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**State Health Plan for
Facilities and Services:
Acute Hospital Inpatient
Obstetric Services**

COMAR 10.24.12

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COMAR 10.24.12
TABLE OF CONTENTS

| | Page |
|---|------|
| .01 Incorporation by Reference | 1 |
| .02 Introduction | 1 |
| .03 Issues and Policies | 5 |
| .04 Review Standards | 15 |
| .05 Definitions | 20 |
| Appendix A: The Maryland Perinatal System Standards | |

.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 for Facilities and Services.

The Maryland Health Care Commission has prepared this chapter of the State Health Plan for Facilities and Services (“State Health Plan” or “SHP”) to meet the current and future health care system needs of all Maryland residents.

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. Health related activities of state agencies must, by law, be consistent with the Plan to the extent their budgets permit.

(2) It is the foundation for the Commission's decisions in its regulatory programs. These programs ensure that changes in services for health care facilities are appropriate and consistent with the Commission's policies. The SHP therefore contains policies, standards and service-specific need projection methodologies that the Commission uses in making Certificate of Need decisions.

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 the private sector. The Commission also takes an active role in promoting change 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.

B. Legal Authority for the State Health Plan for Facilities and Services

The State Health Plan for Facilities and Services is adopted under Maryland’s health planning law, Maryland Code Annotated,¹ Health-General §19-118(a)(2). This Chapter fulfills

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

the Commission's legal responsibility to adopt a State Health Plan for Facilities and Services at least every five years and to review and amend the Plan annually, or as necessary.

Health-General Article §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.

The authority of the Plan with respect to the responsibilities of other state agencies and departments is stated in §19-118(f):

All state agencies and departments, directly or indirectly involved with or responsible for any aspect of regulating, funding, or planning for the health care industry or persons involved in it, shall carry out their responsibilities in a manner consistent with the State Health Plan for Facilities and Services and available fiscal resources.

In addition, §19-115(b) provides that the Governor shall direct, as necessary, a State officer or agency to cooperate in carrying out the function of the Commission.

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 purposes of the Commission, as provided under §19-103(c), are 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;

COMAR 10.24.12

(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;

(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 modified health benefit plan for medical savings accounts;

(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 payers;

(11) Develop a uniform set of effective benefits to be offered as substantial, available, and affordable coverage in the non-group market in accordance with §15-606 of the Insurance Article;

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

(13) Promote the availability of information to consumers on charges by practitioners and reimbursements from payers.

The Commission has sole authority to prepare and adopt the State Health Plan for Facilities and Services and to issue Certificate of Need decisions and exemptions based on that Plan. Subsection §19-118(e) requires the Secretary of Health and Mental Hygiene to make annual recommendations to the Commission on the Plan and permits the Secretary to review and

COMAR 10.24.12

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, the Commission coordinates with the hospital rate-setting program of the Health Services Cost Review Commission to assure access to care at reasonable costs. The Commission also coordinates its activities with the Maryland Insurance Administration. Any changes to the State Health Plan are also submitted to the Governor and become effective 45 days thereafter, unless the Governor notifies the Commission of an intent to modify or revise the Plan or any amended chapter.

D. Plan Content and Applicability.

This chapter of the State Health Plan for Facilities and Services is applicable to all matters regarding obstetric services, and supersedes all material regarding obstetric services currently found in the Acute Inpatient Services Chapter, COMAR 10.24.10. The policies in this chapter of the State Health Plan for Facilities and Services are intended to encourage rational decisions about obstetric service capacity, cost effectiveness, institutional efficiency, appropriate utilization, and maintenance or improvements in access and quality of care.

Under §19-120(a)(4)(j) of the Health-General Article, Annotated Code of Maryland, a Certificate of Need is required for the establishment of an obstetric service. A merged asset system may be granted an exemption from Certificate of Need review to establish an obstetric service at a member hospital if another member hospital in Maryland has an approved obstetric service, regardless of whether the proposed new site may be located in a different jurisdiction, if the Commission finds that the proposed service reconfiguration is not inconsistent with this chapter of the SHP, will result in more efficient and effective delivery of health care services and is in the public interest.

.03 Issues and Policies

A. Introduction.

Improving perinatal outcomes for both mother and baby is an important public policy goal in Maryland. Infant mortality is the focus of The Governor's Commission on Infant Mortality Prevention. The goals and priorities of this Commission include reducing the percentage of low birth weight births in Maryland, and addressing racial disparities in infant mortality. The Perinatal and Maternal Health Division in the Department of Health and Mental Hygiene's Center for Maternal and Child Health (MCH) supports perinatal systems building through public outreach and provider education with several programs. MCH collaborated with the Maryland Institute of Emergency Medical Services System (MIEMSS) to define hospital standards for levels of perinatal care, and is working with MIEMSS on the accreditation process for hospitals participating in the perinatal referral and transport system. MCH administers the Improved Pregnancy Outcome Program to improve pregnancy outcomes in each jurisdiction. Through this program, the Fetal Infant Mortality Review process operates in each jurisdiction. MCH also administers the Crenshaw Perinatal Health Initiative, and oversees maternal mortality review, fetal and infant mortality review and the Pregnancy Risk Assessment Monitoring System survey. With the Vital Statistics Administration, the MCH reviews maternal mortality data. The Department's Vital Statistics Administration also reports infant mortality statistics in the *Maryland Vital Statistics Annual Report*, and in an annual report on infant mortality in Maryland.

Infant mortality has consistently been higher in Maryland than in the United States, and this disparity has increased in recent years, according to the Department's Health Improvement Plan². In 1998 the U.S. neonatal mortality rate, or deaths occurring in the first 28 days of life, was 4.8 deaths per 1,000 live births, while the Maryland rate was 6.3 deaths per 1,000 live births, more than 31 percent higher than the U.S. average rate. By 2002, the gap had narrowed, with Maryland's rate at 5.5 and the U.S. rate at 4.7. Causes of neonatal death are most often associated with premature birth or very low birth weight. In fact, low birth weight is associated with a poor pregnancy outcome for both baby and mother.

² "Health Improvement Plan, Public Health Action for the First Decade, 2000-2010", A Product of: Healthy Maryland Project 2010, Working Draft #4, August 2000.

B. Statement of Issues and Policies.**(1) A System of Perinatal Care in Maryland.**

One effective strategy for addressing poor pregnancy outcomes is management of known high risk deliveries to assure they receive care in the most appropriate setting. Maryland has an effective perinatal system that fosters referral and transfer of high risk deliveries to designated perinatal centers. This system assures that high risk deliveries are treated at the nearest obstetrics program with the appropriate level of capabilities. The perinatal system standards developed by DHMH are designed to improve hospital-specific birth outcomes. The statewide perinatal system includes defined levels of care based on the standards for Level I, Level II and Level III-or-higher for both obstetric and nursery capabilities. A Level III-or-higher nursery service is considered a neonatal intensive care unit (NICU), and is regulated as a specialized service under the health planning statute. These levels of perinatal care are described in Appendix A.

Although outcomes improve for high risk deliveries, particularly low birth weight infants, at Level III-or-higher perinatal centers, outcomes for term and normal birth weight infants may not differ between the perinatal level of services.³ Therefore, it is appropriate for hospitals to have different levels of care in order to support this statewide system of care as reflected in the Maryland Perinatal System Standards. The following policies are established to maintain a high standard of quality in Maryland's perinatal services.

Policy 1.1 Each hospital providing obstetric services in Maryland shall comply with the essential requirements for its level of perinatal program, as defined in the most current version of the Maryland Perinatal System Standards.

Policy 1.2 A Level I or Level II nursery, consistent with the needs of the service area shall be established when a hospital initiates an obstetric service. The Commission will only consider a Level III-or-higher designation, which includes a Neonatal Intensive Care Unit that requires a separate Certificate of Need, at hospitals that have been operating at high program volumes, as defined in this chapter, for at least three years.

(2) Health Care Insurance Coverage.

Because lack of prenatal care is strongly associated with an increased risk for low birth weight infants, premature delivery, and maternal and infant mortality and morbidity, improved access to prenatal care is a second strategy to improve maternal and infant outcomes. Statistics show that the incidence of very low birth weight babies increases significantly when prenatal care is received later in pregnancy.⁵ More than three percent of all births in Maryland in 2002 received late (beginning in the third trimester) or no prenatal care (2,584, up from 2,144 in 1999), and these births were associated with almost 14 percent of very low birth weight and low birth weight (3.1 and 10.7 percent, respectively) births in that year.⁶ Maryland's percentage of women receiving late or no prenatal care has increased from 2.6 percent in 1997 to 3.6 percent in 2002, whereas the U.S. average has declined from 3.9 percent to 3.6 percent in the same time period. This lack of early prenatal care, which is crucial to improved pregnancy outcomes, precludes timely diagnosis and management of maternal and fetal problems that can be more common among medically and socio-demographically disadvantaged women.⁷

Availability of health care coverage alone does not assure access to prenatal care. Over 96 percent of hospital obstetric discharges in Maryland are paid for by commercial HMOs, commercial insurance or the Maryland Medical Assistance program, indicating that the availability of paid prenatal care is fairly high. The Medical Assistance program was the payer source for over 21,600 (30 percent) obstetric discharges in 1999.⁸ Over 16,400 of those discharges were patients in the managed care or MCO program. Even so, 5,200 Medicaid discharges were covered by Medicaid's fee-for-service program rather than the MCO program, another indicator of potential problems receiving prenatal care.⁹ This program provides full services for women not eligible for the MCO plan (residents without citizenship), and for those eligible but who register late. Only 1,514 of the over 71,000 obstetric discharges in 1999 were categorized as self pay and charity care (2 percent), or without insurance coverage at the time of

⁴ Paneth, N., et.al., "The Choice of Place of Delivery. Effect of Hospital Level on Mortality in all Singleton Births in New York City"; *Am J Dis Child*, 1987 Jan; 141(1): 60-4.

⁵ [Maryland Vital Statistics Annual Report, 1999, Table 20, p.73.]

⁶ *Maryland Vital Statistics, Annual Report, 2002.*

⁷ "Barriers to Enrollment in Medi-Cal Lead to Inadequate Prenatal Care for Some Disadvantaged Women in California", *AHRQ Research Activities*; No. 249, May 2001, p.5.

⁸ Maryland Hospital Discharge Abstract Database.

⁹ Eligibility for Maryland Medical Assistance for pregnant women is 250 percent of the federal poverty level (\$44,125 for a family of four, as of July 1, 2001).

delivery. Hospitals should contribute to efforts to identify and inform pregnant women of their potential availability for medical assistance whenever possible. Because all hospitals have provisions built into their rate structure for the provision of charity care, it is important they have a charity care policy covering obstetric patients.

Neither adequate coverage for prenatal care nor early entry to prenatal care can assure that the care is complete. Reasons for delayed or missed prenatal care are varied, but are likely related more to problems of awareness or social issues than to lack of financial access. The Maryland Commission on Infant Mortality Prevention released a report in November 2000 titled *Impact of Managed Care on Prenatal Care Use*. A major issue identified in the report was barriers to prenatal care. The report recommends greater efforts using community health workers and community-based advertising and awareness about Medicaid eligibility and other community resources. The local health departments' Healthy Start Programs and DHMH's Improved Pregnancy Outcome Program are two public programs helping to reduce barriers to prenatal care in each Maryland jurisdiction. The following policies are established to help reduce the barriers to prenatal care.

- Policy 2.1** **All Marylanders should have access to appropriate hospital obstetric services regardless of their ability to pay for those services.**

- Policy 2.2** **All Maryland hospital obstetric programs should provide information on Medicaid eligibility and other publicly funded programs for those patients without adequate insurance coverage.**

- Policy 2.3** **All hospital obstetric programs should, in cooperation with their community, local health department, and the Department of Health and Mental Hygiene, identify and target the uninsured, underinsured and indigent patients in their service area who may need prenatal care and obstetric services, and offer free or reduced price perinatal care including educational programs, prenatal health screenings, prenatal care and obstetric services.**

(3) Perinatal Outcomes Assessment.

A significant amount of evidence in the literature suggests a relationship between hospital volumes and improved outcomes. In a recent review of this issue, the Institute of Medicine notes that in a literature review of the relationship between volume of health services and health related outcomes, a statistically significant association between higher volume and better outcome was observed in three quarters of the studies reviewed, and in all of the studies judged

to have the soundest research methods.⁹ The report states that volume is only an imprecise indicator of quality, but may be the best available proxy indicator of quality, particularly when combined with the development of appropriate processes of care that underlie the relationship. However, there is little information on the clinical processes of care or the necessary institutional experience that contribute to reducing variations and promoting better outcomes.

Research specific to obstetric services focuses primarily on low birth weight infants. This research indicates that outcomes for low birth weight infants are better at Level III centers, those with neonatal intensive care units, and supports the regional system for high risk deliveries. Some research also indicates mortality for normal birth weight infants does not differ by level of perinatal center.¹⁰ One study finds that differences in perinatal complication rates are not statistically significant based on volume for all birth weights.¹¹ However, there is some indication in the literature that volume may have an association with cost effectiveness.^{12,13,14}

There are many strategies to improve outcomes, such as minimum program volumes, educational strategies to correct avoidable medical errors and improve professional skills, public disclosure of data on volume and other quality indicators or use of professionally accepted guidelines that are intended to promote better outcomes. For example, the American Academy of Pediatrics and the American College of Obstetricians and Gynecologists have published "*Guidelines for Perinatal Care*" that applies specifically to hospital obstetric programs, describing the structures and clinical processes of care believed to be associated with better outcomes.

Another example is the comparative performance evaluation tool or "report card". In 1999, the MHCC was charged with developing and implementing a system to comparatively evaluate the quality of care outcomes and performance measurements of hospitals on an objective basis, §19-135(e). The purpose of developing a performance measurement system is to

⁹ "Interpreting the Volume-Outcome Relationship in the Context of Health Care Quality; Workshop Summary"; Maria Hewitt for the Committee on Quality of Health Care in America and the National Cancer Policy Board; Institute of Medicine; Washington, D.C.; 2000.

¹⁰ Paneth, N. et.al., *ibid.*

¹¹ Garcia, et.al., "Effect of Academic Affiliation and Obstetric Volume on Clinical Outcome and Cost of Childbirth"; *Obstetrics & Gynecology*; Vol. 97, No. 4, April 2001, pp. 567-576.

¹² Garcia, et.al., *ibid.*

¹³ Virginia Health Planning Agencies, "Obstetrics Program Volume and Infant Mortality; Virginia Hospitals, 1979-1989"; December, 1991.

¹⁴ "The Status and Future of Small Maternity Services in Iowa"; Hein, H.A., *JAMA*; 1986, Apr 11; 255(14): 1899-903.

provide an incentive for hospitals to improve the quality of care, and to educate consumers. The enabling legislation states that this can be accomplished by establishing a common set of performance measurements and disseminating the findings of the performance measurements to providers, consumers, and other interested parties. The Commission issues these findings in a report specific to hospital obstetrics services as an integral part of the hospital report. While this report currently presents descriptive information on Maryland hospitals' obstetric services and types of deliveries, future versions of the report will include process and outcome measures.

To support public and private efforts to improve perinatal outcomes, the following policies are established.

Policy 3.1 **The Commission supports efforts of the Department of Health and Mental Hygiene and other stakeholders to identify ways to improve pregnancy outcomes, including research into the effect of volume and other factors that are believed to contribute to improved outcomes.**

Policy 3.2 **The Commission supports the public dissemination of comparative performance measures related to obstetric services, as part of its hospital performance evaluation system.**

(4) Cost Effectiveness of Additional Obstetric Services.

The benefits to a hospital and its community of establishing an obstetric service must be weighed against the potential costs to the whole system of perinatal services in Maryland. Several factors impact cost effectiveness.

To be cost effective, a service must be able to maintain expensive resources, including providers, equipment and support staff. Birth rate projections indicate relatively stable demand for at least the next 20 years. Thus any newly established obstetric service will be re-allocating stable volumes rather than allocating new admissions. New programs would necessarily result in lower volumes at existing programs. Lower patient volume means a total loss of the revenue associated with those volumes, but only a partial decrease in the expenses associated with those volumes. Cost pressures and hospital rates have been increasing, and are expected to continue over the next several years. Additional overhead expenses due to duplication of the infrastructure needed to support new programs will likely add costs to the health care system. Obstetric programs require professional staff, currently in short supply, to be available 24 hours

COMAR 10.24.12

per day, seven days per week. Duplication of services will add direct staffing costs and indirect overhead to the system, and increased competition for nurses could further increase staffing costs. In addition, increased competition for patients could result in capital expenditures to capture market share, putting additional pressure on hospital rates, and leaving some hospitals to carry an increasing burden of high risk, high cost patients.

Commission review of data from the Maryland Health Services Cost Review Commission (HSCRC) on obstetric program expenses indicates that, among hospitals with Level I and II perinatal programs, the higher cost programs are all among the lower volume programs.¹⁶ The higher cost programs have obstetric volumes of 1,200 cases or less. Some low volume programs have very low expenses per case, indicating a large degree of variability in expenses among the low volume providers. On the other hand, large volume programs showed much less variability in expenses per case.

In calendar year 1999, Maryland's hospital obstetric program volumes, including non-delivery obstetric cases, ranged from approximately 250 to 7,300 cases. The average was 2,001 and the mid point was 1,721. Low volume as well as higher volume programs can be found in both metropolitan and non-metropolitan areas. Obstetric programs can be classified based on program volumes as follows:¹⁷

| Program Size by Number of Obstetric Discharges | | Annual Number of Cases |
|--|---------------------------------|--------------------------|
| High Volume Programs | Very High Volume High Volume | 4,000 + 2,000 – 3,999 |
| Medium Volume Programs | Medium Volume | 1,000 – 1,999 |
| Low Volume Programs | Low Volume Very Low Volume | 500 – 999 <500 |

In metropolitan areas, where a critical mass of patients should be able to support higher volumes, public policy can promote cost effective obstetric services. In non-metropolitan areas, it may not be possible for all hospitals to maintain high volume, cost effective obstetric programs and provide adequate access within established travel time standards. In these cases, the

¹⁶ Health Services Cost Review Commission's Quarterly Statistical Reports, FY2000.

¹⁷ *Effect of Academic Affiliation and Obstetric Volume on Clinical Outcome and Cost of Childbirth*; Garcia, et.al., *Obstetrics & Gynecology*; Vol. 97, No. 4, April 2001, pp. 567-576.

potential inefficiencies and risks of small obstetrics programs can be minimized by conformity with Maryland's perinatal system standards.

The Commission will approve an application to establish an obstetric program only if it offers the best balance between program effectiveness and costs to the health care system as a whole. New programs should have a positive impact on patients and on the health care system in terms of the rates charged, quality, and financial and geographic access. The impact of a new service on existing providers should not inappropriately diminish the quality of care, financial and geographic access to care, or cost effectiveness. The incremental cost to the health care system must be justified by the value added by increased geographic access of a new service considering the total cost of the service, including duplication of fixed costs, and effects on other providers. Based on the HSCRC's data indicating greater cost effectiveness at obstetric programs over 1,200 cases annually, and the classification of program size in the Garcia study, the Commission establishes the annual volume of cases necessary for cost effectiveness as 1,000 in metropolitan areas and 500 cases in non-metropolitan areas. A hospital will be required to close a new obstetrics program if it cannot achieve these volumes within three years. An existing program's volumes should not decline below 1,000 cases annually as the result of Commission action approving additional obstetrics capacity. Therefore, the Commission establishes the following policies:

Policy 4.1 The burden of demonstrating need for additional obstetric program capacity rests with the applicant. In determining whether a new obstetric service should be established, the Commission shall consider, at a minimum,

(a) the historical and projected service area of the applicant hospital, obstetric service utilization forecasts, the number of providers of hospital obstetric services in the applicant hospital's service area, the anticipated medical staff which will utilize the proposed obstetric service and the proportion of their patients expected to use the proposed service;

(b) information on the number of uninsured, underinsured, indigent and otherwise underserved obstetric patients in the applicant's primary service area, and an estimate of the number of women not receiving adequate prenatal care;

(c) any data and/or analyses provided by the applicant outlining improvements in the delivery of obstetric services to the defined service area population anticipated to result from implementation of the proposed

project, such as improvements in patient care outcomes, lower costs than that currently available in the service area, improvements in geographic or financial access to care, improvements in continuity of care, or improvements in the acceptability or cultural competency of obstetric care for the defined service area population or specific segments of that population;

(d) any demographic or health service utilization data and/or analyses providing a perspective on the need for the proposed project which is significantly different from that found in the Commission's forecast of obstetric service utilization; and

(e) any other relevant information on the unmet needs for obstetric services in the service area.

Policy 4.2 New perinatal programs should only be established in service areas projected to have stable or declining levels of demand for hospital obstetric services if the establishment of the new program will demonstrably benefit the service area population in access, quality and/or cost effectiveness, and the value of this benefit is determined by the Commission to be greater than the increased cost resulting from distributing the projected volumes for hospital obstetric and nursery services over a larger number of hospital programs.

Policy 4.3 Hospital obstetrics programs should maintain a minimum volume of at least 1,000 obstetric cases per year in metropolitan jurisdictions or 500 cases per year in non-metropolitan jurisdictions, and 2,000 discharges annually for a Level III or higher program, to assure cost effectiveness.

Policy 4.4 As a condition of CON and CON exemption approval for additional obstetrics program capacity, the Commission will require an applicant to agree to close the obstetric service if the new service fails to meet the 1,000 case minimum volume of obstetric discharges for metropolitan areas, or the 500 case minimum volume for non-metropolitan areas, for any two consecutive years.

Policy 4.5 Low volume and very low volume obstetric programs should work with the Health Services Cost Review Commission to assure the cost effectiveness of the obstetric and nursery services.

(5) Geographic Access.

Geographic access to obstetric services in Maryland, as measured by travel times, is excellent. Approximately 98.5 percent of Maryland's female residents between the ages of 15 and 44 are within 30 minutes one-way average automobile travel time from a hospital obstetric service. New obstetric programs, while able to further reduce travel times, will not substantially

COMAR 10.24.12

improve geographic access. The potential for closures of hospitals or hospital obstetric services, on the other hand, could have a negative impact on geographic access, particularly in non-metropolitan areas. Therefore, the following policy is established to guide downsizing and relocation decisions.

Policy 5.1 **Hospital obstetrics services should be no more than a 30 minute one-way average automobile travel time under normal driving conditions for at least 90 percent of the population.**

.04 Review Standards

The standards in this section are intended to guide Certificate of Need and CON exemption reviews involving new acute hospital inpatient obstetric services, existing services proposed to be relocated to newly constructed space, and existing services proposed to be located in renovated space. Standards (1) through (6) apply to all applicants. Standards (7) through (14) apply only to applicants for a new perinatal service. Standard (15) applies only to applicants with an existing obstetric service.

(1) Need. All applicants must quantify the need for the number of beds to be assigned to the obstetric service, consistent with the approach outlined in Policy 4.1. Applicants for a new perinatal service must address Policy 4.1.

(2) The Maryland Perinatal System Standards. Each applicant shall demonstrate the ability of the proposed obstetric program and nursery to comply with all essential requirements of the most current version of Maryland's Perinatal System Standards, as defined in the perinatal standards, for either a Level I or Level II perinatal center.

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

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

(i) annual notice by a method of dissemination appropriate to the hospital's patient population (for example, radio, television, newspaper);

(ii) posted notices in the admissions office, business office and emergency areas within the hospital

(iii) 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

(iv) 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.

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

COMAR 10.24.12

(4) Medicaid Access. Each applicant shall provide a plan describing how the applicant will assure access to hospital obstetric services for Medical Assistance enrollees, including:

(a) an estimate of the number of Medical Assistance enrollees in its primary service area, and

(b) the number of physicians that have or will have admitting privileges to provide obstetric or pediatric services for women and infants who participate in the Medical Assistance program.

(5) Staffing. Each applicant shall provide information on the proposed staffing, associated number and type of FTEs, projected expenses per FTE category and total expenses, for labor and delivery, post partum, nursery services, and other related services, including nurse staffing, non-nurse staffing and physician coverage, at year three and at maximum projected volumes; if applicable, current staffing and expenses should also be included.

(6) Physical Plant Design and New Technology. All applicants must describe the features of new construction or renovation that are expected to contribute to improvements in patient safety and/or quality of care, and describe expected benefits.

(7) Nursery. An applicant for a new perinatal service shall demonstrate that the level of perinatal care, including newborn nursery services, will be consistent with the needs of the applicant's proposed service area.

(8) Community Benefit Plan. Each applicant proposing to establish a new perinatal service will develop and submit a Community Benefit Plan addressing and quantifying the unmet community needs in obstetric and perinatal care within the applicant's anticipated service area population. This Plan should include an outreach program component, and should provide a detailed description of the manner in which the proposed perinatal service will meet these needs, and the resources required. At a minimum, the Community Benefit Plan must include:

(a) a needs assessment related to obstetric and nursery services for the proposed program's service area population, including a description of the manner in which the proposed perinatal service will satisfy unmet needs identified in the needs assessment,

(b) measurable and time-limited goals and objectives for health status improvements pursuant to which the Plan can be evaluated; and

COMAR 10.24.12

- (c) information on the structure, staffing and funding of the Plan;
- (d) documentation of community support and involvement in program planning for the Plan by other agencies, organizations or institutions which will be involved, directly or indirectly, with the Plan;
- (e) an implementation scheme for the Community Benefit Plan.
- (f) Applicants must commit to implementation of the Community Benefit Plan and continuing commitment to the Plan as a condition of Commission approval, and as an ongoing condition of providing obstetric services.
- (g) Applicants must agree to submit an Annual Report to the Commission which will include:
 - (i) an evaluation of the achievement of the goals and objectives of the Community Benefit Plan; and
 - (ii) information on staffing levels and the total costs of any programs implemented as part of the Community Benefit Plan.
- (9) Source of Patients. An applicant for a new obstetric service shall demonstrate that the majority of its patients will come from its primary service area.
- (10) Non-metropolitan Jurisdictions. A proposed obstetrics program in non-metropolitan jurisdictions, as defined in the chapter, shall demonstrate that physicians with admitting privileges to provide obstetric services have offices for patient visits within the primary service area of the hospital.
- (11) Designated Bed Capacity. An applicant for a new obstetric service shall designate a number of the beds from within the hospital's licensed acute care beds that will comprise the proposed obstetric program.
- (12) Minimum Volume.
 - (a) An applicant for a new obstetrics program must be able to demonstrate to the Commission's satisfaction that the proposed program can achieve a minimum volume of 1,000 admissions annually in metropolitan jurisdictions, or 500 cases annually in non-metropolitan jurisdictions, within 36 months of initiation of the program.
 - (b) As a condition of approval, the applicant shall accept a requirement that it will close the obstetric program, and its authority to operate will be revoked, if:

COMAR 10.24.12

(i) it fails to meet the minimum annual volume for any 24 consecutive month period, and

(ii) it fails to provide good cause for its failure to attain the minimum volume, and a feasible corrective action plan for how it will achieve the minimum volume within a two year period.

(13) Impact on the Health Care System.

(a) An application for a new perinatal program will be approved only if its likely impact on the volumes of obstetric discharges at any existing obstetric program, after the three year start-up period, will not exceed 20 percent of an existing program's current or projected volume.

(b) When determining whether to approve an application for an obstetrics program the Commission will consider whether an existing program's payer mix of obstetrics patients will significantly change as a result of the proposed program, and the existing program will have to care for a disproportionate share of the indigent obstetrics patients in its service area; and

(c) When determining whether to approve an application for an obstetrics program the Commission will also consider the impact on a hospital with an existing program that has undertaken a capital expenditure project for which it has pledged pursuant to H-G Article §19-120(k) not to increase rates for that project, so long as the pledge was based, at least in part, on assumptions about obstetric volumes.

(d) The Commission may consider evidence:

(i) from an applicant as to why rules (a) through (c) should not apply to the applicant, or;

(ii) from a very low volume program (fewer than 500 annual obstetric discharges) as to why a lower volume impact should apply.

(14) Financial Feasibility. Hospitals applying for a Level I or II perinatal program must clearly demonstrate that the hospital has the financial and non-financial resources necessary to implement the project, and that the average charge per admission for new perinatal programs will be less than the current statewide average charge for Level I and Level II perinatal programs. When determining whether to approve an application for an obstetric program, the Commission will consider the following:

COMAR 10.24.12

(a) the applicant's projected sources of funds to meet the program's total expenses for the first three years of operation,

(b) the proposed unit rates and/or average charge per case for the perinatal services,

(c) evidence that the perinatal service will be financially feasible at the projected volumes and at the minimum volume standards in this Plan, and

(d) the written opinions or recommendations of the HSCRC.

(15) Outreach Program. Each applicant with an existing perinatal service shall document an outreach program for obstetric patients in its service area who may not have adequate prenatal care, and provide hospital services to treat those patients. The program shall address adequate prenatal care, prevention of low birth weight and infant mortality, and shall target the uninsured, under-insured, and indigent patients in the hospital's primary service area, as defined in COMAR 10.24.01.01.B.

.05 Definitions

(1) Hospital Obstetric Services. DRGs 370 - 379, and 382 - 384.

(2) Metropolitan Areas. For purposes of this plan chapter, metropolitan areas include: Anne Arundel, Baltimore, Calvert, Carroll, Charles, Frederick, Harford, Howard, Montgomery, Prince George's, St. Mary's and Washington counties and Baltimore City.

(3) Non-Metropolitan Areas. For purposes of this plan chapter, non-metropolitan areas include: Allegany, Caroline, Cecil, Dorchester, Garrett, Kent, Queen Anne's, Somerset, Talbot, Wicomico and Worcester counties.

(4) Primary Service Area. Defined in COMAR 10.24.01.01.B.

Appendix

THE MARYLAND PERINATAL SYSTEM STANDARDS

| STANDARD | TITLE | SUMMARY |
|----------|-------------------------------|---|
| I | Organization | Refers to the administration of a hospital perinatal program |
| II | Obstetrical Unit Capabilities | Refers to the resources of equipment, supplies, and personnel needed for the delivery unit within the hospital |
| III | Nursery Unit Capabilities | Refers to the resources of equipment, supplies, and personnel needed for the nursery unit within the hospital |
| IV | Obstetric Personnel | Describes the roles, responsibilities, and availability of obstetric personnel in the perinatal program |
| V | Pediatric Personnel | Describes the roles, responsibilities, and availability of pediatric personnel in the perinatal program |
| VI | Other Personnel | Describes the roles, responsibilities, and availability of other personnel in the perinatal program |
| VII | Laboratory | Refers to the resources of equipment, supplies, and personnel needed for the laboratory unit within the hospital |
| VIII | Radiology/ Ultrasound | Refers to the resources of equipment, supplies, and personnel needed for the radiology and ultrasound units within the hospital |
| IX | Equipment | Refers to the availability of specific equipment needed for the perinatal program |
| X | Medications | Refers to the availability of specific medications needed for the perinatal program |

| | | |
|------|-------------------------------------|---|
| XI | Continuing Education Programs | Refers to the need for continuing education for all health care providers involved in providing perinatal care and to the roles and responsibilities of the hospitals in continuing education |
| XII | Prevention/Public Education | Describes the hospital's roles and responsibilities in prevention of poor perinatal outcomes and public education |
| XIII | Quality Management | Describes the quality management process that is required for hospital perinatal programs |
| XIV | Policies, Protocols, and Guidelines | Identifies the administrative and medical policies and protocols that must be in place for a perinatal program |

LIST OF ABBREVIATIONS

- I Level I, which is a hospital with a perinatal program which may provide care to newborns ≥ 36 weeks gestational age or $\geq 1,800$ grams, as defined by these standards
- II Level II, which is a hospital with a perinatal program which may provide care to newborns ≥ 32 weeks gestational age or $\geq 1,500$ grams, as defined by these standards
- III Level III, which is a hospital with a perinatal program which may provide medical intensive care to newborns \geq than 26 weeks gestational age or ≥ 800 grams, as defined by these standards
- III+ Level III Plus, which is a hospital with a perinatal program which must be geographically near a Level IV perinatal center, may provide medical intensive care for newborns of all gestational ages and birth weights, and may provide selected specialty services, as defined by these standards
- IV Level IV, which is a hospital with a perinatal program which provides comprehensive neonatal and obstetrical services including all subspecialty services, as defined in these standards
- E Essential requirement for level of perinatal center
- O Optional requirement for level of perinatal center
- NA Not Applicable

THE MARYLAND PERINATAL SYSTEM DESIGNATION AND VERIFICATION STANDARDS, REVISED 1/98

| | I | II | III | III+ | IV |
|---|---|----|-----|------|----|
| STANDARD I. ORGANIZATION | | | | | |
| 1.1 The hospital's Board of Directors, administration, and medical and nursing staffs shall demonstrate commitment to its specific level of perinatal center designation and to the care of perinatal patients. This commitment shall be demonstrated by: | | | | | |
| a) A Board resolution that the hospital agrees to meet the Maryland Perinatal System Standards for its specific level of designation | E | E | E | E | E |
| b) Participation in the Maryland Perinatal System, as defined by this document, including submission of patient care data to MIEMSS and DHMH for system and quality management | E | E | E | E | E |
| c) Assurance that all perinatal patients will receive medical care commensurate with the level of the hospital's designation | E | E | E | E | E |
| d) A Board resolution, bylaws, contracts, budgets -- all specific to the perinatal program -- indicating the hospital's commitment to the financial, human, and physical resources and to the infrastructure that are necessary to support the hospital's level of perinatal center designation | E | E | E | E | E |
| 1.2 The hospital must be licensed by the Maryland Department of Health and Mental Hygiene (DHMH) as an acute care hospital. | E | E | E | E | E |
| 1.3 The hospital must be accredited by the Joint Commission on Accreditation of Healthcare Organizations (JCACHO). | E | E | E | E | E |

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| | | I | II | III | III+ | IV |
| 1.4 | The hospital must have a certificate of need (CON) issued by the Maryland Health Resources Planning Commission (HRPC) for its neonatal intensive care unit and/or approval from the Health Services Cost Review Commission (HSCRC) for a neonatal intensive care unit cost center. | NA | NA | E | E | E |
| 1.5 | The hospital must maintain current equipment and technology to support optimal perinatal care for the level of the hospital's perinatal center designation. | E | E | E | E | E |
| 1.6 | If maternal or neonatal air transports are accepted, then the hospital shall have a heliport, helipad, or access to a helicopter landing site near the hospital. | NA | NA | E | E | NA |
| 1.7 | The hospital shall have a heliport, helipad, or access to a helicopter landing site near the hospital. | NA | NA | NA | NA | E |
| STANDARD II. OBSTETRICAL UNIT CAPABILITIES | | | | | | |
| 2.1 | The hospital must demonstrate its capability of providing uncomplicated and complicated obstetrical care through written standards, protocols, or guidelines, including those for the following: | | | | | |
| | a) unexpected obstetrical care problems; | E | E | E | E | E |
| | b) fetal monitoring, including internal scalp electrode monitoring; | E | E | E | E | E |
| | c) initiating a cesarean delivery within 30 minutes of the decision to deliver; | E | E | E | E | E |
| | d) selection and management of high-risk obstetrical patients which it can manage, or | E | E | E | E | E |
| | management of all high-risk obstetrical patients | NA | NA | NA | NA | E |
| 2.2 | The hospital must demonstrate its capability of providing critical care services appropriate for obstetrical patients. | O | O | O | O | E |

| | I | II | III | III+ | IV |
|---|----|----|-----|------|----|
| 2.3 The hospital must have a written plan for initiating maternal transports to an appropriate level. | E | E | E | E | E |
| 2.4 The hospital must have a written protocol for the acceptance of maternal transports from other institutions. | NA | NA | E | E | E |
| 2.5 The hospital must have approval for an accredited maternal-fetal medicine fellowship program. | O | O | O | O | E |
| STANDARD III. NURSERY UNIT CAPABILITIES | | | | | |
| 3.1 The hospital must demonstrate its capability of providing uncomplicated and complicated neonatal care through written standards, protocols, or guidelines, including those for the following: | | | | | |
| a) resuscitation and stabilization of unexpected neonatal problems; | E | E | E | E | E |
| b) selection and management of high-risk neonatal patients which it can manage, or | E | E | E | E | E |
| management of all neonatal patients, including those requiring pediatric cardiothoracic surgery, surgery for complex congenital defects (excepting extracorporeal membrane oxygenation or ECMO) | NA | NA | NA | NA | E |
| 3.2 The hospital must have geographic proximity to a Level IV perinatal center so that patients requiring Level IV services may be transported in less than 30 minutes by non-emergency travel. | O | O | O | E | NA |
| 3.3 The hospital must demonstrate that it can provide a full range of genetic diagnostic services for family, fetus, and infant. | O | O | O | O | E |
| 3.4 The hospital must have approval for an accredited neonatology fellowship program. | O | O | O | O | E |

| | I | II | III | III+ | IV |
|---|---|----|-----|------|----|
| STANDARD IV. OBSTETRIC PERSONNEL | | | | | |
| 4.1 A physician board-certified or an active candidate for board-certification in obstetrics/gynecology or family practice shall be on staff and have responsibility for obstetrical services. | E | NA | NA | NA | NA |
| 4.2 A physician board-certified in obstetrics and gynecology shall be on staff and have responsibility for obstetrical services. | O | E | E | E | E |
| 4.3 A physician (or physicians) board-certified or an active candidate for board-certification in maternal-fetal medicine shall be on staff and have full-time responsibility for high-risk obstetrical services. For the purposes of this standard, full-time means one full time equivalent (F.T.E.). | O | O | E | E | E |
| 4.4 For a hospital without a physician board-certified in maternal-fetal medicine on staff, there is a consulting arrangement, by telephone, with a physician board-certified in maternal-fetal medicine. | E | E | NA | NA | NA |
| 4.5 A physician or certified nurse-midwife shall be present, within 10 minutes of the delivery area, when a patient is in active labor. | E | NA | NA | NA | NA |
| 4.6 A physician board-certified or an active candidate for board-certification in obstetrics/gynecology or family practice shall be present, within 10 minutes of the delivery area, when a patient is in active labor. | O | E | NA | NA | NA |
| 4.7 A physician or certified nurse-midwife shall be present at all deliveries. | E | E | E | E | E |
| 4.8 A physician board-certified or an active candidate for board-certification in obstetrics and gynecology shall be present in-house 24 hours a day. | O | O | E | E | E |

| | I | II | III | III+ | IV |
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| STANDARD V. PEDIATRIC PERSONNEL | | | | | |
| 5.1 A physician board-certified or an active candidate for board-certification in pediatrics or family practice shall be on staff and have responsibility for nursery services. | E | NA | NA | NA | NA |
| 5.2 A physician board-certified in pediatrics shall be on staff and have responsibility for nursery services. | O | E | E | E | E |
| 5.3 A physician (or physicians) board-certified or an active candidate for board-certification in neonatology shall be on staff and have full-time responsibility for neonatal intensive care unit services. For the purposes of this standard, full-time means one full time equivalent (F.T.E.). | O | O | E | E | E |
| 5.4 For a hospital without a physician board-certified in neonatology on staff, there is a consulting arrangement, by telephone, with a physician board-certified in neonatology. | E | E | NA | NA | NA |
| 5.5 A Neonatal Resuscitation Program (NRP) certified professional with training in acute care of the depressed newborn and skilled in neonatal endotracheal intubation and resuscitation shall be immediately available. | E | E | E | E | E |
| 5.6 When an infant requiring Level II neonatal services is present in the hospital, a pediatrician or neonatal nurse practitioner shall be present within 10 minutes of the delivery area and nursery at all times. | O | E | NA | NA | NA |
| 5.7 A pediatrician, pediatric resident (beyond post-graduate year two training), or neonatal nurse practitioner shall be present in-house 24 hours a day and assigned to the delivery area and nursery and not shared with other units in the hospital. | O | O | E | E | E |
| 5.8 A physician board-certified or an active candidate for board-certification in neonatology shall be present in-house within 30 minutes. | O | O | E | E | E |

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| | | I | II | III | III+ | IV |
| 5.9 | The hospital shall have written pediatric cardiology and pediatric surgery consultation and referral agreements in place. | O | O | E | E | NA |
| 5.10 | The hospital shall have pediatric medical and surgical subspecialists (including cardiology, neurology, hematology, genetics, cardiothoracic surgery, and neurosurgery) on staff, and if needed, in-house within 30 minutes. | O | O | O | O | E |
| STANDARD VI. OTHER PERSONNEL | | | | | | |
| 6.1 | An anesthesiologist or nurse-anesthetist shall be available so that cesarean delivery may be initiated within 30 minutes of the decision to deliver. | E | E | E | E | E |
| 6.2 | A physician board-certified or an active candidate for board-certification in anesthesiology or a nurse-anesthetist (working under the supervision of a physician board-certified or an active candidate for board certification in anesthesiology) shall be present, within 10 minutes of the delivery area, when a patient is in active labor. | O | E | NA | NA | NA |
| 6.3 | A physician board-certified or an active candidate for board-certification in anesthesiology shall be present in-house 24 hours a day. | O | O | E | E | E |
| 6.4 | If the hospital performs neonatal surgery, then a board-certified anesthesiologist with experience in pediatric anesthesiology shall be present for the surgery. | NA | NA | E | E | E |
| 6.5 | The hospital shall have a radiologist on staff capable of providing interventional radiology services. | O | O | E | E | E |
| 6.6 | The hospital shall have obstetric and neonatal diagnostic imaging available 24 hours a day, provided by obstetricians or radiologists with special interest and experience in maternal and neonatal disease and its complications. | O | O | E | E | E |

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|------|---|---|----|-----|------|----|
| | | I | II | III | III+ | IV |
| 6.7 | The hospital shall have a registered dietician or other health care professional with knowledge of and experience in parenteral/enteral high-risk management on staff. | O | O | E | E | E |
| 6.8 | The hospital perinatal program shall have a medical social worker with a Master's degree and experience in perinatal services on staff (i.e., a LCSW or Licensed Clinical Social Worker). | O | O | E | E | E |
| 6.9 | The hospital shall have a respiratory therapist skilled in neonatal ventilator management present in-house 24 hours a day. | O | O | E | E | E |
| 6.10 | The hospital shall have written genetic diagnostic and counseling services consultation and referral agreements in place. | O | O | E | E | E |
| 6.11 | The hospital shall have a pediatric neurodevelopmental follow-up program or written referral arrangements for neurodevelopmental follow-up. | O | O | E | E | E |
| 6.12 | A hospital shall have a registered nurse available to the obstetrical unit and nursery 24 hours a day. | E | E | E | E | E |
| 6.13 | The hospital perinatal program shall have a registered nurse with a Master's degree and experience in high-risk obstetric and neonatal nursing on staff. | O | O | E | E | E |
| 6.14 | The hospital must have a written plan for assuring nurse/patient ratios as per current <i>Guidelines For Perinatal Care.</i> | E | E | E | E | E |

| | I | II | III | III+ | IV |
|--|---|----|-----|------|----|
| STANDARD VII. LABORATORY | | | | | |
| 7.1 The laboratory must have the capability of reporting: | | | | | |
| a) hematocrit, serum glucose, and blood gas within 15 minutes | E | E | E | E | E |
| b) complete blood count, micro blood chemistries, blood type and match, Coombs test, bacterial smear results, and coagulation studies (prothrombin time or PT, partial thromboplastin time or PTT, fibrinogen) within 1 hour | E | E | E | E | E |
| c) bacterial culture and sensitivity within 48 hours | E | E | E | E | E |
| d) fetal scalp pH within 5 minutes (if fetal scalp pH testing is being utilized at the hospital) | O | E | E | E | E |
| e) serum magnesium within 1 hour | O | E | E | E | E |
| f) urine electrolytes within 6 hours | O | O | E | E | E |
| g) special amniotic fluid tests (e.g., lecithin-sphingomyelin or L/S ratio, phosphatidylglycerol or PG) within 6 hours | O | O | E | E | E |
| 7.2 Blood bank technicians shall be present in-house 24 hours a day. | O | E | E | E | E |
| 7.3 For hospitals without blood bank technicians in-house 24 hours a day, technicians shall be present in the hospital within 30 minutes. | E | NA | NA | NA | NA |
| 7.4 The hospital must have molecular, cytogenetic, and biochemical genetic laboratory capabilities readily available. | O | O | O | O | E |

| | I | II | III | III+ | IV |
|--|--|----|-----|------|----|
| STANDARD VIII. RADIOLOGY/ULTRASOUND | | | | | |
| 8.1 | Portable obstetric ultrasound equipment must be present in the delivery area. | O | E | E | E |
| 8.2 | If portable obstetric ultrasound equipment is not present in the delivery area, then the equipment must be available to the delivery area. | E | NA | NA | NA |
| 8.3 | Portable x-ray equipment must be available to the nursery. | E | E | E | E |
| 8.4 | Portable head ultrasound for newborns must be available to the nursery. | O | E | E | E |
| 8.5 | Physician interpretation of x-rays and sonograms must be available on a 24 hour a day basis. | E | E | E | E |
| 8.6 | Computerized tomography (CT) capability must be available in-house. | O | O | E | E |
| 8.7 | Magnetic resonance imaging (MRI) capability, with the services of appropriate support staff, must be available in-house. | O | O | O | E |
| 8.8 | Neonatal echocardiography must be available in-house. | O | O | E | E |
| 8.9 | The hospital must have a pediatric cardiac catheterization laboratory and appropriate staff. | O | O | O | E |
| 8.10 | The hospital must have equipment for performing interventional radiology services. | O | O | E | E |

| | I | II | III | III+ | IV |
|--|---|----|-----|------|----|
| STANDARD IX. EQUIPMENT | | | | | |
| 9.1 The hospital has all of the following equipment and supplies immediately available for the next potential patient: | E | E | E | E | E |
| a) O2 analyzer, stethoscope, intravenous infusion pumps | | | | | |
| b) radiant heated bed in delivery room and available in the nursery | | | | | |
| c) oxygen hood with humidity | | | | | |
| d) bag and masks capable of delivering up to 100% oxygen to the infant | | | | | |
| e) orotracheal tubes | | | | | |
| f) aspiration equipment | | | | | |
| g) laryngoscope | | | | | |
| h) umbilical vessel catheters and insertion tray | | | | | |
| i) cardiac monitor | | | | | |
| j) pulse oximeter | | | | | |
| k) phototherapy unit | | | | | |
| l) doppler blood pressure for newborns | | | | | |
| 9.2 The hospital shall have a neonatal intensive care unit bed set up and equipment available at all times for an emergency admission. | O | O | E | E | E |
| 9.3 The hospital shall have fetal diagnostic testing and monitoring equipment for non-stress and stress testing, amniocentesis, and ultrasound examinations. | O | O | E | E | E |
| 9.4 The hospital must have intravascular blood pressure monitors. | O | O | E | E | E |
| 9.5 The hospital must have laser coagulation capability. | O | O | E | E | E |

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|-------------------------|---|---|----|-----|------|----|
| | | I | II | III | III+ | IV |
| 9.6 | The hospital must have a full range of invasive maternal monitoring available to the delivery area, including equipment for central venous pressure and arterial monitoring. | O | O | E | E | E |
| 9.7 | The hospital must be capable of providing high frequency ventilation for neonates of all birth weights. | O | O | O | O | E |
| STANDARD X. MEDICATIONS | | | | | | |
| 10.1 | Emergency medications, as listed in the <i>Neonatal Resuscitation Program</i> of the American Academy of Pediatrics/American Heart Association (AAP/AHA), must be present in the delivery area and nursery. | E | E | E | E | E |
| 10.2 | Surfactant and prostaglandin E1 must be immediately available to the nursery. | E | E | E | E | E |
| 10.3 | All emergency resuscitation medications to initiate and maintain resuscitation, in accordance with Advanced Cardiac Life Support (ACLS) guidelines, must be present in the delivery area. | E | E | E | E | E |
| 10.4 | The following medications must be in the delivery area or immediately available to the delivery area: a) oxytocin b) Methergine c) Prostin/15M | E | E | E | E | E |

| | I | II | III | III+ | IV |
|--|----|----|-----|------|----|
| STANDARD XI. CONTINUING EDUCATION PROGRAMS | | | | | |
| 11.1 | E | E | E | E | E |
| The hospital shall provide periodic continuing education programs for physicians, nurses, and allied health personnel on staff concerning the treatment and care of obstetrical and neonatal patients. | | | | | |
| 11.2 | NA | NA | E | E | E |
| The hospital shall participate in perinatal case reviews and provide continuing education programs for referral hospitals. | | | | | |
| STANDARD XII. PREVENTION/PUBLIC EDUCATION | | | | | |
| 12.1 | E | E | E | E | E |
| The hospital shall collaborate with the Department of Health and Mental Hygiene in developing, monitoring, and evaluating the effectiveness of infant mortality prevention and public education programs. | | | | | |
| STANDARD XIII. QUALITY MANAGEMENT | | | | | |
| 13.1 | E | E | E | E | E |
| The hospital must have a multi-disciplinary continuous quality improvement program for improving maternal and neonatal health outcomes. | | | | | |
| 13.2 | E | E | E | E | E |
| The hospital shall conduct perinatal case reviews which include an audit of all maternal, fetal, and neonatal deaths; all very low birth weight births; and all maternal and neonatal transports. | | | | | |
| 13.3 | E | E | E | E | E |
| The hospital shall, at an appropriate multi-disciplinary forum, periodically review the performance of the perinatal program, including trends, all deaths, all transfers, problem identification and solution, issues identified from the quality management process, and systems issues. | | | | | |
| 13.4 | E | E | E | E | E |
| The hospital must provide documentation of quality management efforts including a) problem identification, b) analysis, c) action plan, d) implementation, and e) reevaluation. | | | | | |

| | I | II | III | III+ | IV |
|--|----|----|-----|------|----|
| STANDARD XIV. POLICIES AND PROTOCOLS | | | | | |
| 14.1 The hospital must have written policies and protocols for the initial stabilization and care of all obstetrical patients. | E | E | E | E | E |
| 14.2 The hospital must have written policies and protocols for the continuing care of obstetrical patients: | | | | | |
| a) ≥ 36 weeks gestation | E | E | E | E | E |
| b) ≥ 32 weeks gestation | NA | E | E | E | E |
| c) ≥ 26 weeks gestation | NA | NA | E | E | E |
| d) at all gestational ages | NA | NA | NA | E | E |
| 14.3 The hospital must have written policies and protocols for the initial stabilization and care of all neonates. | E | E | E | E | E |
| 14.4 The hospital must have written policies and protocols for the continuing care of neonates: | | | | | |
| a) $\geq 1,800$ grams, if oxygen is not required beyond the immediate stabilization period (up to 6 hours post-delivery) | E | E | E | E | E |
| b) $\geq 1,500$ grams, if (a) $\geq 60\%$ oxygen is not required beyond the immediate stabilization period, (b) an arterial catheter for blood pressure or blood gas monitoring is not required, (c) exchange transfusion is not required. | NA | E | E | E | E |
| c) ≥ 800 grams birth weight | NA | NA | E | E | E |
| d) of all birth weights | NA | NA | NA | E | E |

| | | | | | |
|---|---|----|-----|------|----|
| | I | II | III | III+ | IV |
| 14.5 The hospital must have maternal and neonatal resuscitation protocols. | E | E | E | E | E |
| 14.6 The hospital shall have written guidelines for the "back transport" of maternal and neonatal patients. | E | E | E | E | E |
| 14.7 The hospital shall have a licensed neonatal transport program or written agreement with a licensed neonatal transport program. | E | E | E | E | E |

REVISED 1/98