STATE HEALTH PLANNING AND DEVELOPMENT AGENCY
ALABAMA STATE HEALTH PLAN
2014-2017
ADMINISTRATIVE CODE

CHAPTER 410-2-3
SPECIALTY SERVICES

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410-2-3-.01   Introduction.  This chapter of the Alabama State Health Plan reviews the status of certain specialty health care services and the need for additional services to address the problems cited in the Priorities section of the Plan. Specialty Services are separately identified for ease of reference and to highlight their importance in the overall planning and regulatory responsibilities. The health care system in Alabama should not be burdened by an unnecessary duplication of expensive services.

Author:  Statewide Health Coordinating Council (SHCC)

410-2-3-.02   Neonatal Services.

(1)   Discussion

(a)   A leading indicator of the health status of a state’s citizens is the infant mortality rate. Alabama has one
of the highest rates in the country. In order to have an impact on infant mortality, the State must make neonatal care accessible and enhance that care which is available.

(b) Maternal and Neonatal service providers are designated as Basic (Level I), Specialty (Level II), or Subspecialty (Level III), depending on their capabilities and expertise.

1. A regionally coordinated system focusing on levels of hospital-based perinatal care has been shown to be effective and to result in improved outcomes for women and their newborns. According to the American College of Obstetricians and Gynecologists and the American Academy of Pediatrics, guidelines for Perinatal Care, Fifth Edition, prenatal care can be delivered more effectively and efficiently by defining the capabilities and expertise of providers and ensuring that pregnant women receive risk-appropriate care. Basic (Level I) care should have the following capabilities and provider types:

   (i) Capabilities - Risk-oriented prenatal care record, physical examination and interpretation of findings, routine laboratory assessment, assessment of gestational age and normal progress of pregnancy, ongoing risk identification, mechanisms for consultation and referral, psychosocial support, childbirth education and care coordination (including referral for ancillary services, such as transportation, food, and housing assistance).

   (ii) Provider Types - Obstetricians, family physicians, certified nurse-midwives, and other advanced-practice nurses with experience, training, and demonstrated competence.

   (iii) Responsibilities - 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 subspecialty care; proper detection and initial care of unanticipated maternal-fetal problems that occur during labor and delivery; capability to perform cesarean delivery within 30 minutes of the decision to do so; availability of appropriate anesthesia, radiology, ultrasound, laboratory and blood bank services on a 24-hour basis; care of postpartum conditions; resuscitation and stabilization of all neonates born in the hospital; evaluation and continuing care of healthy neonates in a nursery or with their mothers until discharge; adequate nursery facilities and support for stabilization of small or ill neonates before transfer to a specialty or subspecialty facility; consultation and transfer arrangements; parent-sibling-neonate visitation; and data collection and retrieval.
2. Specialty (Level II) providers should have:

   (i) Capabilities - Basic care capabilities plus fetal diagnostic testing (e.g., biophysical tests, amniotic fluid analysis, basic ultrasonography, and expertise in management of medical and obstetric complications.

   (ii) Provider Types - Obstetricians.

   (iii) Responsibilities - Provision of some enhanced services as well as basic care services as described in 1(iii); care of appropriate high-risk women and fetuses, both admitted and transferred from other facilities; stabilization of severely ill newborns before transfer; treatment of moderately ill larger preterm and term newborns; and data collection and retrieval.

3. Subspecialty (Level III) providers should have:

   (i) Capabilities - Basic and specialty care plus advanced fetal diagnoses (e.g., targeted ultrasonography, fetal echo-cardiology); advanced therapy (e.g., intrauterine fetal transfusion and treatment of cardiac arrhythmias); medical, surgical, neonatal, and genetic consultation; and management of severe maternal complications.

   (ii) Provider Types - Maternal-fetal medicine specialists and reproductive geneticists with experience, training and demonstrated competence.

   (iii) Responsibilities - Provision of comprehensive perinatal care services for both admitted and transferred women and neonates of all risk categories, including basic and specialty care services as described previously; evaluation of new technologies and therapies; and data collection and retrieval. Neonatal services must continue to receive regional planning.

4. Regional Subspecialty Perinatal Health Care Center - Not all subspecialty perinatal health care hospitals must act as regional centers; however, regional organization of perinatal health care services requires that there be coordination in the development of specialized series, professional continuing education to maintain competency and the collection of data on long-term outcomes to evaluate both the effectiveness of delivery of perinatal health care services and the safety and efficacy of new therapies and technologies.

5. Specific responsibilities include: provision of comprehensive perinatal health care services at and above those of subspecialty care facilities; responsibility for regional
perinatal health care service organization and coordination including: maternal and neonatal transport, outreach support and regional educational programs, research support and initial evaluation of new technologies and therapies, and analysis and evaluation of regional data, including those on perinatal complications and outcomes.

(2) Planning Policies

(a) In order to ensure that appropriate prenatal and neonatal services are available in Alabama:

1. Each of the five (5) designated regional perinatal centers will have a high-risk nursery.

2. The State Perinatal Advisory Committee will continue to advise the State Health Officer in the planning, organization, and evaluation of the Perinatal Program, which will address the coordination of services to improve preconceptional, interconceptional and prenatal health for women at high risk for poor outcomes of pregnancy.

3. The Alabama Perinatal Program will facilitate state, regional and local/community collaboration, interest and action regarding health care needs and services to reduce maternal, and childhood morbidity and mortality.

4. The Alabama Perinatal Program will assess the quality and effectiveness of the health care systems for women and infants through the collection, analysis and reporting of data.

5. The State should strengthen the Alabama Perinatal Program to implement programs that address recommendations issued by the State Perinatal Advisory Council (SPAC) in 2002:

   (i) Public Awareness Campaigns

   (ii) Smoking Cessation Interventions

   (iii) Statewide Fetal Infant Mortality Review Teams

   (iv) Evidence-Based Medicine/Best Practices

   (v) Regionalization of Perinatal Care

   (vi) Care Coordination Services

   (vii) Transportation for Women and Infants
6. The State should continue to implement all sections of the federal Omnibus Budget Reconciliation Act that affect prenatal and neonatal services.

7. The State should improve the accessibility of services for maternity and pediatric patients through expansion and improvement of services to women and children.

Author: Statewide Health Coordinating Council (SHCC)

410-2-3-.03 Cardiac Services.

(1) Fixed-Based Cardiac Catheterization Laboratories

(a) Discussion

1. During the past four decades, an evolution in cardiac catheterization has taken place. The role of the cardiac catheterization laboratory has progressed from study of cardiac function and anatomy for purposes of diagnosis to evaluation of candidates for surgery and finally to providing catheter-based, nonsurgical interventional treatment. This progress has stimulated an increase in demand for cardiac catheterization services.

2. From about 1982 to the present, there has been an unprecedented proliferation of cardiac catheterization services, which have now been expanded to a wider group of patients and diseases. The increase in patients and laboratories has been stimulated by the development of nonsurgical catheterization laboratory-based therapeutic procedures for palliation of both stable and unstable ischemic heart disease as well as selected valvular and congenital heart diseases, arrhythmias, and other problems. Many noncardiac diagnostic and therapeutic vascular procedures are now being performed in cardiac catheterization laboratory settings, but this area is still evolving. As newer cardiac diagnostic and treatment modalities are developed, it is
highly likely that the role of cardiac catheterization will continue to evolve.

3. Fixed-based cardiac catheterization services are the only acceptable method for providing cardiac catheterization services to the people in Alabama.

4. For purposes of this section, a cardiac catheterization “procedure equivalent” is defined as a unit of measure which reflects the relative average length of time one patient spends in one session in a cardiac catheterization laboratory. One procedure equivalent equals 1.5 hours utilization time.

(b) Planning Policies

1. Planning Policy. Diagnostic catheterizations shall be weighed as 1.0 equivalents, while therapeutic/interventional catheterizations (Percutaneous Transluminal Coronary Angioplasty (PTCA), directional coronary atherectomy, rotational coronary atherectomy, intracoronary stent deployment, and intracoronary fibrinolysis, cardiac valvuloplasty, and similarly complex therapeutic procedures) and pediatric catheterizations shall be weighed as 2.0 equivalents. Electrophysiology shall be weighed as 3.0 equivalents for diagnostic and 4.0 equivalents for therapeutic procedures. For multi-purpose rooms, each special procedure which is not a cardiac catheterization procedure, performed in such rooms shall be weighed as one equivalent.

2. Planning Policy - New Institutional Service. New “fixed-based” cardiac catheterization services shall be approved only if the following conditions are met:

   (i) Each facility in the county has performed at least 1,000 equivalent procedures per unit for the most recent year;

   (ii) An applicant for diagnostic/therapeutic cardiac catheterization must project that the proposed service shall perform a minimum of 875 equivalent procedures (60% of capacity) annually within three years of initiation of services;

   (iii) An applicant for diagnostic catheterization only must project that the proposed service shall perform a minimum of 750 procedures per room per year within three years of initiation of services;

   (iv) At least two physicians, licensed in Alabama, with training and experience in cardiac catheterization shall provide coverage at the proposed facility.
3. Planning Policy - Expansion of Existing Service. Expansion of an existing cardiac catheterization service shall only be approved if:

   (i) If an applicant has performed 1,000 equivalent procedures per unit (80% of capacity) for each of the past two years, the facility may apply for expansion of catheterization services regardless of the utilization of other facilities in the county;

   (ii) Adult and pediatric procedures may be separated for those institutions with a dedicated pediatric catheterization lab in operation on the effective date of this section.

4. Planning Policy. Pediatric cardiac catheterization laboratories shall only be located in institutions with comprehensive pediatric services, pediatric cardiac surgery services, and a tertiary pediatric intensive care unit.

5. All cardiac catheterization services without open-heart surgical capability ("OSS") shall have written transfer agreements with an existing open-heart program located within 45 minutes by air or ground ambulance service door to door from the referring facility. Acute care hospitals providing diagnostic cardiac catheterization services may provide emergency interventional/therapeutic cardiac catheterization procedures. Notwithstanding anything in the State Health Plan to the contrary, an acute care hospital without on site open-heart surgery capability may provide elective percutaneous coronary intervention (PCI) if the following criteria are met:

   (i) The hospital shall maintain twenty-four (24) hour, seven (7) day a week continuous coverage by at least one interventional cardiologist and catheterization laboratory team for primary PCI treatment of ST elevation myocardial infarction;

   (ii) The hospital shall participate in a recognized national registry for cardiac catheterizations and PCI procedures, such as the National Cardiovascular Data Registry (NCDR);

   (iii) The hospital shall obtain informed patient consent for all elective PCI procedures, including an informed consent process in which it is clearly stated that the hospital does not offer OSS, and which clearly states that the patient may request at any time to be transferred to a hospital with OSS to undergo the PCI procedure;
(iv) The hospital shall conduct quarterly quality review of the elective PCI services under supervision of its serving interventional cardiologists;

(v) The hospital shall demonstrate that applicable requirements in Planning Policy 2 (ii) of this subsection (Ala. Admin. Code 410-2-3-.03(1)(b)(2)) will be met; and

(vi) Hospitals shall use their best efforts to perform a minimum of 200 PCI cases per year. Any hospital performing less than 150 cases per year after the second full year of PCI operations must agree to an independent quality review of its program by an outside interventional cardiologist who is a member of the American College of Cardiology and to report a summary of such quality review confidentially to the Executive Director of SHPDA.

The CON Review Board shall consider the most recent recommendations/guidelines for cardiac catheterizations adopted by the American College of Cardiology Foundation, the American Heart Association Task Force on Practice Guidelines, and the Society for Cardiovascular Angiography and Interventions as an informational resource in considering any CON application for elective PCI services.

6. Planning Policy. Applicants for new or expanded cardiac catheterization services must demonstrate that sufficient numbers of qualified medical, nursing, and technical personnel will be available to ensure that quality health care will be maintained and without detrimentally affecting staffing patterns at existing programs within the same service area.

(2) Open Heart Surgery

(a) Discussion

1. “Open heart surgery” is a descriptive term for any surgical procedure that involves opening the chest to operate on the heart. But when people talk about “open heart surgery,” they are usually referring to coronary artery bypass surgery, a procedure where the surgeon uses a blood vessel from the patient’s own body to “bypass” a blockage in one of the arteries supplying blood to the heart. (www.dh.org)

2. In the last forty years, open-heart surgery has emerged from operating rooms of medical centers to become a mainstay of advanced medical treatment. In the year 2000, 686,000 open-heart surgeries were performed in the United States; and while the procedure has become commonplace, it still requires
uncommon skill and the most advance technology to insure successful outcome. (www.americanheart.org)

3. Highly specialized open-heart operations require very costly, highly specialized manpower, and facility resources. Thus, every effort should be made to limit duplication and unnecessary expenditures for resources related to the performance of open-heart operations, while maintaining high quality of care.

4. Based on recommendations by various professional organizations and health planning agencies, a minimum of 200 heart operations should be performed annually to maintain quality of patient care and to minimize the unnecessary duplication of health resources. In order to prevent duplication of existing resources which may not be fully utilized, the opening of new open heart surgery units should be contingent upon existing units operating, and continuing to operate, at a level of at least 350 operations per year.

5. In units that provide services to children, lower targets are indicated because of the special needs involved. In case of units that provide services to both adults and children, at least 200 open-heart operations should be performed including 75 for children.

6. In some areas, open-heart surgical teams, including surgeons and specialized technologists, are utilizing more than one institution. For these institutions, the guidelines may be applied to the combined number of open-heart operations performed by the surgical team where an adjustment is justifiable and promotes more cost-effective use of available facilities and support personnel. In such cases, in order to maintain quality care, a minimum of 75 open-heart operations in any institution is advisable.

7. Data collection and quality assessment and control activities should be part of all open-heart surgery programs.

(b) Planning Policies

1. Planning Policy. Applicants for new and expanded adult open-heart surgery facilities shall project a minimum of 200 adult open-heart operations annually, 150 of which shall be coronary artery bypass graphs (CABG), within three years after initiation of service.

2. Planning Policy. Applicants for new and expanded pediatric open-heart surgery facilities shall project a minimum of 100 pediatric open-heart operations annually within three years after initiation of service.
410-2-3-.04 Oncology—Radiation Therapy Services.

(1) Discussion: Radiation therapy, surgery, and medical oncology-chemotherapy combined are often the most effective treatment for cancer. Specific planning for these modes of treatment is necessary to insure proper cost and quality of care for the citizens of Alabama. Surgery is often a “one-time” service and may or may not be offered close to the patient’s home. Radiation therapy and chemotherapy are generally provided on a daily basis for an extended period of time, and so are often more accessible if provided close to a patient’s residence.

(2) Definition: “Radiation Therapy” is a clinical specialty in which ionizing radiation is used for treatment of cancer. The predominant form of radiation therapy involves an external source of radiation whose energy is focused on the diseased area. “Oncology” is the discipline devoted to the delivery of specialized care to those patients afflicted with cancer. The delivery of care to these patients involves the diagnosis of cancer, the staging and determining the distribution
of cancer and the treatment of cancer. Treatments involve coordination of care often with radiation oncologist and surgeons. The primary mode of treatment in these patients is with chemotherapy, hormonal therapy and immunotherapy.

(3) Surgery for cancer is usually provided in a hospital setting and may be done on an outpatient and/or inpatient basis.

(4) Medical oncology/chemotherapy is the introduction of certain chemical agents into a patient’s body to inhibit or prevent the growth of cancerous cells and may be done on an inpatient or outpatient basis.

(5) Planning Policies

(a) Planning Policy: A megavoltage radiation therapy unit (which is a single megavoltage machine or energy source) shall serve a population of at least 150,000 persons and perform 6,000 treatments/patients visits annually within three years after initiation.

(b) Planning Policy: No additional megavoltage units shall receive approval unless each existing megavoltage unit in the county is performing at least 6,000 treatments/patient visits per year.

(c) Planning Policy: When applying the standard of 6,000 treatments per year, the limited specialized use of special purpose and extra high energy machines shall also receive consideration.

(d) Preference for new radiation therapy services shall be given to those applicants who combine/locate co-existent with chemotherapy treatment modalities, as these are most accessible when provided in a single location.

Note: The numerical standards contained in the above Planning Policies were obtained from Radiation Oncology in Integrated Cancer Management Report of the Inter-Society Council for Radiation Oncology, November 1986.

(6) Data on Oncology services is available from the State Health Planning and Development Agency.

Author: Statewide Health Coordinating Council (SHCC)


410-2-3-.05 End Stage Renal Disease Services.

(1) Discussion. Prior to the 1972 enactment of Section 299 i of Public Law 92-603, End Stage Renal Disease services were provided almost exclusively for the general population in the Jefferson County area. Financing was derived from a number of sources, some with unpredictable reliability. Since the advent of Section 299 i, and its stable source of establishment, the supply of End Stage Renal Disease services in the state has dramatically increased. The supply of these services now dictates that a specific need determination is needed to guide the future development of these units.

(a) Those who suffer with End Stage Renal Disease have inadequate function to support life. Individuals with end-stage disease must rely in kidney dialysis or peritoneal dialysis to survive. End Stage Renal Disease may be caused by a number of problems including diabetes, sickle cell disease, hypertension and congenital renal disease (polycystic kidney disease).

(b) In 1991 the Legislature declared that it was in the best interest of the state and its residents for kidney disease treatment centers to be established and operated throughout the state so that any patient needing such treatment would be able to utilize a hemodialysis unit located within a reasonable distance of their home. §22-21-278 Code of Ala. 1975 allows kidney disease treatment centers with ten stations or less to operate in 61 of 67 counties without Certificate of Need approval. Centers in Jefferson, Limestone, Madison, Mobile, Montgomery and Shelby counties are required to receive certificate of need approval for any dialysis stations.

(c) In order to further expand access to End Stage Renal Disease treatment in rural areas, any existing kidney disease treatment center located in a county that does not contain all or any part of a Class 1, 2, or 3 municipality (as such classes are defined in sections 11-40-12 and 11-40-13, Code of Ala. 1975) shall qualify for this exception to the need methodology set forth in 410-2-3-.05(2) to add up to six (6) stations if the existing kidney disease treatment center can demonstrate an average weekly utilization at or above the Optimal Utilization of eighty percent (80%) of Present Capacity (as such terms are defined in 410-2-3-.05(2)) for a period of ten (10) consecutive weeks within the six (6) months immediately preceding...
the filing of a Letter of Intent for the additional stations. Such additional stations shall be considered an exception to the need methodology set forth within 410-2-3-.05(2) and shall be considered regardless of the utilization of any other kidney disease treatment centers in the county. However, any present in-center stations developed pursuant to a CON granted under this provision will thereafter be included in future need methodology calculations in accordance with 410-2-3-.05(2).

1. In addition to such additional information that may be required by SHPDA, a kidney disease treatment center seeking a CON under this provision must provide the following information:

   (i) Demonstration of compliance with the utilization rate in paragraph (1)(c);

   (ii) The existing kidney disease treatment center has not been granted a CON for an increase of stations under this section within the preceding twelve (12) month period, which twelve (12) month time period begins to run upon the issuance of a license by the Alabama Department of Public Health for the additional stations in accordance with paragraph (1)(c); and

   (iii) The kidney disease treatment center must have been licensed for at least one (1) year as an End Stage Renal Disease treatment center.

(d) On June 11, 2003, the Alabama Legislature passed legislation that the Alabama Department of Public Safety provide to the Alabama Organ Center (AOC) the names of all individuals who have indicated their intent to become organ donors on their license. Approximately 1,114,000 names will be added to the Legacy Organ and Tissue Donor Registry. When a potential organ donor is referred to the AOC, that information will be checked against the registry to see if the patient is listed. The information will be presented to the patient’s next of kin.

(e) Other states with registries have noted increases in donation. This is the goal for Alabama.

(2) Planning Policies

(a) The determination of need for additional hemodialysis stations will be based on the utilization of present in-center hemodialysis stations (capacity at the time of application as utilized by census at the time of application) and any anticipated increases of census.
1. In calculating the present capacity, “Isolation Stations” (stations reserved for Hepatitis-B positive patients) and stations used for home hemodialysis training will be removed from the total number of stations at the facility. No further reduction of station count will be made for down-time, transients, or back-up of home patients, since provision is made for these in the Optimal Utilization Criterion.

2. Present Capacity is defined as two shifts per day, six days per week, based on the fact that most patients require three dialysis treatments per week. Third shift (“evening dialysis”) will not be considered in calculating capacity since patient demand for this shift is erratic and unpredictable.

3. Optimal Utilization is defined as 80% of present capacity, thus making provision for cost-effective use of services and orderly growth, as well as reserving some capacity for down-time, transients, and back up of home patients. Optimal capacity is, therefore, 9.6 dialysis treatments per station per week (.80 x 12 dialysis treatments/station/week = 9.6 dialysis treatments/station/week).

4. Maximum Optimal Capacity is defined as the number of patients that can receive treatment under optimal capacity on a three dialysis treatment per week schedule.

EXAMPLE:

<table>
<thead>
<tr>
<th>Total Stations</th>
<th>20</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dialysis Treatments/Station/Week</td>
<td>X</td>
</tr>
<tr>
<td>Capacity</td>
<td>240 Available Dialysis Treatments/Week</td>
</tr>
</tbody>
</table>

Optimal Utilization

<table>
<thead>
<tr>
<th>X</th>
<th>.80</th>
</tr>
</thead>
</table>

Optimal Capacity

| 192 Available Dialysis Treatments/Week |

Patient Usage

| 3 Dialysis Treatments/Week |
|÷| 64 Patients |

Maximum Optimal Census

Projection of census will be submitted in a yearly fashion for the three years subsequent to the date of application. Note that much of the first year will be consumed by the application process (both state and federal), construction or renovation and licensure process. Calculations of anticipated census are to be based on:

1. Present In-Center Hepatitis-Negative Hemodialysis Patients.
(i) Other patients treated by the facility in the home settings[(Home Hemodialysis, Continuous Ambulatory Peritoneal Dialysis (CAPD), Continuous Cyclic Peritoneal Dialysis (CCPD)], will be excluded; Hepatitis-B positive patients will be excluded unless the application specifically addresses the need for Hepatitis-B positive stations;

(ii) Note that if more than one End Stage Renal Disease facility exists within the defined service area, all present dialysis stations and present patients in all End Stage Renal Disease facilities must be considered in developing a demonstration of need.

2. New End Stage Renal Disease patients projections shall be based on:

(i) The total population of the county in which the stations are to be located plus any contiguous county that does not have a dialysis center.

(ii) Incidence Rate: The definition of incidence rate is the rate at which new events occur in a population. The formula to determine incidence rate is as follows: The numerator is the number of new events occurring in a defined period; the denominator is the population at risk of experiencing the event during this period. Applicant will use the 2010 state average of 421/million/year or the sum of 749/million non-white population/year plus 270/million white population/year within the service area. In 2010 there were 2041 new patients.

(iii) Note that if more than one End Stage Renal Disease facility exists within the service area, the historical distribution of patients between the facilities will be used in determining the number of new patients who will seek services at the applying facility.

(iv) Loss Rate:

(I) Death: 16.2% of the sum of the in-center census at the start of each new year plus new patients during the year.

(II) Transplantation: 2.8% of the sum of the in-center census at the start of each new year plus new patients.

(III) Home Training: 8.0% of new patients.

I. Incidence Rate: statewide average of 2010 421/million/year, or 749/million non-white population/year plus 270/million white population/year.
II. Loss Rate:

Death: 16.2% of initial census plus new patients.
Transplant: 2.8% of initial census plus new patients.
Home Training: 8.0% of new patients.
EXAMPLE:
In-Center Census Start of Year: 100 Patients
New Patients During Year: 50/150 Patients
Less: 16.2% Death 24
Less: 2.8% Transplant 4
Less: 8.0% Home Training 412
In-Center Census, Year End 110

Note: Figures for incidence rates and loss rates were obtained from the 2010 Network 8, Inc. Annual Report http://www.esrdnetwork8.org.

3. A kidney transplant is a surgical procedure by which a healthy kidney is removed from one person and implanted in the ESRD patient. Transplantation is, ideally, a one-time procedure: if the donated kidney functions properly, the patient can live a relatively normal life. There is only one transplant center operating in Alabama. The University of Alabama Hospital located in Birmingham is one of the largest kidney transplant centers in the country with 266 transplants in 2010. The number of patients waiting for transplants is 474.

4. A free-standing licensed pediatric facility shall have the ability to make application directly to the Certificate of Need Review Board for the purpose of adding dialysis stations serving pediatric patients, provided it can clearly demonstrate that the need cannot be met by existing ESRD facilities.

Author: Statewide Health Coordinating Council (SHCC)

410-2-3-.06 Magnetic Resonance Imaging (MRI). This section repealed per Act Num.: 2003-331
Bill Num.: H-322
16 - JUN - 03.

Author: Statewide Health Coordinating Council (SHCC)

410-2-3-.07 Extracorporeal Lithotresis. This section repealed per Act Num.: 2003-331
Bill Num.: H-322
16 - JUN - 03.

Author: Statewide Health Coordinating Council (SHCC)

410-2-3-.08 New Technology.

(1) Definition

(a) New technology is emerging equipment (1) intended for use in the diagnosis and/or treatment of medical conditions; (2) for which adequate data is not yet available to fully develop State Health Plan criteria and standards on a technology-specific basis; and (3) whose cost exceeds the thresholds established in §22-21-263, Code of Ala. 1975. New technologies often involve costly capital expenditures and significant increases in operational costs. Therefore, adequate standards and criteria shall be established to determine need, efficiency and appropriateness as required by §22-21-266, Code of Ala. 1975.

(b) Emerging equipment shall be considered new technology prior to and for eighteen (18) months following its approval by the Food and Drug Administration (FDA). After 18 months, equipment initially classified as new technology shall be treated as any other major medical equipment ($22-21-263, Code of
(c) New technology provisions do not apply to the acquisition of equipment to be used solely for research.

(2) Process

(a) Prior to approval of a new technology by the FDA, applications for certificate of need for the subject technology shall not be approved by the CON Review Board unless technology-specific criteria have been adopted by the Statewide Health Coordinating Council (SHCC) and approved by the Governor for inclusion in the State Health Plan.

(b) To facilitate this process (and thereby avoid unwarranted delays in equipment acquisition), providers considering acquisition of new technology shall notify the State Health Planning and Development Agency in writing of their interest at the earliest possible date. Within ten (10) days of such notification, the Chairman of the SHCC shall appoint the leader of a technology-specific task force to complete development of criteria and standards for review of the identified new technology within 60 days. At a minimum, such standards shall incorporate the Planning Policy requirements section.

(c) The earliest point at which CON approval for new technology shall be granted is the point at which technology-specific criteria and standards have been adopted. However, should such criteria and standards not be in place before FDA approval is granted, then beginning with FDA approval and extending for eighteen (18) months, or until technology-specific criteria and standards are adopted and approved by the Governor, whichever comes first, the requested new technology shall be reviewable using the Planning Policy criteria incorporated as a portion of this section. Under these circumstances, a CON may be granted if the project meets the threshold requirements and discretionary provisions stated in the Planning Policy and is consistent with other pertinent statutory, regulatory, and State Health Plan provisions for determining need, efficiency, and appropriateness of proposed equipment acquisitions.

(d) Following adoption of a technology-specific section of the State Health Plan, the Statewide Health Coordinating Council shall review the new section eighteen (18) months after approval of the specific technology by the FDA. The
basis for such review may include utilization, financial, and demographic data obtained from clinical use of the equipment in Alabama, nationally, and internationally. SHCC’s 18-month review may result in (1) continuation of the State Health Plan standards, (2) removal of the technology-specific section from the State Health Plan, or (3) modification of the standards for continued inclusion in the State Health Plan.

(3) Planning Policy. In addition to all other statutory, regulatory, and State Health Plan requirements, all applicants for new technology shall meet the following:

(a) Threshold Requirements

1. Applicants for new technology shall demonstrate that they will have the ability to employ staff who are adequately trained and qualified. Demonstration of operators’ competence may include appropriate residency training, formal continuing medical education courses, and on-the-job training. The applicant must also demonstrate the ability to employ adequate numbers of trained technical staff and support personnel to work in conjunction with the operators.

2. Applicants requesting new technology shall demonstrate that the new technology is needed by the population of a defined geographic area. Estimates of need shall be based upon the number of patients who will use the service, classified by diagnosis and by county of residence. Institution-based data alone shall not be sufficient to meet this requirement. The effect the new technology may have on utilization of existing technology or procedure shall be considered.

3. Before acquiring new technology, the applicant shall have complementary services available for support and evaluation purposes and must show the capability for providing adequate quality assurance.

4. Applicants shall guarantee uninsured (those not covered by Medicare, Medicaid, Blue Cross/Blue Shield or commercial insurance coverage) patients equal access to the new technology.

5. A new technology must be offered in the most cost effective manner at reasonable charges (professional and facility), especially where only one or a few applicants will have an opportunity to acquire the new technology early in its development.

6. Applicants requesting the new technology must agree to report basic utilization, insurance, financial, and
demographic data (including patient origin data by diagnosis and patient insurance status) in the frequency and format prescribed by the SHPDA to permit an evaluation of the technology, to facilitate regional and statewide planning for diffusion, and to monitor compliance with the provisions above.

(b) Discretionary Provisions

1. All potential patients shall have access to new technology. To the extent that is medically-indicated, a new technology shall be available 24 hours a day, seven days a week on an emergency (on-call) basis.

2. Provision shall be made for participation in research, resident training, and continuing medical education for physicians, nurses, and technicians, as appropriate.

3. Whenever possible, the applicant shall acquire new equipment in conjunction with other providers. If such sharing in acquisition is not possible, the applicant shall demonstrate efforts to establish a multi-provider referral system.

Author: Statewide Health Coordinating Council (SHCC)


410-2-3-.09 Transplantation Services.

(1) Definition. Transplantation is the process in which an organ or tissue from one person is surgically implanted into another person to replace diseased, damaged, or defective organs or tissue. For purposes of this section transplantation services include kidney, heart, lung, liver, bone marrow, and pancreas transplants.

(2) General. Transplantation is a costly, specialized service due in part to the resources required to operate such a service. Resources include donated organs or tissue, medical transplant specialists, and other technical expertise. The availability of these resources are limited and as such transplant services shall be limited to ensure the quality, availability, and cost effectiveness of such services. Studies have indicated that transplant centers and surgical teams with
more experience generally have fewer complications and higher survival rates.

(3) Statistics. According to The Organ Procurement & Transplantation Network (optn.org):

(a) As of July 2003, more than 83,000 people were on the national waiting list for organ transplant.

(b) In 2001 there were:

(i) 12,528 deceased and living organ donors

(ii) 24,076 life saving organ transplants

(iii) 84,798 registrations on the waiting list at the end of the year

(iv) 6,439 people who died while waiting

(4) Planning Policies.

(a) Applicants proposing to initiate a transplant service shall demonstrate that all existing similar transplant services within the state are operating at 80 percent of capacity or that those programs are unwilling to accept additional transplant patients.

(b) Applicants for transplant service shall demonstrate that qualified medical and technical personnel, licensed in Alabama, are available and that existing transplant services within the state will not be detrimentally affected.

(c) Applicants for a transplant service shall provide documentation of approved participation in an organ donor network.

(d) Facilities with existing transplant services shall be given priority consideration over the development of new transplant facilities.

Author: Statewide Health Coordinating Council (SHCC)


410-2-3-.10  **In Home Hospice Services.**

(1) Discussion

(a) Hospice care is a choice made to enhance end of life. Hospice focuses on caring and comfort for patients and not curative care. In most cases, care is provided in the patient’s place of residence. It is the intent of this section to address health planning concerns relating to hospice services provided in the patient’s place of residence. For coverage of hospice services provided on an inpatient basis, please see Section 410-2-4-.15.

(2) Definitions

(a) Hospice Program. A “Hospice Program” is defined as a public agency, private organization, or subsidiary of either of these that is primarily engaged in providing Hospice Care to the terminally ill individual and families and is separately licensed by the State of Alabama and certified by Centers for Medicare/Medicaid Services (CMS) for the provision of all required levels of Hospice Care.

(b) Hospice. “Hospice” is a coordinated program providing a continuum of home and inpatient care for the terminally ill patient and family and/or significant other. It employs an interdisciplinary team acting under the direction of an identifiable hospice administration. The program provides palliative and supportive care to meet the special needs arising out of the physical, emotional, spiritual, social and economic stresses which are experienced during the final stages of illness and bereavement. The care is available twenty-four hours a day, seven days a week.

(3) Availability and Accessibility

(a) Hospice services must be obtainable by all of the residents of the State of Alabama. The care must be available to all terminally ill persons and their families without regard to age, gender, national origin, disability, diagnosis, cost of care, ability to pay or life circumstances.

(b) Physicians and other referral sources may be unfamiliar with the total scope of services offered by hospice; accessibility may be limited due to a lack of awareness. Every provider should provide an active community informational program to educate consumers and professionals to the availability, nature, and extent of their hospice services provided.

(4) Inventory
(a) As of this date, hospice services are believed to be available in all 67 counties. Hospice programs are licensed by the Alabama Department of Public Health.

(5) Quality

(a) Quality is that characteristic which reflects professionally and technically appropriate patient services. Each provider must establish mechanisms for quality assurance including procedures for resolving concerns identified by patients, physicians, family members, or others in patient care or referral. Providers should also develop internal quality assurance and grievance procedures.

(b) Providers are encouraged to achieve a utilization level, which promotes cost effective service delivery.

(c) Hospice programs are required to meet or exceed the current Medicare Hospice Conditions of Participation, as adopted by CMS, and codified in the Code of Federal Regulations, along with State Licensure Regulations of the Department of Public Health. Licensed programs are required to meet the data collection requirements addressed in section 6 (f) (1) of this document.

(6) In Home Hospice Services Need Methodology

(a) Purpose. The purpose of this in home hospice services need methodology is to identify, by county, the number of hospice providers needed to assure the continued availability, accessibility, and affordability of quality care for residents of Alabama. A corporate entity must obtain a CON for each office, branch or parent. However, relocation, within the same county of an already established office that has previously obtained a CON and is not expanding services, does not require applying for a new CON.

(b) General. Formulation of this methodology was accomplished by a committee of the Statewide Health Coordinating Council (SHCC). The committee, which provided its recommendations to the SHCC, was composed of providers and consumers of health care, and received input from the hospice providers and other affected parties. Only the SHCC, with the Governor’s final approval, can make changes to this methodology, except that SHPDA staff shall annually update statistical information to reflect more current population and utilization. Such updated information is available for a fee upon request. Adjustments are addressed in paragraph (e) below.
(c) Basic Methodology.

1. The SHCC approved the following methodology with the understanding that additional data is required in order to conduct a thorough investigation of both the appropriateness and accuracy of any need projections derived from it. To properly analyze the methodology, no determination of need will be made by SHPDA until December 31, 2014. SHPDA staff will utilize this time to analyze the methodology using data obtained through all Alabama Hospice Providers who are required, through this section, to collect and provide data as required by SHPDA on an annual basis. SHPDA will present to the SHCC a preliminary finding of projected need based on the aforementioned methodology prior to the end of the aforementioned 3 year period, to allow the SHCC to assess the results and determine if the methodology should be further revised through an amendment to the SHP.

2. Need Assessment for Hospice Services

3. The need for additional Hospice Services shall be calculated as follows:

\[
HPR = \frac{\text{Hospice Deaths by County}}{\text{Total Deaths by County}}
\]

Whereas:
\[
HPR = \text{The Hospice Penetration Rate}
\]

Hospice Deaths by County is defined as the total deaths of those served in hospice care for the specific county. Data shall be obtained through all licensed Alabama Hospice providers who are required, through this document, to collect and provide data to SHPDA annually.

Total Deaths by County is defined as the total deaths from all causes in the specific county. Data shall be obtained from the Alabama Department of Public Health Center for Health Statistics.

This formula is recommended by the National Hospice and Palliative Care Organization which utilizes this formula to report national hospice penetration rates. In completing the formula to establish need, SHPDA will match the year of hospice deaths with the most recent year of total deaths as provided by the Alabama Department of Public Health Center for Health Statistics.

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1 Obtained through all Alabama Hospice providers who are required, through this section, to collect and provide data to SHPDA on an annual basis.
4. Review Criteria - An application to establish or expand hospice services in a county shall be consistent with this Plan if:

(i) The Hospice penetration rate in the proposed county is less than forty (40) percent.

(ii) Each approved hospice agency in the proposed county has been operational for at least thirty six (36) months; and

(iii) Only one (1) application may be approved in each county during any approval cycle as defined by the Statewide Health Coordinating Council, or as implemented by SHPDA;

(d) Planning Policies

1. SHPDA staff shall collect data from all licensed hospice providers on an annual basis, on a survey instrument to be developed by SHPDA Staff with input from the Alabama Hospice and Palliative Care Organization. The survey instrument shall be designed to collect all data necessary to support the In Home Services Need Methodology discussed above and in order to maintain their CON and their good standing with SHPDA, licensed hospice providers shall respond as directed.

2. Hospice need projections will be based on a three-year planning horizon.

3. Planning will be on a countywide basis.

(e) Adjustments. The need for hospice providers, as determined by the methodology, is subject to adjustments by the SHCC. SHCC may adjust the need for hospice services in an individual county or counties if an applicant documents the existence of at least one of the following conditions:

1. Absence of services by a hospice certified for Medicaid and Medicare in the proposed county, and evidence that the applicant will provide Medicaid and Medicare-certified hospice service in the county; or

2. Absence of services by a hospice in the proposed county that serves patients regardless of the patient’s ability to pay, and evidence that the applicant will provide services for patients regardless of ability to pay.

(f) There were numerous in-home hospice service providers providing services under Alabama Department of Public
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Health ("ADPH") licensure as of the May 13, 2009 effective date of Alabama Act 2009-492 (the "Act"), which amended Code of Ala. 1975, §22-21-260(6) (1975 as amended) to include "hospice service providers" within the definition of a health care facility. The Act also amended Code of Ala. 1975, §22-4-2(7) (1975 as amended) to include "hospice services" within the definition of a "health care facility" and amended Code of Ala. 1975, §22-21-29 (1975 as amended) by eliminating the provision that had placed a moratorium on ADPH’s licensing of hospices, except for those applicants that had obtained a letter of non-reviewability from SHDPA by July 7, 2006 and filed an application for licensure as a hospice with ADPH within twelve (12) months thereafter. On August 17, 2009 the Alabama Attorney General issued an Opinion that while existing providers are required to obtain a Certificate of Need ("CON") to Continue operations, SHPDA may adopt an emergency rule allowing such providers to continue to operate within an expedited timeframe that allows consideration of their CON applications upon a finding of an immediate danger to the public health, safety or welfare.

2. On August 31, 2009 Governor Riley approved Rule 410-2-3-.10ER, which had been passed by the Statewide Health Coordinating Council ("SHCC"). Pursuant to this emergency rule, in-home hospice service providers in existence as of the effective date of Alabama Act 2009-492 were allowed to obtain CONs under a non-substantive review procedure, thus preventing any unnecessary disruption of services in authorized counties. The rule also provided for the collection of data needed for the development of a long-term need methodology. Need was presumed for any provider that demonstrated that it was providing service under ADPH license in a particular county as of May 13, 2009 or during the preceding twelve months.

3. Each entity that (1) was licensed by the Department of Public Health to provide in-home hospice services in a county, based upon a non-reviewability determination letter issued to the entity by the Alabama State Health Planning and Development Agency under Code of Ala. 1975, §22-21-29(d) (1975 as amended) listing said county, but did not provide service by May 13, 2009 or during the preceding twelve months; or (2) that established itself with the Alabama State Health Planning and Development Agency by obtaining a non-reviewability determination letter by July 7, 2006 under the former provisions of Code of Ala. 1975, §22-21-29(d) (1975 as amended), and timely filed its application for licensure as a hospice provider with the Alabama Department of Public Health in particular counties ("the contemplated service area") within twelve (12) months thereafter and is not deemed to have abandoned its licensure application, shall be entitled to file for a Certificate of Need for the contemplated service area under the non-substantive review
process, with need presumed, using such application forms as may be required by SHPDA. Hospice providers obtaining a CON pursuant to this Section (3) shall file a single application and be granted a single CON encompassing all of the qualifying counties. For purposes of this Section only, an entity shall be considered a separate hospice provider for each Medicare Provider Number held at the time of application (e.g., if an entity has multiple hospice provider numbers, a separate application must be filed, and CON issued, for each); provided, however, that a corporate entity having multiple provider numbers shall not receive more than one CON per county. Such CON authority may not be subsequently divided, e.g., a hospice provider may not separate such authority into separate CONs for future disposition. All applications submitted pursuant to the non-substantive review provisions of 410-2-3-.10(2)(b) and (c) shall include an acknowledgement of this restriction. Any CON authority granted pursuant to this section shall be combined, under a single CON, with any other CON authority obtained under the same provider number under Certificate of Need Review Board emergency rule 410-1-5C-.01ER.

4. Following adoption by SHCC of the Hospice Services Need Methodology, all hospice providers which did not receive a CON pursuant to the non-substantive review process are required to undergo full Certificate of Need review.

5. Any hospice services provider which obtains a CON, either pursuant to the non-substantive review process or after full Certificate of Need Review, that subsequently fails to substantially comply on a timely basis (subject to any authorized extensions) to an annual data request from the SHPDA staff adopted in conjunction with long-term need methodology shall be assumed to have ceased operations as of the end of such period until such time as the provider complies full with all outstanding SHPDA data request. Any provider that is deemed to have ceased operating under this chapter shall be prohibited from submitting any CON application for additional authority or from seeking consideration by SHDPA of such facility's utilization data to oppose another provider’s CON application. In accordance with Rule 410-1-11-.08(2), should such cessation of operation continue for an uninterrupted period of twelve months or longer, the provider’s CON shall be deemed abandoned. SHPDA shall file a report with the Alabama Department of Public Health of any provider who is deemed to have abandoned its CON under this section.

Author: Statewide Health Coordinating Council (SHCC)
History: New Rule: Filed October 18, 2004; effective November 22, 2004. Amended: Filed February 1, 2010; effective
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Health Planning


410-2-3-.11 *Air Ambulance.*

(1) Definition:

(a) Fixed wing (FW) air ambulance is the transportation by a fixed wing aircraft that is certified by the Federal Aviation Administration (FAA) as a fixed wing air ambulance and the provision of medically necessary services and supplies.

(b) Rotary Wing (RW) air ambulance is the transportation by a helicopter that is certified by the FAA as a rotary wing ambulance, including the provision of medically necessary supplies and services.

(2) Planning Policy:

(a) An applicant applying for an air ambulance service must identify a specific service area and any/all existing providers of air ambulance services in the proposed service area.

(b) The applicant must provide documentation of the aircraft selection and the reason/s for the selection of that type of aircraft.

(c) A copy of the Federal Aviation Administration (FAA) Air Charter Certificate and documentation of the approved operations’ specifications for air ambulance operations for the proposed aircraft must be provided.

(d) The applicant must project the number of estimated transports within the proposed service area and the estimated population and hospital facilities that will be served. Patient transport configurations must also be included.

(e) The applicant must give a description of the proposed base or operations center and the ability to provide air ambulance services on a 24 hour per day, seven-day per week basis, identifying the means to access and communicate with the air ambulance personnel on duty.
(f) The impact of the proposed service on existing services, and the basis for analysis should be assessed and considered. The applicant must provide a statement about the impact the proposed service is expected to have on any air ambulance service within 75 miles.

**Author:** Statewide Health Coordinating Council (SHCC)

**Statutory Authority:** Code of Ala. 1975, §22-21-260(4).