

**CERTIFICATION OF ADMINISTRATIVE RULES
FILED WITH THE LEGISLATIVE SERVICES AGENCY
OTHNI LATHRAM, DIRECTOR**

(Pursuant to Code of Alabama 1975, §41-22-6, as amended).

I certify that the attached is/are correct copy/copies of rule/s as promulgated and adopted on Thursday, April 11, 2024, and filed with the agency secretary on Friday, April 12, 2024.

AGENCY NAME: State Health Planning and Development Agency Alabama
State Health Plan 2020-2023

INTENDED ACTION: Repeal and Replace

RULE NO.: Chapter 410-2-3
(If amended rule, give specific paragraph, subparagraphs, etc., being amended)

RULE TITLE: Specialty Services

ACTION TAKEN: State whether the rule was adopted with or without changes from the proposal due to written or oral comments:

Adopted without changes. No public comments were received. No changes to the rule originally published in the Alabama Administrative Monthly were made. The rule was adopted, was supported by all those who participated in the rule-making proceeding.

NOTICE OF INTENDED ACTION PUBLISHED IN VOLUME XLII, ISSUE NO. 5, AAM,
DATED THURSDAY, FEBRUARY 29, 2024.

STATUTORY RULEMAKING AUTHORITY: Code of Alabama, 1975 22-21-260(4)

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APR 19, 2024
LEGISLATIVE SVC AGENCY

Emily T Marsal

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Certifying Officer or his or her
Deputy

(NOTE: In accordance with §41-22-6(b), as amended, a proposed rule is required to be certified within 90 days after completion of the notice.)

STATE HEALTH PLANNING AND DEVELOPMENT AGENCY ALABAMA

2024-2027 STATE HEALTH PLAN
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)

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

History: Effective May 18, 1993. **Amended:** Filed June 19, 1996; effective July 25, 1996. **Repealed and New Rule:** Filed October 18, 2004; effective November 22, 2004. **Amended (SHP Year Only):** Filed December 2, 2014; effective January 6, 2015. **Repealed and New Rule:** Published March 31, 2020; effective May 15, 2020.

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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) In an effort to see that babies are delivered at the most appropriate hospital depending on the level of care needed, the Alabama Department of Public Health (ADPH) convened a multidisciplinary stakeholder group to review the most recent perinatal guidelines published by the American Academy of Pediatrics (AAP) and provided recommendations. The group developed the Alabama Perinatal Regionalization System Guidelines to help clarify the expectations of hospitals and their staff for each level of care, and these Guidelines were approved by both the State Perinatal Advisory Committee and the State Committee of Public Health. Each year, hospitals will use the Alabama Perinatal Regionalization System Guidelines, along with the accompanying verbiage from the AAP-Levels of Neonatal Care, to self-declare the level of neonatal services provided (by completion of the State Health Planning and Development Agency (SHPDA) Hospital Annual Report.

(http://www.alabamapublichealth.gov/perinatal/assets/perinatal_regionalization_system_guidelines.pdf).

(c) Neonatal service providers are designated as Well Newborn Nursery (Level I); Special Care Nursery (Level II); NICU (Level III); or Regional NICU (Level IV) depending on their capabilities and expertise.

1. A Well Newborn Nursery (Level I) should have the following capabilities and provider types:

a. Capabilities. Evaluate and provide postnatal care to stable term newborn infants; stabilize and provide care for infants born 35 - 37 weeks gestation that remain physiologically stable; stabilize newborn infants who are ill and those born at less than 35 weeks gestation until transfer to a higher level of care; and have staff trained in neonatal resuscitation in house for deliveries.

b. Provider Types. Pediatricians, family physicians, nurse practitioners, and other advanced practice registered nurses (with relevant experience, training, and demonstrated competence in perinatal care).

c. 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. Special Care Nursery (Level II) providers should have:

a. Capabilities. Level I capabilities plus: provide care for infants born greater than or equal to 32 weeks gestation and weighing greater than or equal to 1,500 grams who have physiologic immaturity or who are moderately ill with problems that are expected to resolve rapidly and are not anticipated to need subspecialty services on an urgent basis; provide care for infants convalescing after intensive care; provide mechanical ventilation for

brief duration (less than 24 hours) or continuous positive airway pressure or both; and stabilize infants born before 32 weeks gestation and weighing less than 1,500 grams until transfer to a neonatal intensive care facility.

b. Provider Types. Level I health care providers plus: pediatric hospitalists, neonatologists, and neonatal nurse practitioners.

c. Responsibilities. Provision of some enhanced services as well as basic care services as described in 1(c); 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:

a. Capabilities. Level II capabilities plus: provide sustained life support; provide comprehensive care for infants born less than 32 weeks gestation and weighing less than 1,500 grams and infants born at all gestational ages and birth weights with critical illness; provide prompt and readily available access to a full range of pediatric medical subspecialists, pediatric surgical specialists, pediatric anesthesiologists, and pediatric ophthalmologists at the site or by prearranged consultative agreement; provide a full range of respiratory support that may include conventional and/or high-frequency ventilation and inhaled nitric oxide; and perform advanced imaging, with interpretation on an urgent basis, including computed tomography, MRI, and echocardiography.

- b. Provider Types. Pediatric medical subspecialists, pediatric anesthesiologists, pediatric surgeons, and pediatric ophthalmologists at the site or a closely related institution by prearranged agreement.
 - c. 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 NICU (Level IV) providers should have:
- a. Capabilities. Level III capabilities plus: located within an institution with the capability to provide surgical repair of complex congenital or acquired conditions (e.g. congenital cardiac malformations that require cardiopulmonary bypass with or without extracorporeal membrane oxygenation); maintain a full range of pediatric medical subspecialists, pediatric surgical subspecialists, and pediatric anesthesiologist consultants continuously available 24 hours a day; facilitate transport, and provide outreach education.
 - b. Provider Types. Level III health care providers plus pediatric surgical subspecialists.
 - c. Responsibilities. Provision of comprehensive perinatal health care services at and above those of NICU (Level III) 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) ADPH 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 pre-conceptional, inter-conceptional 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 continue to strengthen the Alabama Perinatal Program to implement programs that address recommendations issued by the State Perinatal Advisory Council (SPAC) in 2002:

- a. Public Awareness Campaigns
- b. Smoking Cessation Interventions
- c. Statewide Fetal Infant Mortality Review Teams
- d. Evidence-Based Medicine/Best Practices
- e. Regionalization of Perinatal Care
- f. Care Coordination Services
- g. Transportation for Women and Infants
- h. Comprehensive Care for Women of Childbearing Age
- i. UAB MCH Program Endowed Chair

6. The State should implement the strategies introduced by the Alabama Perinatal Program in

the Alabama Perinatal Health Act Annual Progress Report for FY2018 Plan for FY 2019:

- a. Expand evidence-based home visitation services.
 - b. Increase utilization of the Screening, Brief Intervention and Referral to Treatment (SIBRT) tool to identify and refer women at risk for alcohol, substance abuse, domestic violence, and post-partum depression for treatment and services.
 - c. Promote safe sleep awareness through education and collaboration.
 - d. Expand the Well-Woman Program so that women of child-bearing age receive pre-conception and inter-conception health as a means to address chronic health conditions before and between pregnancies.
 - e. Provide education to women and families on the benefits of breastfeeding for both mom and baby.
 - f. Promote and improve the system of perinatal regionalization which is designed to ensure women have access to hospitals equipped to provide the most appropriate level of care for their pregnancy needs.
 - g. Educate healthcare providers and women who have experienced a spontaneous preterm birth about benefits, processes, and access to 17P (Hydroxyprogesterone Caproate), a hormone treatment prescribed to reduce the risk of a subsequent spontaneous preterm birth.
7. The State should continue to implement all sections of the federal Omnibus Budget Reconciliation Act that affect prenatal and neonatal services.
 8. The State should improve the accessibility of services for maternity and pediatric patients through expansion and improvement of services to women and children.

The State should work to improve the percentage of overall participation in newborn screenings.

Author: Statewide Health Coordinating Council (SHCC)

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

History: Effective March 8, 1996. **Amended:** Filed June 19, 1996; effective July 25, 1996. **Repealed and New Rule:** Filed October 18, 2004; effective November 22, 2004. **Amended (SHP Year Only):** Filed December 2, 2014; effective January 6, 2015.

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410-2-3-.03

(1)

Cardiac Services.

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. Certain cardiac

catheterization procedures are now offered in physicians' offices outside of the usual hospital environment.

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 performed in such rooms which is not a cardiac catheterization procedure 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:

- a. Each facility in the county has performed at least 1,000 equivalent procedures per unit for the most recent year;
- b. 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;

c. 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; and

d. 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:

a. 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;

b. Adult and pediatric procedures may be separated for those institutions with a dedicated pediatric catheterization lab in operation.

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. Planning Policy

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:

- a. 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;
- b. The hospital shall participate in a recognized national registry for cardiac catheterizations and PCI procedures, such as the National Cardiovascular Data Registry (NCDR);
- c. 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;
- d. The hospital shall conduct quarterly quality review of the elective PCI services under supervision of its serving interventional cardiologists;
- e. The hospital shall demonstrate that applicable requirements in Planning Policy 2 (b) of this subsection (Ala. Admin. Code 410-2-3-.03(1)(b)(2)) will be met; and

- f. 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 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.

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 2005, 699,000 open-heart surgeries were performed in the United States; and while the procedure has become commonplace, it still requires uncommon skill and the most advanced technology to insure successful outcomes. (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 grafts (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.

3. Planning Policy

There shall be no additional adult open heart units initiated unless each existing unit in the county is operating and is expected to continue to operate at a minimum of 350 adult operations per year; provided, that to insure availability and accessibility, one adult open heart unit shall be deemed needed in each county not having an open heart surgery unit in which the current population estimate exceeds 150,000 without consideration of other facilities (as published by the Center for Business and Economic Research, University of Alabama).

4. Planning Policy

There shall be no additional pediatric open-heart units initiated unless each existing unit in the service area is operating and is expected to continue to operate at a minimum of 130 pediatric open-heart operations per year.

Author: Statewide Health Coordinating Council (SHCC)

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

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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 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 oncologists and surgeons. The primary modes of treatment for these patients are 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/patient visits annually within three (3) years of 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 (i.e. radiosurgery, stereotactic body radiation therapy, proton therapy) and extra high energy machines shall also receive consideration. Furthermore, if

existing equipment does not offer integrated kilovoltage image guidance and multi-leaf collimator-based intensity modulated radiation therapy, existing equipment will not be considered in applying the 6,000 treatment per year rule as long as the competing or replacement equipment includes these features.

(d) Preference for new radiation therapy services shall be given to those applicants who combine/locate co-existent with chemotherapy treatment modalities, as these services 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)

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

History: Effective March 8, 1996. **Amended:** Filed June 19, 1996; effective July 25, 1996. **Repealed and New Rule:** Filed October 18, 2004; effective November 22, 2004. **Amended (SHP Year Only):** Filed December 2, 2014; effective January 6, 2015.

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

(1) Discussion

(a) Those who suffer with End Stage Renal Disease have inadequate renal function to support life. Individuals with end-stage disease must rely on 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 Alabama, 1975, allows kidney disease treatment centers with ten (10) stations or less located in a Class 3, 4, 5, 6, 7 or 8 municipality to be established without a Certificate of Need. Kidney disease treatment centers located in a Class 4, 5, 6, 7, or 8 municipality located in a county in which a Class 1, 2 or 3 municipality, or any part of such municipality, are located 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 Alabama, 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:

- a. Demonstration of compliance with the utilization rate in paragraph (1)(c);

- b. 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

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

(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 in 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 downtime, transients, and back up of home patients. Optimal capacity is 9.6 dialysis treatments per station per week ($.80 \times 12$ dialysis treatments/station/week = 9.6 dialysis treatments/station/week).

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

EXAMPLE (Numbers not reflective of a specific reporting timeframe):

Total Stations		20	
Dialysis Treatments/Station/Week	x	12	
Present Capacity Dialysis Treatments/Week			240 Available
Optimal Utilization	x	.80	
Maximum Optimal Capacity			192 Available Dialysis Treatments/Week
Patient Usage	÷	3 Dialysis Treatments/Week	
Maximum Optimal Census			64 Patients

(b) 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.

a. 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;

b. 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 patient projections shall be based on:

a. 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.

- b. 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 statewide total incidence rate, or the sum of the statewide non-white incidence rate plus the statewide white incidence rate, from the most recently published statistical update produced by the Agency.

- c. 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.

(i) Loss Rate:

EXAMPLE (Numbers not reflective of a specific reporting timeframe):

In-Center Census Start of Year:	100 Patients
New Patients During Year:	<u>50</u>
	150
Less:16% Death	24
Less:5% Transplant	8
Less:11% Home Training	<u>6</u>
In-Center Census, Year End	112

Note: As of October 2018, Network 8, Inc. does not publish the data tables on its website. SHPDA is authorized to continue utilization of the most recent data provided to the Agency by Network 8, Inc. upon request. Requests for information contained in data tables must be obtained by interested parties directly from Network 8, Inc.

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.

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)

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

History: Effective May 18, 1993. **Amended:** Filed June 19, 1996; effective July 25, 1996. **Amended:** Filed March 19, 1997; effective April 12, 1997. **Repealed and New Rule:** Filed October 18, 2004; effective November 22, 2004. **Amended:** Filed June 30, 2006; effective August 4, 2006. **Amended:** Filed January 24, 2012; effective February 28, 2012. **Amended:** Filed December 2, 2014; effective January 6, 2015. **Repealed and New Rule:** Published March 31, 2020; effective May 15, 2020. **NOTE:** Statistically Updated: August 3, 1994. These updates reflect changes in inventories, utilization, population, and need projections, effective August 3, 1994. Statistically Updated: effective August 21, 1995. **Repealed and New Rule:** Published April 30, 2024; effective June 14, 2024.

410-2-3-.06 **Reserved.**

Author: Statewide Health Coordinating Council (SHCC)

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410-2-3-.07 **Reserved.**

Author: Statewide Health Coordinating Council (SHCC)

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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 Alabama, 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 Alabama, 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 eighteen (18) months, equipment initially classified as new technology shall be treated as any other major medical equipment (§ 22-21-263, Code of Alabama, 1975) acquisition; if technology-specific criteria are made a part of the State Health Plan, they shall apply, and where no technology-specific section exists, other pertinent statutory, regulatory and State Health Plan provisions shall govern.
- 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 sixty (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, with the advice and consent of the Health Care Information and Data Advisory Council, 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)

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

History: Effective May 18, 1993. **Amended:** Filed June 19, 1996; effective July 25, 1996. **Repealed and New Rule:** Filed October

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Year Only): Filed December 2, 2014; effective January 6, 2015.

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effective June 14, 2024.

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 is 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 April 2018, more than 114,000 people were on the national waiting list for organ transplant.

(b) In 2018 there were:

1. 17,566 deceased and living organ donors;
2. 36,529 lifesaving organ transplants;
3. 124,601 registrations on the waiting list as of May 8, 2019; and
4. 5,918 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 (80%) 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)

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

History: Effective May 18, 1993. **Amended:** Filed June 19, 1996; effective July 25, 1996. **Repealed and New Rule:** Filed October 18, 2004; effective November 22, 2004. **Amended (SHP Year Only):** Filed December 2, 2014; effective January 6, 2015. **Repealed and New Rule:** Published March 31, 2020; effective May 15, 2020.

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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 available in all sixty-seven (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.

(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 parent. Relocation within the CON Authorized service area of a branch or parent provider 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 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. Adjustments are addressed in paragraph (e) below.

(c) Basic Methodology

- 1. Need Assessment for Hospice Services
- 2. The need for additional Hospice Services shall be calculated as follows:

$HPR = \text{Hospice Deaths by County} / \text{Total Deaths by County}$

Where as:

HPR= 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 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.

3. Review Criteria

An application to establish or expand hospice services in a county shall be consistent with this Plan if:

- a. The Hospice penetration rate in the proposed county is less than forty percent (40%).
 - b. Each approved hospice agency in the proposed county has been operational for at least thirty-six (36) months in Alabama; and
 - c. 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.
4. The SHCC has determined that additional information is required in order to conduct a thorough examination of both the appropriateness and accuracy of any need projections derived from this methodology. Therefore, no determination of need shall be made by SHPDA for a minimum of two (2) years following the effective date of this Plan. During this two (2) year period, SHPDA shall review the data collected on the Annual Report for Hospice Providers (form HPCE4) to determine the appropriateness and accuracy of the methodology provided in this section. SHPDA shall also investigate and analyze the impact of utilizing only the total number of "hospice eligible" deaths, rather than the total number of deaths

in a county, to determine the impact of utilizing an alternate value as a part of the methodology. Further, SHPDA shall work with the SHCC to determine the impact of other aspects of this section to determine whether additional changes to this section, beyond potential changes to the methodology, should be considered by the SHCC.

(d) Planning Policies

1. SHPDA staff shall collect data from all licensed hospice providers on an annual basis, on a survey instrument developed by SHDPA staff with the advice and consent of the Health Care Information and Data Council. The survey instrument shall be designed to collect all data necessary to support the In-Home Services Need methodology discussed above.
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. The 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 services in the county; or
2. Absence of services by a hospice in the proposed county for patients regardless of ability to pay, and evidence that the applicant will provide services for patients regardless of ability to pay.

For a listing of In-Home Hospice providers or the most current statistical need projections in Alabama contact the Data Division as follows:

MAILING ADDRESS
(U. S. Postal Service)

STREET ADDRESS
Commercial Carrier)

PO BOX 303025
MONTGOMERY, AL 36130-3025

100 NORTH UNION STREET, SUITE 870
MONTGOMERY, AL 36104

TELEPHONE:
(334) 242-4103

FAX:
(334) 242-4113

EMAIL:
data.submit@shpda.alabama.gov

WEBSITE:
<http://www.shpda.alabama.gov>

Author: Statewide Health Coordinating Council (SHCC)

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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 reasons 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 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 seventy-five (75) miles.

Author: Statewide Health Coordinating Council (SHCC)

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

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