree to a transfer. In the case of midwifery birth centers, there may be no such physician. Consequently, this section is being amended to also allow “the midwife responsible for the medical care in the case of a referring midwifery birth center” to agree to a transfer.

Comment: Several commenters stated that the establishment process and accreditation fees would not be affordable for small, rural midwifery birth centers, and that those centers serving low-income groups who pay for care out-of-pocket may risk financial failure.

Response: The Department acknowledges that there are costs associated with compliance with these regulations, but that there may be foundation grants available to help defray some of these costs. These regulations are intended to ensure quality. The Department made no changes to the regulation in response to this comment.