MISSISSIPPI STATE DEPARTMENT OF HEALTH

MEMORANDUM

TO: **Interested Parties**

FROM: **Rachel E. Pittman, Chief**
Division of Health Planning and Resource Development

THROUGH: **Donald E. Eicher, III, Director**
Office of Health Policy and Planning

DATE: **March 11, 2009**

Re: **Proposed Changes to the FY 2010 Mississippi State Health Plan**

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On April 8, 2008, the Division of Health Planning and Resource Development will request the Mississippi State Board of Health to adopt "Notice of Intent" of changes to the criteria and standards of the FY 2010 Mississippi State Health Plan in order to initiate the planning process. Copies of the proposed changes to the criteria and standards of the *FY 2010 State Health P*lan may be found on our website at www.msdh.state.ms.us or www.healthyMS.com, choose Regulation and Licensure and click on Certificate of Need; at the Secretary of State's Office; and in the Office of Health Policy and Planning.

Written comments will be accepted during the period of March 11, 2009, to April 3, 2009. In addition, a hearing will be held on this matter on March 27, 2009, at 10:00 a.m. in the Health Services Conference Room, 2nd Floor, Osborne Building, at the Mississippi State Department of Health, 570 Woodrow Wilson Avenue, Jackson, Mississippi.

The major changes in criteria and standards proposed as recommended by the Board of Health CON Task Force are:

1. **Acute Care Chapter**

    a. **New General Hospital Service Areas**

b. **New General Acute Care Hospital criteria for counties located in an underdeveloped General Hospital Service Area with a rapidly growing population**

2. **Update of Obstetrical Services**

3. **Update of Neonatal Special Care Services**

CERTIFICATE OF NEED

CRITERIA AND STANDARDS
FOR
NURSING HOME BEDS

100 Certificate of Need Criteria and Standards for Nursing Home Beds

Note: Should the Mississippi State Department of Health receive a Certificate of Need application regarding the acquisition and/or otherwise control of major medical equipment or the provision of a service for which specific CON criteria and standards have not been adopted, the application shall be deferred until the Department of Health has developed and adopted CON criteria and standards. If the Department has not developed CON criteria and standards within 180 days of receiving a CON application, the application will be reviewed using the general CON review criteria and standards presented in the *Mississippi Certificate of Need Review Manual* and all adopted rules, procedures, and plans of the Mississippi State Department of Health.

100.01 106.01 Policy Statement Regarding Certificate of Need Applications for the Offering of Nursing Home Care Services

1. Legislation

   a. The 1990 Mississippi Legislature imposed a permanent moratorium which prohibits the MSDH from granting approval for or issuing a Certificate of Need to any person proposing the new construction of, addition to, expansion of, or conversion of vacant hospital beds to provide skilled or intermediate nursing home care, except as specifically authorized by statute.

   b. Effective July 1, 1990, any health care facility defined as a psychiatric hospital, skilled nursing facility, intermediate care facility, intermediate care facility for the mentally retarded, or psychiatric residential treatment facility that is owned by the State of Mississippi and under the direction and control of the State Department of Mental Health is exempted from the requirement of the issuance of a Certificate of Need under Section 41-7-171 et seq., for projects which involve new construction, renovation, expansion, addition of new beds, or conversion of beds from one category to another in any such defined health care facility.

   c. The 1999 Mississippi Legislature temporarily lifted the 1990 moratorium to allow a 60-bed nursing facility to be added to each of 26 counties with the greatest need between the years 2000 and 2003. The Legislature also permitted CONs for 60 nursing facility beds for individuals with Alzheimer's disease in the northern, central, and southern parts of each of the Long-Term Care Planning Districts, for a total of 240 additional beds.

   d. Effective April 12, 2002, no health care facility shall be authorized to add any beds or convert any beds to another category of beds without a Certificate of Need.

   e. Effective March 4, 2003, if a health care facility has voluntarily delicensed some of its existing bed complement, it may later relicense some or all of its delicensed beds without the necessity of having to acquire a Certificate of Need. The Department of Health shall maintain a record of the delicensing health care facility and its voluntarily delicensed beds and continue counting

those beds as part of the state's total bed count for health care planning purposes.

2. Long-Term Care Planning Districts (LTCPD): The MSDH shall determine the need for additional nursing home care beds based on the LTCPDs as outlined on Map 8-1. The MSDH shall calculate the statistical need for beds in each LTCPD independently of all other LTCPDs.

3. Bed Need: The need for nursing home care beds is established at:

   0.5 beds per 1,000 population aged 64 and under
   10 beds per 1,000 population aged 65-74
   36 beds per 1,000 population aged 75-84
   135 beds per 1,000 population aged 85 and older

4. Population Projections: The MSDH shall use population projections as presented in Table 8-1 when calculating bed need. These population projections are the most recent projections prepared by the Center for Policy Research and Planning of the Institutions of Higher Learning.

5. Bed Inventory: The MSDH shall review the need for additional nursing home beds using the most recent information available regarding the inventory of such beds.

6. Size of Facility: The MSDH shall not approve construction of a new or replacement nursing home care facility for less than 60 beds. However, the number of beds authorized to be licensed in a new or replacement facility may be less than 60 beds.

7. Definition of CCRC: The Glossary of this *Plan* presents the MSDH's definition of a "continuing care retirement community" for the purposes of planning and CON decisions.

8. Medicare Participation: The MSDH strongly encourages all nursing homes participating in the Medicaid program to also become certified for participation in the Medicare program.

9. Alzheimer's/Dementia Care Unit: The MSDH encourages all nursing home owners to consider the establishment of an Alzheimer's/Dementia Care Unit as an integral part of their nursing care program.

100.02 Certificate of Need Criteria and Standards for Nursing Home Care Beds

If the legislative moratorium were removed or partially lifted, the MSDH would review applications for the offering of nursing home care under the statutory requirements of Sections 41-7-173 (h) subparagraphs (iv) and (vi), 41-7-191, and 41-7-193, Mississippi Code of 1972, as amended. The MSDH will also review applications for Certificate of Need according to the applicable policy statements contained in this *Plan*; the general criteria listed in the *Mississippi Certificate of Need Review Manual*; all adopted rules, procedures, and plans of the MSDH; and the specific criteria and standards listed below.

Certificate of Need review is required for the offering of nursing home care services, as defined, if the capital expenditure exceeds $2,000,000; if the licensed bed capacity is increased through the conversion or addition of beds; or if nursing home care services have not been provided on a regular basis by the proposed provider of such services within the period of twelve (12) months prior to the time such services would be offered. Certificate of Need review is required for the construction, development, or otherwise establishment of new nursing home care beds regardless of capital expenditure.

1. **Need Criterion: The applicant shall document a need for nursing home care beds using the need methodology as presented herein: The Long-Term Care Planning District wherein the proposed facility will be located must show a need using the following ratio:**

   0.5 beds per 1,000 population aged 64 and under
   10 beds per 1,000 population aged 65-74
   36 beds per 1,000 population aged 75-84
   135 beds per 1,000 population aged 85 and older

2. The applicant shall document the number of beds that will be constructed, converted, and/or licensed as offering nursing home care services.

3. The MSDH should consider the area of statistical need as one criterion when awarding Certificates of Need in the case of competing applications.

4. Any applicant applying for nursing home beds who proposes to establish an Alzheimer's/Dementia Care Unit shall affirm that the applicant shall fully comply with all licensure regulations of the MSDH for said Alzheimer's/Dementia Care Unit.

100.03 Certificate of Need Criteria and Standards for Nursing Home Beds As Part of a Continuing Care Retirement Community (CCRC)

Entities desiring to establish nursing home beds as part of a CCRC shall meet all applicable requirements, as determined by the MSDH, of the policy statements and general CON criteria and standards in the Mississippi Certificate of Need Review Manual and the CON criteria and standards for nursing home beds established in this State Health Plan.

101 Policy Statement Regarding Certificate of Need Applications for a Pediatric Skilled Nursing Facility

1. The 1993 Mississippi Legislature authorized the Department of Health to issue a Certificate of Need for the construction of a pediatric skilled nursing facility not to exceed 60 new beds.

2. A pediatric skilled nursing facility is defined as an institution or a distinct part of an institution that is primarily engaged in providing to inpatients skilled nursing care and related services for persons under 21 years of age who require medical, nursing care, or rehabilitation services for the rehabilitation of injured, disabled, or sick persons.

3. The MSDH will review applications for the construction of pediatric skilled nursing facility beds using the general CON review criteria and standards contained in the *Mississippi Certificate of Need Review Manual*, criteria and standards for nursing homes and MR/DD facilities contained in the *State Health Plan*, and all adopted rules, procedures, and plans of the Mississippi State Department of Health.

4. Effective April 12, 2002, no health care facility shall be authorized to add any beds or convert any beds to another category of beds without a Certificate of Need under the authority of Section 41-7-191(1)(c).

5. Effective March 4, 2003, if a health care facility has voluntarily delicensed some of its existing bed complement, it may later relicense some or all of its delicensed beds without the necessity of having to acquire a Certificate of Need. The Department of Health shall maintain a record of the delicensing health care facility and its voluntarily delicensed beds and continue counting those beds as part of the state's total bed count for health care planning purposes.

102 Long-Term Care Beds for Individuals with Mental Retardation and Other Developmental Disabilities

Mississippi has 2,765 licensed beds classified as ICF/MR (intermediate care facility for the mentally retarded). The Department of Mental Health (MDMH) operates five comprehensive regional centers that contain 2,076 active licensed and staffed beds. There are also five proprietary facilities operate the remaining 669 beds. The residents of the MDMH's regional centers, although they have mental retardation/developmental disabilities, also have severe physical disabilities that result in their requiring care at the nursing home level. Regular nursing facilities are not equipped to serve these individuals.

Map 8-2 shows the MR/DD Long-Term Care Planning Districts and Table 8-4 presents the MR/DD nursing home bed need by Planning District. Both the map and table appear in the criteria and standards section of this chapter.

103 Certificate of Need Criteria and Standards for Nursing Home Care Services for Mentally Retarded and other Developmentally Disabled Individuals

103.01 Policy Statement Regarding Certificate of Need Applications for the Offering of Nursing Home Care Services for Mentally Retarded and Other Developmentally Disabled Individuals

1. Legislation

   a. The 1990 Mississippi Legislature imposed a permanent moratorium which prohibits the MSDH from granting approval for or issuing a CON to any person proposing the new construction, addition to, or expansion of an intermediate care facility for the mentally retarded (ICF/MR).

   b. Effective July 1, 1990, any health care facility defined as a psychiatric hospital, skilled nursing facility, intermediate care facility, intermediate care

facility for the mentally retarded, or psychiatric residential treatment facility which is owned by the State of Mississippi and under the direction and control of the State Department of Mental Health is exempted from the requirement of the issuance of a Certificate of Need under Section 41-7-171 et seq., for projects which involve new construction, renovation, expansion, addition of new beds, or conversion of beds from one category to another in any such defined health care facility.

c. Effective April 12, 2001, no health care facility shall be authorized to add any beds or convert any beds to another category of beds without a Certificate of Need.

d. Effective March 4, 2003, if a health care facility has voluntarily delicensed some of its existing bed complement, it may later relicense some or all of its delicensed beds without the necessity of having to acquire a Certificate of Need. The Department of Health shall maintain a record of the delicensing health care facility and its voluntarily delicensed beds and continue counting those beds as part of the state's total bed count for health care planning purposes.

2. MR/DD Long-Term Care Planning Districts (MR/DD LTCPD): The need for additional MR/DD nursing home care beds shall be based on the MR/DD LTCPDs as outlined in Map 8-2

3. Bed Need: The need for MR/DD nursing home care beds is established at one bed per 1,000 population less than 65 years of age.

4. Population Projections: The MSDH shall use population projections as presented in Table 8-2 when calculating bed need.

5. Bed Limit: No MR/DD LTCPD shall be approved for more than its proportioned share of needed MR/DD nursing home care beds. No application shall be approved which would over-bed the state as a whole.

6. Bed Inventory: The MSDH shall review the need for additional MR/DD nursing home care beds utilizing the most recent information available regarding the inventory of such beds.

103.02 Certificate of Need Criteria and Standards for Nursing Home Beds for Mentally Retarded and Other Developmentally Disabled Individuals

If the legislative moratorium were removed or partially lifted, the Mississippi State Department of Health would review applications for MR/DD nursing home care beds under the statutory requirements of Sections 41-7-173 (h) subparagraph (viii), 41-7-191, and 41-7-193, Mississippi Code 1972, as amended. The MSDH will also review applications for Certificate of Need according to the applicable policy statements contained in this *Plan;* the general criteria as listed in the *Mississippi Certificate of Need Review Manual*; all adopted rules, procedures, and plans of the Mississippi State Department of Health; and the specific criteria and standards listed below.

Certificate of Need review is required for the offering of MR/DD nursing home care services, as defined, if the capital expenditure exceeds $2,000,000; if the licensed bed capacity is increased through the conversion or addition of beds; or if MR/DD nursing home care services have not been provided on a regular basis by the proposed provider of such services within the period of twelve (12) months prior to the time such services would be offered. Certificate of Need review is required for the construction, development, or otherwise establishment of new MR/DD nursing home care beds regardless of capital expenditure.

1. **Need Criterion: The applicant shall document a need for MR/DD nursing home care beds using the need methodology as presented below. The applicant shall document in the application the following:**

   a. **using the ratio of one bed per 1,000 population under 65 years of age, the state as a whole must show a need; and**

   b. **the MR/DD Long-Term Care Planning District (LTCPD) where the proposed facility/beds/services are to be located must show a need.**

2. The applicant shall document the number of beds that will be constructed/converted and/or licensed as offering MR/DD nursing home care services.

3. The MSDH shall give priority consideration to those CON applications proposing the offering of MR/DD nursing home care services in facilities which are 15 beds or less in size.

CERTIFICATE OF NEED
CRITERIA AND STANDARDS
FOR
ACUTE PSYCHIATRIC,
CHEMICAL DEPENDENCY,
AND
PSYCHIATRIC RESIDENTIAL
TREATMENT FACILITY BEDS/SERVICES

100 Certificate of Need Criteria and Standards for Acute Psychiatric, Chemical Dependency, and Psychiatric Residential Treatment Facility Beds/Services

Note: Should the Mississippi State Department of Health receive a Certificate of Need application regarding the acquisition and/or otherwise control of major medical equipment or the provision of a service for which specific CON criteria and standards have not been adopted, the application shall be deferred until the Department of Health has developed and adopted CON criteria and standards. If the Department has not developed CON criteria and standards within 180 days of receiving a CON application, the application will be reviewed using the general CON review criteria and standards presented in the *Mississippi Certificate of Need Review Manual* and all adopted rules, procedures, and plans of the Mississippi State Department of Health.

100.01 Policy Statement Regarding Certificate of Need Applications for Acute Psychiatric, Chemical Dependency, and Psychiatric Residential Treatment Facility Beds/Services

1. An applicant must provide a "reasonable amount" of indigent/charity care as described in Chapter I of this *Plan*.

2. Mental Health Planning Areas: The Department of Health shall use the state as a whole to determine the need for acute psychiatric beds/services, chemical dependency beds/ services, and psychiatric residential treatment beds/services. Tables 9-7, 9-8, and 9-9 give the statistical need for each category of beds.

3. Public Sector Beds: Due to the public sector status of the acute psychiatric, chemical dependency, and psychiatric residential treatment facility beds operated directly by the Mississippi Department of Mental Health (MDMH), the number of licensed beds operated by the MDMH shall not be counted in the bed inventory used to determine statistical need for additional acute psychiatric, chemical dependency, and psychiatric residential treatment facility beds.

4. Comments from Department of Mental Health: The Mississippi State Department of Health shall solicit and take into consideration comments received from the Mississippi Department of Mental Health regarding any CON application for the establishment or expansion of inpatient acute psychiatric, chemical dependency, and/or psychiatric residential treatment facility beds.

5. Separation of Adults and Children/Adolescents: Child and adolescent patients under 18 years of age must receive treatment in units which are programmatically and physically distinct from adult (18+ years of age) patient units. A single facility may house adults as well as adolescents and children if both physical design and staffing ratios provide for separation.

6. Separation of Males and Females: Facilities must separate males and females age 13 and over for living purposes (e.g., separate rooms and rooms located at separate ends of the halls, etc.).

7. Dually Diagnosed Patients: It is frequently impossible for a provider to totally predict or control short-term deviation in the number of patients with mixed psychiatric/

addictive etiology to their illnesses. Therefore, the Department will allow deviations of up to 25 percent of the total licensed beds as "swing-beds" to accommodate patients having diagnoses of both psychiatric and substance abuse disorders. However, the provider must demonstrate to the Division of Licensure and Certification that the "swing-bed" program meets all applicable licensure and certification regulations for each service offered, i.e., acute psychiatric, chemical dependency, and psychiatric residential treatment facility services, before providing such "swing-bed" services.

8. Comprehensive Program of Treatment: Any new mental health beds approved must provide a comprehensive program of treatment that includes, but is not limited to, inpatient, outpatient, and follow-up services, and in the case of children and adolescents, includes an educational component. The facility may provide outpatient and appropriate follow-up services directly or through contractual arrangements with existing providers of these services.

9. Medicaid Participation: An applicant proposing to offer acute psychiatric, chemical dependency, and/or psychiatric residential treatment facility services or to establish, expand, and/or convert beds under any of the provisions set forth in this section or in the service specific criteria and standards shall affirm in the application that:

   a. the applicant shall seek Medicaid certification for the facility/program at such time as the facility/program becomes eligible for such certification; and

   b. the applicant shall serve a reasonable number of Medicaid patients when the facility/program becomes eligible for reimbursement under the Medicaid Program. The application shall affirm that the facility will provide the MSDH with information regarding services to Medicaid patients.

10. Licensing and Certification: All acute psychiatric, chemical dependency treatment, dual diagnosis beds/services, and psychiatric residential treatment facility beds/services must meet all applicable licensing and certification regulations of the Division of Health Facilities Licensure and Certification. If licensure and certification regulations do not exist at the time the application is approved, the program shall comply with such regulations following their effective date.

11. Psychiatric Residential Treatment Facility: A psychiatric residential treatment facility (PRTF) is a non-hospital establishment with permanent licensed facilities that provides a twenty-four (24) hour program of care by qualified therapists including, but not limited to, duly licensed mental health professionals, psychiatrists, psychologists, psychotherapists, and licensed certified social workers, for emotionally disturbed children and adolescents referred to such facility by a court, local school district, or the Department of Human Services, who are not in an acute phase of illness requiring the services of a psychiatric hospital and who are in need of such restorative treatment services. For purposes of this paragraph, the term "emotionally disturbed" means a condition exhibiting one or more of the following characteristics over a long period of time and to a marked degree, which adversely affects educational performance:

   a. an inability to learn which cannot be explained by intellectual, sensory, or health factors;

   b. an inability to build or maintain satisfactory relationships with peers and teachers;

c. inappropriate types of behavior or feelings under normal circumstances;

d. a general pervasive mood of unhappiness or depression; or

e. a tendency to develop physical symptoms or fears associated with personal or school problems.

An establishment furnishing primarily domiciliary care is not within this definition.

12. Certified Educational Programs: Educational programs certified by the Department of Education shall be available for all school age patients. Also, sufficient areas suitable to meet the recreational needs of the patients are required.

13. Preference in CON Decisions: Applications proposing the conversion of existing acute care hospital beds to acute psychiatric and chemical dependency beds shall receive preference in CON decisions provided the application meets all other criteria and standards under which it is reviewed.

14. Dedicated Beds for Children's Services: It has been determined that there is a need for specialized beds dedicated for the treatment of children less than 14 years of age. Therefore, of the beds determined to be needed for child/adolescent acute psychiatric services and psychiatric residential treatment facility services, 25 beds under each category, for a total of 50 beds statewide, shall be reserved exclusively for programs dedicated to children under the age of 14.

15. Effective April 12, 2002, no health care facility shall be authorized to add any beds or convert any beds to another category of beds without a Certificate of Need under the authority of Section 41-7-191(1)(c).

16. Effective March 4, 2003, if a health care facility has voluntarily delicensed some of its existing bed complement, it may later relicense some or all of its delicensed beds without the necessity of having to acquire a Certificate of Need. The Department of Health shall maintain a record of the delicensing health care facility and its voluntarily delicensed beds and continue counting those beds as part of the state's total bed count for health care planning purposes.

100.02 General Certificate of Need Criteria and Standards for Acute Psychiatric, Chemical Dependency, and/or Psychiatric Residential Treatment Facility Beds/Services

The Mississippi State Department of Health will review applications for a Certificate of Need for the establishment, offering, or expansion of acute psychiatric, chemical dependency treatment, and/or psychiatric residential treatment beds/services under the applicable statutory requirements of Sections 41-7-173, 41-7-191, and 41-7-193, Mississippi Code of 1972, as amended. The MSDH will also review applications for Certificate of Need according to the policies in this *Plan*; the general criteria listed in the *Mississippi Certificate of Need Review Manual*; all adopted rules, procedures, and plans of the Mississippi State Department of Health; and the general and service specific criteria and standards listed below.

The offering of acute psychiatric, chemical dependency treatment, and/or psychiatric residential treatment facility services is reviewable if the proposed provider has not offered those services on a regular basis within the period of twelve (12) months prior to the time such services would be offered. The construction, development, or other establishment of a new health care facility to provide acute psychiatric, chemical dependency treatment, and/or psychiatric residential treatment services requires CON review regardless of capital expenditure.

1. **Need Criterion:**

   a. **New/Existing Acute Psychiatric, Chemical Dependency, and/or Psychiatric Residential Treatment Facility Beds/Services**: The applicant shall document a need for acute psychiatric, chemical dependency, and/or psychiatric residential treatment facility beds using the appropriate bed need methodology as presented in this section under the service specific criteria and standards.

   b. Projects which do not involve the addition of acute psychiatric, chemical dependency, and/or psychiatric residential treatment facility beds: The applicant shall document the need for the proposed project. Documentation may consist of, but is not limited to, citing of licensure or regulatory code deficiencies, institutional long-term plans duly adopted by the governing board, recommendations made by consultant firms, and deficiencies cited by accreditation agencies (JCAHO, CAP, etc.).

   c. **Projects which involve the addition of beds**: The applicant shall document the need for the proposed project. Exception: Notwithstanding the service specific statistical bed need requirements as stated in "a" above, the Department may approve additional beds for facilities which have maintained an occupancy rate of at least 80 percent for the most recent 12-month licensure reporting period or at least 70 percent for the most recent two (2) years.

   d. **Child Psychiatry Fellowship Program**: Notwithstanding the service specific statistical bed need requirements as stated in "a" above, the Department may approve a 15-bed acute child psychiatric unit at the University of Mississippi Medical Center for children aged 4-12 to provide a training site for psychiatric residents.

2. The application shall affirm that the applicant will record and maintain, at a minimum, the following information regarding charity care and care to the medically indigent and make such information available to the Mississippi State Department of Health within 15 business days of request:

   a. source of patient referral;

   b. utilization data, e.g., number of indigent admissions, number of charity admissions, and inpatient days of care;

   c. demographic/patient origin data;

   d. cost/charges data; and

e. any other data pertaining directly or indirectly to the utilization of services by medically indigent or charity patients which the Department may request.

3. A CON applicant desiring to provide or to expand chemical dependency, psychiatric, and/or psychiatric residential treatment facility services shall provide copies of signed memoranda of understanding with Community Mental Health Centers and other appropriate facilities within their patient service area regarding the referral and admission of charity and medically indigent patients.

4. Applicants should also provide letters of comment from the Community Mental Health Centers, appropriate physicians, community and political leaders, and other interested groups that may be affected by the provision of such care.

5. The application shall document that within the scope of its available services, neither the facility nor its participating staff shall have policies or procedures which would exclude patients because of race, color, age, sex, ethnicity, or ability to pay.

The application shall document that the applicant will provide a reasonable amount of charity/indigent care as provided for in Chapter I of this *Plan*.

100.03 Service Specific Certificate of Need Criteria and Standards for Acute Psychiatric, Chemical Dependency, and/or Psychiatric Residential Treatment Facility Beds/Services

100.03.01 Acute Psychiatric Beds for Adults

1. The Mississippi State Department of Health shall base statistical need for adult acute psychiatric beds on a ratio of **0.21 beds per 1,000 population aged 18 and older for 2010** in the state as a whole as projected by the Division of Health Planning and Resource Development. Table 9-7 presents the statistical need for adult psychiatric beds.

2. The applicant shall provide information regarding the proposed size of the facility/unit. Acute psychiatric beds for adults may be located in either freestanding or hospital-based facilities. Freestanding facilities should not be larger than 60 beds. Hospital units should not be larger than 30 beds. Patients treated in adult facilities and units should be 18 years of age or older.

3. The applicant shall provide documentation regarding the staffing of the facility. Staff providing treatment should be specially trained for the provision of psychiatric and psychological services. The staff should include both psychiatrists and psychologists and should provide a multi-discipline psychosocial medical approach to treatment.

100.03.02 Acute Psychiatric Beds for Children and Adolescents

1. The Mississippi State Department of Health shall base statistical need for child/adolescent acute psychiatric beds on a ratio of **0.55 beds per 1,000 population aged 7 to 17 for 2010** in the state as a whole as projected by the Division of Health

Planning and Resource Development. Table 9-7 presents the statistical need for child/adolescent psychiatric beds. Of the specified beds needed, 25 beds are hereby set aside exclusively for the treatment of children less than 14 years of age.

2. The applicant shall provide information regarding the proposed size of the facility/unit. Acute psychiatric beds for children and adolescents may be located in freestanding or hospital-based units and facilities. A facility should not be larger than 60 beds. All units, whether hospital-based or freestanding, should provide a homelike environment. Ideally, a facility should provide cottage-style living units housing eight to ten patients. Because of the special needs of children and adolescents, facilities or units which are not physically attached to a general hospital are preferred. For the purposes of this *Plan*, an adolescent is defined as a minor who is at least 14 years old but less than 18 years old, and a child is defined as a minor who is at least 7 years old but less than 14 years old.

3. The applicant shall provide documentation regarding the staffing of the facility. Staff should be specially trained to meet the needs of adolescents and children. Staff should include both psychiatrists and psychologists and should provide a multi-discipline psychosocial medical approach to treatment. The treatment program must involve parents and/or significant others. Aftercare services must also be provided.

4. The applicant shall describe the structural design of the facility in providing for the separation of children and adolescents. In facilities where both children and adolescents are housed, the facility should attempt to provide separate areas for each age grouping.

100.03.03 Chemical Dependency Beds for Adults

1. The Mississippi State Department of Health shall base statistical need for adult chemical dependency beds on a ratio of **0.14 beds per 1,000 population aged 18 and older for 2010** in the state as a whole as projected by the Division of Health Planning and Resource Development. Table 9-8 presents the statistical need for adult chemical dependency beds.

2. The applicant shall provide information regarding the proposed size of the facility/unit. Chemical dependency treatment programs may be located in either freestanding or hospital-based facilities. Facilities should not be larger than 75 beds, and individual units should not be larger than 30 beds. The bed count also includes detoxification beds. Staff should have specialized training in the area of alcohol and substance abuse treatment, and a multi-discipline psychosocial medical treatment approach which involves the family and significant others should be employed.

3. The applicant shall describe the aftercare or follow-up services proposed for individuals leaving the chemical dependency program. Chemical dependency treatment programs should include extensive aftercare and follow-up services.

4. The applicant shall specify the type of clients to be treated at the proposed facility. Freestanding chemical dependency facilities and hospital-based units should provide services to substance abusers as well as alcohol abusers.

100.03.04 Chemical Dependency Beds for Children and Adolescents

1. The Mississippi State Department of Health shall base statistical need for child/adolescent chemical dependency beds on a ratio of **0.44 beds per 1,000 population aged 12 to 17 for 2010** in the state as a whole as projected by the Division of Health Planning and Resource Development. Table 9-8 presents the statistical need for child/adolescent chemical dependency beds.

2. The applicant shall provide information regarding the proposed size of the facility/unit. Chemical dependency beds may be located in either freestanding or hospital-based facilities. Because of the unique needs of the child and adolescent population, facilities shall not be larger than 60 beds. Units shall not be larger than 20 beds. The bed count of a facility or unit will include detoxification beds.

   Facilities or units, whether hospital-based or freestanding, should provide a home-like environment. Ideally, facilities should provide cottage-style living units housing eight to ten patients. Because of the special needs of children and adolescents, facilities or units which are not physically attached to a general hospital are preferred.

3. The applicant shall provide documentation regarding the staffing of the facility. Staff should be specially trained to meet the needs of adolescents and children. Staff should include both psychiatrists and psychologists and should provide a multi-discipline psychosocial medical approach to treatment. The treatment program must involve parents and significant others. Aftercare services must also be provided.

4. The applicant shall describe the structural design of the facility in providing for the separation of the children and adolescents. Child and adolescent patients shall be separated from adult patients for treatment and living purposes.

5. The applicant shall describe the aftercare or follow-up services proposed for individuals leaving the chemical dependency program. Extensive aftercare and follow-up services involving the family and significant others should be provided to clients after discharge from the inpatient program. Chemical dependency facilities and units should provide services to substance abusers as well as alcohol abusers.

100.03.05 Psychiatric Residential Treatment Facility Beds/Services

1. The Mississippi State Department of Health shall base statistical need for psychiatric residential treatment beds on a ratio of **0.4 beds per 1,000 population aged 5 to 21 for 2010** in the state as a whole as projected by the Division of Health Planning and Resource Development. Table 9-9 presents the statistical need for psychiatric residential treatment facility beds.

2. The application shall state the age group that the applicant will serve in the psychiatric residential treatment facility and the number of beds dedicated to each age group (5 to 13, 14 to 17, and 18 to 21).

3. The applicant shall describe the structural design of the facility for the provision of services to children less than 14 years of age. Of the beds needed for psychiatric

residential treatment facility services, 25 beds are hereby set aside exclusively for the treatment of children less than 14 years of age. An applicant proposing to provide psychiatric residential treatment facility services to children less than 14 years of age shall make provision for the treatment of these patients in units which are programmatically and physically distinct from the units occupied by patients older than 13 years of age. A facility may house both categories of patients if both the physical design and staffing ratios provide for separation.

4. This criterion does not preclude more than 25 psychiatric residential treatment facility beds being authorized for the treatment of patients less than 14 years of age. However, the Department shall not approve more psychiatric residential treatment facility beds statewide than specifically authorized by legislation (Miss. Code Ann. § 41-7-191 et. seq). (Note: the 298 licensed and CON approved beds indicated in Table 9-4 were the result of both CON approval and legislative actions).

5. The applicant shall provide information regarding the proposed size of the facility/unit. A psychiatric residential treatment facility should provide services in a homelike environment. Ideally, a facility should provide cottage-style living units not exceeding 15 beds. A psychiatric residential treatment facility should not be larger than 60 beds.

6. The applicant shall provide documentation regarding the staffing of the facility. Staff should be specially trained to meet the treatment needs of the age category of patients being served. Staff should include both psychiatrists and psychologists and should provide a multi-discipline psychosocial medical approach to treatment. The treatment program must involve parents and/or significant others. Aftercare/follow-up services must also be provided.

Table 9 - 1
Statewide Acute Psychiatric Bed Need
2009

Bed Category and Ratio	2010 Projected Population	Projected Bed Need	Licensed/CON Approved/Abeyance Beds	Difference
Adult Psychiatric: 0.21 beds per 1,000 population aged 18+	2,238,274	470	555	-85
Child/Adolescent Psychiatric: 0.55 beds per 1,000 population aged 7 to 17	452,740	249	233	16

Sources: Applications for Renewal of Hospital License for Calendar Year 2008 and FY 2007 Annual Hospital Report; and Division of Health Planning and Resource Development calculations

Table 9 - 2
Statewide Chemical Dependency Bed Need
2009

Bed Category and Ratio	2010 Projected Population	Projected Bed Need	Licensed/CON Approved Beds	Difference
Adult Chemical Dependency: 0.14 beds per 1,000 population aged 18+	2,238,274	313	311	2
Child/Adolescent Chemical Dependency: 0.44 beds per 1,000 population aged 12 to 17	251,695	111	52	59

Sources: Applications for Renewal of Hospital License for Calendar Year 2008 and FY 2007 Annual Hospital Report; Division of Health Planning and Resource Development calculations, April 2008

Table 9 - 3
Statewide Psychiatric Residential
Treatment Facility Bed Need
2009

Age Cohort	Bed Ratio per 1,000 Population	2010 Projected Population	Projected Bed Need	Licensed/CON Approved Beds	Difference
5 to 21	0.4	704,365	282	298	-16

Sources: Applications for Renewal of Hospital License for Calendar Year 2008 and FY 2007 Annual Hospital Report; and Division of Health Planning and Resource Development calculations, April 2008

CERTIFICATE OF NEED

CRITERIA AND STANDARDS
FOR
OBSTETRICAL SERVICES

100 Certificate of Need Criteria and Standards for Obstetrical Services

Note: Should the Mississippi State Department of Health receive a Certificate of Need application regarding the acquisition and/or otherwise control of major medical equipment or the provision of a service for which specific CON criteria and standards have not been adopted, the application shall be deferred until the Department of Health has developed and adopted CON criteria and standards. If the Department has not developed CON criteria and standards within 180 days of receiving a CON application, the application will be reviewed using the general CON review criteria and standards presented in the *Mississippi Certificate of Need Review Manual* and all adopted rules, procedures, and plans of the Mississippi State Department of Health.

100.01 Policy Statement Regarding Certificate of Need Applications for the Offering of Obstetrical Services

1. An applicant is required to provide a reasonable amount of indigent/charity care as described in Chapter 1 of this *Plan*.

2. Perinatal Planning Areas (PPA): The MSDH shall determine the need for obstetrical services using the Perinatal Planning Areas as outlined on Map 10-3 at the end of this chapter.

3. ~~Optimum Utilization: For planning and CON purposes, optimum utilization is defined as 60 percent occupancy per annum for all existing OB beds in an OB unit.~~

4. Travel Time: Obstetrical services should be available within one (1) hour normal travel time of 95 percent of the population in rural areas and within 30 minutes normal travel time in urban areas.

5. ~~Dedicated Beds: An applicant proposing to offer obstetrical services shall dedicate a minimum of six (6) beds.~~

6. Preference in CON Decisions: The MSDH shall give preference in CON decisions to applications that propose to improve existing services and to reduce costs through consolidation of two basic obstetrical services into a larger, more efficient service over the addition of new services or the expansion of single service providers.

7. Patient Education: Obstetrical service providers shall offer an array of family planning and related maternal and child health education programs that are readily accessible to current and prospective patients.

8. Levels of Care: Basic Perinatal Centers (provide basic inpatient care for pregnant women and newborns without complications.

Specialty Perinatal Centers – provide management for certain high-risk pregnancies, including maternal referrals from basic care centers as well as basic perinatal services.

Subspecialty Perinatal Centers – provide inpatient care for maternal and fetal complications as well as basic and specialty care.

9. An applicant proposing to offer obstetrical services shall be equipped to provide basic perinatal services in accordance with the guidelines contained in the *Minimum Standards of Operation for Mississippi Hospitals*. § 130, Obstetrics and Newborn Nursery. Hospitals proposing to offer specialty and subspecialty care for high risk neonates shall conform to the recommendations of the American Academy of Pediatrics, Policy Statement, Levels of Neonatal Care (PEDIATRICS Vol. 114 No. 5 November 2004).

10. An applicant proposing to offer obstetrical services shall agree to provide an amount of care to Medicaid mothers/babies comparable to the average percentage of Medicaid care offered by other providers of the requested service within the same, or most proximate, geographic area.

100.02 Certificate of Need Criteria and Standards for Obstetrical Services

The Mississippi State Department of Health will review applications for a Certificate of Need to establish obstetric services under the statutory requirements of Sections 41-7-173, 41-7-191, and 41-7-193, Mississippi Code of 1972, as amended. The MSDH will also review applications for Certificate of Need according to the general criteria listed in the *Mississippi Certificate of Need Review Manual*; all adopted rules, procedures, and plans of the Mississippi State Department of Health; and the specific criteria and standards listed below.

The establishment of obstetrical services or the expansion of the existing service shall require approval under the Certificate of Need statute if the $2,000,000 capital expenditure threshold is crossed.

Provision for individual units should be consistent with the regionalized perinatal care system involved. Those facilities desiring to provide obstetric services shall meet the Basic facility minimum standards as listed under *Guidelines for the Operation of Perinatal Units* found in Section D of this *Plan*.

1. **Need Criterion:**

   a. **the application shall demonstrate how the applicant can reasonably expect to deliver a minimum of 150 babies the first full year of operation and 250 babies by the second full year. In this demonstration, the applicant shall document the number of deliveries performed in the proposed obstetric service area (as described in Section 100.01 (4) above) by hospital.**

   ~~the applicant shall demonstrate, subject to verification by the Mississippi State Department of Health, that all existing OB beds within the proposed~~

~~**Perinatal Planning Area have maintained an optimum utilization rate of 60 percent for the most recent 12-month reporting period.**~~

2. ~~Any facility offering obstetrical services shall have designated obstetrical beds~~.

3. The application shall document that the facility will provide one of the three types of perinatal services: Basic, Specialty, or Subspecialty.

4. The facility shall provide full-time nursing staff in the labor and delivery area on all shifts. Nursing personnel assigned to nursery areas in Basic Perinatal Centers shall be under the direct supervision of a qualified professional nurse.

5. Any facility proposing the offering of obstetrical services shall have written policies delineating responsibility for immediate newborn care, resuscitation, selection and maintenance of necessary equipment, and training of personnel in proper techniques.

6. The application shall document that the nurse, anesthesia, neonatal resuscitation, and obstetric personnel required for emergency cesarean delivery shall be in the hospital or readily available at all times.

7. The application shall document that the proposed services will be available within one (1) hour normal driving time of 95 percent of the population in rural areas and within 30 minutes normal driving time in urban areas.

8. The applicant shall affirm that the hospital will have protocols for the transfer of medical care of the neonate in both routine and emergency circumstances.

9. The application shall affirm that the applicant will record and maintain, at a minimum, the following information regarding charity care and care to the medically indigent and make it available to the Mississippi State Department of Health within 15 business days of request:

    a. source of patient referral;

    b. utilization data e.g., number of indigent admissions, number of charity admissions, and inpatient days of care;

    c. demographic/patient origin data;

    d. cost/charges data; and

    e. any other data pertaining directly or indirectly to the utilization of services by medically indigent or charity patients which the Department may request.

10. The applicant shall document that within the scope of its available services, neither the facility nor its participating staff shall have policies or procedures which would exclude patients because of race, age, sex, ethnicity, or ability to pay.

CERTIFICATE OF NEED

CRITERIA AND STANDARDS
FOR
NEONATAL SPECIAL CARE SERVICES

101 Certificate of Need Criteria and Standards for Neonatal Special Care Services

Note: Should the Mississippi State Department of Health receive a Certificate of Need application regarding the acquisition and/or otherwise control of major medical equipment or the provision of a service for which specific CON criteria and standards have not been adopted, the application shall be deferred until the Department of Health has developed and adopted CON criteria and standards. If the Department has not developed CON criteria and standards within 180 days of receiving a CON application, the application will be reviewed using the general CON review criteria and standards presented in the *Mississippi Certificate of Need Review Manual* and all adopted rules, procedures, and plans of the Mississippi State Department of Health.

101.01 Policy Statement Regarding Certificate of Need Applications for the Offering of Neonatal Special Care Services

1. An applicant is required to provide a reasonable amount of indigent/charity care as described in Chapter 1 of this *Plan*.

2. Perinatal Planning Areas (PPA): The MSDH shall determine the need for ~~obstetrical services~~ neonatal special care services using the Perinatal Planning Areas as outlined on Map 10-3 at the end of this chapter.

3. Bed Limit: The total number of neonatal special care beds should not exceed four (4) per 1,000 live births in a specified PPA as defined below:

    a. one (1) intensive care (subspecialty)bed per 1,000 live births; and

    b. three (3) intermediate (specialty)care beds per 1,000 live births.

4. Size of Facility: A single neonatal special care unit (Specialty or Subspecialty) should contain a minimum of 15 beds.

~~5. Optimum Utilization: For planning and CON purposes, optimum utilization is defined as 75 percent occupancy per annum for all existing providers of neonatal special care services within an applicant's proposed Perinatal Planning Area.~~

6. Levels of Care:

    Basic — Units provide uncomplicated care.

    Specialty — Units provide basic, intermediate, and recovery care as well as specialized services.

    Subspecialty — Units are staffed and equipped for the most intensive care of newborns as well as intermediate and recovery care.

7. An applicant proposing to offer neonatal special care services shall agree to provide an amount of care to Medicaid babies comparable to the average percentage of Medicaid care offered by the other providers of the requested services.

101.02 Certificate of Need Criteria and Standards for Neonatal Special Care Services

The Mississippi State Department of Health will review applications for a Certificate of Need to establish neonatal special care services under the statutory requirements of Sections 41-7-173, 41-7-191, and 41-7-193, Mississippi Code of 1972, as amended. The MSDH will also review applications for Certificate of Need according to the general criteria listed in the *Mississippi Certificate of Need Review Manual*; all adopted rules, procedures, and plans of the Mississippi State Department of Health; and the specific criteria and standards listed below.

Neonatal special care services are reviewable under Certificate of Need when either the establishment or expansion of the services involves a capital expenditure in excess of $2,000,000.

Those facilities desiring to provide neonatal special care services shall meet the capacity and levels of neonatal care for the specified facility (Specialty or Subspecialty) as previously listed under ~~*Minimum Standards of Care for Neonatal Special Care Services.*~~ the recommendations of the American Academy of Pediatrics, Policy Statement, Levels of Neonatal Care (PEDIATRICS Vol. 114 No. 5 November 2004)

1. **Need Criterion: The application shall demonstrate that the Perinatal Planning Area (PPA) wherein the proposed services are to be offered had a minimum of 3,600 deliveries for the most recent 12-month reporting period ~~and that each existing provider of neonatal special care services within the proposed PPA maintained an optimum utilization rate of 75 percent for the most recent 12-month period~~. The MSDH shall determine the need for neonatal special care services based upon the following:**

   a. one (1) neonatal intensive (subspecialty) care bed per 1,000 live births in a specified Perinatal Planning Area for the most recent 12-month reporting period; and

   b. three (3) neonatal intermediate (specialty) care beds per 1,000 live births in a specified Perinatal Planning Area for the most recent 12-month reporting period.

   Projects for existing providers of neonatal special care services which seek to expand capacity by the addition or conversion of neonatal special care beds: The applicant shall document the need for the proposed project. The applicant shall demonstrate that the facility in question has maintained an occupancy rate for neonate special care services of at least 70 percent for the most recent two (2) years or 80 percent neonate special care service occupancy rate for the most recent year, notwithstanding the neonate special care bed need outlined in Table 10-4 below. The applicant may be approved for such additional or conversion of neonate special care beds to meet the projected demand balanced with optimum utilization rate for the Perinatal Planning Area.

2. A single neonatal special care unit (Specialty or Subspecialty) should contain a minimum of 15 beds (neonatal intensive care and/or neonatal intermediate care). An adjustment downward may be considered for a specialty unit when travel time to an alternate unit is a serious hardship due to geographic remoteness.

3. The application shall document that the proposed services will be available within one (1) hour normal driving time of 95 percent of the population in rural areas and within 30 minutes normal driving time in urban areas.

4. The application shall document that the applicant has established referral networks to transfer infants requiring more sophisticated care than is available in less specialized facilities.

5. The application shall affirm that the applicant will record and maintain, at a minimum, the following information regarding charity care and care to the medically indigent and make it available to the Mississippi State Department of Health within 15 business days of request:

   a. source of patient referral;

   b. utilization data e.g., number of indigent admissions, number of charity admissions, and inpatient days of care;

   c. demographic/patient origin data;

   d. cost/charges data; and

   e. any other data pertaining directly or indirectly to the utilization of services by medically indigent or charity patients which the Department may request.

6. The applicant shall document that within the scope of its available services, neither the facility nor its participating staff shall have policies or procedures which would exclude patients because of race, age, sex, ethnicity, or ability to pay.

101.03 Neonatal Special Care Services Bed Need Methodology

The determination of need for neonatal special care beds/services in each Perinatal Planning Area will be based on four (4) beds per 1,000 live births as defined below.

1. One (1) neonatal intensive (subspecialty) care bed per 1,000 live births in the most recent 12-month reporting period.

2. Three (3) neonatal intermediate (specialty) care beds per 1,000 live births in the most recent 12-month reporting period.

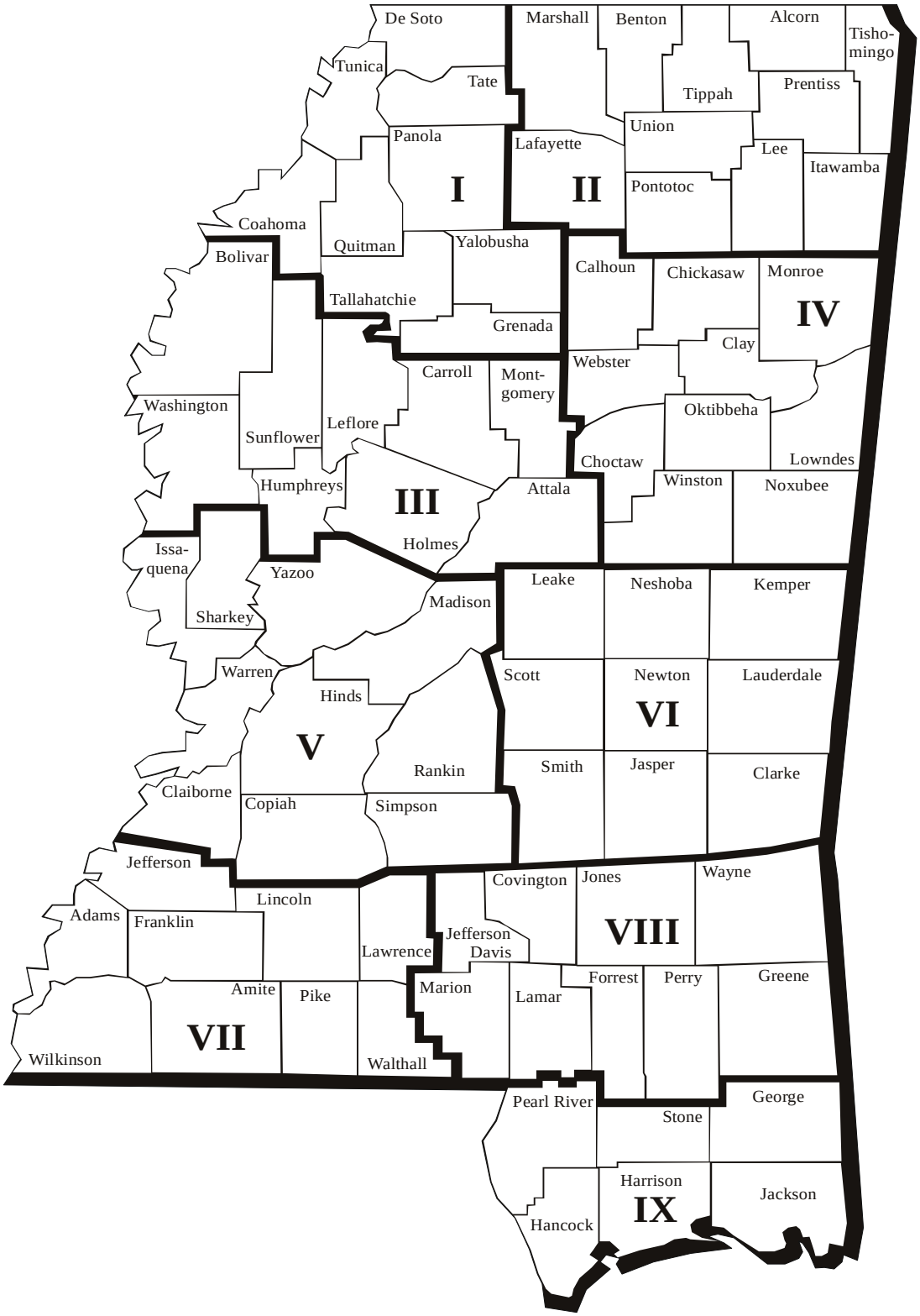
Table ~~8-4~~ 4- 1
Neonatal Special Care Bed Need
2008

Perinatal Planning Areas	Number Live Births[1]	Neonatal Intensive Care Bed Need	Neonatal Intermediate Care Bed Need
PPA I	4,912	5	15
PPA II	5,063	5	15
PPA III	4,150	4	12
PPA IV	3,601	4	11
PPA V	10,217	10	31
PPA VI	3,988	4	12
PPA VII	2,758	3	8
PPA VIII	4,893	5	15
PPA IX	6,464	6	19
State Total	**46,046**	**46**	**138**

[1] By Place of Birth
Sources: Mississippi State Department of Health, Division of Licensure and Certification; and Division of Health Planning and Resource Development Calculations, 2008

Source: Bureau of Public Health Statistics

Map ~~8-3~~ 4- 1
Perinatal Planning Areas



GUIDELINES FOR THE OPERATION OF PERINATAL UNITS (OBSTETRICS AND NEWBORN NURSERY)

Guidelines for the Operation of Perinatal Units (Obstetrics and Newborn Nursery)

102 Organization

Obstetrics and newborn nursery services shall be under the direction of a member of the staff of physicians who has been duly appointed for this service and who has experience in maternity and newborn care.

There shall be a qualified professional registered nurse responsible at all times for the nursing care of maternity patients and newborn infants.

Provisions shall be made for pre-employment and annual health examinations for all personnel on this service.

Physical facilities for perinatal care in hospitals shall be conducive to care that meets the normal physiologic and psychosocial needs of mothers, neonates and their families. The facilities provide for deviations from the norm consistent with professionally recognized standards/guidelines.

The obstetrical service should have facilities for the following components:

1. Antepartum care and testing
2. Fetal diagnostic services
3. Admission/observation/waiting
4. Labor
5. Delivery/cesarean birth
6. Newborn nursery
7. Newborn intensive care (Specialty and Subspecialty care only)
8. Recovery and postpartum care
9. Visitation

103 Staffing

The facility is staffed to meet its patient care commitments consistent with professionally recognized guidelines. There must be a registered nurse immediately available for direct patient care.

104 Levels of Care

104.01 Basic Care-Level 1

1. Surveillance and care of all patients admitted to the obstetric service, with an established triage system for identifying high-risk patients who should be transferred to a facility that provides specialty or sub-specialty care
2. Proper detection and supportive care of unanticipated maternal-fetal problems that occur during labor and delivery
3. Capability to begin an emergency cesarean delivery within 30 minutes of the decision to do so
4. Availability of blood bank services on a 24-hour basis
5. Availability of anesthesia, radiology, ultrasound, and laboratory services available on a 24-hour basis
6. Care of postpartum conditions
7. Evaluation of the condition of healthy neonates and continuing care of these neonates until their discharge
8. Resuscitation and stabilization of all neonates born in hospital
9. Stabilization of small or ill neonates before transfer to a specialty or sub-specialty facility
10. Consultation and transfer agreement
11. Nursery care
12. Parent-sibling-neonate visitation
13. Data collection and retrieval
14. Quality improvement programs, maximizing patient safety

104.02 Specialty Care-Level 2

1. Performance of basic care services as described above
2. Care of high-risk mothers and fetuses both admitted and transferred from other facilities
3. Stabilization of ill newborns prior to transfer
4. Treatment of moderately ill larger preterm and term newborns

104.03 Sub-specialty Care-Level 3

1. Provision of comprehensive perinatal care services for both admitted and transferred mothers and neonates of all risk categories, including basic and specialty care services as described above
2. Evaluation of new technologies and therapies

3. Maternal and neonate transport.

4. Training of health-care providers

105 Perinatal Care Services

105.01 Antepartum Care

There should be policies for the care of pregnant patients with obstetric, medical, or surgical complications and for maternal transfer.

105.02 Intra-partum Services: Labor and Delivery

Intra-partum care should be both personalized and comprehensive for the mother and fetus. There should be written policies and procedures in regard to:

1. Assessment
2. Admission
3. Medical records (including complete prenatal history and physical)
4. Consent forms
5. Management of labor including assessment of fetal well-being:
    a. Term patient
    b. Preterm patients
    c. Premature rupture of membranes
    d. Preeclampsia/eclampsia
    e. Third trimester hemorrhage
    f. Pregnancy Induced Hypertension (PIH)
6. Patient receiving oxytocics or tocolytics
7. Patients with stillbirths and miscarriages
8. Pain control during labor and delivery
9. Management of delivery
10. Emergency cesarean delivery (capability within 30 minutes)
11. Assessment of fetal maturity prior to repeat cesarean delivery or induction of labor
12. Vaginal birth after cesarean delivery
13. Assessment and care of neonate in the delivery room
14. Infection control in the obstetric and newborn areas

15. A delivery room shall be kept that will indicate:

    a. The name of the patient
    b. Date of delivery
    c. Sex of infant
    d. Apgar
    e. Weight
    f. Name of physician
    g. Name of person assisting
    h. What complications, if any, occurred
    i. Type of anesthesia used
    j. Name of person administering anesthesia

16. Maternal transfer

17. immediate postpartum/recovery care

18. Housekeeping

105.03 Newborn Care

There shall be policies and procedures for providing care of the neonate including:

1. Immediate stabilization period
2. Neonate identification and security
3. Assessment of neonatal risks
4. Cord blood, Coombs, and serology testing
5. Eye care
6. Subsequent care
7. Administration of Vitamin K
8. Neonatal screening
9. Circumcision
10. Parent education
11. Visitation
12. Admission of neonates born outside of facility

13. Housekeeping

14. Care of or stabilization and transfer of high-risk neonates

105.04 Postpartum Care

There shall be policies and procedures for postpartum care of mother:

1. Assessment
2. Subsequent care (bed rest, ambulation, diet, care of the vulva, care of the bowel and bladder functions, bathing, care of the breasts, temperature elevation)
3. Postpartum sterilization
4. Immunization: RHIG and Rubella
5. Discharge planning

Source: Guidelines for Perinatal Care, Second, Fourth, and Sixth Editions, American Academy of Pediatrics and the American College of Obstetricians and Gynecologists, 1988, 1992, and 2007.

CERTIFICATE OF NEED

CRITERIA AND STANDARDS
FOR
ACUTE CARE

100 Certificate of Need Criteria and Standards for General Acute Care

Note: Should the Mississippi State Department of Health receive a Certificate of Need application regarding the acquisition and/or otherwise control of major medical equipment or the provision of a service for which specific CON criteria and standards have not been adopted, the application shall be deferred until the Department of Health has developed and adopted CON criteria and standards. If the Department has not developed CON criteria and standards within 180 days of receiving a CON application, the application will be reviewed using the general CON review criteria and standards presented in the *Mississippi Certificate of Need Review Manual* and all adopted rules, procedures, and plans of the Mississippi State Department of Health.

100.01 Policy Statement Regarding Certificate of Need Applications for General Acute Care Hospitals and General Acute Care Beds

1. Acute Care Hospital Need Methodology: With the exception of psychiatric, chemical dependency, and rehabilitation hospitals, the Mississippi State Department of Health (MSDH) will use the following methodologies to project the need for general acute care hospitals:

   a. **Counties Without a Hospital** - The MSDH shall determine hospital need by multiplying the state's average annual occupied beds (1.72 in FY 2007) per 1,000 population by the estimated 2010 county population to determine the number of beds the population could utilize. A hospital with a maximum of 100 beds may be considered for approval if: (a) the number of beds needed is 100 or more; (b) there is strong community support for a hospital; and (c) a hospital can be determined to be economically feasible.

   b. **Counties With Existing Hospitals** - The MSDH shall use the following formula to determine the need for an additional hospital in a county with an existing hospital:

      $$\mathbf{ADC + K(\sqrt{ADC})}$$

      Where: ADC = Average Daily Census

      K = Confidence Factor of 2.57

      The formula is calculated for each facility within a given General Hospital Service Area (GHSA); then beds available and beds needed under the statistical application of the formula are totaled and subtracted to determine bed need or excess within each GHSA. Map 11-2 delineates the GHSAs. The MSDH may consider approval of a hospital with a maximum of 100 beds if: (a) the number of beds needed is 100 or more; (b) there is strong community support for a hospital; and (c) a hospital can be determined to be economically feasible.

   c. **Counties Located in an Underdeveloped General Hospital Service Area and With a Rapidly Growing Population -** Notwithstanding the need formula in b. above, any county with a population in excess of 140,000 people; projecting a population growth rate in excess of ten (10) percent over the next ten (10) year period; and its General Hospital Service Area does not presently exceed a factor of three (beds per 1,000 population); may

be considered for a new acute care hospital not to exceed one hundred (100) beds, in that county.

Further, any person proposing a new hospital must meet the following conditions:

1.) Provide an amount of indigent care in excess of the average of the hospitals in the General Hospital Service Area as determined by the State Health Officer;

2.) Provide an amount of Medicaid care in excess of the average of the hospitals in the General Hospital Service Area as determined by the State Health Officer; and

3.) If the county in which the proposed hospital is adjacent to a county without a hospital, the applicant must establish outpatient services in the adjacent county without a hospital; and

4.) Fully participate in the Trauma Care System at a level to be determined by the Department for a reasonable number of years to be determined by the State Health Officer.

2. Need in Counties Without a Hospital: Seven counties in Mississippi do not have a hospital: Amite, Benton, Carroll, Issaquena, Itawamba, Kemper, and Tunica. Most of these counties do not have a sufficient population base to indicate a potential need for the establishment of a hospital, and all appear to receive sufficient inpatient acute care services from hospitals in adjoining counties.

3. Expedited Review: The MSDH may consider an expedited review for Certificate of Need applications that address only license code deficiencies, project cost overruns, and relocation of facilities or services.

4. Capital Expenditure: For the purposes of Certificate of Need review, transactions which are separated in time but planned to be undertaken within 12 months of each other and which are components of an overall long-range plan to meet patient care objectives shall be reviewed in their entirety without regard to their timing. For the purposes of this policy, the governing board of the facility must have duly adopted the long-range plan at least 12 months prior to the submission of the CON application.

5. No health care facility shall be authorized to add any beds or convert any beds to another category of beds without a Certificate of Need.

6. If a health care facility has voluntarily delicensed some of its existing bed complement, it may later relicense some or all of its delicensed beds without the necessity of having to acquire a Certificate of Need. The Department of Health shall maintain a record of the delicensing health care facility and its voluntarily delicensed beds and continue counting those beds as part of the state's total bed count for health care planning purposes.

100.02 Certificate of Need Criteria and Standards for the Establishment of a General Acute Care Hospital

The Mississippi State Department of Health (MSDH) will review applications for a Certificate of Need to construct, develop, or otherwise establish a new hospital under the applicable statutory requirements of Sections 41-7-173, 41-7-191, and 41-7-193, Mississippi Code of 1972, as amended. The MSDH will also review applications for Certificate of Need according to the general criteria listed in the *Mississippi Certificate of Need Review Manual*; all adopted rules, procedures, and plans of the MSDH; and the specific criteria and standards listed below.

1. **Need Criterion: The applicant shall document a need for a general acute care hospital using the appropriate need methodology as presented in this section of the Plan. In addition, the applicant must meet the other conditions set forth in the need methodology**.

2. The application shall document that the applicant will provide a "reasonable amount" of indigent/charity care as described in Chapter I of this *Plan*.

100.03 Certificate of Need Criteria and Standards for Construction, Renovation, Expansion, Capital Improvements, Replacement of Health Care Facilities, and Addition of Hospital Beds

The Mississippi State Department of Health (MSDH) will review applications for a Certificate of Need for the addition of beds to a health care facility and projects for construction, renovation, expansion, or capital improvement involving a capital expenditure in excess of $2,000,000 under the applicable statutory requirements of Sections 41-7-173, 41-7-191, and 41-7-193, Mississippi Code of 1972, as amended. The MSDH will also review applications for Certificate of Need according to the general criteria listed in the *Mississippi Certificate of Need Review Manual*; all adopted rules, procedures, and plans of the MSDH; and the specific criteria and standards listed below.

The construction, development, or other establishment of a new health care facility, the replacement and/or relocation of a health care facility or portion thereof, and changes of ownership of existing health care facilities are reviewable regardless of capital expenditure.

1. <u>Need Criterion:</u>

   a. **Projects which do not involve the addition of any acute care beds**: The applicant shall document the need for the proposed project. Documentation may consist of, but is not limited to, citing of licensure or regulatory code deficiencies, institutional long-term plans (duly adopted by the governing board), recommendations made by consultant firms, and deficiencies cited by accreditation agencies (JCAHO, CAP, etc.). In addition, for projects which involve construction, renovation, or expansion of emergency department facilities, the applicant shall include a statement indicating whether the hospital will participate in the statewide trauma system and describe the level of participation, if any.

   b. **Projects which involve the addition of beds**: The applicant shall document the need for the proposed project. In addition to the documentation required as stated in Need Criterion (1)(a), the applicant shall document that the facility in question has maintained an occupancy rate of at least 70 percent for the most recent two (2) years.

2. Bed Service Transfer/Reallocation/Relocation: Applications proposing the transfer, reallocation, and/or relocation of a specific category or sub-category of bed/service from another facility as part of a renovation, expansion, or replacement project shall document that the applicant will meet all regulatory/licensure requirements for the type of bed/service being transferred/reallocated/relocated.

3. Charity/Indigent Care: The application shall affirm that the applicant will provide a "reasonable amount" of indigent/charity care as described in Chapter I of this *Plan*.

4. The application shall demonstrate that the cost of the proposed project, including equipment, is reasonable in comparison with the cost of similar projects in the state.

   a. The applicant shall document that the cost per square foot (per bed if applicable) does not exceed the median construction costs, as determined by the MSDH, for similar projects in the state within the most recent 12-month period by more than 15 percent. The Glossary of this *Plan* provides the formulas to be used by MSDH staff in calculating the cost per square foot for construction and/or construction/renovation projects.

   b. If equipment costs for the project exceed the median costs for equipment of similar quality by more than 15 percent, the applicant shall provide justification for the excessive costs. The median costs shall be based on projects submitted during the most recent six-month period and/or estimated prices provided by acceptable vendors.

5. The applicant shall specify the floor areas and space requirements, including the following factors:

   a. The gross square footage of the proposed project in comparison to state and national norms for similar projects.

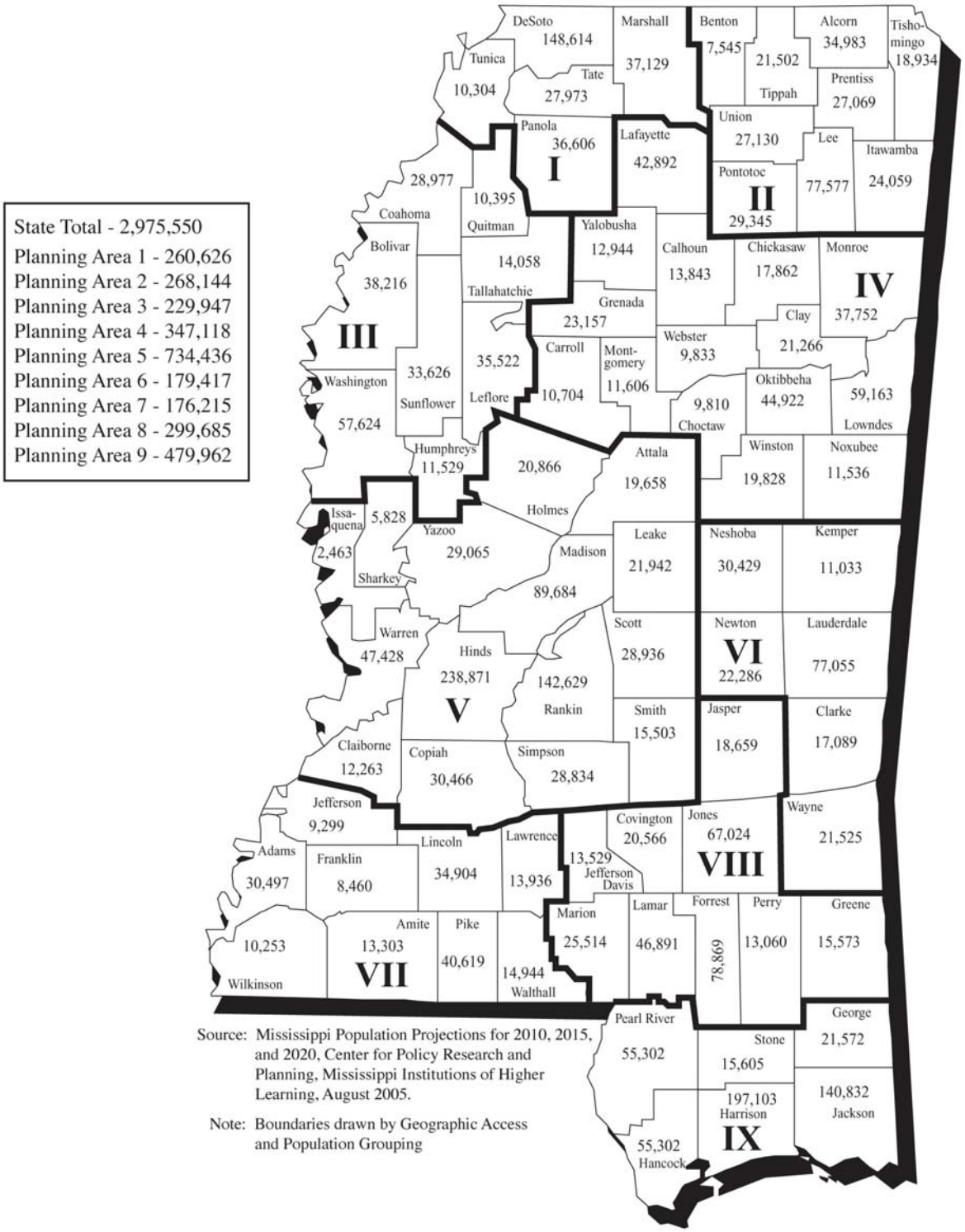
   b. The architectural design of the existing facility if it places restraints on the proposed project.

   c. Special considerations due to local conditions.

6. If the cost of the proposed renovation or expansion project exceeds 85 percent of the cost of a replacement facility, the applicant shall document their justification for rejecting the option of replacing said facility.

7. The applicant shall document the need for a specific service (i.e. perinatal, ambulatory care, psychiatric, etc.) using the appropriate service specific criteria as presented in this and other sections of the *Plan*.

Map 11- 1
General Hospital Service Areas



Source: Mississippi Population Projections for 2010, 2015, and 2020, Center for Policy Research and Planning, Mississippi Institutions of Higher Learning, August 2005.

Note: Boundaries drawn by Geographic Access and Population Grouping

100.04 Certificate of Need Criteria and Standards for Swing-Bed Services

The Mississippi State Department of Health will review applications for a Certificate of Need (CON) to establish swing-bed services under the applicable statutory requirements of Sections 41-7-173, 41-7-191, and 41-7-193, Mississippi Code of 1972, as amended. The MSDH will also review applications for CON according to the general criteria listed in the *Mississippi Certificate of Need Review Manual*; all adopted rules, procedures, and plans of the MSDH; and the specific criteria and standards listed below.

1. **Need Criterion: The application shall document that the hospital will meet all federal regulations regarding the swing-bed concept**. However, a hospital may have more licensed beds or a higher average daily census (ADC) than the maximum number specified in federal regulations for participation in the swing-bed program.
2. The applicant shall provide a copy of the Resolution adopted by its governing board approving the proposed participation.
3. If the applicant proposes to operate and staff more than the maximum number of beds specified in federal regulations for participation in the swing-bed program, the application shall give written assurance that only private pay patients will receive swing-bed services.
4. The application shall affirm that upon receiving CON approval and meeting all federal requirements for participation in the swing-bed program, the applicant shall render services provided under the swing-bed concept to any patient eligible for Medicare (Title XVIII of the Social Security Act) who is certified by a physician to need such services.
5. The application shall affirm that upon receiving CON approval and meeting all federal requirements for participation in the swing-bed program, the applicant shall not permit any patient who is eligible for both Medicaid and Medicare or is eligible only for Medicaid to stay in the swing-beds of a hospital for more than 30 days per admission unless the hospital receives prior approval for such patient from the Division of Medicaid.
6. The application shall affirm that if the hospital has more licensed beds or a higher average daily census than the maximum number specified in federal regulations for participation in the swing-bed program, the applicant will develop a procedure to ensure that, before a patient is allowed to stay in the swing-beds of the hospital, there are no vacant nursing home beds available within a 50-mile radius (geographic area) of the hospital. The applicant shall also affirm that if the hospital has a patient staying in the swing-beds of the hospital and the hospital receives notice from a nursing home located within a 50-mile radius that there is a vacant bed available for that patient, the hospital shall transfer the swing-bed patient to the nursing home within five days, exclusive of holidays and weekends, unless the patient's physician certifies that the transfer is not medically appropriate.
7. The applicant shall provide copies of transfer agreements entered into with each nursing facility within the applicant's geographic area.
8. An applicant subject to the conditions stated in Criterion #5 shall affirm in the application that they will be subject to suspension from participation in the swing-bed program for a reasonable period of time by the Department of Health if the Department, after a hearing complying with due process, determines that the hospital has failed to comply with any of those requirements.

CERTIFICATE OF NEED

CRITERIA AND STANDARDS
FOR
THERAPEUTIC RADIATION SERVICES

100 Certificate of Need Criteria and Standards for Therapeutic Radiation Services

Note: Should the Mississippi State Department of Health receive a Certificate of Need application regarding the acquisition and/or otherwise control of major medical equipment or the provision of a service for which specific CON criteria and standards have not been adopted, the application shall be deferred until the Department of Health has developed and adopted CON criteria and standards. If the Department has not developed CON criteria and standards within 180 days of receiving a CON application, the application will be reviewed using the general CON review criteria and standards presented in the *Mississippi Certificate of Need Review Manual* and all adopted rules, procedures, and plans of the Mississippi State Department of Health.

100.05 Policy Statement Regarding Certificate of Need Applications for the Acquisition or Otherwise Control of Therapeutic Radiation Equipment, and/or the Offering of Therapeutic Radiation Services (other than Stereotactic Radiosurgery)

1. Service Areas: The Mississippi State Department of Health shall determine the need for therapeutic radiation services/units/equipment by using the General Hospital Service Areas as presented in this chapter of the *Plan*. The MSDH shall determine the need for therapeutic radiation services/units/equipment within a given service area independently of all other service areas. Map 11-2 shows the General Hospital Service Areas.

2. Equipment to Population Ratio: The need for therapeutic radiation units (as defined) is determined to be one unit per 157,908 population (see methodology in this section of the *Plan*). The MSDH will consider out-of-state population in determining need only when the applicant submits adequate documentation acceptable to the Mississippi State Department of Health, such as valid patient origin studies.

3. Limitation of New Services: When the therapeutic radiation unit-to-population ratio reaches one to 157,908 in a given general hospital service area, no new therapeutic radiation services may be approved unless the utilization of all the existing machines in a given hospital service area averaged 8,000 treatments or 320 patients per year for the two most recent consecutive years as reported on the "Renewal of Hospital License and Annual Hospital Report." For the purposes of this policy Cesium-137 teletherapy units, Cobalt-60 teletherapy units designed for use at less than 80 cm SSD (source to skin distance), old betatrons and van de Graaf Generators, unsuitable for modern clinical use, shall not be counted in the inventory of therapeutic radiation units located in a hospital service area.

4. Expansion of Existing Services: The MSDH may consider a CON application for the acquisition or otherwise control of an additional therapeutic radiation unit by an existing provider of such services when the applicant's existing equipment has exceeded the expected level of patient service, i.e., 320 patients per year or 8,000 treatments per year for the two most recent consecutive years as reported on the facility's "Renewal of Hospital License and Annual Hospital Report."

5. Equipment Designated for Backup: Therapeutic radiation equipment designated by an applicant as "backup" equipment shall not be counted in the inventory for CON purposes.

Any treatments performed on the "backup" equipment shall be attributed to the primary equipment for CON purposes.

6. Definition of a Treatment: For health planning and CON purposes a patient "treatment" is defined as one individual receiving radiation therapy during a visit to a facility which provides megavoltage radiation therapy regardless of the complexity of the treatment or the number of "fields" treated during the visit.

7. Use of Equipment or Provision of Service: Before the equipment or service can be utilized or provided, the applicant desiring to provide the therapeutic radiation equipment or service shall have CON approval or written evidence that the equipment or service is exempt from CON approval, as determined by the Mississippi State Department of Health.

100.06 Certificate of Need Criteria and Standards for the Acquisition or Otherwise Control of Therapeutic Radiation Equipment and/or the Offering of Therapeutic Radiation Services (other than Stereotactic Radiosurgery)

The Mississippi State Department of Health will review Certificate of Need applications for the acquisition or otherwise control of therapeutic radiation equipment and/or the offering of therapeutic radiation services under the applicable statutory requirements of Sections 41-7-173, 41-7-191, and 41-7-193, Mississippi Code of 1972, as amended. The MSDH will also review applications for Certificate of Need according to the general criteria listed in the *Mississippi Certificate of Need Review Manual*; all adopted rules, procedures, and plans of the Mississippi State Department of Health; and the specific criteria and standards listed below.

The acquisition or otherwise control of therapeutic radiation equipment is reviewable if the equipment cost exceeds $1,500,000. The offering of therapeutic radiation services is reviewable if the proposed provider has not provided those services on a regular basis within the period of twelve (12) months prior to the time such services would be offered.

1. **Need Criterion: The applicant shall document a need for therapeutic radiation equipment/service by complying with any one of the following methodologies:**

    a. **the need methodology as presented in this section of the *Plan*;**

    b. **demonstrating that all existing machines in the service area in question have averaged 8,000 treatments per year or all machines have treated an average of 320 patients per year for the two most recent consecutive years; or**

    c. **demonstrating that the applicant's existing therapeutic equipment has exceeded the expected level of patients service, i.e. 320 patients per year/unit, or 8,000 treatments per year/unit for the most recent 24-month period.**

2. The applicant must document that access to diagnostic X-ray, CT scan, and ultrasound services is readily available within 15 minutes normal driving time of the therapeutic radiation unit's location.

3. An applicant shall document the following:

a. The service will have, at a minimum, the following full-time dedicated staff:

   i. One board-certified radiation oncologist-in-chief

   ii. One dosimetrist

   iii. One certified radiation therapy technologist certified by the American Registry of Radiation Technologists

   iv. One registered nurse

b. The service will have, at a minimum, access to a radiation physicist certified or eligible for certification by the American Board of Radiology.

   Note: One individual may act in several capacities. However, the application shall affirm that when a staff person acts in more than one capacity, that staff person shall meet, at a minimum, the requirements for each of the positions they fill.

4. The applicant shall affirm that access will be available as needed to brachytherapy staff, treatment aides, social workers, dietitians, and physical therapists.

5. Applicants shall document that all physicians who are responsible for therapeutic radiation services in a facility, including the radiation oncologist-in-chief, shall reside within 60 minutes normal driving time of the facility.

6. The application shall affirm that the applicant will have access to a modern simulator capable of precisely producing the geometric relationships of the treatment equipment to a patient. This simulator must produce high quality diagnostic radiographs. The applicant shall also affirm that the following conditions will be met as regards the use of the simulator:

   a. If the simulator is located at a site other than where the therapeutic radiation equipment is located, protocols will be established which will guarantee that the radiation oncologist who performs the patient's simulation will also be the same radiation oncologist who performs the treatments on the patient.

   b. If the simulator uses fluoroscopy, protocols will be established to ensure that the personnel performing the fluoroscopy have received appropriate training in the required techniques related to simulation procedures.

      Note: X-rays produced by diagnostic X-ray equipment and photon beams produced by megavoltage therapy units are unsuitable for precise imaging of anatomic structures within the treatment volume and do not adequately substitute for a simulator.

7. The application shall affirm that the applicant will have access to a computerized treatment planning system with the capability of simulation of multiple external beams, display isodose distributions in more than one plane, and perform dose calculations for brachytherapy implants.

   Note: It is highly desirable that the system have the capability of performing CT based treatment planning.

8. The applicant shall affirm that all treatments will be under the control of a board certified or board eligible radiation oncologist.

9. The applicant shall affirm that the proposed site, plans, and equipment shall receive approval from the MSDH Division of Radiological Health before service begins.

10. The application shall affirm that the applicant will establish a quality assurance program for the service, as follows:

    a. The therapeutic radiation program shall meet, at a minimum, the physical aspects of quality assurance guidelines established by the American College of Radiology (ACR) within 12 months of initiation of the service.

    b. The service shall establish a quality assurance program which meets, at a minimum, the standards established by the American College of Radiology.

11. The applicant shall affirm understanding and agreement that failure to comply with criterion #10 (a) and (b) may result in revocation of the CON (after due process) and subsequent termination of authority to provide therapeutic radiation services.

100.06.01 Therapeutic Radiation Equipment/Service Need Methodology

1. Treatment/Patient Load: A realistic treatment/patient load for a therapeutic radiation unit is 8,000 treatments or 320 patients per year.

2. Incidence of Cancer: The American Cancer Society (ACS) estimates that Mississippi will experience 13,400 new cancer cases in 2007 (excluding basal and squamous cell skin cancers and in-situ carcinomas except urinary bladder cancer). Based on a population of 2,975,551 (year 2010) as estimated by the Center for Policy Research and Planning, the cancer rate of Mississippi is 4.50 cases per 1,000 population.

3. Patients to Receive Treatment: The number of cancer patients expected to receive therapeutic radiation treatment is set at 45 percent.

4. Population to Equipment Ratio: Using the above stated data, a population of 100,000 will generate 450 new cancer cases each year. Assuming that 45 percent will receive radiation therapy, a population of 157,908 will generate approximately 320 patients who will require radiation therapy. Therefore, a population of 157,908 will generate a need for one therapeutic radiation unit.

100.06.02 Therapeutic Radiation Equipment Need Determination Formula

1. Project annual number of cancer patients.

General Hospital Service		4.50 cases*
Area Population	X	1,000 population = New Cancer Cases

*Mississippi cancer incidence rate

2. Project the annual number of radiation therapy patients.

   New Cancer Cases X 45% = Patients Who Will Likely Require Radiation Therapy

3. Estimate number of treatments to be performed annually.

   Radiation Therapy Patients X 25 Treatments per Patient (Avg.) = Estimated Number of Treatments

4. Project number of megavoltage radiation therapy units needed.

   Est. # of Treatments = Projected Number of Units Needed
   8,000 Treatments per Unit

5. Determine unmet need (if any)Projected Number of Units Needed — Number of Existing Units = Number of Units Required (Excess)

100.07 Policy Statement Regarding Certificate of Need Applications for the Acquisition or Otherwise Control of Stereotactic Radiosurgery Equipment and/or the Offering of Stereotactic Radiosurgery.

1. Service Areas: The Mississippi State Department of Health shall determine the need for stereotactic radiosurgery services/units/equipment by using the actual stereotactic radiosurgery provider's service area.

2. Equipment to Population Ratio: The need for stereotactic radiosurgery units is determined to be the same as for radiotherapy, for 2007, a population of 157,908. The therapeutic radiation need determination formula is outlined in Section 109.02.02 above.

3. Accessibility: Nothing contained in these CON criteria and standards shall preclude the University of Mississippi School of Medicine from acquiring and operating stereotactic radiosurgery equipment, provided the acquisition and use of such equipment is justified by the School's teaching and/or research mission. However, the requirements listed under the section regarding the granting of "appropriate scope of privileges for access to the stereotactic radiosurgery equipment to any qualified physician" must be met.

4. Expansion of Existing Services: The MSDH may consider a CON application for the acquisition or otherwise control of an additional stereotactic radiosurgery unit by an existing provider of such services when the applicant's existing equipment has exceeded the expected level of patient service, i.e., 900 treatments per year for the two most recent consecutive years as reported on the facility's "Renewal of Hospital License and Annual Hospital Report."

5. Facilities requesting approval to add stereotactic radiosurgery services should have an established neurosurgery program and must be able to demonstrate previous radiosurgery service experience.

6. All stereotactic radiosurgery services should have written procedures and policies for discharge planning and follow-up care for the patient and family as part of the institution's overall discharge planning program.

7. All stereotactic radiosurgery services should have established protocols for referring physicians to assure adequate post-operative diagnostic evaluation for radiosurgery patients.

8. The total cost of providing stereotactic radiosurgery services projected by prospective providers should be comparable to the cost of other similar services provided in the state.

9. The usual and customary charge to the patient for stereotactic radiosurgery should be commensurate with cost.

100.08 Certificate of Need Criteria and Standards for the Acquisition or Otherwise Control of Stereotactic Radiosurgery Equipment and/or the Offering of Stereotactic Radiosurgery

The Mississippi State Department of Health will review Certificate of Need applications for the acquisition or otherwise control of stereotactic radiosurgery equipment and/or the offering of stereotactic radiosurgery services under the applicable statutory requirements of Sections 41-7-173, 41-7-191, and 41-7-193, Mississippi Code of 1972, as amended. The MSDH will also review applications for Certificate of Need according to the general criteria listed in the *Mississippi Certificate of Need Review Manua*l; all adopted rules, procedures, and plans of the Mississippi State Department of Health; and the specific criteria and standards listed below.

The acquisition or otherwise control of stereotactic radiosurgery equipment is reviewable if the equipment cost exceeds $1,500,000. The offering of stereotactic radiosurgery services is reviewable if the proposed provider has not provided those services on a regular basis within the period of twelve (12) months prior to the time such services would be offered.

1. **Need Criterion: The applicant shall document a need for stereotactic radiosurgery equipment/service by reasonably projecting that the proposed new service will perform at least 900 stereotactic radiosurgery treatments in the third year of operation. No additional new stereotactic radiosurgery services should be approved unless the number of stereotactic radiosurgery treatments performed with existing units in the state average 900 treatments or more per year.**

2. Staffing:

   a. The radiosurgery programs must be established under the medical direction of two co-directors, one with specialty training and board certification in neurosurgery and the other with specialty training and board certification in radiation oncology, with experience in all phases of stereotactic radiosurgery.

   b. In addition to the medical co-directors, all stereotactic radiosurgery programs should have a radiation physicist who is certified in radiology, or who holds an advanced degree in physics with two to three years experience working under the direction of a radiation oncologist, and a registered nurse present for each stereotactic radiosurgery performed.

   c. The applicant shall document that the governing body of the entity offering stereotactic radiosurgery services will grant an appropriate scope of privileges for access to the stereotactic radiosurgery equipment to any qualified physician who applies for privileges. For the purpose of this criterion, "Qualified Physician" means a doctor of medicine or

osteopathic medicine licensed by the State of Mississippi who possesses training in stereotactic radiosurgery and other qualifications established by the governing body.

3. Equipment:

   a. Facilities providing stereotactic radiosurgery services should have dosimetry and calibration equipment and a computer with the appropriate software for performing stereotactic radiosurgery.

   b. The facility providing stereotactic radiosurgery services should also have access to magnetic resonance imaging, computed tomography, and angiography services.

CERTIFICATE OF NEED

CRITERIA AND STANDARDS
FOR
DIAGNOSTIC IMAGING SERVICES

101 Certificate of Need Criteria and Standards for Diagnostic Imaging Services

Note: Should the Mississippi State Department of Health receive a Certificate of Need application regarding the acquisition and/or otherwise control of major medical equipment or the provision of a service for which specific CON criteria and standards have not been adopted, the application shall be deferred until the Department of Health has developed and adopted CON criteria and standards. If the Department has not developed CON criteria and standards within 180 days of receiving a CON application, the application will be reviewed using the general CON review criteria and standards presented in the *Mississippi Certificate of Need Review Manual* and all adopted rules, procedures, and plans of the Mississippi State Department of Health.

101.01 Magnetic Resonance Imaging Services (MRI)

101.01.01 Policy Statement Regarding Certificate of Need Applications for the Acquisition or Otherwise Control of Magnetic Resonance Imaging (MRI) Equipment and/or the Offering of MRI Services

1. CON Review Requirements: The Certificate of Need process regarding the acquisition or otherwise control of MRI equipment and/or the offering of MRI services involves separate requirements for CON review: (a) an entity proposing to acquire or otherwise control MRI equipment must obtain a CON to do so if the capital expenditure for the MRI unit and related equipment exceeds $1,500,000; and (b) an entity proposing to offer MRI services must obtain a CON before providing such services.

2. CON Approval Preference: The Mississippi State Department of Health shall give preference to those applicants proposing to enter into joint ventures utilizing mobile and/or shared equipment. However, the applicant must meet the applicable CON criteria and standards provided herein and the general criteria and standards contained in the currently approved *Mississippi Certificate of Need Review Manual.*

3. For purposes of this Plan, a mobile MRI unit is defined as an MRI unit operating at two or more host sites and that has a central service coordinator. The mobile MRI unit shall operate under a contractual agreement for the provision of MRI services at each host site on a regularly scheduled basis.

4. The conversion from mobile MRI service to fixed MRI service is considered the establishment of a new MRI service and requires CON review.

5. Utilization of Existing Units: No new MRI services shall be approved unless all existing MRI service in the applicant's defined service area performed an average of 1,700 MRI procedures per existing and approved MRI scanner during the most recent

12 month reporting period and the proposed new services would not reduce the utilization of existing providers in the service area.

6. Population-Based Formula: The MSDH shall use a population-based formula as presented at the end of this chapter when calculating MRI need. Also, the formula will use historical and projected use rates by service area and patient origin data. The population-based formula is based on the most recent population projections prepared by the Center for Policy Research and Planning of the Institutions of Higher Learning. The applicant shall project a reasonable population base to justify the provision of 2,700 procedures by the second year of operation.

7. The required minimum service volumes for the establishment of services and the addition of capacity for mobile services shall be prorated on a "site by site" basis based on the amount of time the mobile services will be operational at each site.

8. Addition of a Health Care Facility: An equipment vendor who proposes to add a health care facility to an existing or proposed route must notify the Department in writing of any proposed changes, i.e. additional health care facilities or route deviations, from those presented in the Certificate of Need application prior to such change.

101.01.02 Certificate of Need Criteria and Standards for the Acquisition or Otherwise Control of Magnetic Resonance Imaging (MRI) Equipment and/or the Offering of MRI Services

The Mississippi State Department of Health will review applications for a Certificate of Need for the acquisition or otherwise control of MRI equipment and/or the offering of MRI services under the applicable statutory requirements of Sections 41-7-173, 41-7-191, and 41-7-193, Mississippi Code of 1972, as amended. The MSDH will also review applications for Certificate of Need according to the general criteria listed in the *Mississippi Certificate of Need Review Manual*; all adopted rules, procedures, and plans of the Mississippi State Department of Health; and the specific criteria and standards listed below.

The acquisition or otherwise control of MRI equipment is reviewable if the equipment cost is in excess of $1,500,000; if the equipment and/or service is relocated; and if the proposed provider of MRI services has not provided such services on a regular basis within the period of twelve (12) months prior to the time such services would be offered.

101.01.03 Certificate of Need Criteria and Standards for the Acquisition or Otherwise Control of MRI Equipment

1. **Need Criterion: The entity desiring to acquire or otherwise control the MRI equipment shall demonstrate a minimum of 2,700 procedures per year by the end of the second year of operation. This criterion includes both fixed and mobile MRI equipment. The applicant must show the methodology used for the projections.**

a. **Applicants for non-hospital based MRI facilities may submit affidavits from referring physicians. MRI procedures projected in affidavits shall be based on actual MRI procedures referred during the year.**

b. **The applicant shall document a reasonable population base to document a minimum of 2,700 procedures will be performed per proposed MRI unit.**

c. **The applicant shall demonstrate that all existing units within its defined service area have performed an average of 1,700 procedures for the most recent 12-month period.**

It is recognized that an applicant desiring to acquire or otherwise control an MRI unit may make or propose to make the MRI unit available to more than one provider of MRI services, some of which may be located outside of Mississippi. In such cases all existing or proposed users of the MRI unit must jointly meet the required service volume of 2,700 procedures annually. If the MRI unit in question is presently utilized by other providers of MRI services, the actual number of procedures performed by them during the most recent 12-month period may be used.

2. In order to receive CON approval to acquire or otherwise control MRI equipment, the applicant shall provide a copy of the proposed contract and document the following:

   a. that the equipment is FDA approved;

   b. that only qualified personnel will be allowed to operate the equipment; and

   c. that if the equipment is to be rented, leased, or otherwise used by other qualified providers on a contractual basis, no fixed/minimum volume contracts will be permitted.

3. Applicants shall provide written assurance that they will record and maintain, at a minimum, the following information and make it available to the Mississippi State Department of Health:

   a. all facilities which have access to the equipment;

   b. utilization by each facility served by the equipment, e.g., days of operation, number of procedures, and number of repeat procedures;

   c. financial data, e.g., copy of contracts, fee schedule, and cost per scan; and

   d. demographic and patient origin data for each facility.

   In addition, if required by the Department, the above referenced information and other data pertaining to the use of MRI equipment will be made available to the MSDH within 15 business days of request. The required information may also be requested for entities outside of Mississippi that use the MRI equipment in question.

4. The entity desiring to acquire or otherwise control the MRI equipment must be a registered entity authorized to do business in Mississippi.

5. Before the specified equipment can be utilized, the applicant desiring to provide the MRI equipment shall have CON approval or written evidence that the equipment is exempt from CON approval, as determined by the Mississippi State Department of Health. Each specified piece of equipment must be exempt from or have CON approval.

101.01.04 Certificate of Need Criteria and Standards for the Offering of fixed or mobile MRI Services

An entity proposing to offer MRI services shall obtain Certificate of Need (CON) approval before offering such services.

1. **Need Criterion: The entity desiring to offer MRI services must document that the equipment shall perform a minimum of 2,700 procedures by the end of the second year of operation. This criterion includes both fixed and mobile MRI equipment. The applicant must show methodology used for the projections.**

   a. **Applicants for non-hospital based MRI facilities may submit affidavits from referring physicians. MRI procedures projected in affidavits shall be based on actual MRI procedures referred during the year.**

   b. **The applicant shall document a reasonable population within its service area to justify 2,700 procedures per proposed MRI unit.**

   c. **The applicant shall demonstrate that all existing units within its defined service area have performed an average of 1,700 procedures for the most recent 12-month period.**

   It is recognized that a particular MRI unit may be utilized by more than one provider of MRI services, some of which may be located outside of Mississippi. In such cases all existing or proposed providers of MRI services must jointly meet the required service volume of 2,700 procedures annually by the end of the second year of operation. If the MRI unit in question is presently utilized by other providers of MRI services, the actual number of procedures performed by them during the most recent 12-month period may be used instead of the formula projections.

2. An applicant desiring to offer MRI services must document that a full range of diagnostic imaging modalities for verification and complementary studies will be available at the time MRI services begin. These modalities shall include, but not be limited to, computed tomography (full body), ultrasound, angiography, nuclear medicine, and conventional radiology.

3. All applicants proposing to offer MRI services shall give written assurance that, within the scope of its available services, neither the facility where the service is provided nor its participating medical personnel shall have policies or procedures which would exclude patients because of race, color, age, sex, ethnicity, or ability to pay.

4. The applicant must document that the following staff will be available:

a. Director - A full-time, board eligible radiologist or nuclear medicine imaging physician, or other board eligible licensed physician whose primary responsibility during the prior three years has been in the acquisition and interpretation of clinical images. The Director shall have knowledge of MRI through training, experience, or documented post-graduate education. The Director shall document a minimum of one week of full-time training with a functional MRI facility.

b. One full-time MRI technologist-radiographer or a person who has had equivalent education, training, and experience, who shall be on-site at all times during operating hours. This individual must be experienced in computed tomography or other cross-sectional imaging methods, or must have equivalent training in MRI spectroscopy.

5. The applicant shall document that when an MRI unit is to be used for experimental procedures with formal/approved protocols, a full-time medical physicist or MRI scientist (see definition in Glossary) with at least one year of experience in diagnostic imaging shall be available in the facility.

6. The applicant shall provide assurances that the following data regarding its use of the MRI equipment will be kept and made available to the Mississippi State Department of Health upon request:

a. Total number of procedures performed

b. Number of inpatient procedures

c. Number of outpatient procedures

d. Average MRI scanning time per procedure

e. Average cost per procedure

f. Average charge per procedure

g. Demographic/patient origin data

h. Days of operation

In addition to the above data recording requirements, the facility should maintain the source of payment for procedures and the total amounts charged during the fiscal year when it is within the scope of the recording system.

7. Before the service can be provided, the CON applicant desiring to offer MRI services shall provide written evidence that the specified MRI equipment provider has received CON approval or is exempt from CON approval as determined by the Mississippi State Department of Health. Each specified piece of equipment must be exempt from or have CON approval.

101.01.05 Population-Based Formula for Projection of MRI Service Volume

$$X * Y \div 1{,}000 = V$$

Where, X = Applicant's Defined Service area population

Y = Mississippi MRI Use Rate*

V = Expected Volume

****Use Rate shall be based on information in the State Health Plan***

101.02 Certificate of Need Criteria and Standards for Digital Subtraction Angiography

The Mississippi State Department of Health will review applications for a Certificate of Need for the acquisition or otherwise control of Digital Subtraction Angiography (DSA) equipment and associated costs under the applicable statutory requirements of Sections 41-7-173, 41-7-191, and 41-7-193, Mississippi Code of 1972, as amended. The MSDH will also review applications for Certificate of Need according to the general criteria listed in the *Mississippi Certificate of Need Review Manual*; all adopted rules, procedures, and plans of the Mississippi State Department of Health; and the specific criteria and standards listed below.

Certificate of Need review is required when the capital expenditure for the purchase of Digital Subtraction Angiography equipment and associated costs exceed $1,500,000, or when the equipment is to be used for invasive procedures, i.e., the use of catheters. The offering of diagnostic imaging services of an invasive nature, i.e. invasive digital angiography, is reviewable if those services have not been provided on a regular basis by the proposed provider of such services within the period of twelve (12) months prior to the time such services would be offered.

1. **Need Criterion: The applicant for DSA services shall demonstrate that proper protocols for screening, consultation, and medical specialty backup are in place before services are rendered by personnel other than those with specialized training.**

For example, if a radiologist without specialized training in handling cardiac arrhythmia is to perform a procedure involving the heart, a cardiologist/cardiosurgeon must be available for consultation/backup.

The protocols shall include, but are not limited to, having prior arrangements for consultation/backup from:

a. a cardiologist/cardiosurgeon for procedures involving the heart;

b. a neurologist/neurosurgeon for procedures involving the brain; and

c. a vascular surgeon for interventional peripheral vascular procedures.

2. Before utilizing or providing the equipment or service, the applicant desiring to provide the digital subtraction angiography equipment or service shall have CON approval or written evidence that the equipment or service is exempt from CON approval as determined by the Mississippi State Department of Health.

101.03 Positron Emission Tomography (PET) Equipment and Services

101.03.01 Policy Statement Regarding Certificate of Need Applications for the Acquisition or Otherwise Control of a Positron Emission Tomography (PET) Scanner and Related Equipment

1. CON Review Requirements: Applicants proposing the acquisition or otherwise control of a PET scanner shall obtain a CON to do so if the capital expenditure for the scanner and related equipment exceeds $1,500,000.

2. Indigent/Charity Care: An applicant shall be required to provide a "reasonable amount" of indigent/charity care as described in Chapter I of this Plan.

3. Service Areas: The state as a whole shall serve as a single service area in determining the need for a PET scanner.

4. Equipment to Population Ratio: The need for a PET scanner is estimated to be one scanner per 300,000 population. The MSDH will consider out-of-state population in determining need only when the applicant submits adequate documentation acceptable to the MSDH, such as valid patient origin studies.

5. Access to Supplies: Applicants must have direct access to appropriate radio-pharmaceuticals.

6. Services and Medical Specialties Required: The proposed PET unit must function as a component of a comprehensive inpatient or outpatient diagnostic service. The proposed PET unit must have the following modalities (and capabilities) on-site or through contractual arrangements:

   a. Computed tomography - (whole body)
   b. Magnetic resonance imaging - (brain and whole body)
   c. Nuclear medicine - (cardiac, SPECT)
   d. Conventional radiography
   e. The following medical specialties during operational hours:
      i. Cardiology
      ii. Neurology
      iii. Neurosurgery
      iv. Oncology

v. Psychiatry

vi. Radiology

7. Hours of Operation: PET facilities should have adequate scheduled hours to avoid an excessive backlog of cases.

8. CON Approval Preference: The MSDH may approve applicants proposing to enter joint ventures utilizing mobile and/or shared equipment.

9. CON Requirements: The criteria and standards contained herein pertain to both fixed and/or mobile PET scanner equipment.

10. CON Exemption: Nothing contained in these CON criteria and standards shall preclude the University of Mississippi School of Medicine from acquiring and operating a PET scanner, provided the acquisition and use of such equipment is justified by the School's teaching and/or research mission. However, the requirements listed under the section regarding the granting of "appropriate scope of privileges for access to the scanner to any qualified physician" must be met. The MSDH shall not consider utilization of equipment/services at any hospital owned and operated by the state or its agencies when reviewing CON applications.

11. Addition to a Health Care Facility: An equipment vendor who proposes to add a health care facility to an existing or proposed route must notify the Department in writing of any proposed changes from those presented in the Certificate of Need application prior to such change, i.e., additional health care facilities or route deviations.

12. Equipment Registration: The applicant must provide the Department with the registration/serial number of the CON-approved PET scanner.

13. Certification: If a mobile PET scanner, the applicant must certify that only the single authorized piece of equipment and related equipment vendor described in the CON application will be utilized for the PET service by the authorized facility/facilities.

14. Conversion from mobile to fixed service: The conversion from mobile PET service site to a fixed PET service site is considered the establishment of a new service and requires CON review.

101.03.02 Certificate of Need Criteria and Standards for the Acquisition or Otherwise Control of a Positron Emission Tomography (PET) Scanner and Related Equipment

The Mississippi State Department of Health will review applications for a Certificate of Need for the acquisition or otherwise control of a PET scanner and related equipment under the applicable statutory requirements of Sections 41-7-173, 41-7-191, and 41-7-193, Mississippi Code of 1972, as amended. The MSDH will also review applications for Certificate of Need according to the general review criteria listed in the *Mississippi Certificate of Need Review Manual*; all adopted rules, procedures, and plans of the Mississippi State Department of Health; and the specific criteria and standards listed below.

The acquisition or otherwise control of a PET scanner and related equipment is reviewable if the equipment cost is in excess of $1,500,000, or if the equipment is relocated. The offering of PET services is reviewable if the proposed provider has not provided those services on a regular basis within the period of twelve (12) months prior to the time such services would be offered.

1. **Need Criterion:**

    a. **The entity desiring to acquire or to otherwise control the PET scanner must project a minimum of 1,000 clinical procedures per year and must show the methodology used for the projection.**

    b. **The applicant shall document a minimum population of 300,000 per PET scanner unit. The Division of Health Planning and Resource Development population projections shall be used.**

2. The entity desiring to acquire or otherwise control the PET equipment must be a registered entity authorized to do business in Mississippi.

3. The MSDH will approve additional PET equipment in a service area with existing equipment only when it is demonstrated that the existing PET equipment in that service area is performing an average of 1,500 clinical procedures per PET unit per year (six clinical procedures per day x 250 working days per year).

4. The application shall affirm that the applicant shall receive approval from the Division of Radiological Health for the proposed site, plans, and equipment before service begins.

5. The applicant shall provide assurances that the following data regarding the PET equipment will be kept and made available to the Mississippi State Department of Health upon request:

    a. total number of procedures performed;

    b. total number of inpatient procedures (indicate type of procedure);

    c. total number of outpatient procedures (indicate type of procedure);

    d. average charge per specific procedure;

e. hours of operation of the PET unit;

f. days of operation per year; and

g. total revenue and expense for the PET unit for the year.

6. The applicant shall provide a copy of the proposed contract and document that if the equipment is to be rented, leased, or otherwise used by other qualified providers on a contractual basis, no fixed/minimum volume contracts will be permitted.

7. Before the specified equipment can be utilized, the applicant desiring to provide the PET equipment shall have CON approval or written evidence that the equipment is exempt from CON approval as determined by the Mississippi State Department of Health. Each specified piece of equipment must be exempt from or have CON approval.

101.03.03 Certificate of Need Criteria and Standards for the Offering of Fixed or Mobile Positron Emission Tomography (PET) Services

The offering of fixed or mobile PET services is reviewable if the proposed provider has not provided those services on a regular basis within the period of twelve (12) months prior to the time such services would be offered.

1. Need Criterion: The entity desiring to offer PET services must document that the equipment shall perform a minimum of 1,000 clinical procedures per year and must show the methodology used for the projection.

2. It is recognized that a particular PET unit may be utilized by more than one provider of PET services, some of which may be located outside of Mississippi. In such cases all existing or proposed providers of PET services utilizing the same PET unit must jointly meet the required service volume of 1,000 procedures annually. If the PET unit in question is presently utilized by other providers of PET services, the actual number of procedures performed by them during the most recent 12-month period may be used.

3. An applicant proposing to provide new or expanded PET services must include written assurances in the application that the service will be offered in a physical environment that conforms to federal standards, manufacturer's specifications, and licensing agencies' requirements. The following areas are to be addressed:

   a. quality control and assurance of radiopharmaceutical production of generator or cyclotron-produced agents;

   b. quality control and assurance of PET tomograph and associated instrumentation;

   c. radiation protection and shielding; and

   d. radioactive emissions to the environment.

4. The application shall affirm that the applicant shall receive approval from the Division of Radiological Health for the proposed site, plans, and equipment before service begins.

5. The applicant shall document provision of an on-site medical cyclotron for radionuclide production and a chemistry unit for labeling radiopharmaceuticals; or an on-site rubidium-82 generator; or access to a supply of cyclotron-produced radiopharmaceuticals from an off-site medical cyclotron and a radiopharmaceutical production facility within a two-hour air transport radius.

6. Applicants for PET shall document that the necessary qualified staff are available to operate the proposed unit. The applicant shall document the PET training and experience of the staff. The following minimum staff shall be available to the PET unit:

    a. If operating a fixed PET unit, one or more nuclear medicine imaging physician(s) available to the PET unit on a full-time basis (e.g., radiologist, nuclear cardiologist) who have been licensed by the state for the handling of medical radionuclides and whose primary responsibility for at least a one-year period prior to submission of the Certificate of Need application has been in acquisition and interpretation of tomographic images. This individual shall have knowledge of PET through training, experience, or documented postgraduate education. The individual shall also have training with a functional PET facility.

    b. If operating a cyclotron on site, a qualified PET radiochemist or radiopharmacist personnel, available to the facility during PET service hours, with at least one year of training and experience in the synthesis of short-lived positron emitting radiopharmaceuticals. The individual(s) shall have experience in the testing of chemical, radiochemical, and radionuclidic purity of PET radiopharmaceutical syntheses.

    c. Qualified engineering and physics personnel, available to the facility during PET service hours, with training and experience in the operation and maintenance of the PET equipment. Engineering personnel are not required on-site for mobile PET units.

    d. Qualified radiation safety personnel, available to the facility at all times, with training and experience in the handling of short-lived positron emitting nuclides. If a medical cyclotron is operated on-site, personnel with expertise in radiopharmacy, radiochemistry, and medical physics would also be required.

    e. Certified nuclear medicine technologists with expertise in computed tomographic nuclear medicine imaging procedures, at a staff level consistent with the proposed center's expected PET service volume.

    f. Other appropriate personnel shall be available during PET service hours which may include certified nuclear medicine technologists, computer programmers, nurses, and radio-chemistry technicians.

7. The applicant shall demonstrate how medical emergencies within the PET unit will be managed in conformity with accepted medical practice.

8. The applicant shall affirm that, in addition to accepting patients from participating institutions, facilities performing clinical PET procedures shall accept appropriate referrals from other local providers. These patients shall be accommodated to the extent possible by extending the hours of service and by prioritizing patients according to standards of need and appropriateness rather than source of referral.

9. The applicant shall affirm that protocols will be established to assure that all clinical PET procedures performed are medically necessary and cannot be performed as well by other, less expensive, established modalities.

10. Applicants will be required to maintain current listings of appropriate PET procedures for use by referring physicians.

11. The applicant shall provide assurances that the following data regarding the PET service will be kept and made available to the Mississippi State Department of Health upon request:

    a. total number of procedures performed;total number of inpatient procedures (indicate type of procedure);
    b. total number of outpatient procedures (indicate type of procedure);

    c. average charge per specific procedure;

    d. hours of operation of the PET unit;

    e. days of operation per year; and

    f. total revenue and expense for the PET unit for the year.

12. Before the specified service can be provided, the applicant desiring to offer the PET service shall provide written evidence that the specified PET equipment provider has CON approval or written evidence that the equipment is exempt from CON approval as determined by the Mississippi State Department of Health. Each specified piece of equipment must be exempt from or have CON approval.

CERTIFICATE OF NEED

CRITERIA AND STANDARDS FOR LONG-TERM ACUTE CARE HOSPITALS/BEDS

102 Certificate of Need Criteria and Standards for Long-Term Acute Care Hospitals/Beds

Note: Should the Mississippi State Department of Health receive a Certificate of Need application regarding the acquisition and/or otherwise control of major medical equipment or the provision of a service for which specific CON criteria and standards have not been adopted, the application shall be deferred until the Department of Health has developed and adopted CON criteria and standards. If the Department has not developed CON criteria and standards within 180 days of receiving a CON application, the application will be reviewed using the general CON review criteria and standards presented in the *Mississippi Certificate of Need Review Manual* and all adopted rules, procedures, and plans of the Mississippi State Department of Health.

102.01 Policy Statement Regarding Certificate of Need Applications for Long-Term Acute Care Hospitals and Long-Term Acute Care Hospital Beds

1. Restorative Care Admissions: Restorative care admissions shall be identified as patients with one or more of the following conditions or disabilities:

   a. Neurological Disorders

      i. Head Injury

      ii. Spinal Cord Trauma

      iii. Perinatal Central Nervous System Insult

      iv. Neoplastic Compromise

      v. Brain Stem Trauma

      vi. Cerebral Vascular Accident

      vii. Chemical Brain Injuries

   b. Central Nervous System Disorders

      i. Motor Neuron Diseases

      ii. Post Polio Status

      iii. Developmental Anomalies

      iv. Neuromuscular Diseases (e.g. Multiple Sclerosis)

      v. Phrenic Nerve Dysfunction

      vi. Amyotrophic Lateral Sclerosis

c. Cardio-Pulmonary Disorders

i. Obstructive Diseases

ii. Adult Respiratory Distress Syndrome

iii. Congestive Heart Failure

iv. Respiratory Insufficiency

v. Respiratory Failure

vi. Restrictive Diseases

vii. Broncho-Pulmonary Dysplasia

viii. Post Myocardial Infarction

ix. Central Hypoventilation

d. Pulmonary Cases

i. Presently Ventilator-Dependent/Weanable

ii. Totally Ventilator-Dependent/Not Weanable

iii. Requires assisted or partial ventilator support

iv. Tracheostomy that requires supplemental oxygen and bronchial hygiene

2. Bed Licensure: All beds designated as long-term care hospital beds shall be licensed as general acute care.

3. Average Length of Stay: Patients' average length of stay in a long-term care hospital must be 25 days or more.

4. Size of Facility: Establishment of a long-term care hospital shall not be for less than 20 beds.

5. Long-Term Medical Care: A long-term acute care hospital shall provide chronic or long-term medical care to patients who do not require more than three (3) hours of rehabilitation or comprehensive rehabilitation per day.

6. Transfer Agreement: A long-term acute care hospital shall have a transfer agreement with an acute care medical center and a comprehensive medical rehabilitation facility.

7. Effective July 1, 1994, no health care facility shall be authorized to add any beds or convert any beds to another category of beds without a Certificate of Need under the authority of Section 41-7-191(1)(c), unless there is a projected need for such beds in the planning district in which the facility is located.

102.02 Certificate of Need Criteria and Standards for the Establishment of a Long-Term Acute Care Hospital and Addition of Long-Term Acute Care Hospital Beds

The Mississippi State Department of Health will review applications for a Certificate of Need for the construction, development, or otherwise establishment of a long-term acute care hospital and bed additions under the applicable statutory requirements of Sections 41-7-173, 41-7-191, and 41-7-193, Mississippi Code of 1972, as amended. The MSDH will also review applications for Certificate of Need according to the general criteria listed in the *Mississippi Certificate of Need Review Manual*; all adopted rules, procedures, and plans of the Mississippi State Department of Health; and the specific criteria and standards listed below.

1. **Need Criterion: The applicant shall document a need for the proposed project. Documentation shall consist of the following:**

    a. **minimum of 450 clinically appropriate restorative care admissions with an average length of stay of 25 days; and**

    b. **a projection of financial feasibility by the end of the third year of operation.**

2. The applicant shall document that any beds which are constructed/converted will be licensed as general acute care beds offering long-term acute care hospital services.

3. Applicants proposing the transfer/reallocation/relocation of a specific category or sub-category of bed/service from another facility as part of a renovation, expansion, or replacement project shall document that they will meet all regulatory and licensure requirements for the type of bed/service proposed for transfer/reallocation/relocation.

4. The application shall affirm that the applicant will provide a "reasonable amount" of indigent/charity care as described in Chapter 1 of this *Plan*.

5. The application shall demonstrate that the cost of the proposed project, including equipment, is reasonable in comparison with the cost of similar projects in the state. The applicant shall document that the cost per square foot (per bed if applicable) does not exceed the median construction costs, as determined by the MSDH, for similar projects in the state within the most recent 12-month period by more than 15 percent. The Glossary of this *Plan* provides the formulas MSDH staff shall use to calculate the cost per square foot of space for construction and/or construction-renovation projects.

6. The applicant shall specify the floor areas and space requirements, including the following factors:

    a. The gross square footage of the proposed project in comparison to state and national norms for similar projects.

    b. The architectural design of the existing facility if it places restraints on the proposed project.

    c. Special considerations due to local conditions.

7. The applicant shall provide copies of transfer agreements entered into with an acute care medical center and a comprehensive medical rehabilitation facility.

CERTIFICATE OF NEED

CRITERIA AND STANDARDS
FOR
CARDIAC CATHETERIZATION SERVICES
AND
OPEN-HEART SURGERY SERVICES

102 Certificate of Need Criteria and Standards for Cardiac Catheterization Services and Open-Heart Surgery Services

Note: Should the Mississippi State Department of Health receive a Certificate of Need application regarding the acquisition and/or otherwise control of major medical equipment or the provision of a service for which specific CON criteria and standards have not been adopted, the application shall be deferred until the Department of Health has developed and adopted CON criteria and standards. If the Department has not developed CON criteria and standards within 180 days of receiving a CON application, the application will be reviewed using the general CON review criteria and standards presented in the *Mississippi Certificate of Need Review Manua*l and all adopted rules, procedures, and plans of the Mississippi State Department of Health.

102.03 Joint Policy Statement Regarding Certificate of Need Applications for the Acquisition or Otherwise Control of Cardiac Catheterization Equipment and/or the Offering of Cardiac Catheterization Services and the Acquisition of Open-Heart Surgery Equipment and/or the Offering of Open-Heart Surgery Services

Heart disease remains the leading cause of death in Mississippi as incidence rates continue to increase, particularly among the African-American population. Studies show that minorities have a higher cardiovascular death rate than whites and are less likely to receive cardiac catheterization and open-heart surgery services than are whites. The disproportionate impact on minorities' health status in general is recognized elsewhere in this *State Health Plan*.

Innovative approaches to address these problems in the cardiac area are needed. It has been shown that statistical methods, such as population base and optimum capacity at existing providers, are not accurate indicators of the needs of the underserved, nor do they address the accessibility of existing programs to the underserved. The goal of these revisions to the State Health Plan is to improve access to cardiac care and to encourage the establishment of additional cardiac catheterization and open-heart surgery programs within the state that can serve the poor, minorities, and the rural population in greater numbers.

To further this goal, the MSDH adopted the following standards:

1. A minimum population base standard of 100,000;

2. The establishment of diagnostic cardiac catheterization services with a caseload of 300 diagnostic catheterization procedures;

3. The establishment of therapeutic cardiac catheterization services with a caseload of 450 diagnostic and therapeutic catheterization procedures;

4. The establishment of open-heart surgery programs with a caseload of 150 open-heart surgeries; and,

5. A minimum utilization of equipment/services at existing providers of 450 cardiac catheterizations, diagnostic and therapeutic, and when applicable, 150 open-heart surgeries.

The MSDH also adopted a provision that it shall not consider utilization of equipment/services at any hospital owned and/or operated by the state or its agencies when reviewing CON applications. The MSDH further adopted standards requiring an applicant to report information regarding catheterization and open-heart programs so as to monitor the provision of care to the medically underserved and the quality of that care.

The MSDH shall interpret and implement all standards in this *Plan* in recognition of the stated findings and so as to achieve the stated goal.

102.04 Policy Statement Regarding Certificate of Need Applications for the Acquisition or Otherwise Control of Cardiac Catheterization Equipment and/or the Offering of Cardiac Catheterization Services

1. Cardiac Catheterization Services: For purposes of the following CON criteria and standards, the term "cardiac catheterization services" or "catheterization services" shall include diagnostic cardiac catheterization services and therapeutic cardiac catheterization services.

   a. "Diagnostic cardiac catheterization" services are defined as, and refer to, cardiac catheterization services which are performed for the purpose of diagnosing, identifying, or evaluating cardiac related illness or disease. Diagnostic cardiac catheterization services include, but are not limited to, left heart catheterizations, right heart catheterizations, left ventricular angiography, coronary procedures, and other cardiac catheterization services of a diagnostic nature. Diagnostic cardiac catheterization services do not include percutaneous transluminal coronary angioplasty (PTCA), transseptal puncture, transthoracic left ventricular puncture, myocardial biopsy, and other cardiac catheterization procedures performed specifically for therapeutic, as opposed to diagnostic, purposes.

   b. "Therapeutic cardiac catheterization" services are defined as, and refer to, cardiac catheterization services which are performed for the purpose of actively treating, as opposed to merely diagnosing, cardiac-related illness or disease. Therapeutic cardiac catheterization services include, but are not limited to, PTCA, transseptal puncture, transthoracic left ventricular puncture and myocardial biopsy.

2. Open-Heart Surgery Capability: The MSDH shall not approve CON applications for the establishment of therapeutic cardiac catheterization services at any facility that does not have open-heart surgery capability; i.e., new therapeutic cardiac catheterization services may not be established and existing therapeutic cardiac catheterization services may not be extended without approved and operational open-heart surgery services in place. This policy does not preclude approval of a Certificate of Need application proposing the concurrent establishment of both therapeutic cardiac catheterization and open-heart surgery services.

3. Service Areas: The need for cardiac catheterization equipment/services shall be determined using the seven designated Cardiac Catheterization/Open-Heart Surgery Planning Areas (CC/OHSPAs) presented in this chapter of the Plan. Map 11-3 shows the CC/OHSPAs.

4. CC/OHSPA Need Determination: The need for cardiac catheterization equipment/ services within a given CC/OHSPA shall be determined independently of all other CC/OHSPAs.

5. Pediatric Cardiac Catheterization: Because the number of pediatric patients requiring study is relatively small, the provision of cardiac catheterization for neonates, infants, and young children shall be restricted to those facilities currently providing the service. National standards indicate that a minimum of 150 cardiac catheterization cases should be done per year and that catheterization of infants should not be performed in facilities which do not have active pediatric cardiac-surgical programs.

6. Present Utilization of Cardiac Catheterization Equipment/Services: The MSDH shall consider utilization of existing equipment/services and the presence of valid CONs for equipment/services within a given CC/OHSPA when reviewing CON applications. The MSDH shall not consider utilization of equipment/services at any hospital owned and/or operated by the state or its agencies when reviewing CON applications. The Mississippi State Department of Health may collect and consider any additional information it deems essential, including information regarding access to care, to render a decision regarding any application.

7. CON Application Analysis: At its discretion, the Department of Health may use market share analysis and other methodologies in the analysis of a CON application for the acquisition or otherwise control of cardiac catheterization equipment and/or the offering of cardiac catheterization services. The Department shall not rely upon market share analysis or other statistical evaluations if they are found inadequate to address access to care concerns.

8. Minimum CC/OHSPA Population: A minimum population base of 100,000 is required for applications proposing the establishment of cardiac catheterization services. The total population within a given CC/OHSPA shall be used when determining the need for services. Population outside an applicant's CC/OHSPA will be considered in determining need only when the applicant submits adequate documentation acceptable to the Mississippi State Department of Health, such as valid patient origin studies.

9. Minimum Caseload: Applicants proposing to offer adult diagnostic cardiac catheterization services must be able to project a caseload of at least 300 diagnostic catheterizations per year. Applicants proposing to offer adult therapeutic cardiac catheterization services must be able to project a caseload of at least 450 catheterizations, diagnostic and therapeutic, per year.

10. Residence of Medical Staff: Cardiac catheterizations must be under the control of and performed by personnel living and working within the specific hospital area. No site shall be approved for the provision of services by traveling teams.

11. Hospital-Based: All cardiac catheterizations and open-heart surgery services shall be located in acute care hospitals. The MSDH shall not approve Certificate of Need applications proposing the establishment of cardiac catheterization/open-heart surgery services in freestanding facilities or in freestanding ambulatory surgery facilities.

102.05 Certificate of Need Criteria and Standards for the Acquisition or Otherwise Control of Diagnostic Cardiac Catheterization Equipment and/or the Offering of Diagnostic Cardiac Catheterization Services

The Mississippi State Department of Health will review applications for a Certificate of Need for the acquisition or otherwise control of diagnostic cardiac catheterization equipment and/or the offering of diagnostic cardiac catheterization services under the applicable statutory requirements of Sections 41-7-173, 41-7-191, and 41-7-193, Mississippi Code of 1972, as amended. The MSDH will also review applications for Certificate of Need according to the general criteria listed in the *Mississippi Certificate of Need Review Manual*; all adopted rules, procedures and plans of the Mississippi State Department of Health; and the specific criteria and standards listed below.

The acquisition or otherwise control of diagnostic cardiac catheterization equipment is reviewable if the equipment costs exceed $1,500,000. The offering of diagnostic cardiac catheterization services is reviewable if the proposed provider has not provided those services on a regular basis within the period of twelve (12) months prior to the time such services would be offered.

1. Need Criterion: The applicant shall document a minimum population base of 100,000 in the CC/OHSPA where the proposed diagnostic cardiac catheterization equipment/service is to be located. Division of Health Planning and Resource Development population projections shall be used.

2. Minimum Procedures: An applicant proposing the establishment of diagnostic cardiac catheterization services only shall demonstrate that the proposed equipment/service utilization will be a minimum of 300 diagnostic cardiac catheterizations per year by its third year of operation.

3. Impact on Existing Providers: An applicant proposing to acquire or otherwise control diagnostic cardiac catheterization equipment and/or offer diagnostic cardiac catheterization services shall document that each existing unit, which is (a) in the CC/OHSPA and (b) within forty-five (45) miles of the applicant, has been utilized for a minimum of 450 procedures (both diagnostic and therapeutic) per year for the two most recent years as reflected in data supplied to and/or verified by the Mississippi State Department of Health. No hospital owned and/or operated by the state or its agencies shall be considered an existing unit in the CC/OHSPA under this section. The Mississippi State Department of Health may collect and consider any additional information it deems essential, including information regarding access to care, to render a decision regarding any application.

4. Staffing Standards: The applicant shall document that it has, or can obtain, the ability to administer the proposed services, provide sufficiently trained and experienced professional staff, and evaluate the performance of the programs. Mississippi State Department of Health staff shall use guidelines presented in *Optimal Resources for Examination of the Heart and Lungs: Cardiac Catheterization and Radiographic Facilities*, published under the auspices of the Inter-Society Commission for Heart Disease Resources, as resource materials when reviewing these items in an application.

5. Staff Residency: The applicant shall certify that medical staff performing diagnostic cardiac catheterization procedures shall reside within forty-five (45) minutes normal driving time of the facility.

6. Recording and Maintenance of Data: Applicants shall provide, as required under licensure standards, written assurance that they will record and maintain utilization data for diagnostic cardiac catheterization procedures (e.g., morbidity data, number of diagnostic cardiac catheterization procedures performed, and mortality data, all reported by race, sex, and payor status) and make such data available to the Mississippi State Department of Health annually.

7. Referral Agreement: An applicant proposing the establishment of diagnostic cardiac catheterization services only shall document that a formal referral agreement with a facility for the provision of emergency cardiac services (including open-heart surgery) will be in place and operational at the time of the inception of cardiac catheterization services.

8. Patient Selection: An applicant proposing to provide diagnostic cardiac catheterization services must (a) delineate the steps which will be taken to insure that high-risk or unstable patients are not catheterized in the facility, and (b) certify that therapeutic cardiac catheterization services will not be performed in the facility unless and until the applicant has received CON approval to provide therapeutic cardiac catheterization services.

9. Regulatory Approval: Before utilizing or providing the equipment or service, the applicant desiring to provide the diagnostic cardiac catheterization equipment or service shall have CON approval or written evidence that the equipment or service is exempt from CON approval as determined by the Mississippi State Department of Health. Each specified piece of equipment must be exempt from or have CON approval.

102.06 Certificate of Need Criteria and Standards for the Acquisition or Otherwise Control of Therapeutic Cardiac Catheterization Equipment and/or the Offering Of Therapeutic Cardiac Catheterization Services

The Mississippi State Department of Health will review applications for a Certificate of Need for the acquisition or otherwise control of therapeutic cardiac catheterization equipment and/or the offering of therapeutic cardiac catheterization services under the applicable statutory requirements of Sections 41-7-173, 41-7-191, and 41-7-193, Mississippi Code of 1972, as amended. The MSDH will also review applications for Certificate of Need according to the general criteria listed in the *Mississippi Certificate of Need Review Manua*l; all adopted rules, procedures and plans of the Mississippi State Department of Health; and the specific criteria and standards listed below.

The acquisition or otherwise control of therapeutic cardiac catheterization equipment is reviewable if the equipment costs exceed $1,500,000. The offering of therapeutic cardiac catheterization services is reviewable if the proposed provider has not provided those services on a regular basis within the period of twelve (12) months prior to the time such services would be offered.

1. **Need Criterion: The applicant shall document a minimum population base of 100,000 in the CC/OHSPA where the proposed therapeutic cardiac catheterization**

equipment/service is to be located. Division of Health Planning and Resource Development population projections shall be used.

2. Minimum Procedures: An applicant proposing the establishment of therapeutic cardiac catheterization services shall demonstrate that the proposed equipment/service utilization will be a minimum of 450 cardiac catheterizations, both diagnostic and therapeutic, per year by its third year of operation. An applicant proposing the establishment of therapeutic cardiac catheterization services who presently offers only diagnostic cardiac catheterization may include in its demonstration of a minimum of 450 cardiac catheterizations per year the number of diagnostic catheterizations that it performs.

3. Impact on Existing Providers: An applicant proposing to acquire or otherwise control therapeutic cardiac catheterization equipment and/or offer therapeutic cardiac catheterization services shall document that each existing unit which is (a) in the CC/OHSPA and (b) within 45 miles of the applicant, has been utilized for a minimum of 450 procedures (both diagnostic and therapeutic) per year for the two most recent years as reflected in data supplied to and/or verified by the Mississippi State Department of Health. No hospital owned and/or operated by the state or its agencies shall be considered an existing unit in the CC/OHSPA under this section. The Mississippi State Department of Health may collect and consider any additional information it deems essential, including information regarding access to care, to render a decision regarding any application.

4. Staffing Standards: The applicant shall document that it has, or can obtain, the ability to administer the proposed services, provide sufficiently trained and experienced professional staff, and evaluate the performance of the programs. Mississippi State Department of Health staff shall use guidelines presented in O*ptimal Resources for Examination of the Heart and Lungs: Cardiac Catheterization and Radiographic Facilities*, published under the auspices of the Inter-Society Commission for Heart Disease Resources, as resource materials when reviewing these items in an application.

5. Staff Residency: The applicant shall certify that medical staff performing therapeutic cardiac catheterization procedures shall reside within forty-five (45) minutes normal driving time of the facility.

6. Recording and Maintenance of Data: Applicants shall provide, as required under licensure standards, written assurance that they will record and maintain separate utilization data for diagnostic and therapeutic cardiac catheterization procedures (e.g., morbidity data, number of diagnostic and therapeutic cardiac catheterization procedures performed and mortality data, all reported by race, sex and payor status) and make that data available to the Mississippi State Department of Health annually.

7. Open-Heart Surgery: An applicant proposing the establishment of therapeutic cardiac catheterization services shall document that open-heart surgery services are available or will be available on-site where the proposed therapeutic cardiac catheterization services are to be offered before such procedures are performed.

8. Regulatory Approval: Before utilizing or providing the equipment or service, the applicant desiring to provide the cardiac catheterization equipment or service shall have CON approval or written evidence that the equipment or service is exempt from CON approval as determined by the Mississippi State Department of Health. Each specified piece of equipment must be exempt from or have CON approval.

9. Applicants Providing Diagnostic Catheterization Services: An applicant proposing the establishment of therapeutic cardiac catheterization services, who is already an existing provider of diagnostic catheterization services, shall demonstrate that its diagnostic cardiac catheterization unit has been utilized for a minimum of 300 procedures per year for the two most recent years as reflected in the data supplied to and/or verified by the Mississippi State Department of Health.

102.07 Policy Statement Regarding Certificate of Need Applications for the Acquisition of Open-Heart Surgery Equipment and/or the Offering of Open-Heart Surgery Services

1. Service Areas: The need for open-heart surgery equipment/services shall be determined using the seven designated Cardiac Catheterization/Open-Heart Surgery Planning Areas (CC/OHSPAs) presented in this chapter of the Plan. Map 11-3 shows the CC/OHSPAs.

2. CC/OHSPA Need Determination: The need for open-heart surgery equipment/services within a given CC/OHSPA shall be determined independently of all other CC/OHSPAs.

3. Pediatric Open-Heart Surgery: Because the number of pediatric patients requiring open-heart surgery is relatively small, the provision of open-heart surgery for neonates, infants, and young children shall be restricted to those facilities currently providing the service.

4. Present Utilization of Open-Heart Surgery Equipment/Services: The Mississippi State Department of Health shall consider utilization of existing open-heart surgery equipment/ services and the presence of valid CONs for open-heart surgery equipment/services within a given CC/OHSPA when reviewing CON applications. The MSDH shall not consider utilization of equipment/services at any hospital owned and/or operated by the state or its agencies when reviewing CON applications. The Mississippi State Department of Health may collect and consider any additional information it deems essential, including information regarding access to care, to render a decision regarding any application.

5. CON Application Analysis: At its discretion, the Department of Health may use market share analysis and other methodologies in the analysis of a CON application for the acquisition or otherwise control of open-heart surgery equipment and/or the offering of open-heart surgery services. The Department shall not rely upon market share analysis or other statistical evaluations if they are found inadequate to address access to care concerns.

6. Minimum CC/OHSPA Population: A minimum population base of 100,000 in a CC/OHSPA (as projected by the Division of Health Planning and Resource Development) is required before such equipment/services may be considered. The total population within a given CC/OHSPA shall be used when determining the need for services. Population outside an applicant's CC/OHSPA will be considered in determining need only when the applicant submits adequate documentation acceptable to the Mississippi State Department of Health, such as valid patient origin studies.

7. Minimum Caseload: Applicants proposing to offer adult open-heart surgery services must be able to project a caseload of at least 150 open-heart surgeries per year.

8. Residence of Medical Staff: Open-heart surgery must be under the control of and performed by personnel living and working within the specific hospital area. No site shall be approved for the provision of services by traveling teams.

102.08 Certificate of Need Criteria and Standards for the Acquisition or Otherwise Control of Open-Heart Surgery Equipment and/or the Offering of Open-Heart Surgery Services

The Mississippi State Department of Health will review applications for a Certificate of Need for the acquisition or otherwise control of open-heart surgery equipment and/or the offering of open-heart surgery services under the applicable statutory requirements of Sections 41-7-173, 41-7-191, and 41-7-193, Mississippi Code of 1972, as amended. The MSDH will also review applications for Certificate of Need according to the general criteria listed in the *Mississippi Certificate of Need Review Manual*; all adopted rules, procedures and plans of the Mississippi State Department of Health; and the specific criteria and standards listed below.

The acquisition or otherwise control of open-heart surgery equipment is reviewable if the equipment cost in excess of $1,500,000. The offering of open-heart surgery services is reviewable if the proposed provider has not provided those services on a regular basis within twelve (12) months prior to the time such services would be offered.

1. **Need Criterion: The applicant shall document a minimum population base of 100,000 in the CC/OHSPA where the proposed open-heart surgery equipment/service is to be located. Division of Health Planning and Resource Development population projections shall be used.**

2. Minimum Procedures: The applicant shall demonstrate that it will perform a minimum of 150 open-heart surgeries per year by its third year of operation.

3. Impact on Existing Providers: An applicant proposing to acquire or otherwise control open-heart surgery equipment and/or offer open-heart surgery services shall document that each facility offering open-heart surgery services which is (a) in the CC/OHSPA and (b) within 45 miles of the applicant, has performed a minimum of 150 procedures per year for the two most recent years as reflected in data supplied to and/or verified by the Mississippi State Department of Health. No hospital owned and/or operated by the state or its agencies shall be considered an existing unit in the CC/OHSPA under this section. The Mississippi State Department of Health may collect and consider any additional information it deems essential, including information regarding access to care, to render a decision regarding any application.

4. Staffing Standards: The applicant shall document that it has, or can obtain, the ability to administer the proposed services, provide sufficiently trained and experienced professional staff, and evaluate the performance of the programs. Department of Health staff shall use guidelines presented in Optimal Resources for Examination of the Heart and Lungs: Cardiac Catheterization and Radiographic Facilities, published under the auspices of the Inter-Society Commission for Heart Disease Resources, and Guidelines and Indications for Coronary Artery Bypass Graft Surgery: A Report of the American College of Cardiology/American Heart Association Task Force on Assessment of Diagnostic and Therapeutic Cardiovascular Procedures (Subcommittee on Coronary

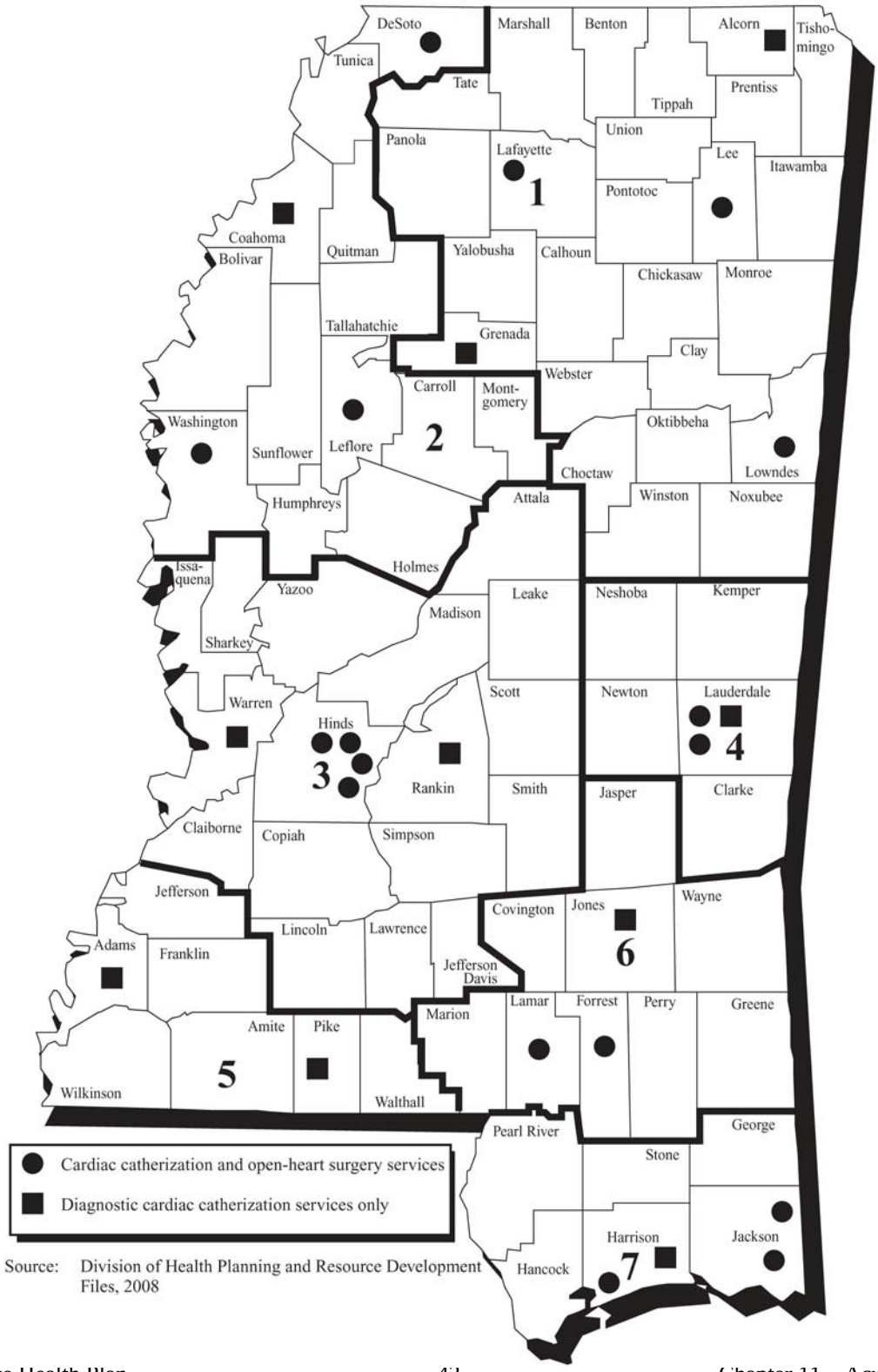
Artery Bypass Graft Surgery), published under the auspices of the American College of Cardiology, as resource materials when reviewing these items in an application.

5. Staff Residency: The applicant shall certify that medical staff performing open-heart surgery procedures shall reside within forty-five (45) minutes normal driving time of the facility. The applicant shall document that proposed open-heart surgery procedures shall not be performed by traveling teams.

6. Recording and Maintenance of Data: Applicants shall provide, as required under licensure standards, written assurance that they will record and maintain utilization data for open-heart surgeries (e.g., morbidity data, number of open-heart surgeries performed and mortality data, all reported by race, sex and payor status) and make such data available to the Mississippi State Department of Health annually.

7. Regulatory Approval: Before utilizing or providing the equipment or service, the applicant desiring to provide the open-heart surgery equipment or service shall have CON approval or written evidence that the equipment or service is exempt from CON approval as determined by the Mississippi State Department of Health. Each specified piece of equipment must be exempt from or have CON approval.

Map 11- 2
Cardiac Catherization/Open Heart Surgery
Planning Areas (CC/OHSPA)
and Location of Existing/CON-Approved Services



Source: Division of Health Planning and Resource Development Files, 2008

CERTIFICATE OF NEED

CRITERIA AND STANDARDS
FOR
COMPREHENSIVE MEDICAL REHABILITATION BEDS/SERVICES

100 Certificate of Need Criteria and Standards for Comprehensive Medical Rehabilitation Beds/Services

Note: Should the Mississippi State Department of Health receive a Certificate of Need application regarding the acquisition and/or otherwise control of major medical equipment or the provision of a service for which specific CON criteria and standards have not been adopted, the application shall be deferred until the Department of Health has developed and adopted CON criteria and standards. If the Department has not developed CON criteria and standards within 180 days of receiving a CON application, the application will be reviewed using the general CON review criteria and standards presented in the *Mississippi Certificate of Need Review Manual* and all adopted rules, procedures, and plans of the Mississippi State Department of Health.

100.01 Policy Statement Regarding Certificate of Need Applications for Comprehensive Medical Rehabilitation Beds/Services

1. Definition: Comprehensive Medical Rehabilitation Services provided in a freestanding comprehensive medical rehabilitation hospital or comprehensive medical rehabilitation distinct part unit are defined as intensive care providing a coordinated multidisciplinary approach to patients with severe physical disabilities that require an organized program of integrated services. These disabilities include: stroke, spinal cord injury, congenital deformity, amputation, major multiple trauma, fractures or the femur (hip fracture), brain injury, polyarthritis, including rheumatoid arthritis, or neurological disorders, including multiple sclerosis, motor neuron disease, polyneuropathy, muscular dystrophy, and Parkinson's Disease.

2. Planning Areas: The state as a whole shall serve as a single planning area for determining the need of comprehensive medical rehabilitation beds/services.

3. Comprehensive Medical Rehabilitation Services:

   Level I - Level I comprehensive medical rehabilitation providers may provide treatment services for all rehabilitation diagnostic categories.

   Level II - Level II comprehensive medical rehabilitation providers may provide treatment services for all rehabilitation diagnostic categories except: (1) spinal cord injuries, (2) congenital deformity, and (3) brain injury.

4. CMR Need Determination: The Mississippi State Department of Health shall determine the need for Level I comprehensive rehabilitation beds/services based upon a formula of 0.08 beds per 1,000 population for the state as a whole.

   The Mississippi State Department of Health shall determine need for Level II comprehensive medical rehabilitation beds/services based upon a formula of 0.0623 beds per 1,000 population for the state as a whole. Table 12-3 shows the current need for comprehensive medical rehabilitation beds.

5. Present Utilization of Rehabilitation Services: When reviewing CON applications, the MSDH shall consider the utilization of existing services and the presence of valid CONs for services.

6. Minimum Sized Facilities/Units: Freestanding comprehensive medical rehabilitation facilities shall contain not less than 60 beds. Hospital-based Level I comprehensive medical rehabilitation units shall contain not less than 20 beds. If the established formula reveals a need for more than ten beds, the MSDH may consider a 20-bed (minimum sized) unit for approval. Hospital-based Level II comprehensive medical rehabilitation facilities are limited to a maximum of 20 beds. New Level II rehabilitation units shall not be located within a 45 mile radius of any other CMR facility.

7. Expansion of Existing CMR Beds: Before any additional CMR beds, for which CON review is required, are approved for any facility presently having CMR beds, the currently licensed CMR beds at said facility shall have maintained an occupancy rate of at least 80 percent for the most recent 12-month licensure reporting period or at least 70 percent for the most recent two years.

8. Priority Consideration: When reviewing two or more competing CON applications, the MSDH shall use the following factors in the selection process, including, but not limited to, a hospital having a minimum of 160 licensed acute care beds as of January 1, 2000; the highest average daily census of the competing applications; location of more than 45 mile radius from an existing provider of comprehensive medical rehabilitation services; proposed comprehensive range of services; and the patient base needed to sustain a viable comprehensive medical rehabilitation service.

9. Children's Beds/Services: Should a CON applicant intend to serve children, the application shall include a statement to that effect.

10. Other Requirements: Applicants proposing to provide CMR beds/services shall meet all requirements set forth in CMS regulations as applicable, except where additional or different requirements, as stated in the *State Health Plan* or in the licensure regulations, are required. Level II comprehensive medical rehabilitation units are limited to a maximum size of 20 beds and must be more than a 45 mile radius from any other Level I or Level II rehabilitation facility.

11. Enforcement: In any case in which the MSDH finds a Level II Provider has failed to comply with the diagnosis and admission criteria as set forth above, the provider shall be subject to the sanctions and remedies as set forth in Section 41-7-209 of the Mississippi Code of 1972, as amended, and other remedies available to the MSDH in law or equity.

12. Effective July 1, 1994, no health care facility shall be authorized to add any beds or convert any beds to another category of beds without a Certificate of Need under the authority of Section 41-7-191(1)(c), unless there is a projected need for such beds in the planning district in which the facility is located.

13. Effective March 4, 2003, if a health care facility has voluntarily delicensed some of its existing bed complement, it may later relicense some or all of its delicensed beds without the necessity of having to acquire a Certificate of Need. The Department of Health shall maintain a record of the delicensing health care facility and its voluntarily delicensed beds and continue counting those beds as part of the state's total bed count for health care planning purposes.

100.02 Certificate of Need Criteria and Standards for Comprehensive Medical Rehabilitation Beds/Services

The MSDH will review applications for a CON for the establishment, offering, or expansion of comprehensive medical rehabilitation beds and/or services under the statutory requirements of Sections 41-7-173, 41-7-191, and 41-7-193, Mississippi Code 1972, Annotated, as amended. The MSDH will also review applications for Certificate of Need according to the general criteria listed in the *Mississippi Certificate of Need Review Manual*; all adopted rules, procedures, and plans of the Mississippi State Department of Health; and the specific criteria and standards listed below.

In addition, comprehensive rehabilitation services are reviewable if the proposed provider has not provided such services on a regular basis within twelve (12) months prior to the time such services would be offered. The twenty (20) bed hospital-based comprehensive medical rehabilitation facilities which are operational or approved on January 1, 2001, are *grandfathered* and shall not be required to obtain a Certificate of Need as long as the services are provided continuously by those facilities and are limited to the diagnoses set forth below for Level II comprehensive medical rehabilitation facilities.

1. **Need Criterion:**

   a. **New/Existing Comprehensive Medical Rehabilitation Beds/Service**s: The need for Level I comprehensive medical rehabilitation beds in the state shall be determined using a methodology of 0.08 beds per 1,000 population. The state as a whole shall be considered as a single planning area.

      The need for Level II comprehensive medical rehabilitation beds in the state shall be determined using a methodology of 0.0623 comprehensive medical rehabilitation beds per 1,000 population. The state as a whole shall be considered a planning area.

   b. **Projects which do not involve the addition of any CMR beds**: The applicant shall document the need for the proposed project. Documentation may consist of, but is not necessarily limited to, citing of licensure or regulatory code deficiencies, institutional long-term plans (duly adopted by the governing board), recommendations made by consultant firms, and deficiencies cited by Accreditation Agencies (JCAHO, CAP).

   c. **Projects which involve the addition of beds**: The applicant shall document the need for the proposed project. Exception: Notwithstanding the service specific need requirements as stated in "a" above, the MSDH may approve additional beds for facilities which have maintained an occupancy rate of at least 80 percent for the most recent 12-month licensure reporting period or at least 70 percent for the most recent two (2) years.

   d. **Level II Trauma Centers**: The applicant shall document the need for the proposed CMR project. Exception: Notwithstanding the forty-five (45) mile radius distance requirement from an existing CMR provider, the MSDH may approve the establishment of a 20-bed Level II CMR unit for any hospital without CMR beds which holds Level II Trauma care designation on July 1, 2003, as well as on the date the Certificate of Need application is filed.

2. Applicants proposing to establish Level I comprehensive medical rehabilitation services shall provide treatment and programs for one or more of the following conditions:

   a. stroke,

   b. spinal cord injury,

   c. congenital deformity,

   d. amputation,

   e. major multiple trauma,

   f. fractures of the femur (hip fracture),

   g. brain injury,

   h. polyarthritis, including rheumatoid arthritis, or

   i. neurological disorders, including multiple sclerosis, motor neuron disease, polyneuropathy, muscular dystrophy, and Parkinson's Disease.

   Applicants proposing to establish Level II comprehensive medical rehabilitation services shall be prohibited from providing treatment services for the following rehabilitation diagnostic categories: (1) spinal cord injury, (2) congenital deformity, and (3) brain injury.

   Facilities providing Level I and Level II comprehensive medical rehabilitation services shall include on their *Annual Report of Hospitals* submitted to the MSDH the following information: total admissions, average length of stay by diagnosis, patient age, sex, race, zip code, payor source, and length of stay by diagnosis.

3. Staffing and Services

   a. Freestanding Level I Facilities

      i. Shall have a Director of Rehabilitation who:

         (1) provides services to the hospital and its inpatient clientele on a full-time basis;

         (2) is a Doctor of Medicine or Osteopathy licensed under state law to practice medicine or surgery; and

         (3) has had, after completing a one-year hospital internship, at least two years of training in the medical management of inpatients requiring rehabilitation services.

      ii. The following services shall be provided by full-time designated staff:

         (1) speech therapy

(2) occupational therapy

(3) physical therapy

(4) social services

iii. Other services shall be provided as required, but may be by consultant or on a contractual basis.

b. Hospital-Based Units

i. Both Level I and Level II hospital-based units shall have a Director of Rehabilitation who:

(1) is a Doctor of Medicine or Osteopathy licensed under state law to practice medicine or surgery;

(2) has had, after completing a one-year hospital internship, at least two years of training or experience in the medical management of inpatients requiring rehabilitation services; and

(3) provides services to the unit and its inpatients for at least 20 hours per week.

ii. The following services shall be available full time by designated staff:

(1) physical therapy

(2) occupational therapy

(3) social services

iii. Other services shall be provided as required, but may be by consultant or on a contractual basis.

100.03 Certificate of Need Criteria and Standards for Children's Comprehensive Medical Rehabilitation Beds/Services

Until such time as specific criteria and standards are developed, the MSDH will review CON applications for the establishment of children's comprehensive medical rehabilitation services under the general criteria and standards listed in the *Mississippi Certificate of Need Review Manual* in effect at the time of submission of the application, and the preceding criteria and standards listed.

100.04 Comprehensive Medical Rehabilitation Bed Need Methodology

The determination of need for Level I CMR beds/services will be based on 0.08 beds per 1,000 population in the state as a whole for the year 2010. Table 12-3 presents Level I CMR bed need.

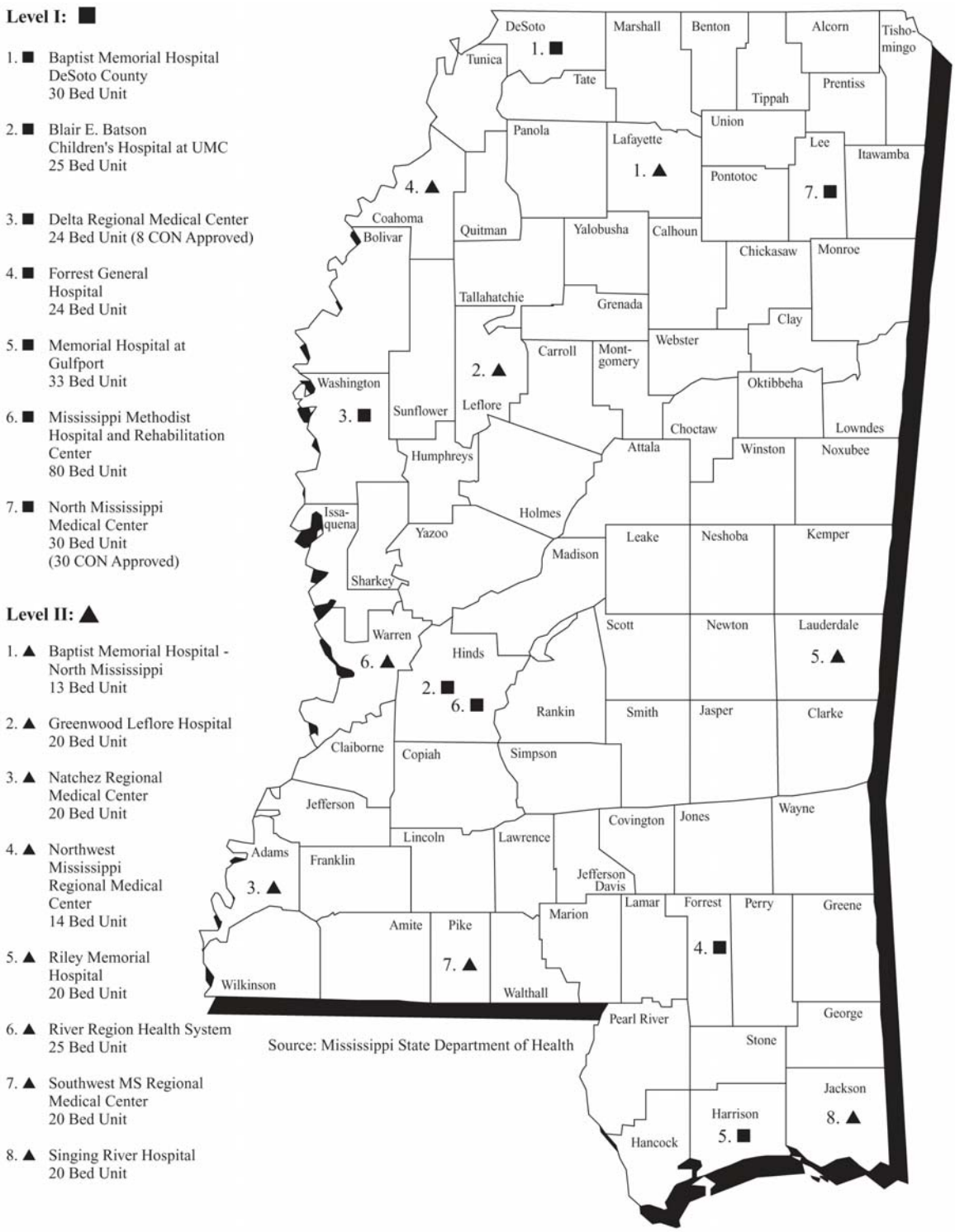
The determination of need for Level II CMR beds/services will be based on 0.0623 beds per 1,000 population in the state as a whole for the year 2010. Table 12-3 presents Level II CMR bed need.

Table 12 - 1
Comprehensive Medical Rehabilitation Bed Need
2007

Level	Estimated Population 2010	Number Licensed/CON-Approved CMR Beds	Number of CMR Beds Needed	Difference
Level I	2,975,551	284	238	-46
Level II	2,975,551	152	185	33

Source: Applications for renewal of hospital license for Fiscal Year 2008; *Mississippi Population Projections 2010, 2015, and 2020*,. Center for Policy Research and Planning, Mississippi Institutions of Higher Learning, August 2005.

Map 12 - 1
Location of Comprehensive
Medical Rehabilitation Facilities Level I and Level II



Source: Mississippi State Department of Health

CERTIFICATE OF NEED
CRITERIA AND STANDARDS
FOR
OTHER HEALTH SERVICES

100 Certificate of Need Criteria and Standards for Ambulatory Surgery Services

Note: Should the Mississippi State Department of Health receive a Certificate of Need application regarding the acquisition and/or otherwise control of major medical equipment or the provision of a service for which specific CON criteria and standards have not been adopted, the application shall be deferred until the Department of Health has developed and adopted CON criteria and standards. If the Department has not developed CON criteria and standards within 180 days of receiving a CON application, the application will be reviewed using the general CON review criteria and standards presented in the *Mississippi Certificate of Need Review Manual* and all adopted rules, procedures, and plans of the Mississippi State Department of Health.

100.01 Policy Statement Regarding Certificate of Need Applications for Ambulatory Surgery Services

1. Ambulatory Surgery Planning Areas (ASPAs): The Mississippi State Department of Health (MSDH) shall use the ASPAs as outlined on Map 13-2 of this Plan for planning and Certificate of Need (CON) decisions. The need for ambulatory surgery facilities in any given ASPA shall be calculated independently of all other ASPAs.

2. Ambulatory Surgery Facility Service Areas: An applicant's Ambulatory Surgery Facility Service Area must have a population base of approximately 60,000 within 30 minutes normal driving time or 25 miles, whichever is greater, of the proposed/established facility. Note: Licensure standards require a freestanding facility to be within 15 minutes traveling time of an acute care hospital and a transfer agreement with said hospital must be in place before a CON may be issued. Additionally, the ambulatory surgery facility service area must have a stable or increasing population.

3. Definitions: The Glossary of this Plan includes the definitions in the state statute regarding ambulatory surgery services.

4. Surgeries Offered: The MSDH shall not approve single service ambulatory surgery centers. Only multi-specialty ambulatory surgery center proposals may be approved for a CON.

5. Minimum Surgical Operations: The minimum of 1,000 surgeries required to determine need is based on five (5) surgeries per operating room per day x 5 days per week x 50 weeks per year x 80 percent utilization rate.

6. Present Utilization of Ambulatory Surgery Services: The MSDH shall consider the utilization of existing services and the presence of valid CONs for services within a given ASPA when reviewing CON applications.

7. Optimum Capacity: The optimum capacity of an ambulatory surgery facility is 800 surgeries per operating room per year. The MSDH shall not issue a CON for the establishment or expansion of an additional facility(ies) unless the existing facilities within the ASPA have performed in aggregate at least 800 surgeries per operating room per year for the most recent 12-month reporting period, as reflected in data supplied to and/or verified by the MSDH. The MSDH may collect additional

information it deems essential to render a decision regarding any application. Optimum capacity is based on four (4) surgeries per operating room per day x 5 days per week x 50 weeks per year x 80 percent utilization rate.

8. Conversion of Existing Service: Applications proposing the conversion of existing inpatient capacity to hospital-affiliated ambulatory surgical facilities located within the hospital shall receive approval preference over detached or freestanding ambulatory surgical facilities if the applicant can show that such conversion is less costly than new construction and if the application substantially meets other adopted criteria.

9. Construction/Expansion of Facility: Any applicant proposing to construct a new facility or major renovation to provide ambulatory surgery must propose to build/renovate no fewer than two operating rooms.

10. Indigent/Charity Care: The applicant shall be required to provide a "reasonable amount" of indigent/charity care as described in Chapter 1 of this Plan.

100.02 Certificate of Need Criteria and Standards for Ambulatory Surgery Services

The MSDH will review applications for a CON for new ambulatory surgery facilities, as defined in Mississippi law, under the statutory requirements of Sections 41-7-173, 41-7-191, and 41-7-193, Mississippi Code of 1972 Annotated, as amended. The MSDH will also review applications submitted for Certificate of Need in accordance with the rules and regulations in the *Mississippi Certificate of Need Review Manual*; all adopted rules, procedures, and plans of the Mississippi State Department of Health; and the specific criteria and standards listed below.

The offering of ambulatory surgery services is reviewable if the proposed provider has not provided those services on a regular basis within twelve (12) months prior to the time such services would be offered. In addition, ambulatory surgery services require CON review when the establishment or expansion of the services involves a capital expenditure in excess of $2,000,000.

1. **Need Criterion: The applicant shall demonstrate that the proposed ambulatory surgery facility shall perform a minimum average of 1,000 surgeries per operating room per year.**

2. The applicant must document that the proposed Ambulatory Surgery Facility Service Area has a population base of approximately 60,000 within 30 minutes travel time.

3. An applicant proposing to offer ambulatory surgery services shall document that the existing facilities in the ambulatory surgery planning area have been utilized for a minimum of 800 surgeries per operating room per year for the most recent 12-month reporting period as reflected in data supplied to and/or verified by the Mississippi State Department of Health. The MSDH may collect additional information it deems essential to render a decision regarding any application.

4. The applicant must document that the proposed program shall provide a full range of surgical services in general surgery.

5. The applicant must provide documentation that the facility will be economically viable within two years of initiation.

6. The proposed facility must show support from the local physicians who will be expected to utilize the facility.

7. Medical staff of the facility must live within a 25-mile radius of the facility.

8. The proposed facility must have a formal agreement with a full service hospital to provide services which are required beyond the scope of the ambulatory surgical facility's programs. The facility must also have a formal process for providing follow-up services to the patients (e.g., home health care, outpatient services) through proper coordination mechanisms.

9. Indigent/Charity Care: The applicant shall affirm that the applicant will provide a "reasonable amount" of indigent/charity care by stating the amount of indigent/charity care the applicant intends to provide.

101 Certificate of Need Criteria and Standards for Home Health Agencies/Services

Note: Should the Mississippi State Department of Health receive a Certificate of Need application regarding the acquisition and/or otherwise control of major medical equipment or the provision of a service for which specific CON criteria and standards have not been adopted, the application shall be deferred until the Department of Health has developed and adopted CON criteria and standards. If the Department has not developed CON criteria and standards within 180 days of receiving a CON application, the application will be reviewed using the general CON review criteria and standards presented in the *Mississippi Certificate of Need Review Manual* and all adopted rules, procedures, and plans of the Mississippi State Department of Health.

101.01 Policy Statement Regarding Certificate of Need Applications for the Establishment of a Home Health Agency and/or the Offering of Home Health Services

1. Service Areas: The need for home health agencies/services shall be determined on a county by county basis.

2. Determination of Need: A possible need for home health services may exist in a county if for the most recent calendar year available that county had fewer home health care visits per 1,000 elderly (65+) population than the average number of visits received per 1,000 elderly (65+) in the "ten-state region" consisting of Alabama, Arkansas, Florida, Georgia, Kentucky, Louisiana, Mississippi, North Carolina, South Carolina, and Tennessee. That number is currently 3,487, as shown in Table 13-4 (CY 2006 is most recent data available).

3. Unmet Need: If it is determined that an unmet need exists in a given county, the unmet need must be equivalent to 50 patients in each county proposed to be served. Based on 2006 data 2,000 visits approximates 50 patients.

4. All CON applications for the establishment of a home health agency and/or the offering of home health services shall be considered substantive and will be reviewed accordingly.

101.02 Certificate of Need Criteria and Standards for the Establishment of a Home Health Agency and/or the Offering of Home Heath Services

If the present moratorium were removed or partially lifted, the MSDH would review applications for a CON for the establishment of a home health agency and/or the offering of home health services under the applicable statutory requirements of Sections 41-7-173, 41-7-191, and 41-7-193, Mississippi Code of 1972, as amended. The MSDH will also review applications submitted for CON according to the general criteria as listed in the *Mississippi Certificate of Need Review Manual*; all adopted rules, procedures, and plans of the MSDH; and the specific criteria and standards listed below.

The development or otherwise establishment of a home health agency requires CON. The offering of home health services is reviewable if the proposed provider has not provided those services on a regular basis within the period of twelve (12) months prior to the time such services would be offered.

1. **Need Criterion: The applicant shall document that a possible need for home health services exists in each county proposed to be served using the methodology contained in this section of the *Plan*.**

2. The applicant shall state the boundaries of the proposed home health service area in the application.

3. The applicant shall document that each county proposed to be served has an unmet need equal to 50 patients, using a ratio of 2,000 patient visits equals 50 patients.

4. The applicant shall document that the home office of a new home health agency shall be located in a county included in the approved service area of the new agency. An existing agency receiving CON approval for the expansion of services may establish a sub-unit or branch office if such meets all licensing requirements of the Division of Licensure.

5. The application shall document the following for each county to be served:

    a. Letters of intent from physicians who will utilize the proposed services.

    b. Information indicating the types of cases physicians would refer to the proposed agency and the projected number of cases by category expected to be served each month for the initial year of operation.

    c. Information from physicians who will utilize the proposed service indicating the number and type of referrals to existing agencies over the previous 12 months.

    d. Evidence that patients or providers in the area proposed to be served have attempted to find services and have not been able to secure such services.

e. Projected operating statements for the first three years, including:

i. total cost per licensed unit;

ii. average cost per visit by category of visit; and

iii. average cost per patient based on the average number of visits per patient.

6. Information concerning whether proposed agencies would provide services different from those available from existing agencies.

101.03 Statistical Need Methodology for Home Health Services

The methodology used to calculate the average number of visits per 1,000 elderly (65+) in the 10-state region is:

1. The 10-state region consists of Alabama, Arkansas, Florida, Georgia, Kentucky, Louisiana, Mississippi, North Carolina, South Carolina, and Tennessee.

2. The 2010 projected population aged 65 and older are estimates from each state.

3. Table 13-4 shows the average number of Medicare paid home health visits per 1,000 elderly (65+) for the 10-state region, according to 2006 data from Palmetto GBA - Medicare Statistical Analysis Department of the Centers for Medicare and Medicaid Services. Figure 13-1 shows the total number of Medicare paid home health visits per 1,000 elderly in the 10-state region.

4. In 2006, the region average of home health visits per 1,000 population aged 65 and older was 3,487. An average patient in the region received 40 home health visits. Therefore 2,000 visits equal 50 patients. Note: The Mississippi average for 2006 was 4,657 visits (Medicare reimbursed) per 1,000 population aged 65 and older, and an average patient received 40 visits.

102 Certificate of Need Criteria and Standards for End Stage Renal Disease Facilities

Note: Should the Mississippi State Department of Health receive a Certificate of Need application regarding the acquisition and/or otherwise control of major medical equipment or the provision of a service for which specific CON criteria and standards have not been adopted, the application shall be deferred until the Department of Health has developed and adopted CON criteria and standards. If the Department has not developed CON criteria and standards within 180 days of receiving a CON application, the application will be reviewed using the general CON review criteria and standards presented in the *Mississippi Certificate of Need Review Manual* and all adopted rules, procedures, and plans of the Mississippi State Department of Health.

102.01 Policy Statement Regarding Certificate of Need Applications for the Establishment of End Stage Renal Disease (ESRD) Facilities

1. Establishment of an ESRD Facility: The provision or proposed provision of maintenance dialysis services constitutes the establishment of an ESRD facility if the proposed provider has not provided those services on a regular basis within the period of twelve (12) months prior to the time such services would be offered.

2. Annual Review Cycle: The MSDH shall accept and process CON applications proposing the establishment of ESRD facilities in accordance with the following review cycle:

    a. Applications may be submitted only during the period beginning July 1 and ending September 1 (5:00 p.m.) each year.

    b. All applications received during this period (July 1 through September 1 each year) which are deemed "complete" by October 1 of the year of submission, will be entered into the 90-day review cycle (October-December cycle).

    c. The State Health Officer will make CON decisions on "complete" applications in the month of December each year.

    d. Any CON application received other than in accordance with the above review cycle shall not be accepted by the Department, but shall be returned to the applicant.

3. Type of Review: CON applications for ESRD services shall be considered substantive as defined under the appropriate *Mississippi State Health Plan*, and "complete" competing applications from the same ESRD Facility Service Area shall be batched.

4. ESRD Facility Service Area: An ESRD Facility Service Area is defined as the area within thirty (30) highway miles of an existing or proposed ESRD facility. ESRD Facility Service Areas, including the Service Areas of existing facilities which overlap with the proposed Service Area, shall be used for planning purposes.

5. CON Approval: A CON application for the establishment of an ESRD facility shall be considered for approval only when each individual facility within an applicant's proposed ESRD Facility Service Area has maintained, at a minimum, an annual or prorated utilization rate of 80 percent as verified by the MSDH. The 12 months prior to the month of submission of the CON application shall be used to determine utilization, if such information is available and verifiable by the Department.

6. Need Threshold: For planning and CON purposes a need for an additional ESRD facility may exist when each individual operational ESRD station within a given ESRD Facility Service Area has maintained an annual utilization rate of 80 percent, i.e. an average of 749 dialyses per station per year.

7. Utilization Definitions:

   a. Full Utilization: For planning and CON purposes, full (100 percent) utilization is defined as an average of 936 dialyses per station per year.

   b. Optimum Utilization: For planning and CON purposes, optimum (75 percent) utilization is defined as an average of 702 dialyses per station per year.

   c. Need Utilization: For planning and CON purposes, need (80 percent) utilization is defined as an average of 749 dialyses per station per year.

These utilization definitions are based upon three (3) shifts per day six (6) days per week, or eighteen (18) shifts per week. Only equipment (peritoneal or hemodialysis) that requires staff assistance for dialysis and is in operation shall be counted in determining the utilization rate. Utilization of equipment in operation less than twelve (12) months shall be prorated for the period of time in actual use.

8. Outstanding CONs: ESRD facilities that have received CON approval but are not operational shall be considered to be operating at 50 percent, which is the minimum utilization rate for a facility the first year of operation.

9. Utilization Data: The Department may use any source of data, subject to verification by the Department, it deems appropriate to determine current utilization or projected utilization of services in existing or proposed ESRD facilities. The source of data may include, but is not limited to, Medicare Certification records maintained by the Division of Health Facilities Licensure and Certification, ESRD Network #8 data, and Centers for Medicare and Medicaid Services (CMS) data.

10. Minimum Expected Utilization: It is anticipated that a new ESRD facility may not be able to reach optimum utilization (75 percent) of four ESRD stations during the initial phase of operation. Therefore, for the purposes of CON approval, an application must demonstrate how the applicant can reasonably expect to have 50 percent utilization of a minimum of four ESRD stations by the end of the first full year of operation; 65 percent utilization by the end of the second full year of operation; and 75 percent utilization by the end of the third full year of operation.

11. Minimum Size Facility: No CON application for the establishment of a new ESRD facility shall be approved for less than four (4) stations.

12. Non-Discrimination: An applicant shall affirm that within the scope of its available services, neither the facility nor its staff shall have policies or procedures which would exclude patients because of race, color, age, sex, ethnicity, or ability to pay.

13. Indigent/Charity Care: An applicant shall be required to provide a "reasonable amount" of indigent/charity care as described in Chapter 1 of this *Plan*.

14. Staffing: The facility must meet, at a minimum, the requirements and qualifications for staffing as contained in 42 CFR 405.2100. In addition, the facility must meet all staffing requirements and qualifications contained in the service specific criteria and standards.

15. Federal Definitions: The definitions contained in 42 CFR 405.2100 through 405.2310 shall be used as necessary in conducting health planning and CON activities.

16. Affiliation with a Renal Transplant Center: ESRD facilities shall be required to enter into a written affiliation agreement with a renal transplant center.

102.02 Certificate of Need Criteria and Standards for End Stage Renal Disease (ESRD) Facilities

The Mississippi State Department of Health will review applications for a Certificate of Need for the establishment of an ESRD facility under the applicable statutory requirements of Sections 41-7-173, 41-7-191, and 41-7-193, Mississippi Code of 1972, as amended. The MSDH will also review applications for Certificate of Need according to the general criteria as listed in the *Mississippi Certificate of Need Review Manual*; all adopted rules, procedures, and plans of the Mississippi State Department of Health; and the specific criteria and standards listed below.

When a provider proposes to offer ESRD services in an ESRD facility service area where he does not currently provide services or proposes to transfer an existing ESRD unit(s) from a current location into a different ESRD facility service area, it will constitute the establishment of a new ESRD health care facility. (Note: The transfer of dialysis stations from an existing ESRD facility to any other location is a relocation of a health care facility or portion thereof and requires Certificate of Need review. Likewise, new dialysis stations placed into service at a site separate and distinct from an existing ESRD facility constitutes the establishment of a new health care facility and requires Certificate of Need review. Dialysis stations placed into service in an individual patient's home or residence, solely for the treatment of the individual patient concerned, are exempt from this regulation.)

102.02.01 Establishment of an End Stage Renal Disease (ESRD) Facility

1. **Need Criterion: An applicant proposing the establishment of a limited care renal dialysis facility or the relocation of a portion of an existing ESRD facility's dialysis stations to another location shall demonstrate, subject to verification by the Mississippi State Department of Health, that each individual existing ESRD facility in the proposed ESRD Facility Service Area has (a) maintained a minimum annual utilization rate of eighty (80) percent, or (b) that the location of the proposed ESRD facility is in a county which does not currently have an**

existing ESRD facility but whose ESRD relative risk score using current ESRD Network 8 data is 1.5 or higher. Note: ESRD Policy Statements 2, 4, 5, and 6 do not apply to criterion 1(b).

2. Number of Stations: The applicant shall state the number of ESRD stations that are to be located in the proposed facility. No new facility shall be approved for less than four (4) dialysis stations.

3. Minimum Utilization: The application shall demonstrate that the applicant can reasonably expect to meet the minimum utilization requirements as stated in ESRD Policy Statement #10.

4. Minimum Services: The application shall affirm that the facility will provide, at a minimum, social, dietetic, and rehabilitative services. Rehabilitative services may be provided on a referral basis.

5. Access to Needed Services: The application shall affirm that the applicant will provide for reasonable access to equipment/facilities for such needs as vascular access and transfusions required by stable maintenance ESRD patients.

6. Hours of Operation: The application shall state the facility's hours of operation each day of the week. The schedule should accommodate patients seeking services after normal working hours.

7. Home Training Program: The application shall affirm that the applicant will make a home training program available to those patients who are medically eligible and receptive to such a program. The application shall affirm that the applicant will counsel all patients on the availability of and eligibility requirements to enter the home/self-dialysis program.

8. Indigent/Charity Care: The application shall affirm that the applicant will provide a "reasonable amount" of indigent/charity care. The application shall also state the amount of indigent/charity care the applicant intends to provide.

9. Facility Staffing: The application shall describe the facility's staffing by category (i.e., registered nurse, technologist, technician, social worker, dietician) as follows:

    a. Qualifications (minimum education and experience requirements)

    b. Specific Duties

    c. Full Time Equivalents (FTE) based upon expected utilization

10. Staffing Qualifications: The applicant shall affirm that the staff of the facility will meet, at a minimum, all requirements and qualifications as stated in 42 CFR, Chapter 4, Subpart U.

11. Staffing Time:

    a. The applicant shall affirm that when the unit is in operation, at least one (1) R.N. will be on duty. There shall be a minimum of two (2) persons for each dialysis shift, one of which must be an R.N.

    b. The applicant shall affirm that the medical director or a designated physician will be on-site or on-call at all times when the unit is in operation. It is desirable to have one other physician to supplement the services of the medical director.

    c. The applicant shall affirm that when the unit is not in operation, the medical director or designated physician and a registered nurse will be on-call.

12. Data Collection: The application shall affirm that the applicant will record and maintain, at a minimum, the following utilization data and make this data available to the Mississippi State Department of Health as required. The time frame for the submission of the utilization data shall be established by the Department.

    a. Utilization data, e.g., days of operation, shifts, inventory and classification of all stations, number of patients in dialysis, transplanted, or expired.

    b. The number of charity/indigent patients (as defined in this *Plan*) served by the facility and the number of dialysis procedures provided to these patients free of charge or at a specified reduced rate.

13. Staff Training: The application shall affirm that the applicant will provide an ongoing program of training in dialysis techniques for nurses and technicians at the facility.

14. Scope of Privileges: The applicant shall affirm that the facility shall provide access to doctors of medicine or osteopathic medicine licensed by the State of Mississippi who possess qualifications established by the governing body of the facility.

15. Affiliation with a Renal Transplant Center: The applicant shall affirm that within one year of commencing operation the facility will enter into an affiliation agreement with a transplantation center. The written agreement shall describe the relationship between the transplantation facility and the ESRD facility and the specific services that the transplantation center will provide to patients of the ESRD facility. The agreement must include at least the following:

    a. time frame for initial assessment and evaluation of patients for transplantation,

    b. composition of the assessment/evaluation team at the transplant center,

    c. method for periodic re-evaluation,

    d. criteria by which a patient will be evaluated and periodically re-evaluated for transplantation, and

    e. signatures of the duly authorized persons representing the facilities and the agency providing the services.

f. Furthermore, the application shall affirm that the applicant understands and agrees that failure to comply with this criterion may (after due process) result in revocation of the Certificate of Need.

102.02.02 Establishment of a Renal Transplant Center

1. **Need Criterion: The applicant shall document that the proposed renal transplant center will serve a minimum population of 3.5 million people.**

2. The applicant shall document that the proposed facility will provide, at a minimum, the following:

   a. medical-surgical specialty services required for the care of ESRD transplant patients;

   b. acute dialysis services;

   c. an organ procurement system;

   d. an organ preservation program; and

   e. a tissue typing laboratory.

3. The applicant shall document that the facility will perform a minimum of 25 transplants annually.