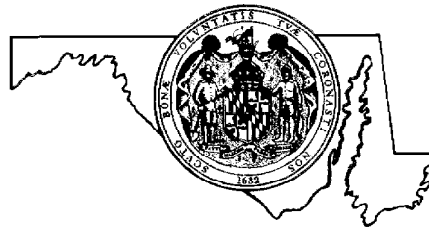


Marilyn Moon, Ph.D.
CHAIR

STATE OF MARYLAND



Rex W. Cowdry, M.D.
EXECUTIVE DIRECTOR

MARYLAND HEALTH CARE COMMISSION

4160 PATTERSON AVENUE – BALTIMORE, MARYLAND 21215
TELEPHONE: 410-764-3460 FAX: 410-358-1236

**STATE HEALTH PLAN FOR FACILITIES AND SERVICES:
SPECIALIZED HEALTH CARE SERVICES -
NEONATAL INTENSIVE CARE SERVICES**

COMAR 10.24.18

Effective February 9, 1998

Supplement 1 Effective December 14, 1998

Supplement 2 Effective October 23, 2006

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**State Health Plan for Facilities and Services: Specialized Health Care Services –
Neonatal Intensive Care Services**

.01 Incorporation by Reference. This Chapter is incorporated by reference in the Code of Maryland Regulations.

.02 Introduction.

A. Purposes of the State Health Plan.

The Maryland Health Care Commission has prepared this Chapter of the State Health Plan for Facilities and Services (State Health Plan) in order to further the mission of health planning, which is to plan to meet the current and future health care system needs of all Maryland residents by assuring access, quality, and cost-efficiency. The Commission views the State Health Plan, of which this Chapter is a part, as a policy blueprint for shaping and reshaping the health care system toward these ends, through the action of public agencies and the cooperation of private actors. Through the State Health Plan, the Commission undertakes an active role in proposing needed changes in the system, including the reallocation of resources to achieve a health care system that is cost-effective, and that balances considerations of affordability, access, and quality. In every aspect of the Plan, and in its individual Certificate of Need decisions, the Commission carefully weighs issues of access to specialized health care services with considerations of quality and cost.

The State Health Plan serves two purposes:

(1) It establishes health care policy to guide the Commission's actions and those of other health-related public agencies, and to foster specific actions in the private sector. Activities of State agencies must, by law, be consistent with the Plan.

(2) It is the legal foundation for the Commission's decisions in its regulatory programs. These programs ensure that appropriate changes in service capacity are encouraged, and that all major expenditures for health care facilities are needed and consistent with the Commission's policies. The State Health Plan therefore contains policies, standards, and service-specific need projection methodologies that

the Commission uses in making Certificate of Need decisions.

B. Legal Authority of the State Health Plan.

The Maryland Health Care Commission is given legal authority under Health-General Article § 19-118, Annotated Code of Maryland,¹ to develop and adopt the State Health Plan. Subsection 19-118 (a) (2) states that the State Health Plan shall include:

- (i) The methodologies, standards, and criteria for certificate of need review; and
- (ii) Priority for conversion of acute capacity to alternative uses where appropriate.²

C. Organizational Setting of the Commission.

The Commission is an independent agency located within the Department of Health and Mental Hygiene for budgetary purposes. The purpose of the Commission, as provided under § 19-103 (c), is to:

(1) Develop health care cost containment strategies to help provide access to appropriate quality health care services for all Marylanders, after consulting with the Health Services Cost Review Commission;

(2) Promote the development of a health regulatory system that provides, for all Marylanders, financial and geographic access to quality health care services at a reasonable cost by advocating policies and systems to promote the efficient delivery of and improved access to health care services, and enhancing the strengths of the current health care service delivery and regulatory system;

(3) Facilitate the public disclosure of medical claims data for the development of public policy;

(4) Establish and develop a medical care data base on health care services rendered by health care practitioners;

¹ Unless otherwise noted, statutory references are to the Health General Article.

² Pursuant to a 2001 statutory revision, the State Health Plan is no longer required to include “identification of unmet needs, excess services, minimum access criteria, and services to be regionalized.” This responsibility and three others, previously found at Health General §§19-121(a)(2)(i)-(iv), were transferred to the Secretary of the Department of Health and Mental Hygiene, to be contained in a State Health Improvement Plan adopted by the Secretary.

(5) Encourage the development of clinical resource management systems to permit the comparison of costs between various treatment settings and the availability of information to consumers, providers, and purchasers of health care services;

(6) In accordance with Title 15, Subtitle 12 of the Insurance Article, develop a uniform set of effective benefits to be included in the Comprehensive Standard Health Benefit Plan, and a uniform set of effective benefits to be included in the Limited Health Benefit Plan;

(7) Analyze the medical care data base and provide, in aggregate form, an annual report on the variations in costs associated with health care practitioners;

(8) Ensure utilization of the medical care data base as a primary means to compile data and information and annually report on trends and variances regarding fees for service, cost of care, regional and national comparisons, and indications of malpractice situations;

(9) Establish standards for the operation and licensing of medical care electronic claims clearinghouses in Maryland;

(10) Reduce the costs of claims submission and the administration of claims for health care practitioners and payors;

(11) Determine the cost of mandated health insurance services in the State in accordance with Title 15, Subtitle 15 of the Insurance Article;

(12) Promote the availability of information to consumers on charges by practitioners and reimbursements from payors; and

(13) Oversee and administer the Maryland Trauma Physician Services Fund in conjunction with the Health Services Cost Review Commission.

The Commission has sole authority to prepare and adopt the State Health Plan and to issue Certificate of Need decisions and exemptions therefrom.

Subsection 19-118 (e) requires the Secretary of Health and Mental Hygiene to make annual

recommendations to the Commission on the State Health Plan and permits the Secretary to review and comment on the specifications used in its development. However, § 19-110 (a) prohibits the Secretary from disapproving or modifying any determinations the Commission makes regarding the State Health Plan. The Commission pursues effective coordination with the Secretary and State health-related agencies in the course of developing its plans and plan amendments. As required by statute, it functions in coordination with the hospital rate-setting program of the Health Services Cost Review Commission (HSCRC) to assure access to care at reasonable costs. The Commission also coordinates its activities with the Maryland Insurance Administration (MIA).

Subsection 19-117 (c) empowers the Governor to notify the Commission of any intent to modify or revise the State Health Plan, or changes in the Plan, within 45 days of its receipt. Otherwise, the plan becomes effective.

D. Plan Content.

The *State Health Plan for Facilities and Services: Specialized Health Care Services – Neonatal Intensive Care Services* comprises one component of the overall State Health Plan for Maryland. The Commission uses the State Health Plan to identify services to be regionalized. The concept of health care regionalization refers to the appropriate distribution of services with regard to their geographic location and level of care. It implies an organized and integrated hierarchy of services with levels of care that are coordinated and mutually supportive. Within the health care delivery system, the population is directed to appropriately staffed and equipped services based on the nature and severity of illness.

At the regional base is primary care, consisting of the diagnostic and therapeutic services most frequently used for common or relatively simple health problems. Primary care addresses most of the community health care needs of a population. In addition to including measures aimed at promoting and maintaining health and preventing disease, it places a strong emphasis on detecting disease in its early stage. More complex problems are generally directed to the intermediate level of secondary care, which

provides the greater range of diagnostic and therapeutic services needed for an acute stage of illness. The most complex health problems are directed to tertiary care, the most technologically sophisticated component of the health care delivery system. Tertiary care interventions tend to occur late in the disease process. They are provided to segments of the population that are the most severely ill and at the highest risk for poor outcomes; by necessity, the diagnostic and therapeutic services are more advanced; and the cost of staffing and equipping these specialized health care services is very high.

Under § 19-120 (j) (2) (iii) (2) of the Health-General Article, Annotated Code of Maryland, and COMAR 10.24.01.02A (4) (b), a Certificate of Need is required for the establishment of an open heart surgery, organ transplant surgery, or burn or neonatal intensive health care service. In current chapters of the State Health Plan, the Commission defines tertiary care as a highly specialized regional acute care program requiring the use of technologically-advanced skills or equipment, or both, including but not limited to the following categories of health care services: organ transplant surgery; open heart surgery; burn care; neonatal intensive care; and shock-trauma. The term "specialized health care services" also encompasses these services by way of illustration, not limitation.

E. Applicability. This Chapter of the State Health Plan is applicable to all matters regarding neonatal intensive health care services, including the establishment of a new neonatal intensive care unit (NICU) and expansion of an existing service to provide comprehensive subspecialty neonatal care, which is the highest, most advanced level of service.

.03 Principles for Planning Specialized Health Care Services.

A. Introduction.

The rationale for identifying a set of principles for specialized health care services is to serve as a guide in developing strategies to achieve the Commission's mission. The principles build on that basic framework and relate to what the Commission considers to be its most important objectives. The principles encourage a consistent approach to planning the development of specialized health care services

and contribute to setting priorities for the allocation of health care resources in general.

In Maryland, increased competition for patients with health insurance, development of networks of health care providers, subspecialization among health care professionals, and diffusion of technology have resulted in an escalation in the level of care provided by some health care facilities, which may conflict with public policy concerning regionalization of health care services. All of the principles discussed below recognize that the resources for providing health care are limited, and they promote using those resources in ways that have the greatest potential of improving the health status of Marylanders while containing total system costs. The key values represented by the principles emphasize matching the major health problems of the population to effective interventions; integrating levels of care within the regional delivery system; balancing optimal health outcomes and cost-efficiency; and achieving equity in terms of reasonable access to services and assurance of quality.

B. Statement of Principles.

- (1) Determination of the level, type, and number of health care resources that are needed should consider (a) the principal health status indicators, and (b) the relative cost and effectiveness of alternatives that significantly reduce disparities among groups and improve the health of the total population.**

The status of a population's health may be measured in a variety of ways, including the prevalence of risk factors, use of preventive services, and rates of disease, injury, or death. The State has declared its commitment to the following major action areas as part of Healthy Maryland Project 2010: improving the statewide public health infrastructure; garnering support to the Maryland business and faith communities; narrowing the gap between public health theory and public health practice; addressing gender, age, cultural, racial, and geographic health disparities; updating Healthy Maryland and other related health status indicators; improving health status measurement capability; improving the quality of local level health data; promoting collaboration among all health promotion advocates; and, broadening participation

from all Maryland communities in Project 2010.³ Through the Department of Health and Mental Hygiene, the State has begun to monitor selected indicators of the health of its population using the national health objectives.⁴ An objective of *Healthy People 2010* is to increase the proportion of very low birth weight (VLBW) infants born at Level III hospitals or subspecialty perinatal centers (facilities for high-risk deliveries and neonates).⁵

The Commission will use its statutory authority to help realize those objectives. In its development of the State Health Plan and evaluation of Certificate of Need applications or requests for exemptions, the Commission will examine and take appropriate administrative notice of documents with objective assessments of major health problems throughout the state and within each region to identify related health resource needs of the highest priority. For indicators associated with specialized health care services, the alternative interventions that are considered may be closely related or widely ranging.

Further, the Commission will help monitor health status using the data that it collects. The Commission recognizes that, in the short term, the availability of data will be the principal determinant of which population-based measures of health status it uses. Over the longer term, the Commission will review the adequacy of the data it uses, identify any additional data required to assess and monitor the health of the population, and participate in the efforts of private and other public health organizations at the local, state, or national level to strengthen existing data collection.

(2) Specialized health care services should be assessed as part of the overall health care delivery system.

Linkages among the levels of care are essential to coordinate transitions between them, minimize the fragmentation of services, and reduce disruptions in continuity. To avoid viewing specialized health care services in isolation, the Commission will place a high priority on systematic integration and look at

³ Maryland Department of Health and Mental Hygiene, *Health Improvement Plan: Public Health Action for the First Decade, 2000-2010, Executive Summary*. Community and Public Health Administration, Office of Health Policy. June 2001, page 8.

⁴ Maryland Department of Health and Mental Hygiene, *Healthy Maryland Chart Book 2002*, Healthy Maryland Project 2010, Community Health Administration, Office of Local Health, November 2002.

⁵ U.S. Department of Health and Human Services, Office of Disease Prevention and Health Promotion, *Healthy People 2010: Volume II*,

the interaction of the specialized services with other components of the health care delivery system within the region. The Commission will pay particular attention to analyses of related preventive services and will work with the Department of Health and Mental Hygiene, other public agencies, and private organizations to identify existing resources and improve the population's access to preventive services in areas where there are shortages.

(3) Any expansion of the number or distribution of specialized health care services should allow the proposed and existing services within the region to achieve and sustain the volumes associated with optimal health outcomes and cost-efficiency.

Specialized health care services require a larger geographic and more substantial population base than other services, to maintain professional skills and control costs. In developing the State Health Plan, the Commission will consider and incorporate objective evidence of adequate volumes for specific categories of specialized health care services. It will measure the performance of the health care system by determining whether existing services are adequately utilized. During reviews of Certificate of Need applications, the Commission will continue to consider the potential adverse effect on quality of care that a project may have by causing a reduction of volume when the volume of services is linked to maintaining the quality of care. Additionally, the Commission will recognize relevant standards related to outcomes or efficiency that are enforced by the Maryland Institute for Emergency Medical Services Systems, State licensing or rate-setting authorities, national accrediting organizations as required by State law, or appropriate professional organizations.

(4) Equity of access to specialized health care services of sufficient quality and at reasonable rates should be assured.

A portion of the State's population achieves reasonable geographic access to specialized health care services by using out-of-state services; their continued use of out-of-state services is not precluded by any of the above principles. The assurance of equity in financial access to specialized health care services

in Maryland is shared by several regulatory agencies, including the Health Services Cost Review Commission, whose rate-setting policies provide financial access to necessary hospital services for all Marylanders, regardless of health insurance status, and address the equitable funding of uncompensated care in the State. In addition to requiring demonstration of ongoing compliance with all federal, State, and local health and safety regulations, the Commission may incorporate in the State Health Plan appropriate information from expert guidelines to ensure that all Marylanders receive specialized health care services that meet the requirements of such guidelines. In view of the differences between Maryland's regulatory environment and that of contiguous states, the Commission will include as part of any formal arrangements with out-of-state providers of specialized health care services a requirement to show evidence of compliance with applicable standards and data reporting regulations to the extent permitted by its authority. The Commission recommends that other State agencies include similar provisions in their formal agreements with out-of-state providers.

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.04 Neonatal Intensive Care Services.**A. Introduction.**

This component of the State Health Plan for Facilities and Services: Specialized Health Care Services focuses on neonatal intensive care services, which are defined as Levels IIIA, IIIB, and IIIC, using the most recent version of the Maryland Perinatal System Standards. Those standards define the requirements for personnel, equipment, and support services for the three levels of neonatal intensive care services. The level of obstetric service must be the same.

(1) Risk Factors and Mortality.

Low birth weight (less than 2,500 grams) is associated with an increased risk of infant mortality. The National Center for Health Statistics has noted that timely, adequate prenatal care may lower the medical complications associated with low birth weight.

The Maryland Department of Health and Mental Hygiene has identified smoking and drug use during pregnancy as significant preventable risk factors affecting low birth weight and prematurity. With regard to demographic factors, babies born to adolescents (younger than the age of 18 years), who are more likely to have late entry into prenatal care, are also at greater risk for prematurity, low birth weight, and infant mortality.

Advanced maternal age has also been identified as a factor for increased neonatal risks. Babies born in multiple deliveries are at greater risk of low birth weight and early death. The National Center for Health Statistics has reported that most of the increase in multiple births, especially triplet and greater, among white women has been related to the increasing use of fertility-enhancing techniques.

In addition to maternal age, other demographic factors related to the risk of a low-birth-weight delivery include socioeconomic status and race. The National Center for Health Statistics has found that higher educational attainment is associated with more timely prenatal care and fewer behaviors during pregnancy that are harmful to a good outcome for the infant.

(2) Regional Service Areas for Neonatal Intensive Care Services.

The four regional service areas designated for the planning of neonatal intensive care services are listed below.

Western Region: Garrett, Allegany, Washington, and Frederick Counties.

Central Region: Baltimore City and Baltimore, Anne Arundel, Carroll, Howard, and Harford Counties.

Southern Region: Montgomery, Prince George's, Calvert, Charles, and St. Mary's Counties.

Eastern Region: Cecil, Kent, Queen Anne's, Caroline, Talbot, Dorchester, Wicomico, Somerset, and Worcester Counties.

Federal law requires hospitals to provide, for women who come to the hospital in labor, necessary stabilizing treatment within the staff and facilities available if the hospital determines that the woman has an emergency medical condition. Included are the following: (1) circumstances in which the absence of immediate medical attention could reasonably be expected to result in placing the health of the woman or unborn child in serious jeopardy; and (2) with regard to a pregnant woman who is having contractions, circumstances in which there is inadequate time to effect a safe transfer to another hospital before delivery, or in which transfer may pose a threat to the health or safety of the woman or unborn child. Federal requirements restrict transfers to another medical facility until the individual's condition has been stabilized. The law also includes a requirement that a hospital that has entered into a provider agreement with the federal Department of Health and Human Services and has specialized capabilities or facilities (such as burn units, shock-trauma units, or neonatal intensive care units) shall not refuse to accept an appropriate transfer of an individual who requires such specialized capabilities or facilities if the hospital has the capacity to treat the individual. Capacity includes numbers and availability of qualified staff as well as beds and equipment.

In Maryland, all hospitals with perinatal services are expected to have written standards, protocols, or guidelines concerning the provision of uncomplicated and complicated obstetrical and neonatal care, including those for the following: (1) unexpected obstetrical care problems; (2) fetal monitoring; (3)

initiating a cesarean delivery within 30 minutes of the decision to deliver; and (4) resuscitation and stabilization of unexpected neonatal problems according to Neonatal Resuscitation Program (NRP) guidelines. According to the Maryland Institute for Emergency Medical Services Systems (MIEMSS), the capabilities exist to transport newborns from their hospital of birth to a hospital that has a neonatal intensive care unit within a reasonable response time.

The supply and distribution of specialized health professionals is an essential component of access to neonatal intensive care services. The American Board of Pediatrics designated neonatal-perinatal medicine as a certified subspecialty of pediatrics. In describing the program requirements for residency education in neonatal-perinatal medicine, the Accreditation Council for Graduate Medical Education indicated that, for a resident to acquire competency in managing the critically ill infant and in the technical aspects of care, an adequate number of infants with a variety of neonatal disorders must be available. Mentioned specifically was the availability of a sufficient number of infants requiring ventilatory assistance and those requiring major surgery.

A hospital may use its NICU bed capacity to provide intensive and intermediate, or step-down, care. Even if a hospital has a separate area designated for such transitional care, it may determine that it is more efficient to consolidate the two groups of patients in the NICU for staffing reasons.

B. Issues and Policies.

(1) Relationship Between Volume and Outcome.

The Technical Advisory Committee on Neonatal Intensive Care Services, appointed by a predecessor agency of the Commission, found that, for neonatal intensive care units, it is not entirely clear to what extent volumes play a role in outcomes. There are few volume-outcome studies specific to NICUs in the literature, and the results are conflicting. A number of articles refer to volume but do not study it per se. The literature focuses more on regionalization of neonatal or perinatal care in relationship to outcome than on volumes and outcomes.

Using birth certificate data linked to infant death certificates and discharge abstracts, a study of

single births in California hospitals during 1990 found that risk-adjusted neonatal mortality was lower for births in hospitals with level III NICUs that had an average daily census (ADC) of at least 15 patients than in centers with lower volumes. This population-based study examined the effect of NICU volume at the hospital of birth, included high-risk births of all weights, and measured death within the first 28 days of life, or within the first year of life, if the infant was continuously hospitalized.⁶ Using 1992 and 1993 data, researchers found a similar volume threshold. The more recent study evaluated the effect of NICU patient volume at the hospital of birth on neonatal mortality of infants with a birth weight of less than 2,000 grams (single births with a weight between 500 and 1,999 grams). Risk-adjusted mortality at large (ADC \geq 15) community NICUs was not statistically different compared with regional NICUs. The researchers recommended additional study of differences within this range of birth weights (for example, among the smallest infants). A community NICU provided long-term ventilator support but not all other specialized services; a regional NICU provided a full range of intensive care, including pediatric subspecialty consultants and surgery. All of the regional NICUs had an ADC \geq 15; few community NICUs (26%) had an average census of 15 or more patients.⁷

A study of NICUs participating in the Vermont Oxford Network during 1991 and/or 1992 found no association between the annual volume of very low birth weight (VLBW) infants and the risk-adjusted mortality rates among those NICUs. The study measured mortality within 28 days of birth. The database included data for infants born at the participating institutions (inborn) as well as infants born elsewhere and transferred/admitted within 28 days of birth (outborn). Infants were followed until discharge from the hospital, including those who were transferred to other hospitals. The researchers defined small NICUs as those having fewer than 47 annual admissions of VLBW infants (from 501 to 1,500 grams); most of the NICUs in this voluntary research network had annual admissions of 47 or more. The sample included

⁶ CS Phibbs, JM Bronstein, E Buxton, RH Phibbs, The Effects of Patient Volume and Level of Care at the Hospital of Birth on Neonatal Mortality, *JAMA* 276 (October 2, 1996):1054-1059.

⁷ J Cifuentes, J Bronstein, CS Phibbs, et al., Mortality in Low Birth Weight Infants According to Level of Neonatal Care at Hospital of Birth, *Pediatrics* 109 (May 2002):745-751.

relatively few very small and very large NICUs.⁸ A study of NICUs in the United Kingdom also found that risk-adjusted mortality was not associated with patient volume. The researchers defined high-volume NICUs as those admitting more than 57 VLBW infants per year; most of the NICUs (78%) had annual admissions of 57 or fewer VLBW infants. The study included infants younger than one month of age who were admitted between March 1998 and April 1999. In-hospital mortality was among the outcomes studied, and the analyses of outcomes included information from other hospitals after transfers of infants. Findings suggested that high-volume NICUs treated the sickest infants, and units caring for sicker infants could make more efficient use of resources than units treating infants who were less sick.⁹

Using the database of the Vermont Oxford Network, a recent study of infants born in network hospitals between 1995 and 2000 found that higher volume significantly reduced mortality. All infants were born in a hospital with a NICU. The study included multiple births; it excluded outborn infants and infants who weighed 500 grams or less at birth. The researchers estimated that in hospitals with fewer than 50 annual admissions of VLBW infants, an additional 10 admissions were associated with an 11% reduction in risk-adjusted mortality. Analyses showed that the annual volume of admissions explained 9% of the variation in in-hospital mortality rates across participating hospitals. The average number of VLBW admissions was 80 per year. Data on average daily census were not readily available.¹⁰

In its Policy Statement on Levels of Neonatal Care, the Committee on Fetus and Newborn of the American Academy of Pediatrics notes that the association of NICU volume and neonatal mortality has not been consistent in this limited literature; however, the volume-outcome relationship tends to be true on average.¹¹

To maintain the competency that neonatologists, nurses, and ancillary-care professionals must

⁸ JD Horbar, GJ Badger, EM Lewit, et al., Hospital and Patient Characteristics Associated With Variation in 28-Day Mortality Rates for Very Low Birth Weight Infants, *Pediatrics* 99 (February 1997):149-156.

⁹ UK Neonatal Staffing Study Group, Patient volume, staffing, and workload in relation to risk-adjusted outcomes in a random stratified sample of UK neonatal intensive care units: a prospective evaluation, *Lancet* 359 (January 12, 2002):99-107.

¹⁰ JA Rogowski, JD Horbar, DO Staiger, et al., Indirect vs Direct Hospital Quality Indicators for Very Low-Birth-Weight Infants, *JAMA* 291 (January 14, 2004):202-209.

¹¹ Committee on Fetus and Newborn, Levels of Neonatal Care, *Pediatrics* 114 (November 2004):1343.

acquire in caring for critically ill infants with a variety of neonatal disorders, the Technical Advisory Committee recommended that there should be a minimum of six to eight patients requiring critical care per day in any neonatal intensive care unit. The Technical Advisory Committee recommended a minimum volume to promote good patient outcomes and more efficient use of neonatal intensive care units. The Technical Advisory Committee also identified the following categories for use as general guidelines for defining NICU babies that require critical care: (1) weight < 1,000 grams; (2) ventilator or nasal continuous positive airway pressure (CPAP); (3) > 40% FiO₂ required to maintain O₂ saturation > 90%; (4) arterial or central venous catheters required; (5) hyperalimentation provides majority of nutritional needs; (6) chest tube(s); (7) major surgical problem; (8) major cardiac problem; (9) pressors required; (10) exchange transfusion required within past 24 hours; and (11) acute deterioration; necrotizing enterocolitis (NEC); septic.

The Perinatal Clinical Advisory Committee, appointed by the Secretary of Health and Mental Hygiene, has recommended specific standards identifying six levels of hospitals with perinatal programs. The Maryland Perinatal System Standards were originally developed in 1995 as a set of voluntary standards. The committee reviews and updates the standards periodically. The Maryland Institute for Emergency Medical Services Systems adopted the Maryland Perinatal System Standards as regulations to designate perinatal referral centers in Maryland and certain perinatal or neonatal referral centers in other states. A licensed neonatal commercial ambulance service may not transport a neonate from one hospital to another hospital for a higher level of care unless the admitting hospital is a perinatal referral center or neonatal referral center. Perinatal referral centers must meet the Level IIIA, IIIB, or IIIC standards. The Institute has established a process of verification to determine that a hospital is in substantial compliance with the standards.

Maryland law authorizes the Health Services Cost Review Commission to set the rates of certain hospital services, and requires the HSCRC to assure each purchaser of the services that the total costs of all services are reasonable, the aggregate rates are related reasonably to the aggregate costs, and rates are set

equitably among all purchasers. In adopting the law, the State intended to maintain the solvency of hospitals that were effective and efficient by providing for the HSCRC's use of standards to determine if a hospital is effectively and efficiently operated and utilized, and alternate rate-setting methods to promote the most effective and efficient use of services.

To promote improved neonatal outcomes and efficient use of neonatal intensive care units, the Commission establishes the following policies:

Policy 1.0 Each hospital providing neonatal intensive care services in Maryland should comply with the essential requirements for its level of perinatal center, as defined in the Maryland Perinatal System Standards.

Policy 1.1 For a Level IIIA, IIIB, or IIIC hospital, the Maryland Institute for Emergency Medical Services Systems should conduct an on-site review of the hospital to verify initially and reverify periodically its compliance with the perinatal standards.

Policy 1.2 Each Level IIIA, IIIB, and IIIC hospital should achieve and maintain designation as a perinatal referral center.

Policy 1.3 A hospital that applies for a Certificate of Need to provide subspecialty or comprehensive subspecialty neonatal care services should be required to enter into an agreement with the HSCRC outlining how the neonatal intensive care cases will be incorporated into the hospital's Charge per Case (CPC) or Total Patient Revenue agreement with HSCRC.

(2) Reasonable Geographic Accessibility to Neonatal Intensive Care Services.

The Technical Advisory Committee recommended that the basic level of perinatal services capable of handling high-risk deliveries, if they happen to occur, should be accessible within one half-hour in Maryland; and high-risk neonatal services should be accessible for family visiting within a travel time of two to three hours. An examination of geographic access to neonatal intensive care services in 1997

showed that portions of the Western and Eastern regions were more than two hours from a neonatal intensive care unit. The Technical Advisory Committee also recommended that, in areas where there may not be enough infants who require high-risk neonatal services to support the establishment of a neonatal intensive care unit, there should be reasonable access to Level II facilities. The perinatal standards are intended to promote the return transport of stabilized maternal and neonatal patients to the referring hospital or to a hospital in greater proximity to the patient's home. All levels of perinatal centers are required to have written guidelines for accepting or transferring mothers or neonates as "back transports," including criteria for accepting the patient and patient information on required care. With regard to back transports, referring Level II hospitals can take babies back from tertiary facilities much sooner than Level I hospitals.

As a related matter, the Technical Advisory Committee observed that the establishment of an excess number of NICU beds may lead to the closure of some units over time. Under those circumstances, the assurance of reasonable geographic access by low-income and uninsured persons becomes especially important. While a travel time of two hours is generally recommended for specialized, high-risk neonatal services, a shorter travel time should be considered for indigent families where available data indicate that such adjustments are appropriate. The Commission establishes the following policies related to geographic accessibility:

Policy 2.0 **A hospital providing perinatal services in Maryland should work with community representatives, other providers, third-party payers, and public agencies to assure reasonable geographic access to integrated, risk-appropriate perinatal services by low-income and uninsured residents of Maryland.**

Policy 2.1 **Hospitals providing perinatal services, including facilities that are part of merged or consolidated hospital systems, should have the necessary referral arrangements to assure that all perinatal patients receive the appropriate**

level of care within reasonable geographic accessibility.

Policy 2.2 The Maryland Insurance Administration should assure that health plans offered by carriers operating in Maryland provide reasonable geographic accessibility to risk-appropriate perinatal services for their members who require such services.

(3) Inter-State Cooperation in Health Data Collection.

Birth certificate data provided through the Vital Statistics Cooperative Program, periodic surveys to collect data on the use of out-of-state hospitals, and available information concerning hospital networks, alliances, and systems show that the referral areas for hospital services cross state boundaries. In considering the patterns of patient migration for perinatal services, the Maryland Institute for Emergency Medical Services Systems has letters of agreement with two out-of-state referral centers, the Children's National Medical Center in Washington, D.C., and the West Virginia University Hospital in Morgantown, West Virginia. The Technical Advisory Committee recommended that the Commission study and consider the issue of improved data collection with the assistance of the Committee on Fetus and Newborn, Department of Health and Mental Hygiene, Health Services Cost Review Commission, Maryland Institute for Emergency Medical Services Systems, Association of Maryland Hospitals and Health Systems, third-party payers, and other interested organizations and parties, including out-of-state providers.

The Technical Advisory Committee recommended that adjustments for severity of illness should be made when comparing clinical outcomes and costs among NICUs. In Maryland, birth weight is the primary way of differentiating between neonatal cases with respect to severity of illness and intensity of resource use. It is used in the adjustments of inpatient charges per admission performed by the Health Services Cost Review Commission, and in the adjustments of neonatal mortality rates calculated by the Vital Statistics Administration in the Department of Health and Mental Hygiene. HSCRC now uses all patient-refined (APR) diagnosis-related groups (DRGs) to determine the case mix of a hospital. APR-DRGs include substantial refinements in severity and neonatal categories. To promote the improved

collection and exchange of data, the Commission establishes the following policy:

Policy 3.0 **The Commission will work with appropriate health planning and data collection agencies located in adjacent states to facilitate the collection and sharing of data on the use of perinatal services.**

C. Commission Program Policies.

(1) Approval Policies.

(a) Compliance with the Maryland Perinatal System Standards. The Commission will approve a proposed new neonatal intensive care unit only if an applicant demonstrates compliance with the Level IIIA, IIIB, or IIIC perinatal system standards.

(b) Minimum Volume Standard. The Commission will approve a new neonatal intensive care unit only if an applicant demonstrates that the unit can sustain an average daily census of at least six critically ill patients. An applicant may show evidence as to why this rule should not apply to the applicant.

(c) Cost Efficiency. A hospital that applies for a Certificate of Need to provide subspecialty or comprehensive subspecialty neonatal care services will be required to enter into an agreement with the HSCRC outlining how the neonatal intensive care cases will be incorporated into the hospital's Charge per Case (CPC) or Total Patient Revenue agreement with HSCRC.

(d) Service to Minority and Indigent Populations. In the case of a comparative review of applications in which all applicants have met all policies and standards, the Commission will give preference to the applicant with an established program to prevent low birth weight and infant mortality with particular outreach to minority and indigent patients in the hospital's regional service area.

In evaluating the effectiveness of the program, the Commission will take into consideration:

(i) The applicant's demonstrated record of serving minority and indigent perinatal patients;

(ii) The applicant's demonstrated record of establishing programs for

outreach to the minority and indigent populations of childbearing age;

(iii) The applicant's evaluation of the effectiveness and efficiency of the intervention program with respect to improved perinatal outcomes or improved perinatal health status of the population served; and

(iv) Evaluation of the effectiveness and efficiency of the applicant's intervention program by a person or persons other than the applicant.

(2) Exemptions from Policies. For any research proposal, regardless of whether or not the proposal is part of a Certificate of Need application, the Commission may waive any of the policies in Regulations .04B or .04C of this Chapter, for a limited time, to be specified by the Commission, and only if the applicant for exemption can demonstrate that a waiver meets the following conditions:

(a) The exemption is necessary to meet the special needs and circumstances of biomedical research projects which are designed to meet a national need, and for which local conditions offer special advantages;

(b) Prior to initiation of the trial, the research project shall be:

(i) Reviewed by each participating institution's Institutional Review Board (IRB), or an equivalent institutional body such as an ethics committee, consistent with the U.S. Department of Health and Human Services' guidelines on the protection of human subjects, 45 CFR 46; and

(ii) If a participating institution does not have an IRB, the proposal shall have written documentation from that institution on its institutional readiness to support the patient care protocol;

(c) The research proposal receives a majority of its funding from a federal agency, other public agency, or private non-profit foundation that has authority over research on human subjects; and

(d) The funding agency or foundation has no financial affiliation with entities that

stand to gain economically from the conduct or outcome of the trial.

D. Certificate of Need Review Standards.

(1) General Standards. All applicants proposing the establishment of a neonatal intensive care unit must meet all standards set forth in this section.

(a) Information Regarding Charges. Each hospital shall provide to the public, upon inquiry, information concerning charges and the range and types of services provided.

(b) Charity Care Policy.

(i) Each hospital shall have a written policy for the provision of charity care for uninsured and under-insured patients to promote access to perinatal services regardless of an individual's ability to pay.

(ii) The policy shall include provisions for, at a minimum, the following:

(a) annual notice by a method of dissemination appropriate to the facility's patient population (e.g., radio, television, newspaper); (b) posted notices in the admissions office, business office, and emergency areas within the hospital; (c) individual notice provided to each person who seeks services in the hospital at the time of community outreach efforts, prenatal services, preadmission, or admission; and (d) within two business days following a patient's initial request for charity care services, application for Medical Assistance, or both, the facility must make a determination of probable eligibility.

(iii) Public notice and information regarding a hospital's charity care policy shall be in a format understandable by the target population.

(c) Rate Reduction Agreement. A hospital that has been identified by the HSCRC as a high cost hospital may be approved for the establishment of a neonatal intensive care unit only if it has agreed to enter into a rate reduction agreement with the Health Services Cost Review Commission, or the Health Services Cost Review Commission has determined that a rate reduction agreement is not necessary.

(2) Neonatal Intensive Care Standards. All applicants proposing the establishment

of a neonatal intensive care unit must meet all standards set forth in this section.

(a) Compliance with the Maryland Perinatal System Standards. Each applicant shall demonstrate compliance with all essential requirements as defined in the most recent version of the perinatal standards, adopted by MIEMSS, for the level of perinatal center specified in the application.

(b) Minimum Unit Volume.

(i) Each applicant shall document a sufficient volume of critically ill patients using the general categories identified in Subsection B(1) of this regulation.

(ii) Each applicant shall document that the proposed neonatal intensive care unit will maintain an average daily census of at least six critically ill patients on a sustained basis. An applicant may show evidence as to why this rule should not apply to the applicant.

(iii) Each applicant for a new neonatal intensive care unit is subject to and shall document compliance with the obstetric volume requirements at COMAR 10.24.12.03B(1) and (4).

(iv) Each applicant shall document that the value added by increased geographic access is justified by the incremental cost to the health care system based on the total cost of the service, not the rates charged for the service.

(c) Outreach Prevention Programs. Each applicant shall document its establishment of a program to prevent low birth weight and infant mortality with particular outreach to minority and indigent patients in the hospital's regional service area.

(d) Data Reporting. Each applicant shall provide any statistical or other information that the Commission needs to plan for the future development of perinatal services in Maryland, as specified in COMAR 10.24.02, and demonstrate compliance with the reporting requirements specified in regulations governing the submission of uniform hospital discharge abstract data and uniform accounting data to the Health Services Cost Review Commission, including the timely reconciliation of those data elements that are common to the case-mix and financial data sets.

E. Definitions.

(1) *Designation* means a process by which a hospital is identified by the Maryland Institute for Emergency Medical Services Systems as an appropriate facility to receive patients with particular injuries or illnesses.

(2) *Essential* means a component of the Maryland Perinatal System Standards that is required for designation.

(3) *Low birth weight* means a birth weight below 2,500 grams.

(4) *Neonate or neonatal patient* means a patient who is less than 28 days old or who has been an inpatient since birth.

(5) *Neonatal referral center* means an out-of-state center operating under an agreement with the Maryland Institute for Emergency Medical Services Systems to provide comprehensive neonatal services.

(6) *Optional* means a component of the Maryland Perinatal System Standards that may be present or available but is not required for designation.

(7) *Perinatal referral center* means a center in Maryland designated by the Emergency Medical Services Board or an out-of-state center operating under an agreement with the Maryland Institute for Emergency Medical Services to provide comprehensive obstetrical and neonatal services.

(8) *Transport* means the emergency transfer of the care of a patient to a risk-appropriate hospital.

(9) *Verification* means the process by which the Maryland Institute for Emergency Medical Services Systems determines that a hospital is in substantial compliance with the standards for its specific level of perinatal center.

(10) *Very low birth weight* means a birth weight below 1,500 grams.

