

CHAPTER 33C

**CERTIFICATE OF NEED AND ACUTE CARE
LICENSURE: REGIONALIZED PERINATAL
SERVICES AND MATERNAL AND
CHILD HEALTH CONSORTIA**

Authority

N.J.S.A. 26:2H-5 and 26:2H-8.

Source and Effective Date

R.2002 d.64, effective March 4, 2002.
See: 33 N.J.R. 2618(a), 34 N.J.R. 1040(a).

Chapter Expiration Date

In accordance with N.J.S.A. 52:14B-5.1c, Chapter 33C, Certificate of Need and Acute Care Licensure: Regionalized Perinatal Services and Maternal and Child Health Consortia, expires on August 31, 2007. See: 39 N.J.R. 829(a).

Chapter Historical Note

Chapter 33C, Certificate of Need: Perinatal Services, was originally codified in Title 8 as Subchapter 8 of Chapter 31. Subchapter 8 of Chapter 31 was adopted as R.1973 d.362, effective January 1, 1974. See: 5 N.J.R. 374(b), 6 N.J.R. 11(a). Subchapter 8 of Chapter 31 was recodified as Chapter 33C, Certificate of Need: Perinatal Services, effective March 20, 1980.

Pursuant to Executive No. 66(1978), Chapter 33C, Certificate of Need: Perinatal Services, was readopted as R.1984 d.360, effective August 6, 1984. See: 16 N.J.R. 1431(a), 16 N.J.R. 2281(c).

Pursuant to Executive Order No. 66(1978), Chapter 33C, Certificate of Need: Perinatal Services, was readopted as R.1989 d.417, effective July 17, 1989. See: 21 N.J.R. 1187(a), 21 N.J.R. 2289(a). Pursuant to Executive No. 66(1978), Chapter 33C, Certificate of Need: Perinatal Services, expired on July 17, 1991.

Chapter 33C, Certificate of Need: Regionalized Perinatal Services, was adopted as R.1992 d.343, effective September 8, 1992 (operative November 1, 1992). See: 24 N.J.R. 2005(a), 24 N.J.R. 3131(a). Pursuant to Executive No. 66(1978), Chapter 33C, Certificate of Need: Regionalized Perinatal Services, expired on September 8, 1997.

Chapter 33C, Certificate of Need and Licensure: Regionalized Perinatal Services and Maternal and Child Health Consortia, consisting of N.J.A.C. 8:33C-4.1(c), was adopted as new rules by R.1998 d.579, effective December 7, 1998. The remainder of Chapter 33C, Certificate of Need and Licensure: Regionalized Perinatal Services and Maternal and Child Health Consortia, was adopted as new rules by R.1999 d.26, effective February 1, 1999. See: 30 N.J.R. 3633(a), 30 N.J.R. 4221(b); 30 N.J.R. 2399(a), 31 N.J.R. 406(a). Chapter 33C, Certificate of Need and Licensure: Regionalized Perinatal Services and Maternal and Child Health Consortia, expired on December 7, 2001.

Chapter 33C, Certificate of Need and Acute Care Licensure: Regionalized Perinatal Services and Maternal and Child Health Consortia, was adopted as new rules by R.2002 d.64, effective March 4, 2002. See: Source and Effective Date.

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SUBCHAPTER 1. GENERAL PROVISIONS

8:33C-1.1 Scope and purpose

(a) The rules contained in this chapter address the certificate of need designation and licensure requirements for a Maternal and Child Health Consortium (MCHC), and for providers seeking and/or requesting a change of the following designations as defined in N.J.A.C. 8:33C-1.2:

1. Community Perinatal Center-Birth Center;
2. Community Perinatal Center-Basic;
3. Community Perinatal Center-Intermediate;
4. Community Perinatal Center-Intensive; and
5. Regional Perinatal Center.

(b) The purpose of this chapter is to:

1. Set forth certificate of need and licensure requirements for all MCHC;
2. Set forth certificate of need and designation requirements for MCHC members providing perinatal services; and
3. Ensure provision of maternal and child health services in a coordinated and cooperative, prevention-oriented manner which is accessible to those in need of care.

8:33C-1.2 Definitions

The following words and terms, when used in this chapter, shall have the following meanings:

“Advanced practice nurse” means a licensed registered professional nurse with certification in a specialty requiring expertise in maternal and child health who has been certified by the New Jersey Board of Nursing, in accordance with N.J.A.C. 13:37-7, Certification of Nurse Practitioners/Clinical Nurse Specialists.

“Back transport” means the act of returning patients to the facility to which they were originally admitted or to their local hospital for further care when the problems that required transport to a higher level facility have been resolved and the patient no longer requires such higher level of care.

“Central service facility” means a health care facility, regulated by the Department, providing essential administrative and clerical support services to two or more direct providers of health care services in a region, which may also include some direct provision of health care services.

“Certified nurse midwife” means a registered professional nurse, licensed as such by the New Jersey State Board of Nursing, who is also a graduate of an accredited school certified by the American College of Nurse Midwives, and

licensed as such by the New Jersey Board of Medical Examiners as required through N.J.A.C. 13:35-2A.

“Co-managed” means for two or more providers to temporarily share responsibility for a patient’s health care.

“Commissioner” means the New Jersey State Commissioner of Health and Senior Services.

“Community Perinatal Center” means a Department-designated Community Perinatal Center-Basic, Community Perinatal Center-Birth Center, Community Perinatal Center-Intensive and Community Perinatal Center-Intermediate collectively.

“Community Perinatal Center-Basic” means a general acute care hospital licensed by the Department in accordance with N.J.A.C. 8:43G, and authorized to provide services to neonates and uncomplicated, low risk maternity patients expected to deliver neonates at least 36 weeks in gestational age and weighing greater than 2,499 grams as well as supportive services to infants returned from Regional or Community Perinatal Center-Intensive facilities, as such services are specified within a formal letter of agreement between the facility and a Regional Perinatal Center.

“Community Perinatal Center-Birth Center” means an ambulatory care facility, or a distinct part of a health care facility separately licensed as an ambulatory care facility, authorized to provide routine prenatal and intrapartum care to low risk maternity patients who are expected to deliver neonates at least 37 weeks of gestational age, weighing greater than 2,499 grams, and requiring less than a 24-hour stay following birth.

“Community Perinatal Center-Intensive” means a general acute care hospital, licensed by the Department in accordance with N.J.A.C. 8:43G, and authorized to provide services to neonates and complicated maternity patients who are expected to deliver neonates at least 28 weeks of gestational age and weighing greater than 999 grams, as such services are specified within a formal letter of agreement between the facility and a Regional Perinatal Center.

“Community Perinatal Center-Intermediate” means a general acute care hospital, licensed by the Department in accordance with N.J.A.C. 8:43G, and authorized to provide services to neonates and complicated maternity patients expected to deliver neonates at least 32 weeks of gestational age and weighing greater than 1,499 grams, as such services are specified within a formal letter of agreement between the facility and a Regional Perinatal Center.

“Consultation” means information or guidance provided by a person recognized as a specialist in a particular medical field. This information may be provided via the telephone or through co-management of the high risk maternal-fetal or neonatal patient.

“Consumer/consumer advocacy organization” means an individual who may receive health care services in a specific health care service region, who is not a health care provider and has no fiduciary interest in a health care service; or an agency or organization which is not a health care provider and advocates for consumers.

“Department” means the New Jersey State Department of Health and Senior Services.

“General member” means any individual, facility or organization with an interest in maternal and child health who has joined a Maternal and Child Health Consortium.

“High risk” or “patient who is at risk” means any patient identified with a medical/obstetrical condition requiring more than routine medical or surgical intervention.

“High risk infant follow-up” means a system of screening and tracking infants with potentially serious health problems or at risk for development delays following discharge from the hospital.

“Hospital” means a New Jersey licensed general acute care hospital.

“Hospital provider” means an individual who is a direct provider of a health care service or has administrative responsibility for a New Jersey licensed general acute care hospital or an individual who is employed by a hospital.

“Hospital service area” means those municipalities in an area determined through the most recent patient origin/market share data collected by the Department to meet one or more of the following criteria:

1. The hospital derives five percent or more of total admissions from the municipality;
2. Greater than 20 percent of residents of the municipality who are hospitalized utilize the subject hospital; or
3. The hospital is located within the municipality.

“Infant” means a child from birth to one year of age.

“In-hospital coverage” means a system whereby a licensed practitioner is physically present in the hospital as required by N.J.A.C. 8:43G-19.

“Intensive care” means a hospital unit in which special equipment and skilled personnel are concentrated to provide immediate and continuous attention to patients who, because of surgery, shock, trauma, serious injury or life threatening conditions, require intensified comprehensive observation and care.

“Intermediate care” means a hospital unit in which special equipment and personnel are available to care for stable, though ill, patients.

“Intermediate birth weight” means a weight of between 1,500 and 2,500 grams at birth.

“Intrapartum” means the period occurring during childbirth or delivery.

“Labor-delivery-recovery-postpartum (LDRP) bed” means a licensed obstetric bed, the primary function of which is to accommodate an obstetrical patient during the

entire course of labor, delivery, recovery, and postpartum periods.

“Letter of agreement” means a document between licensed perinatal and pediatric health care providers and an MCHC, or a document between a Regional Perinatal Center and a Community Perinatal Center, developed in cooperation with the MCHC, which defines the relationship between the parties, specifies all tasks to be provided by each party, and is signed by a representative of each party to the agreement who is authorized to bind the party to such an agreement.

“Low birth weight” means a weight of less than 2,500 grams at birth.

“Maternal and Child Health Consortium (MCHC)” means a voluntary formed nonprofit organization which is licensed as a central service facility by the Department as specified in these rules, and incorporated under Section 501(c)(3) of the United States Internal Revenue Code.

“Maternal and child health service region” means a MCHC’s designated geographically contiguous perinatal and pediatric service delivery area.

“Maternal-fetal transport” means transport of a high risk pregnant patient (that is, a patient diagnosed with a fetal condition which will require stabilization or resuscitation of the infant during the neonatal period, a patient with a severe maternal illness, and other cases in which care by a perinatologist is required) from one facility to another facility able to provide the appropriate level of care.

“Member in good standing” means a MCHC member that has made timely payment of its financial assessment (based on a budget approved by the Department), in accordance with the MCHC’s by-laws.

“Mid-level practitioner” means a certified nurse midwife or advanced practice nurse as set forth in N.J.A.C. 13:35-2A, or a physician assistant as set forth in N.J.A.C. 13:35-2B.

“Neonatal” means the period up to 28 days after birth.

“Neonatal intensive care” means a hospital intensive care unit staffed with specially trained nursing personnel and containing specialized support equipment for treatment of newborn infants who require intensified, comprehensive observation and care exceeding that provided in pediatric acute or newborn nursing units.

“Neonatal transport” means a situation where a team is deployed from one facility to evaluate and stabilize the condition of a neonate at another facility, with the intent of transferring the neonate to the team’s facility for a higher level of care, as medically appropriate.

"Neonate" or "newborn" means a child from the moment of birth up to 28 days thereafter.

"Neonatologist" means a physician who is board certified in pediatrics with a certification in neonatology from the American Board of Pediatrics, Sub-Board of Neonatal/Perinatal Medicine or the American Osteopathic Board of Pediatrics, Sub-Board of Neonatology.

"Non-hospital provider" means an individual who is a health care provider or has administrative responsibility for a health care facility but is not employed by a hospital.

"Obstetrician" means a physician who is certified, or eligible for certification by the American Board of Obstetrics and Gynecology, Inc., or the American Osteopathic Board of Obstetrics and Gynecology.

"On-call coverage" means a system whereby a licensed practitioner is readily available to be at the facility within 30 minutes of initial contact as described in N.J.A.C. 8:43G-19.

"Pediatrician" means a physician who is certified or eligible for certification by the American Board of Pediatrics or the American Osteopathic Board of Pediatrics.

"Perinatal" means the period from the 20th week of gestation through the neonatal period.

"Perinatologist" means a physician who is board certified in obstetrics/ gynecology with additional certification in maternal-fetal medicine from the American Board of Obstetrics and Gynecology, Inc., Division of Maternal-Fetal Medicine or the American Osteopathic Board of Obstetrics, Sub-Board of Maternal-Fetal Medicine.

"Postpartum" means the period up to, and including, six weeks following birth.

"Preconceptional care" means assessing an individual for risk factors and counseling the individual prior to pregnancy.

"Prenatal (antepartal)" means the period of fetal development prior to birth.

"Provider" means an individual who is a provider of health care either directly through the provision or administration of health services or indirectly by having a fiduciary interest in such services.

"Referral" means a situation where the attending physician transfers the responsibility of the patient's care to a physician specializing in either neonatal or maternal-fetal medicine at the Regional Perinatal Center. Such a transfer of responsibility can consist of consultation only with the attending physician retaining care responsibility or continued management by the Regional Perinatal Center through delivery.

"Regional Perinatal Center" means a general acute care hospital which is designated and licensed to provide care to high risk mothers and neonates. Such a facility provides consultation, referral, transport and follow-up to other members of its Maternal and Child Health Consortium.

"Regional perinatal and pediatric plan" means the three year plan developed and updated annually by the existing or proposed MCHC, which describes how prenatal, intrapartum, newborn and infant follow-up services and pediatric services are delivered in the maternal and child health service region, as well as strategies for improving services.

"Regional transport system" means a system developed by the MCHC which includes written policies and procedures for the triage of mothers and/or infants to the most appropriate level of care in accordance with formal letters of agreement.

"Regionalized services" means services which are planned and delivered within a specific geographic zone for the best use of financial and medical resources such as staffing, equipment, facilities, education and expertise to coordinate appropriate quality health care to a specific population.

"Risk reduction services" means specific perinatal addiction prevention and intervention services which may be provided individually or on a regional basis.

"Risk reduction specialist" means a registered professional nurse, a licensed or certified social worker, or other professional in a maternal and child health addiction-related field who has specialized training and experience in perinatal addiction.

"Total quality improvement program" means an ongoing and systematic process designed to review, measure and evaluate quality of care and perinatal and pediatric outcomes.

"Transfer" means a temporary or permanent shift in responsibility for a patient's health care management from one provider to another.

"Transport" means the process whereby the attending physician or certified nurse midwife at the Birth Center or Community Perinatal Center determines that the status of the patient has become acutely high risk and arranges for the transfer of the patient to a higher level facility, and includes maternal-fetal and/or neonatal transport.

"Ventilatory support" means the application of positive pressure ventilation and oxygen through mechanical devices, including continuous positive airway pressure (CPAP).

"Very low birth weight" means a weight of less than 1,500 grams at birth.

8:33C-2.5 Staffing requirements of the Regional Maternal and Child Health Consortia

Each MCHC applicant shall document the ability to recruit, at a minimum, staffing levels in accordance with the MCHC licensure standards, as set forth at N.J.A.C. 8:33C-7.3.

8:33C-2.6 Functions of the regional Maternal and Child Health Consortia

(a) MCHC certificate of need applications shall include documentation of the ability to provide the following services, consistent with the MCHC licensure standards, as set forth in this chapter:

1. A regional perinatal and pediatric plan;
2. A region-wide system for on-going total quality improvement;
3. A system for the provision of regional professional and consumer education;
4. A regional perinatal transport system; and
5. A system for the provision of infant follow-up services.

8:33C-2.7 Regional perinatal and pediatric plan

(a) Each MCHC certificate of need applicant shall submit a regional perinatal and pediatric plan to the Department for approval, with projections for the following three years, as the basis for the establishment of the consortium. The regional perinatal and pediatric plan shall include each of the components listed in (b) below, and shall be updated and approved by the Department annually.

(b) The specific components of the regional perinatal and pediatric plan shall include the following:

1. A needs assessment which describes the status of the maternal and child health services region at the time the plan is developed with respect to: the occurrence of infant mortality; low birth weight births; the proposition of women receiving risk appropriate prenatal care; number of births to adolescents; the occurrence of pediatric mortality and morbidity for children from birth to 21 years of age; and social, cultural, economic and demographic factors influencing the perinatal and pediatric needs of the communities served by the maternal and child health service region;
2. A description of current perinatal and pediatric services in the region at the time the plan is developed, including Medicaid managed care providers. This description shall include a list, by county, of all of the following:
 - i. Practicing obstetric, prenatal care and family planning providers;
 - ii. Practicing perinatal specialists, both nursing and medical;

iii. Practicing pediatric care providers, including family practice, primary care providers, and specialists serving children from birth to 21 years of age;

iv. A list of sites, both licensed ambulatory and private practice, where preconceptional health, family planning, genetic counseling, prenatal care, school based youth services, local government (child health conferences), pediatric primary care, pediatric long term care, pediatric rehabilitation services, mental health services, early intervention programs, child evaluation centers, and other specialized services are provided;

v. A description, by hospital, of the existing inpatient maternity, newborn and pediatric services to include all of the following:

- (1) The number of traditional labor, delivery, recovery and postpartum beds, and/or the number of multi-function rooms, that is, labor-delivery-recovery or labor-delivery-recovery-postpartum rooms;
- (2) Licensed intermediate care bassinet capacity and utilization;
- (3) Licensed intensive care bassinet capacity and utilization;
- (4) Licensed pediatric bed capacity and utilization;
- (5) Licensed pediatric intensive care bed capacity and utilization;
- (6) The number of pediatric admissions to hospitals without licensed pediatric beds;
- (7) The number of pediatric patients admitted for ambulatory care sensitive diagnoses; and
- (8) Documentation of the appropriate in-house and on-call coverage commitments by professional staff for ambulatory, emergency department and inpatient services in each facility;

vi. A list of sites where high-risk infant follow-up programs are provided; and

vii. A list of hospitals designated by the Department as Level I or Level II trauma centers;

3. An assessment of gaps in services developed by comparing the identified needs described in (b)1 above, with the current resources described in (b)2 above. A description of the potential need for new services or changes in the distribution of existing services within the region shall also be included;

4. A list of objectives that address identified gaps in existing hospital and community services within the region, and measurable outcome criteria and methods to achieve those objectives.

5. A plan that describes the use of mid-level practitioners, such as obstetric and pediatric nurse practitioners,

family planning nurse practitioners, certified nurse midwives, other advanced practice nurses, and physician assistants, especially in areas of assessed provider shortages;

6. A prevention plan that describes both clinical (inpatient and ambulatory) and nonclinical services to be provided to mothers and families in the maternal and child health service region (both at risk and general) to help reduce the incidence of identified behaviorally-based perinatal problems, and includes a comprehensive risk assessment protocol;

7. A plan to assure access to culturally sensitive, community-based, preventive and primary services by all children that includes well-child and 24 hour sick care; and

8. A plan to develop an infant tracking system of all newborns in need of primary care.

8:33C-2.8 Projection of need for intermediate and intensive bassinets

(a) The MCHC regional perinatal plan shall identify the need for intensive bassinets at the time the plan is developed as determined by the Department through use of the following methodology.

$$\frac{(axb) + (cxd) + (exf) + (gxh) + (ixj) + (kcl) + (mxn) + (oxp)}{365} \times 1.18$$

where

- a = Regional number of live births <1,000 grams discharged alive plus the regional number of live births 1,000 to 1,500 grams with a significant operating room procedure discharged live
- b = Statewide average length of stay for patient type defined in a above
- c = Regional number of live births <1,500 grams not included in a above
- e = Regional number of live births > or = 1,500 grams but <2,500 grams with a significant operating room procedure with major multiple problems
- f = Statewide average length of stay for type of patients described in e above
- g = Regional number of live births > or = 1,500 grams but <2,000 grams either (1) with a significant operating room procedure, but without multiple major problems or (2) without a significant operating room procedure, but with multiple major problems
- h = Statewide average length of stay for patients described in g above
- i = Regional number of live births > or = 2,000 grams but <2,500 grams either (1) with a significant operating room procedure, but without multiple major problems or (2) without a significant operating room procedure, but with multiple major problems
- j = Statewide average length of stay for patients described in i above
- k = Regional number of live births > or = 1,500 grams but <2,500 grams with a major problem, but without a significant operating room procedure
- n = Statewide average length of stay for patients described in m above
- o = Regional number of live births > or = 2,500 grams with a significant operating room procedure and multiple major problems
- p = Statewide average length of stay for patients described in o above

(b) The MCHC shall determine the need for intermediate bassinets in accordance with the methodology developed by the MCHC and identified in its approved regional perinatal and pediatric plan.

(c) The MCHC shall project the need for intensive and intermediate bassinets for the next four years as follows:

1. For the number of intermediate birth weights and very low birth weights, the MCHC shall use the average data reported to the Department for the two years prior to the certificate of need submission.

2. For the Statewide average length of stay per birth weight category, the MCHC shall use the Statewide average length of stay determined by the Department most recent to the date of the certificate of need submission.

8:33C-2.9 Distribution of intermediate and intensive bassinets

(a) Regional Perinatal Centers or Community Perinatal Centers-Intensive shall provide neonatal intensive care. The final allocation of such bassinets shall be made by the Commissioner through the certificate of need review process.

(b) The minimum size of any neonatal intensive care unit shall be six bassinets. The minimum size of any neonatal intermediate care unit shall be four bassinets. Waiver of the minimum size of a neonatal intermediate care unit may be obtained from the Commissioner in cases where geographic inaccessibility is demonstrated and where no additional costs will be incurred. Waiver of the minimum size of a neonatal intensive care unit is not available and none shall be granted. Applicants seeking a waiver shall follow the process set forth at N.J.A.C. 8:33C-4.4(c).

8:33C-2.10 Regional professional and consumer education

The MCHC certificate of need application shall describe planned actions for providing or coordinating an ongoing program of professional and consumer education which covers the maternal and child health service region.

8:33C-2.11 Total quality improvement program

The MCHC certificate of need application shall describe planned actions for establishing a total quality improvement plan which includes all components specified in the MCHC licensure standards, as set forth at N.J.A.C. 8:33C-5. The plan shall include the development of fetal, infant and child death review systems in coordination with the Department. The regional total quality improvement plan, and any subsequent modification(s) thereof, shall be reviewed and approved by the Department prior to implementation.

8:33C-2.12 Regional maternal-fetal and neonatal transport system

The MCHC certificate of need application shall describe a plan for a regional maternal-fetal and neonatal (perinatal) transport system in accordance with N.J.A.C. 8:43G-19. The transport plan shall be reviewed and approved by the Department subsequent to approval of the MCHC certificate of need application in accordance with the provisions set forth at N.J.A.C. 8:33C-5.1.

8:33C-4.2 Licensure

(a) The Department shall issue a license to a regional MCHC when the applicant demonstrates it is in compliance with the provisions set forth in N.J.S.A. 26:2H-1 et seq., the requirements set forth in this chapter and all other applicable licensure standards.

(b) The Department shall renew a MCHC's license annually on the original licensure date, or within 30 days thereafter, but dated back to the original licensure date, following receipt of the required licensure fee from the MCHC, if the MCHC continues to be in compliance with all licensure and certificate of needs standards applicable to it.

1. The Department shall issue a statement for the required licensure fee to the MCHC at least 30 days prior to the MCHC's annual licensure renewal date.

2. The Department shall not issue a renewal license to an MCHC if its license has been suspended or revoked prior to the annual license renewal date.

(c) The license shall be conspicuously posted in the main office of the MCHC.

(d) The license shall not be assignable or transferable, and it shall be void immediately if the MCHC ceases to operate.

8:33C-4.3 Surrender of license

(a) The MCHC shall notify the Department at least 30 days prior to the voluntary surrender of a license. Whenever a license is subject to voluntary surrender, revocation, nonrenewal, or suspension it shall be returned to the Certificate of Need and Acute Care Licensure Program of the Department within seven working days after the voluntary surrender, revocation, non-renewal, or suspension.

(b) If the MCHC plans to cease operation, within seven working days after the MCHC ceases operation it shall notify the Department of the location where records shall be stored and of methods for their retrieval within 10 business days.

8:33C-4.4 Waiver

(a) The Commissioner or his or her designee, in accordance with the general purposes and intent of N.J.S.A. 26:2H-1 et seq., and the rules in this chapter, may waive sections of these rules pertaining to licensure requirements if, in his or her opinion, such waiver would not endanger the life, safety, or health of patient(s) or the public and failure to grant such waiver would result in undue hardship to the applicant.

(b) A MCHC seeking a waiver of the licensure rules shall apply in writing to the Director of the Certificate of Need and Acute Care Licensure Program of the Department.

(c) A written request for waiver shall include all of the following:

1. The specific rule(s) or part(s) of the rule(s) for which waiver is requested;
2. Reasons for requesting a waiver, including a statement of the type and degree of hardship that would result to the MCHC if a waiver is not approved;
3. An alternative proposal which would ensure patient health, safety and welfare; and
4. Documentation to support the request for waiver and the reasons submitted therefor.

(d) The Department, in its discretion, may request additional information before processing a request for waiver, as needed. Failure to supply the requested information may result in denial of the application for waiver.

8:33C-4.5 Action against a licensee

If the Department determines that operational deficiencies exist which may cause the MCHC to be out of compliance with this chapter and/or any other applicable rules, the Department may require that all services, or a portion thereof, provided within the MCHC cease. This may be done simultaneously with, or in lieu of, action to revoke licensure and/or impose a fine. The Commissioner or his or her designee shall notify the MCHC in writing of such determination, including the reasons therefor.

8:33C-4.6 Hearings

If the Department proposes to suspend, revoke and/or impose other lawful remedies, the licensee may request a hearing which shall be conducted pursuant to the Administrative Procedure Act, N.J.S.A. 52:14B-1 et seq. and 52:14F-1 et seq. and the Uniform Administrative Procedure Rules, N.J.A.C. 1:1.

8:33C-4.7 Relocation

An MCHC that relocates, voluntarily or involuntarily, shall submit a licensing application for review and approval to the Department, along with a nonrefundable fee of \$250.00, prior to its relocation.

8:33C-4.8 Transfer of ownership

An MCHC that transfers ownership, voluntarily or involuntarily, shall submit a licensing application for review and approval by the Department, with a nonrefundable fee of \$1,000 prior to any transfer of ownership.

SUBCHAPTER 5. MINIMUM REQUIREMENTS FOR LICENSURE OF MATERNAL AND CHILD HEALTH CONSORTIA

8:33C-5.1 Required services

(a) The MCHC shall develop and implement a three-year regional perinatal and pediatric plan which takes into con-

sideration all certificate of need application criteria set forth in this chapter, approved but unimplemented certificate of need applications, and the levels of care offered by licensed providers of perinatal and pediatric services. The regional perinatal and pediatric plan shall be updated and approved by the Department annually. The three year regional perinatal plan and the annual update, as appropriate, shall be submitted to the Department on or before October 1 of every year.

(b) The MCHC shall develop and implement a system for discharge planning, infant follow-up and child health care coordination in the MCHC region. This system shall assure post-discharge continuity of care and shall be linked to necessary resources, such as:

1. Primary care services for all children in need of a primary care provider;
2. Referral to follow-up services for high risk infants. Guidelines, compliance with which is not mandatory, are available from the Department of Health and Senior Services, Regional Services Program, PO Box 364, Trenton, New Jersey 08625-0364, telephone (609) 292-5616;
3. Case management provided in coordination with Special Child and Adult Health Services County Case Management Units, as appropriate;
4. Home follow-up; and
5. Counseling services to parents, especially those experiencing perinatal and infant loss including, when appropriate, referral to the Sudden Infant Death Syndrome Resource Center established pursuant to N.J.S.A. 52:17B-88.

(c) The MCHC, in conjunction with the designated Regional Perinatal Center shall establish, coordinate and monitor a regional transport system. This system shall include written policies and procedures for triage of mothers, neonates and/or infants to a facility designated and licensed to provide the most appropriate level of care, in accordance with formal letters of agreement between the MCHC and its Regional Perinatal Center(s) and Community Perinatal Centers. The regional transport system and any subsequent modification(s) thereof shall be reviewed and approved by the Department prior to implementation. The regional transport system plan shall include:

1. Documentation of current transport capabilities with actual transport numbers based on the most recent year available at the time licensure application is made;
2. A planned system to insure appropriate maternal-fetal, neonatal and/or infant transport to facilities designated and licensed to provide appropriate levels of advanced care;
3. A planned system for back transports of mothers, neonates and infants, where appropriate;

4. Written policies and procedures for maternal-fetal, neonatal and infant transports which specify that the most at-risk mothers, neonates and infants shall be triaged and transported, as soon as possible, to the facility designated and licensed to provide the most advanced appropriate level of care within the region, in accordance with these rules and N.J.A.C. 8:43G-19;

5. Written policies and procedures governing circumstances when the maternal and child health service region does not have a bed or bassinet available to accommodate a transport in accordance with the regional maternal-fetal, neonatal and infant transport plan; and

6. Documentation of existing pediatric transport capabilities.

(d) The MCHC shall provide or coordinate on-going, area wide professional education for all perinatal and pediatric service providers in the region, including, at least, regularly scheduled regional conferences. The MCHC shall provide or coordinate consumer education which is demographically appropriate to the region. The MCHC shall have in place a mechanism to assess the effectiveness of the regional education program annually.

(e) The MCHC shall establish a region-wide program for quality assurance which includes total quality improvement and regular collection and analysis of data which is designed to identify the nature and severity of health-service problems. The program and any subsequent modification(s) thereof shall be reviewed and approved by the Department prior to implementation, to assure that funds are allocated to fulfill the programmatic requirements as set forth in these rules. As part of the quality assurance program, the MCHC shall recommend, implement and monitor corrective action, based upon the data collected. The MCHC's plan for the region-wide program shall address at least the following:

1. A uniform regional system for automated data collection;
2. Management of the program by a specific subcommittee of the MCHC, which subcommittee shall meet at least quarterly;
3. Policies and procedures for collecting, abstracting and reporting data to the appropriate subcommittee, for use in quality assurance activities; and
4. Criteria for review of perinatal and pediatric statistics and pathology, including, but not limited to the following:
 - i. Transports with death;
 - ii. Noncompliance with rules regarding birth weight and gestational age;
 - iii. Cases in which no prenatal care was received;
 - iv. All maternal deaths;

- v. All fetal deaths over 2,500 grams not diagnosed as having known lethal anomalies;
- vi. Selected pediatric deaths and/or adverse outcomes (to be specified in the plan);
- vii. Immunization of children two years of age in accordance with the provisions of N.J.A.C. 8:57, Communicable Diseases; and
- viii. Admissions for ambulatory care sensitive diagnoses in children.

8:33C-5.2 Data reporting requirements

(a) The MCHC shall carry out the following responsibilities in accordance with N.J.S.A. 26:1A-37 through 37.4.

1. Upon request, the MCHC shall submit any documents and/or data which are required to be kept, to the Department, including, but not limited to, formal letters of agreement between the MCHC member facilities;
2. The MCHC shall collect, maintain and submit to the Department data required by its obligations to comply with N.J.A.C. 8:33E-5.1(a) through (e); and
3. On or before October 1 of every year, the MCHC shall submit to the Department, for review and approval, an annual budget plan for the next calendar year. The budget plan shall identify all projected salary and non-salary costs necessary to implement both the regional perinatal and pediatric plan and the functions listed in N.J.A.C. 8:33C-5.1. The budget plan must also identify revenue sources adequate to support the expenses submitted therein, which shall include the amounts to be paid the MCHC by all member hospitals.

(b) The MCHC shall be required to comply with patient confidentiality requirements set forth in N.J.A.C. 8:43G, Hospital Licensing Standards, and N.J.S.A. 26:1A-37 through 37.4.

8:33C-5.3 Compliance with laws and rules

(a) If the MCHC provides direct medical services and/or nursing services, it shall comply with the applicable sections of N.J.A.C. 8:43A, Manual of Standards for Licensure of Ambulatory Care Facilities.

(b) The MCHC shall comply with patient confidentiality requirements as specified in Hospital Licensing Standards, N.J.A.C. 8:43G. The MCHC shall assure that all patient care records it possesses will be kept confidential. Information in the patient's records shall not be released to anyone outside the MCHC without the patient's approval, unless another health care facility to which the patient was transferred requires the information, or unless the release of the information is required and permitted by law, a third-party payment contract, a medical peer review, or the Department. The MCHC may release anonymous data about the patient for studies containing aggregated statistics.

(c) The MCHC shall comply with applicable Federal, State, and local laws, rules, and regulations.

(d) No MCHC shall be operated by any person convicted of a crime relating adversely to the person's capacity to operate the MCHC.

8:33C-5.4 Policy and procedure manual

(a) The MCHC shall develop, implement, and, in accordance with the schedule set forth therein, periodically review a policy and procedure manual governing the organization and operation of the MCHC. Each review of the manual shall be documented. The manual shall include at least the following:

1. A written statement describing the MCHC's objectives and the services provided by the MCHC, both directly and by MCHC members;
2. An organizational chart delineating the lines of authority, responsibility, and accountability for the administration of the MCHC;
3. Definition and specification of the MCHC's business hours, hours of operation, and full working week;
4. A system of patient referral to sources of primary, secondary and tertiary health care; and
5. Policies and procedures for the maintenance of personnel records for each employee, including, at minimum, the employee's name, previous employment, educational background, credentials, license number with effective date and date of expiration (where applicable), professional certification (where applicable), verification of credentials, records of physical examinations, job description, records of staff orientation and staff education, and job performance evaluations.

(b) The policy and procedure manual shall be available in the main office of the MCHC and accessible at all times to representatives of the Department, MCHC staff, MCHC members and the public.

8:33C-5.5 Reportable events

(a) The MCHC shall report to the Department the termination of employment of the administrator/executive director and the name and qualifications of that person's replacement, within seven days of the termination.

(b) The MCHC shall report to the Department whenever a hospital loses status as a member in good standing, within 15 days of the delinquency.

8:33C-5.6 Notices

(a) The MCHC shall conspicuously post a notice in its main office, that the following information is available within the facility during business hours:

1. All waivers granted by the Department, if any;

2. The list of deficiencies, if any, from the last annual licensure inspection and certification survey report and the list of deficiencies, if any, from any valid complaint investigation during the past 12 months;

3. The names and addresses of the members of the governing authority; and

4. The hours of operation and the business hours of the MCHC.

7. Development of an allocation and collection system to ensure adequate revenue from members of the MCHC who have been assessed dues, in accordance with the by-laws, necessary to fund the budget approved by the Department in accordance with N.J.A.C. 8:33C-5.1(e).

SUBCHAPTER 6. GOVERNING AUTHORITY

8:33C-6.1 Appointment of the MCHC governing authority

The MCHC shall have a governing authority appointed in accordance with N.J.A.C. 8:33C-2.3, which shall assume legal responsibility for the management, operation, and financial viability of the MCHC.

8:33C-6.2 Responsibility of the governing authority

(a) The governing authority shall be responsible for at least the following:

1. Adoption and documented review of written by-laws, or their equivalent, in accordance with a schedule established by the governing authority;

2. Development and documented review of all policies and procedures, in accordance with a schedule established by the governing authority;

3. Establishment and implementation of a system whereby patient and staff grievances and/or recommendations, including those relating to patient rights, can be identified. This system shall include a feedback mechanism through management to the governing authority, specifying what action was taken;

4. Establishment of a governing authority meeting schedule, as well as a meeting schedule for the governing authority's committees, and/or their equivalents. The governing authority shall conduct the meetings, and shall keep formal minutes of all of its meetings and its committee meetings;

5. Delineation of the duties of the officers of any governing authority committees, or their equivalent. When the governing authority establishes committees, or their equivalent, their purpose, structure, responsibilities, and authority, and the relationship of the committee to other entities within the MCHC, shall be fully documented;

6. Establishment of the qualifications of members and officers of the governing authority; the procedures for electing and appointing officers; and the terms of service for members, officers, and committee chairpersons or their equivalent; and

SUBCHAPTER 7. ADMINISTRATION

8:33C-7.1 Appointment of administrator/executive director

The governing authority shall appoint an administrator or executive director who shall be accountable to the governing authority. The administrator or executive director shall meet all of the qualifications set forth in N.J.A.C. 8:33C-7.3.

8:33C-7.2 Administrative/executive director's responsibilities

(a) The administrator shall be responsible for at least the following:

1. Planning and administration of the managerial, operational, fiscal, and reporting components of the MCHC, as determined by the governing authority; and

2. Establishing and maintaining liaison relationships with the Department, with MCHC staff and service departments, with member support services departments, with member community resources departments, and with consumers.

8:33C-7.3 Staff qualifications

(a) Each MCHC shall have on staff:

1. An administrative/executive director who has a master's degree and at least three years of administrative or supervisory experience in health care planning or administration or finance, at least one year of which shall have been in maternal and child health services;

2. A registered professional nurse with a master's degree in nursing, public health or public administration from an accredited college or university and certification by the National Certification Corporation for the Obstetric, Gynecologic and Neonatal Nursing Specialties or the American Nurses Association, and two years of experience in clinical maternal and child nursing; and

3. Adequate staff to perform the functions set forth in N.J.A.C. 8:33C-5.1 and implement the regional perinatal and pediatric plan, including, but not limited to:

i. A research/data specialist with training in research methods and experience in data analysis; and

ii. A community outreach coordinator with a bachelor's degree from an accredited college or university with one year of experience in community outreach.