CHAPTER 33C

CERTIFICATE OF NEED: REGIONALIZED PERINATAL SERVICES

Authority

N.J.S.A. 26:2H–1 et seq., specifically 26:2H–5.

Source and Effective Date

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).

Executive Order No. 66(1978) Expiration Date

Chapter 33C, Certificate of Need: Regionalized Perinatal Services, expires September 8, 1997.

Chapter Historical Note

Chapter 33C, Certificate of Need: Perinatal Services, was filed on December 18, 1973 as R.1973 d.362 and became effective on January 1, 1974. See: 5 N.J.R. 374(b), 6 N.J.R. 11(a). Revisions were filed and became effective on March 13, 1974, as R.1974 d.65. See: 6 N.J.R. 9(a), 6 N.J.R. 140(c). Further revisions were filed on October 21, 1975 as R.1975 d.315, and became effective on December 1, 1975. See: 7 N.J.R. 362(a), 7 N.J.R. 503(a). Additional revisions were filed and became effective on May 23, 1977 as R.1977 d.182. See: 8 N.J.R. 550(a), 9 N.J.R. 269(a). Additional amendments were filed and became effective on February 15, 1978, as R.1978 d.49. See: 9 N.J.R. 562(a), 10 N.J.R. 103(b). Amendments to Appendix B became effective September 19, 1979 as R.1979 d.369. See: 11 N.J.R. 328(a), 11 N.J.R. 549(c). Chapter 33C was recodified, effective March 20, 1980, from its prior location at N.J.A.C. 8:31–8. Further amendments were filed and became effective August 20, 1984 as R.1984 d.360. See: 16 N.J.R. 1431(a), 16 N.J.R. 2281(a). Chapter 33C was readopted upon filing, August 6, 1984, as R.1984 d.360. See: 16 N.J.R. 1431(a), 16 N.J.R. 2281(c). Pursuant to Executive Order No. 66(1978), Chapter 33C 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 became effective September 8, 1992. See: Source and Effective Date.

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SUBCHAPTER 13. ENFORCEMENT AND SANCTIONS

SUBCHAPTER 1. GENERAL PROVISIONS

8:33C–1.1 Scope and Purpose

The New Jersey Department of Health currently licenses and regulates inpatient and outpatient providers of obstetric and pediatric services in licensed general acute hospitals and freestanding ambulatory care centers throughout the State. The effort to lower infant and maternal mortality and improve child health requires that these services be linked into organized regional service delivery networks. The purpose of this chapter is to establish criteria and standards for review of certificate of need applications from Regional Maternal and Child Health Consortia, to designate Perinatal Centers within each region, to specify the requirements for regional perinatal needs assessment and planning, to specify criteria for regional prevention activities, and to specify the minimum utilization required to assure quality perinatal services.

8:33C–1.2 Definitions

The following words and terms, when used in this chapter, shall have the following meanings, unless the context clearly indicates otherwise:

"Central service facility" means a health care facility, regulated by the Department of Health, 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.

"Clinical nurse coordinator or supervisor" means a registered professional nurse, currently licensed by the New Jersey State Board of Nursing, who has administrative responsibility over the areas of labor, delivery, recovery, the nurseries, postpartum and antepartum units.

"Commissioner" means the New Jersey State Commissioner of Health.

"Community perinatal center" means any licensed facility providing preconceptional, prenatal, intrapartum, including delivery of the patient, and postpartum care to women.

"Consumer" means an individual who may receive specific health care services in a specific consortium region and who is not a health care provider and has no fiduciary interest in a health care service.

"High 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 developmental delays following discharge from the hospital.

"Hospital provider" means an individual who is a direct provider of a health care service or has administrative responsibility for a health care facility which is a licensed acute care hospital or who is employed by a hospital.

"Infant" means a child from the period from birth to one year of age.

"In-hospital coverage" means a system whereby an individual is physically present in the hospital.

"Intensive care" means a hospital unit in which are concentrated special equipment and skilled personnel for the care of seriously ill patients requiring immediate and continuous attention.

"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 any neonate weighing between 1500 and 2500 grams at birth.

"Intrapartum" means the period occurring during childbirth or delivery.

"Letter of agreement" means the document signed by both the Regional Perinatal Center and the Community Perinatal Center which defines the relationship between the two centers and specifies all tasks to be provided. If there is more than one hospital within the region able to meet the qualifications of a Regional Perinatal Center, then the Regional Perinatal Centers first develop cooperative letters of agreement with each other; then with the Community Perinatal Centers within the region, facilitated by the Regional Maternal and Child Health Consortia. The letters of agreement are then submitted by the Regional Maternal and Child Health Consortia as part of the certificate of need application.

"Low birth weight" means any neonate weighing less than 2500 grams at birth.

"Maternal and child health service region" means the perinatal and pediatric service delivery area. Contained within each region is at least one Regional Perinatal Center, one Regional Pediatric Center and the balance, Community Perinatal Centers and Community Pediatric Centers.

"Maternal-fetal transport" means the transport of the high risk patient for maternal management.

"Mid-level practitioner" means a certified nurse midwife or a nurse practitioner.

"Neonatal (newborn)" means the period up to 28 days after birth.

"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 health care facility but is not employed by a hospital.

"Nurse practitioner" means a registered professional nurse with a current New Jersey license who has completed an accredited nurse practitioner certification program and is certified by a national professional organization.

"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 an individual is readily available to be at the facility within 30 minutes of initial contact.

"One-stop shopping" means the integration of all services for the purpose of primary care access at a single site.

"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 before and after birth; defined in New Jersey and generally accepted as week 20 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.

"Physician" means a person who is licensed or authorized as such by the New Jersey State Board of Medical Examiners.

"Postpartum" means the period up to 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 occurring prior to birth, with reference to the fetus.

"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.

"Public health nursing home visits" means visits made or supervised by a licensed registered professional nurse who is employed by a local health department or home health agency. This includes those visits made by the nurse or by a community outreach worker or volunteer under the direction of the nurse.

"Referral" means the process whereby the attending physician at the Community Perinatal Center transfers the responsibility of the patient's care to a physician specializing in either neonatal or maternal-fetal medicine at the Regional Perinatal Center. This can consist of consultation only with transfer back to the care of the attending physician or continued follow-up by the Regional Perinatal Center through delivery.

"Regional perinatal activities" means the activities of the Regional Maternal and Child Health Consortia which include the development of the regional perinatal plan, the development of a region wide system for total quality im-

provement, the development of a plan for perinatal transport, the provision of regional professional education and the development of a system to resolve conflicts.

"Regional Perinatal Center" means a licensed perinatal care facility able to provide a full range of perinatal services to its own patient population and support to its own regional affiliates.

"Regional Maternal and Child Health Consortium" means a voluntarily formed non-profit organization, incorporated under Section 501(c)(3) of the Internal Revenue Code, consisting of all inpatient, ambulatory perinatal and pediatric care providers and related community organizations in a maternal and child health service region, licensed as a central service facility by the Department of Health.

"Regional perinatal plan" means the plan developed by the Regional Maternal and Child Consortia which describes how prenatal, intrapartum, newborn and infant follow-up services are delivered in the region. The plan is submitted to the Department of Health as part of the certificate of need application.

"Regionalization" means the planning and delivery of services 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.

"Total quality improvement program" means the process designed to review quality of care and perinatal outcomes. Total quality improvement is an activity of the individual facilities and the Regional Maternal and Child Health Consortia.

"Transport" means the process whereby the attending physician at the Community Perinatal Center assesses that the status of the patient has become acutely high risk and arranges for the transfer of the care of the patient to the specialist at the Regional Perinatal Center via moving the patient with an emergency vehicle.

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

"Very low birth weight" means any neonate weighing less than 1500 grams at birth.

8:33C–1.3 Submission of Certificate of Need applications

(a) Applications for the establishment of Regional Maternal and Child Health Consortia to service specific maternal and child health regions shall be batched and reviewed in accordance with N.J.A.C. 8:33.

(b) Individual requests for designation of Regional Perinatal Centers and Community Perinatal Centers shall only be accepted as part of the certificate of need application of a Regional Maternal and Child Health Consortium.

(c) Certificate of Need applications for Regional Perinatal Centers and Community Perinatal Centers shall be submitted to the Local Advisory Boards and the Department of Health and shall be completed in accordance with the prescribed certificate of need rules at N.J.A.C. 8:33.

8:33C–1.4 Maternal and child health service regions

(a) A maternal and child health service region is a service area containing the full spectrum of care for the purpose of providing accessible and effective comprehensive, risk-appropriate care to all pregnant women and their infants, children, including children with special health care needs, and adolescents. The maternal and child health service region shall consist of perinatal and pediatric service regions.

(b) To be designated as a maternal and child health service region for the purposes of this chapter, the certificate of need application shall specify that (using data provided by New Jersey Department of Health for the last three consecutive years of data available or the most recent year which is consistently applied in all applications within a region) in the proposed region there are sufficient hospital members, with a three-year documented history of transfer relationships, to deliver a minimum of 10,000 women a year or provide risk appropriate care to 100 very low birth weight neonates a year. (As the number of low birth weight infants changes, the Department shall revise the minimum of 100 accordingly, in accordance with the requirements of the Administrative Procedure Act (N.J.S.A. 52:14B–1 et seq.) and N.J.A.C. 1:30.) The certificate of need application shall further specify that service regions shall have a geographic distribution which enables the development of a rational and cohesive network of services, recognizing existing transportation and patient referral patterns.

(c) The Commissioner may, at his or her discretion, grant a waiver to the delivery requirement of 10,000 women a year, if the applicant has been able to provide quantifiable evidence of severe problems of access to needed perinatal services due to geographic isolation. In no case may the number of deliveries be below 8,000 women per year.

(d) At least one facility which is currently willing and able to meet the qualifications for a Regional Perinatal Center shall be listed as such in the Certificate of Need application. If there is more than one facility which is willing and able to meet the qualifications for a Regional Perinatal Center, then those facilities shall develop cooperative letters of agreement with each other. The Regional Perinatal Centers shall then develop letters of agreement with the Community Perinatal Centers, facilitated by the Regional Maternal and Child Health Consortium.

8:33C–1.5 Service evaluation

All applicants for Regional Maternal and Child Health Consortia, Regional Perinatal Centers and Community Perinatal Centers shall agree to make their staff and records available for evaluation of the effectiveness of their perinatal services by staff of the New Jersey Department of Health or its designee. This evaluation and its outcome shall be a requirement of continued reimbursement through the rates. Such an evaluation shall measure effectiveness and shall be in addition to the inspection of basic compliance with licensing requirements.

SUBCHAPTER 2. REGIONAL MATERNAL AND CHILD HEALTH CONSORTIA

8:33C–2.1 Membership

(a) The perinatal and pediatric facilities within the proposed service region shall form a Regional Maternal and Child Health Consortium. Applicants for the Regional Maternal and Child Health Consortium shall be an association which shall include all agencies in the region involved in the delivery of perinatal and pediatric health services. Specifically, the Regional Maternal and Child Health Consortium shall include, but not be limited to, as general members:

1. All licensed acute care hospitals with obstetric and/or pediatric services and birthing centers;

2. All licensed ambulatory care facilities which provide prenatal care and care to infants and families with children up to age 18;

3. Professional organizations, non-profit organizations, and local or county governmental agencies concerned with the needs of families with infants, children and adolescents, including those with special health care needs, for example, community health centers, local health departments, Women, Infants and Children (WIC) and family planning agencies, local advisory boards, and Human Services Advisory Councils; and

4. Voluntary and consumer organizations, such as Healthy Mothers, Healthy Babies Coalitions.

8:33C–2.2 Governance of the region

(a) All members of the maternal and child health service region which agree to associate and apply to become the Regional Maternal and Child Health Consortium shall formally establish a non-profit corporation consistent with the Internal Revenue Code under Title 26 of the United States Code Section 501(c)(3).

(b) The non-profit organization established in accordance with (a) above shall develop by-laws, voted upon by the general membership, which will establish participatory governance by all member organizations and will define the specific composition of a Board of Directors. Each member agency shall have one membership vote in the organization.

(c) The Board of Directors shall be nominated from and voted upon by the general membership. The Board shall consist of a minimum of 18 to 21 members, one-third hospital providers, one-third non-hospital providers and one-third consumers. The composition shall be such as to assure appropriate representation of agencies concerned with women's reproductive health and the needs of pregnant women, infants, young children, adolescents and children with special needs. At least two members shall be physicians, holding a current New Jersey license, one who is board eligible or certified in obstetrics, and one who is board eligible or certified in pediatrics. At least one member shall be a registered professional nurse, holding a current New Jersey license with a certification in either maternal and child health nursing or in community health nursing. At least one member shall be a health officer.

8:33C–2.3 Budget

The Regional Maternal and Child Health Consortium shall develop a budget plan which links all projected salary and non-salary costs, as described under N.J.A.C. 8:33C–2.5, to the regional perinatal plan. Subsequent to certificate of need approval, in order to receive funding under Chapter 83 reimbursement or other funding mechanism, the Regional Maternal and Child Health Consortium shall provide a budget assessment demonstrating that the benefits achieved justify the costs incurred. A projected budget and budget assessment shall be provided to the Department annually.

8:33C–2.4 Data reporting

(a) All Regional and Community Perinatal Center applicants shall indicate their willingness to comply with the following data reporting:

1. B2 Quarterly Inpatient Utilization Report; and

2. New Jersey Department of Health Maternity and Newborn Services Reporting System.

(b) All Regional and Community Perinatal Center applicants shall provide, as requested by the Regional Maternal and Child Health Consortium and the Department of Health, individual patient data, compiled from the comprehensive patient record, for the purpose of regional and State total quality improvement program monitoring.

(c) The Regional Maternal and Child Health Consortia shall be required to comply with patient confidentiality requirements as specified in Hospital Licensing Standards N.J.A.C. 8:43G–4.1(a)21.

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

The Consortia shall have staffing requirements in accordance with N.J.A.C. 8:35, Maternal and Child Health Consortium Licensing Standards.

8:33C–2.6 Functions of the Regional Maternal and Child Health Consortia

(a) Regional Maternal and Child Health Consortia applications shall describe their functions, which shall consist primarily of:

1. The development of a regional perinatal and pediatric plan;

2. The development of a region-wide system for total quality improvements;

3. The provision of regional professional education;

4. The development of a plan for a perinatal transport system;

5. The development of a plan for the provision of infant follow-up services; and

6. The development of a system to resolve conflicts within the region.

(b) The application shall also describe the responsibility of the regional board of directors in determining the manner in which each function will be accomplished.

8:33C–2.7 Regional perinatal plan

(a) The Regional Maternal and Child Health Consortia shall develop and submit a plan, to be called the regional perinatal plan, which describes how prenatal (specifically, community-based), intrapartum, newborn and infant follow-up services are to be delivered in the region. In addition, planned outreach and education activities shall be included. The regional perinatal plan shall be submitted to the Department of Health for approval as the basis for the certificate of need application which will designate individual hospitals as Regional Perinatal Centers or Community Perinatal Centers. Certificate of need applications for new, expanded, or replacement perinatal services will require compliance with this chapter and the regional perinatal plan. The certificate of need may be denied if compliance is not demonstrated.

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

1. A needs assessment which describes the current status of the region with respect to the occurrence of infant mortality, low birth weight births, availability of preconceptional and prenatal care, and intrapartum, newborn, intermediate and intensive care services, proportion of women receiving risk appropriate prenatal care, fertility rates and social, cultural, economic and demographic factors influencing the perinatal needs of the communities served by the region;

2. A description of perinatal services in the region, in existence at the time of application. This description shall include a list, by county, of all of the following:

i. Currently practicing obstetric, prenatal care and family planning providers, specifying those providers who accept Medicaid and who are HealthStart certified;

ii. Currently practicing perinatal specialists, both nursing and medical;

iii. Currently practicing pediatric care providers, both primary and specialists, serving children under the age of two, specifying those providers who accept Medicaid and who are HealthStart certified;

iv. A list of sites, both licensed ambulatory and private practice, where family planning, genetic counseling, prenatal care, and pediatric primary care is provided;

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

(1) The number and occupancy rate of labor, delivery, recovery and postpartum beds;

(2) Normal newborn bassinet capacity and utilization;

(3) Intermediate care bassinet capacity and utilization;

(4) Intensive care bassinet capacity and utilization; and

(5) Documentation of coverage commitments by professional staff in each facility for ambulatory, emergency department and inpatient services;

vi. Existing maternal and newborn transport capabilities (include actual number of transports, sent or received in the most recent year available at the time of application); and

vii. The current number of at risk infant follow-up programs and the number of infants in follow-up for the most recent year available at the time of application.

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. The Regional Maternal and Child Health Consortium shall develop a specific formula for estimating the annual needs in the region utilizing data from the preceding two years and projecting the needs for the upcoming four years. This formula shall cover the maternal and child health service region's needs in the following areas:

i. Prenatal care services;

ii. Antepartum beds;

iii. Capacity to transport laboring mothers and sick neonates;

iv. Labor, delivery and postpartum beds;

v. Intermediate care bassinets; and

vi. Intensive care bassinets;

4. A demonstration of the overall need for intensive care bassinets, utilizing the methodology contained in (b)4i below, and for intermediate bassinets. The overall need shall be based on data from the preceding two years and a projection of the needs for the next four years. The number of births, the number of intermediate weight births, and the number of very low birth weight births shall be the same as those reported to the Department for the most recently available year. The Statewide average length of stay per birth weight category shall be determined by the Department every two years.

i. The total number of intensive care bassinets approved for all Regional and Community Perinatal Centers in each region shall be determined by the following formula:

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

where

a = Regional number of live births < 1000 grams discharged alive plus the regional number of live births 1000–1500 grams with a significant operating room procedure discharged alive

b = Statewide average length of stay for type of patients defined in a above

c = Regional number of live births < 1500 grams not included in a above

d = Statewide average length of stay for type of patients described in c above

e = Regional number of live births > or equal to 1500 grams but < 2500 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 equal to or > 1500 grams but < 2000 grams either with a significant operating room procedure without multiple major problems or with multiple major problems without a significant operating room procedure

h = Statewide average length of stay for patients described in g above

i = Regional number of live births equal to or > 2000 grams but < 2500 grams either with a significant operating room procedure without multiple major problems or with multiple major problems without a significant operating room procedure

j = Statewide average length of stay for patients described in i above

k = Regional number of live births equal to or > 1500 grams but < 2500 grams with a major problem but without a significant operating room procedure

l = Statewide average length of stay for type of patients described in k above

m = Regional number of live births equal to or > 2500 grams with a significant operating room procedure without multiple major problems, or multiple major problems without a significant operating room procedure

n = Statewide average length of stay for patients described in m above

o = Regional number of live births equal to or > 2500 grams with a significant operating room procedure and multiple major problems

p = Statewide average length of stay for patients described in o above

ii. Regional Perinatal Centers shall be the preferred provider for rendering neonatal intensive care. In no case shall intermediate or intensive bassinets be approved at both Regional and Community Perinatal Centers which will duplicate the same need delineated by (b)4i above. The final allocation of such bassinets shall be made by the Commissioner, taking into account the existing interim and approved intermediate and intensive care bassinets in each region and following the approval of the Regional Maternal and Child Health Consortium;

5. The minimum size of any intensive neonatal care unit shall be six bassinets. The minimum size of any intermediate neonatal care unit shall be four bassinets. Waiver to the minimum size of an intermediate unit only may be considered by the Commissioner in cases where geographic inaccessibility can be demonstrated and where no additional costs will be incurred;

6. A definition of specific objectives, based on the assessment of gaps, using measurable outcome criteria, to address the gaps in existing hospital and community services within the region. For example, an objective could be lowering the very low birth weight rate by a specified percentage through several stated intervention approaches. Provider and patient behaviors which can result in poor utilization of services, non-participation in care, lack of coordinated services, and other perinatal service delivery problems shall also be addressed;

7. A plan to encourage the use of mid-level practitioners, such as obstetric and pediatric nurse practitioners, family planning nurse practitioners and certified nurse midwives, especially in areas of assessed provider shortages;

8. A prevention plan which describes both clinical (inpatient and ambulatory) and non-clinical services to be provided to mothers and families in the region (both at risk and general) to help reduce the incidence of identified, behaviorally based perinatal problems. This section shall include the need for improved coordination of services with emphasis on the "one-stop shopping" service integration concept. In addition, the prevention plan shall address outreach and education regarding nutrition, smoking, drug and alcohol consumption during pregnancy, availability and utilization of genetic services, family planning and preconception counseling. The plan shall also document involvement and participation of community based organizations already serving the at risk population and communities; and

9. The activities planned, by specific organization members, to achieve the described objectives. This plan should include specific patient care services and areas of planned expansion. The list of activities shall also include:

i. Specific letters of agreement, valid for at least four years, between each Community Perinatal Center and the Regional Perinatal Centers in the region as to the scope of services to be provided by each facility. If there is more than one hospital able to meet the qualifications of a Regional Perinatal Center, then the Regional Perinatal Centers shall first develop cooperative letters of agreement with each other, then with the Community Perinatal Centers in the region, facilitated by the Consortia.

Administrative Correction in (b)4.
See: 24 N.J.R. 3727(a).

8:33C–2.8 Regional professional education

(a) The Regional Maternal and Child Health Consortium application shall describe the organization's planned actions for providing or coordinating an ongoing area-wide program of professional education to all perinatal service providers in its region. These programs shall include joint input from neonatal/perinatal physicians and neonatal/perinatal clinical nurse specialists. Regularly scheduled regional conferences shall, at a minimum, cover the following areas:

1. Review and management of the major perinatal maternal illnesses occurring in the region;

2. Review and update for the identification and management of major neonatal conditions occurring in the region;

3. Development of appropriate hospital and community based linkages to insure maternal and newborn followup; and

4. Techniques and methods of risk assessment and providing culturally sensitive, risk appropriate prenatal care for antepartal women.

8:33C–2.9 Total quality improvement program

(a) The Regional Maternal and Child Health Consortium shall describe how it will meet its responsibility for establishing a total quality improvement process which covers all aspects of perinatal service. This process shall be managed by a specific subcommittee which shall meet at least quarterly and shall include all the components specified in N.J.A.C. 8:35.

(b) The Regional Maternal and Child Health Consortium application shall assure that each member hospital has a perinatal total quality improvement system, in accordance with N.J.A.C. 8:35–3.1(f). The regional total quality improvement plan developed by the subcommittee shall be reviewed by the Department and shall receive Department approval prior to its implementation.

8:33C–2.10 Plan for a perinatal transport system

(a) The Regional Maternal and Child Health Consortia application shall assure the responsibility of the Regional Maternal and Child Health Consortia to develop or enhance a regional maternal and neonatal transport system in order to insure timely access by the patient to risk-appropriate care. The Regional Maternal and Child Health Consortium shall develop and submit a plan which describes the transport system for at-risk intrapartum women and neonates. The transport system plan shall include:

1. Documentation of current transport capabilities with appropriate data, based on the most recent year available at the time of application actual transports;

2. Planned system, and needed enhancements to the system, to insure appropriate maternal and newborn transport for advanced levels of care;

3. Planned system, and needed enhancements for back (return) transports, of mothers or infants;

4. A written policy and procedure protocol for maternal and neonatal transports shall be developed by the Regional Maternal and Child Health Consortium. It shall be made clear in this protocol that the most at-risk infants and mothers shall be triaged and transported to the most advanced appropriate level of care within the region, in accordance with the letters of agreement.

5. Under circumstances where the proposed region does not have a bed or bassinet available to accommodate a transport, in accordance with the region's transport plan, the Regional Perinatal Center is responsible for making arrangements for transport to an adjacent Regional Perinatal Center. Regional Perinatal Centers are encouraged, in the State of New Jersey, whenever possible, to cooperate across consortia boundaries in accepting patients when capacity is reached in any region.

8:33C–2.11 Infant follow-up

The Regional Maternal and Child Health Consortia shall assure that a system for appropriate discharge planning and infant follow-up exists, in accordance with N.J.A.C. 8:35.

8:33C–2.12 Conflict resolution

Each Regional Maternal and Child Health Consortium shall assure the development of a conflict resolution mechanism in accordance with N.J.A.C. 8:35.

SUBCHAPTER 3. COMMUNITY–BASED SERVICES

8:33C–3.1 Services; agencies

(a) As part of the certificate of need application, the Regional Maternal and Child Health Consortia shall document the involvement of community based services in the development of the regional perinatal plan. The eligible agencies shall include, but not be limited to, the following:

1. Local and/or county health departments;
2. Women, Infants and Children (WIC) agencies;
3. County Boards of Social Services;
4. March of Dimes;
5. Healthy Mothers, Healthy Babies Coalitions;
6. Family planning agencies;
7. Church or local community groups (such as urban leagues);
8. Home health agencies;
9. Alcohol and drug treatment agencies;
10. Community health centers;
11. Local advisory boards; and
12. Special Child Health Services County Case Management Units (when not administered by local health departments).

8:33C–3.2 Functions of community based service members

(a) The community based service members of the Regional Maternal and Child Health Consortium shall be primarily responsible for determining the medical/social maternal and child health needs of the community and for providing input into the prevention plan as part of the Regional Maternal and Child Health Consortium application. The prevention plan shall be incorporated in the regional perinatal plan as described in N.J.A.C. 8:33C–2.7(b)8. The component issues shall be addressed as follows:

1. Capacity of Services—The members should determine if there is an adequate number of providers/services to meet the maternal and child health needs of the community. They should also describe if the services accept Medicaid, are HealthStart certified, and the waiting time for first appointments.

2. Accessibility of Services—The members should describe the days and hours of operation, the location, transportation, child care availability, and service integration design.

3. Cultural Sensitivity—The members should assess the existing services to determine if they are sensitive to the cultural diversity of the community.

4. Outreach—Additional emphasis needs to be placed on outreach activities. As part of the regional perinatal plan, the members shall develop a plan to encourage women to seek early preconceptional and prenatal care, remain in prenatal care and return for preventive postpartum, family planning and pediatric services.

SUBCHAPTER 4. GENERAL REQUIREMENTS FOR FACILITIES WITH OBSTETRIC AND/OR NEWBORN SERVICES

8:33C–4.1 Application requirements

Individual Community Perinatal Center or Regional Perinatal Center applications shall be submitted as part of the Regional Maternal and Child Health Consortium's certificate of need application, by any licensed facility that provides or plans to provide prenatal, intrapartum, and postpartum care to women and their newborns. The requirements specified in N.J.A.C. 8:33C–4 through 6 shall be the basis for planning services.

8:33C–4.2 Compliance

(a) All Regional Perinatal Centers and Community Perinatal Centers shall demonstrate the ability to be in compliance with current hospital licensure standards, N.J.A.C. 8:43G–19.

(b) All Regional Perinatal Centers and Community Perinatal Centers shall document in the certificate of need application that ambulatory prenatal, postpartum, and normal newborn care is provided, and that these services are in accordance with the HealthStart Standards, N.J.A.C. 10:49–3, and the Standards for Obstetric–Gynecologic Services published by the American College of Obstetricians and Gynecologists. In the interest of continuity of care, consideration should be given to granting privileges to all private practitioners (including obstetricians, family practitioners and certified nurse midwives) providing obstetric care, if all hospital-specific criteria are met.

8:33C–4.3 Comprehensive perinatal record

(a) As part of routine prenatal care, all providers within the region shall agree to use a comprehensive standardized perinatal record. This record shall include, at a minimum, a separate, identifiable section to assess for all risk factors. All antepartal patients shall be assessed for risk during the first prenatal visit and updated during subsequent visits. Additional sections of this comprehensive record shall include:

1. A complete reproductive and gynecologic history, history of medical illnesses and surgery, history of substance use (tobacco, alcohol and drugs), family illnesses, behavioral and environmental assessment, nutritional and social assessment, psychological history and risk status;

2. A complete physical exam;

3. A section for laboratory results and procedures; and

4. A plan of care.

8:33C–4.4 Consultation services

(a) Consultation services shall routinely be available from:

1. Registered dieticians or nutritionists;

2. Geneticists and genetic counselors;

3. Social workers;

4. Public health nurses;

5. Other physician specialties (medical, surgical, radiology, and pathology);

6. Pediatric subspecialists (infectious disease specialists, general surgeons, etc.); and

7. Lactation consultants.

8:33C–4.5 Description of services provided

(a) Each Regional Perinatal Center and Community Perinatal Center application shall describe how it will provide services based on its capabilities and the needs described in the regional perinatal plan, and shall demonstrate in the certificate of need application that the following services, and personnel, are in existence at the time of application for the certificate of need:

1. Community Perinatal Center–Birthing Center;

2. Community Perinatal Center–Basic;

3. Community Perinatal Center–Intermediate;

4. Community Perinatal Center–Intensive;

5. Regional Perinatal Center; and

6. Designated Specialty Acute Care Children's Hospitals.

8:33C–4.6 Basis for provision of services

The services which any Community Perinatal Center is authorized to perform shall be based on the expressed interest of the facility, the needs of its community, as described in the regional perinatal plan, the capabilities of its staff and the facility's physical resources. The approved tasks may range from those performed by a birthing center, which provides non-surgical maternity care for low risk women and normal newborns, to the tasks of a facility which provides a specified range of neonatal special care services, but does not have the broad range of high risk maternal care and regional service responsibilities of a Regional Perinatal Center.

8:33C–4.7 Management of at-risk patients

All Community Perinatal Centers shall describe, in writing, the method of management for patients assessed to be at risk during the prenatal period, which should include referral to a provider with advanced capabilities in maternal-fetal medicine for initial consultation. After the initial consultation, management of the patient should be provided in accordance with N.J.A.C. 8:33C–9.4(a). Letters of agreement between all facilities within a region shall be specific regarding the coordination of services, transports, and referrals.

SUBCHAPTER 5. BIRTHING CENTERS

8:33C–5.1 Definition; affiliation required; care to be provided

A Community Perinatal Center–Birthing Center applicant shall consist of any licensed facility which provides routine intrapartum care to less than 500 uncomplicated maternity patients per year. Routine, uncomplicated intrapartum care is defined as care not requiring surgical intervention. At a minimum, birthing centers shall demonstrate an affiliation with a Community Perinatal Center–Intermediate facility or higher capability for obstetric and pediatric support. Prenatal, postpartum and newborn care shall be provided in accordance with N.J.A.C. 8:33C–4.

8:33C–5.2 Personnel

(a) The Community Perinatal Center–Birthing Center shall demonstrate that it has professional staff able to provide routine services to patients delivering at the center. This professional staff shall include, at a minimum, 24 hour a day, seven day a week on-call coverage of the center's services by:

1. A certified nurse midwife, in accordance with standards of the Board of Medical Examiners, as set forth in N.J.A.C. 13:35–2.6 through 2.12, or a physician with obstetrical training and experience;

2. A board eligible or certified obstetrician for consultation who has admitting privileges at a Community Perinatal Center–Intermediate maternity service hospital;

3. A board eligible or certified pediatrician; and

4. A registered nurse.

8:33C–5.3 Services

(a) Proposed routine intrapartum services shall be limited to:

1. Use of local anesthetics;

2. Performance of an episiotomy and repair;

3. Repair of lower third vaginal lacerations only; and

4. Systemic analgesia.

(b) The Community Perinatal Center–Birthing Center shall be prohibited from:

1. General and conduction anesthesia;

2. Inhibiting, stimulating or augmenting labor with chemical agents; and

3. The use of obstetric forceps or other surgical intervention.

8:33C–5.4 High risk mothers and neonates

Criteria for transfer of mothers and infants shall be in accordance with the standards of the Board of Medical Examiners governing solo management by certified nurse midwives as set forth in N.J.A.C. 13:35–2.6 through 2.12.

SUBCHAPTER 6. COMMUNITY PERINATAL CENTER–BASIC

8:33C–6.1 Definition; care to be provided

The Community Perinatal Center–Basic facility applicants shall consist of licensed hospitals which provide services primarily for uncomplicated maternity and normal newborn patients. They are characterized by physically separated facilities for labor and delivery with Cesarean section capability within the perinatal suite. They must also provide supportive care for infants returned from Regional or Community Perinatal Center–Intensive care facilities. These facilities shall provide care to patients expected to deliver neonates greater than 2499 grams and 36 weeks gestation. Any facility with less than 800 deliveries per year can not apply for a level greater than Community Perinatal Center–Basic. Prenatal, postpartum and newborn care is to be provided in accordance with N.J.A.C. 8:33C–4 and N.J.A.C. 8:43G–19.

8:33C–6.2 High risk mothers and neonates

(a) Community Perinatal Center–Basic applicants shall assure that maternal-fetal transports be made as soon as possible to the facility with advanced capabilities in accordance with the regional perinatal plan and letters of agreement between facilities.

(b) Community Perinatal Center–Basic applicants shall assure that any high risk neonate delivered at the Community Perinatal Center–Basic shall be immediately transported, following stabilization, to the facility with advanced capabilities as specified in the terms of the regional perinatal plan and letters of agreement.

SUBCHAPTER 7. COMMUNITY PERINATAL CENTER–INTERMEDIATE

8:33C–7.1 Definition; care to be provided

The Community Perinatal Center–Intermediate facility applicants shall meet all the requirements of routine prenatal care, postpartum, newborn, and Community Perinatal Center–Basic, as specified in N.J.A.C. 8:33C–4 and 6 and N.J.A.C. 8:43G–19. In addition, it shall also provide assurance for care for some complicated maternity patients and neonates. These facilities shall provide care to patients expected to deliver neonates greater than 1499 grams and 32 weeks gestation.

8:33C–7.2 High risk mothers and neonates

(a) Community Perinatal Center–Intermediate applicants shall assure that maternal-fetal transports shall be made as soon as possible to the facility with advanced capabilities in accordance with the regional perinatal plan.

(b) Community Perinatal Center–Intermediate applicants shall assure that any high risk infant anticipated as requiring ventilatory support longer than 48 hours cumulatively or otherwise with needs exceeding the facility's capabilities as described in the letter of agreement shall be transported as soon as possible after delivery to the facility with advanced capabilities as specified in the terms of the regional perinatal plan and letters of agreement and in accordance with N.J.A.C. 8:43G–19.20.

Administrative Correction to (b).
See: 24 N.J.R. 3727(a).

SUBCHAPTER 8. COMMUNITY PERINATAL CENTER–INTENSIVE

8:33C–8.1 Definition; care to be provided

The Community Perinatal Center–Intensive facility applicants shall meet all of the requirements as specified in N.J.A.C. 8:33C–4, 6 and 7 and N.J.A.C. 8:43G–19. Additionally, it shall also provide assurance for care for complicated maternity patients and neonates in accordance with the scope of functions described in the regional perinatal plan. These facilities shall provide care to patients expected to deliver neonates greater than 999 grams and 28 weeks gestation.

8:33C–8.2 High risk mothers and neonates

(a) Community Perinatal Center–Intensive applicants shall assure that maternal-fetal transports, for patients exceeding its capability, will be made, as soon as possible, to the facility with advanced capabilities for care in accordance with the regional perinatal plan.

(b) Community Perinatal Center–Intensive applicants shall assure that any high risk infant delivered at the Community Perinatal Center–Intensive in need of specialized services or exceeding its capability must be transported to the facility with advanced capabilities as specified in the terms of the regional perinatal plan and letters of agreement.

(c) Community Perinatal Center–Intensive applicants shall assure that any high risk infant managed at the Community Perinatal Center–Intensive is followed in accordance with Department of Health, Special Child Health Services' standards for High Risk Infant Screening and Tracking or is referred to a Regional Perinatal Center for high risk infant screening and tracking services as specified in the letters of agreement.

SUBCHAPTER 9. REGIONAL PERINATAL CENTER

8:33C–9.1 Documentation of services

Regional Perinatal Center applicants shall document their ability to provide the full range of perinatal services defined for the Community Perinatal Center N.J.A.C. 8:33C–4, 6, 7 and 8 and N.J.A.C. 8:43G–19 as well as the tertiary services defined in N.J.A.C. 8:33C–9.2.

8:33C–9.2 Designation criteria

(a) The Regional Perinatal Center shall document that the following criteria were met for the most recent year or the average of the last three consecutive years of data available and which is consistently applied in all applications within a region in order to be designated a Regional Perinatal Center:

1. Annual acceptance of over 80 maternal referrals or transports; and

2. Provision of full neonatal management to over 40 very low birth weight infants annually.

8:33C–9.3 Personnel

(a) The Regional Perinatal Center shall demonstrate that it has a full complement of professional staff who are able to provide advanced clinical services to patients treated at the Regional Perinatal Center, and who also have sufficient time and interest to provide regional consultation and training to insure regional access to risk appropriate perinatal expertise and staff development. Staffing qualifications and availability shall comply with N.J.A.C. 8:43G–19.

(b) The Regional Perinatal Center shall document that it has routinely available consultation services from other professionals, including, but not limited to:

1. A geneticist and genetic counselor;

2. A registered dietician;

3. Public health nursing; and

4. Pediatric subspecialists (that is, infectious disease specialists) and pediatric general surgeons and surgical subspecialists.

(c) In the interest of continuity of care, Regional Perinatal Centers should give consideration to granting privileges to all practitioners providing obstetric care from community perinatal centers, if all hospital-specific criteria are met. These providers are encouraged to obtain a perinatal consult for their high risk patients managed at the Regional Perinatal Center.

(d) The Regional Perinatal Center shall document that all registered nurses have completed a continuing education course in maternal-fetal or neonatal nursing within one year of the application for the certificate of need.

8:33C–9.4 Services

(a) The Regional Perinatal Center shall document its ability to provide, on a continuous basis, care for high risk mothers who have a broad spectrum of conditions including preexisting maternal disorders such as significant heart, renal or metabolic diseases, chronic infectious diseases, substance abuse, as well as major complications of pregnancy. It must also document the ability to care for high risk newborns who may be very low birth weight in need of complex neonatal respiratory and metabolic support, or other infants in need of major or surgical intervention in accordance with N.J.A.C. 8:43G–19.

(b) The Regional Perinatal Center shall document its ability to provide the full range of prenatal, to include antenatal testing, postpartum and infant health services to families in the region. It shall have a distinct prenatal clinic service devoted to women identified as high risk. The perinatologist shall be responsible for the direction of care for the women in this service and available to provide consultation to the attending physicians.

(c) The Regional Perinatal Center shall agree to maintain, on a continuous basis, neonatal intensive care services, in order to assure the maintenance of appropriate skill levels and expertise of the staff.

8:33C–9.5 Consultation, referral, transport and follow-up

(a) The Regional Perinatal Center application shall document that the perinatologists at the Regional Perinatal Center shall be available on a 24 hour basis to provide consultation to the attending physicians at the Community Perinatal Centers. Consultation by the perinatologist may be provided by:

1. Provision of telephone consultation to the attending physician at the community based setting or Community Perinatal Center;

2. Co-management with the attending physician of the stabilized at risk patient at the community based setting or Community Perinatal Center. Ongoing consultation by the perinatologist shall be provided as needed for the duration of the patient's pregnancy; or

3. Total management of the high risk patient referred by the attending physician at the Community Perinatal Center to the perinatologist at the Regional Perinatal Center.

(b) The Regional Perinatal Center shall specify the conditions requiring maternal/fetal or neonatal transport.

(c) The Regional Perinatal Centers shall also document that they receive the majority of transports for the region.

(d) The Regional Perinatal Center shall provide documentation that high risk infant follow-up services are provided in accordance with the guidelines established by the Department of Health, Special Child Health Services.

SUBCHAPTER 10. SPECIALTY ACUTE CARE CHILDREN'S HOSPITALS

8:33C–10.1 Services required

(a) The designated Specialty Acute Care Children's Hospitals, as specified in N.J.S.A. 26:2H–18a, shall be recognized for the provision of highly specialized regional neonatal care. They must meet all of the criteria for the neonatal services of the Regional Perinatal Center in N.J.A.C. 8:33C–9 but are not required to provide obstetric services. This shall include 24 hour a day, seven day a week in-hospital coverage by a neonatologist.

(b) These services shall include the capability of performing sub-specialty surgical procedures. They shall document leadership in providing the latest technology in neonatal medicine and statewide consultation.

Administrative Correction.
See: 25 N.J.R. 580(a).

SUBCHAPTER 11. LETTERS OF AGREEMENT

8:33C–11.1 Referrals and transports

(a) The letters of agreement between facilities shall specify that any patient requiring specialized perinatal care shall be referred to a provider with privileges at a Community Perinatal Center–Intensive or Regional Perinatal Center as specified in the letter of agreement and regional perinatal plan in accordance with N.J.A.C. 8:43G–19.

(b) Maternal-fetal and neonatal transports shall be provided by the Community Perinatal Center only if these services are approved activities delineated in the letter of agreement with the Regional Perinatal Center in accordance with N.J.A.C. 8:43G–19.

SUBCHAPTER 12. REVIEW CRITERIA

8:33C–12.1 Application review; general

Perinatal designations and certificate of need will be granted to Regional Maternal and Child Health Consortia for all facilities within their maternal and child health service region. Applications from the Regional Maternal and Child Health Consortia must contain all the individual facility applications for perinatal services with their letters of agreement and be submitted as one package with the regional perinatal plan. Applications shall be reviewed by Local Advisory Boards and the Department of Health for compliance with the State Health Plan and in accordance with the certificate of need process.

8:33C–12.2 Maternal and Child Health Consortia application review criteria

(a) Applications for Regional Maternal and Child Health Consortia shall be reviewed on the basis of the following criteria:

1. Full compliance with all standards and guidelines in this chapter;

2. The appropriate plan for region wide access to preconceptional, prenatal, intrapartum, postpartum, family planning and pediatric services by all women and infants in the region including the medically indigent and those covered by Medicaid;

3. Development of the most cost effective linkages with existing providers of prenatal care; and

4. Content of plans to overcome existing gaps in and barriers to care.

8:33C–12.3 Regional and Community Perinatal Centers application review criteria

(a) Applications for Regional and Community Perinatal Centers will be reviewed for the following:

1. Community need for the services being proposed as stated in the regional plan;

2. Documentation that all facilities are in compliance with these rules;

3. The demonstration of effective linkages with other components in the proposed regional system of care; and

4. Documentation of the need for advanced maternal and newborn care in the region.

8:33C–12.4 Change in designation

Applications for a change in designation shall be considered a significant change in scope and shall follow the full certificate of need review process through the Regional Maternal and Child Health Consortia.

8:33C–12.5 Change in number of bassinets; renovation; construction

Applications submitted for a change in the number of bassinets, or renovation, or construction must be submitted separately, adhere to the certificate of need rules for such projects and initially be endorsed by the Regional Maternal and Child Health Consortia for comment and approval.

SUBCHAPTER 13. ENFORCEMENT AND SANCTIONS

8:33C–13.1 Participation

Facilities providing obstetric inpatient hospital services shall participate in a Regional Maternal and Child Health Consortia. Failure to participate shall be deemed as not providing an appropriate array of services and continuity of care. Such failure to participate may be cause for having obstetrical services excluded from the hospital reimbursement rates.

8:33C–13.2 Shift or change of participation

The shift of a facility participating in one Regional Maternal and Child Health Consortium to another shall occur without break in time and only on the express approval of the Department of Health once the facility had gone through the conflict resolution process as specified in N.J.A.C. 8:33C–2.12.

8:33C–13.3 Monitoring

The Department shall monitor compliance with the terms and conditions of approved applications for Regional Maternal and Child Health Consortia, Regional Perinatal Centers and Community Perinatal Centers. The Department will determine if operations of the Regional Maternal and Child Health Consortium or any of its component agencies materially complies with the presentations made in the Regional Maternal and Child Health Consortium's application for its certificate of need and all conditions assigned to its certificate of need approval.

8:33C–13.4 Reimbursement

Only those Regional Material and Child Health Consortia that have been approved through the certificate of need process shall have the Regional Maternal and Child Health Consortia's and their constituent hospitals' expenditures included either in the hospital reimbursement rates or an alternate funding mechanism.

8:33C–13.5 Penalties

Failure to document compliance with the certificate of need application and all conditions assigned them shall result in licensing sanctions and the disallowance of reimbursement for non-conforming practices.