# STATE HEALTH PLANNING AND DEVELOPMENT AGENCY



4-2027 Alabama State Health Plan

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#### ALABAMA STATE HEALTH PLAN 2024-2027 STATE HEALTH PLANNING AND DEVELOPMENT AGENCY

## **Chapter 410-2-1 Introduction to Health Planning**

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- 410-2-1-.02 Overview of Chapters
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#### 410-2-1-.01 Statutory Authority.

The Alabama State Health Plan (SHP) is required by § 22-21-260(4), Code of Alabama, 1975.

Author: Statewide Health Coordinating Council (SHCC).

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

History: Filed October 18, 2004; Effective November 22, 2004. Amended (SHP Year Only): Filed December 2, 2014; Effective January 6, 2015. Repealed and New: Filed March 16, 2020; Effective May 15, 2020.

# 410-2-1-.02 Overview of Chapters

(1) The Alabama State Health Plan is divided into five chapters.

(2) Chapter I, Introduction to Health Planning, provides the Statutory Authority, the Health Planning Structure in Alabama, the Alabama Health Policy Analysis, Data Collection and Publication, and the Overview of the State Health Plan. These sections provide information to the public and to providers about the statutory authority granted to the Statewide Health Coordinating Council ("SHCC"); information on the makeup of the SHCC and its various committees; the methods of Health Policy determinations by the Governor and execution through the SHCC and the Certificate of Need Review Board ("CONRB"); the methods of collection of data utilized by the State Health Planning and Development Agency ("SHPDA") in support of the *State Health Plan*; and a brief overview of the organization of this Plan.

(3) Chapter II, Health Priorities, provides an identification and summary of the health issues in the state, and reflect the priorities identified by the Governor and/or the SHCC as critical items that should be addressed by various state agencies and/or private entities to improve the overall health of all Alabamians. Where applicable, discussion of certain health priorities may reference other agencies that address those issues. The issues discussed in this Chapter, along with any recommendations provided, are meant to supplement the actions, policies, and initiatives put forward by other state agencies, the Legislature, and the Governor's office, to ensure a common set of priorities and goals are established and reinforced throughout all state health care and regulatory services.

(4) Chapters III, Specialty Services, and IV, Facilities, focus on resources. These chapters identify both existing and needed health care resources. The planning methodologies for such resources are based on economic and social criteria for health care resources allocation. Chapter III focuses on those resources that do not usually require a stand-alone facility to operate, or do not require a physical "bed" in order for services to be provided. Chapter IV focuses on those resources that usually do require a stand-alone facility to operate, or require a physical "bed" for services to be provided. More provider types addressed in these sections have statistical formulas, called "methodologies", which are used to determine need for additional services. Many also define a planning area in which need is to be provided, some more specialized services will have defined regions, instead of the county, as a planning area.

(5) Chapter V, Alabama Health Statistics and Revision Procedures contains sources for support data and other information pertinent to the *State Health Plan*. Additionally, sections exist in this chapter which explain the procedures for adjusting or amending the *State Health Plan*; the methods for updating the methodologies for services utilizing finite needs; the requirements for SHCC compliance with the Open Meetings Act; and the method of notifications in compliance with the Open Meetings Act. A list of the current standing committees of the SHCC, and the State Health Plan responsibilities assigned to each committee is also included in this Chapter.

Author: Statewide Health Coordinating Council (SHCC).

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

History: Filed October 18, 2004; Effective November 22, 2004. Amended (SHP Year Only): Filed December 2, 2014; Effective January 6, 2015. Repeal and New: Filed March 16, 2020; Effective May 15, 2020.

## 410-2-1-.03 Health Planning Structure in Alabama

(1) The Alabama Statewide Health Coordinating Council (SHCC) is charged by statute and the Governor to prepare a State Health Plan (SHP) every three (3) years. Revisions may be accomplished as necessary, however the SHCC is required to review, and where appropriate revise, the SHP on at least an annual basis. The *State Health Plan* shall be utilized by the Certificate of Need (CON) Review Board pursuant to § 22-21-264, Code of Alabama, 1975, in the CON review process, and by other entities to the overall health systems development and operation in Alabama. The provisions of this plan are severable. If any part of this plan is declared invalid or unconstitutional, that declaration shall not affect the part which remains.

(2) The SHCC shall consist of not less than sixteen (16) members, the majority of whom shall be consumers. They are appointed by the Governor for staggered terms of one (1) to three (3) years and shall serve until reappointed or a replacement is appointed.

The SHCC chairman shall appoint committees and/or task forces to address specific (3) subjects of the SHP and shall appoint chairs of each. The committees or task forces shall elect their own Vice-Chair and Secretary from their membership. Committees shall be composed of only SHCC members. Task forces may have SHCC and non-SHCC members. A current list of the SHCC Committees, with a list of their responsibilities and the corresponding sections of the SHP, shall be maintained by the Agency on the SHPDA website at www.shpda.alabama.gov or any successor address maintained by the Agency. Committee reports shall be directed to the SHCC. Task force reports may or may not be presented directly to the SHCC at the discretion of the SHCC chairman. The SHCC shall hear and make decisions on the acceptance or adoption of the SHP, and any amendments or adjustments thereto, subject, at the chairman's discretion, to preliminary review and recommendation by the appropriate committee. Procedures for an amendment or adjustment to specific provisions of the SHP are addressed in ALA. ADMIN CODE r 410-2-5-.04, Plan Revision Procedures, and 410-2-5-.05, Application for State Health Plan Adjustment. Statistical updates to reflect more current population and utilization data may be accomplished by staff with the approval of the SHCC chairman.

(4) Parliamentary procedure shall be conducted within the sound discretion of the SHCC chairman and the committee and task force chairs, according to the latest version of Robert's Rules of Order, Newly Revised, except as otherwise specified in these rules.

(5) The Governor is the final approval authority for the SHP and any amendments/adjustments by the SHCC, subject to the provisions of the Alabama Administrative Procedures Act (APA).

Author: Statewide Health Coordinating Council (SHCC).

Statutory Authority: §§ 22-21-260(2) and (4), 22-21-264, and 22-4-7, <u>Code of Alabama</u>, 1975. History: Filed October 18, 2004; Effective November 22, 2004. Amended (SHP Year Only): Filed December 2, 2014; Effective January 6, 2015. Repeal and New: Filed March 16, 2020; Effective May 15, 2020.

# 410-2-1-.04 Alabama Health Policy Analysis

(1) Policy is defined as a definite course or method of action selected from among alternatives and in light of given conditions to guide and determine present and future decisions. Policy may be expressed in writing or it may be implied by actions and commitments. Action policy may imply, in fact, that no policy is desired, thereby leaving the decision makers free to meet any given condition with actions that may or may not be considered as precedent setting.

(2) Basic to analyzing Alabama State Health Policy is the determination of who sets the policies and how or to what degree these policies interface to meet a general overall health policy.

(3) Health policy in Alabama finds its basis in State statutes as determined by the Legislature, State budgets, decisions and expectations of the Governor, expressions of the Statewide Health Coordinating Council in the *State Health Plan*, and regulatory decisions made by the State Certificate of Need Review Board.

(4) The Governor, through the cabinet and legislative programs, expresses a general health policy for maximizing a high rate of wellness for all citizens. The Governor's actions indicate a special concern for child health, infant mortality, prevention, the socio/medical problems of teenage pregnancy, the availability and accessibility of health care in the rural areas, the special health problems of the elderly, mentally ill, and disabled, and treatment of opioid addictions. The Governor's concerns are manifested in budget requests and funding in these areas through the various state agencies, such as the State Health Planning and Development Agency, the Alabama Medicaid Agency, the Alabama Department of Mental Health, the Alabama Department of Public Health, and the Alabama Department of Human Resources.

(5) The Governor's concern for overall health planning and development is highlighted by the appointment of providers and consumers to function in the planning and regulatory areas.

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## 410-2-1-.05 Data Collection and Publication

(1) Efficient health planning and Certificate of Need decisions are dependent upon the availability of reliable health care data. Accurate inventories of existing resources and accurate utilization statistics are required in the *State Health Plan* to continue accurately projecting the need for additional health care facilities, equipment, and services that are subject to regulation herein.

(2) In 2015 the Alabama Health Planning Facilitation Act ("Act") was enacted. The Act was written to "…provide for certain mandatory health care reporting to SHPDA, to designate the SHPDA as the agency to collect, compile, and analyze the collected reports; to establish and provide for the membership of the Health Care Information and Data [Advisory] Council; to require that the SHPDA, after receiving advice and guidance from the council, adopt rules to implement this act; to provide for penalties for failure [to] make the required reports; and to require the SHPDA to meet certain deadlines or lose its authority to require the reporting." The Health Care Information and Data Advisory Council ("HCIDAC") consists of representatives of CON authorized providers, the Statewide Health Coordinating Council, and the Certificate of Need Review Board, and has authority to review the survey instruments used by the Agency to collect utilization of data collected by the Agency in furtherance of its mission. The Act further provided for the development and implementation of an electronic filing system for mandatory reports by providers with the Agency.

(3) The HCIDAC, in conjunction with the CON Review Board and the Agency, developed new rules defining a "mandatory reporter"; reviewed and revised the survey instruments used by mandatory reporters to submit utilization data to the Agency; and defined electronic filing, for the purposes of the rule, as e-mailing completed mandatory reports to an e-mail address specifically created by the Agency for use in processing said reports. Amended rules related to the Act, including the new survey instruments, were approved by the CON Review Board in January 2016. Additional rules regarding enforcement of the mandate, including administrative penalties and the ability to bar providers deemed noncompliant from participating in the CON process, were also approved. The HCIDAC further directed the Agency to research the development and implementation of an online filing system for the submission of both mandatory reports and for filings related to the Certificate of Need program in general in order to increase both the efficiency and the transparency of all interactions with the Agency.

(4) SHPDA, at the direction of the HCIDAC, is working with the Alabama Office of Information Technology ("OIT") to develop and implement an online filing system that will address all filings made with the Agency. The system will also allow for the purchase of copies of documents previously filed with the Agency, including CON applications, mandatory reports, etc. The system, once developed, is expected to be implemented in three stages.

(a) Stage one will require that all new projects (CON applications, letters of non-reviewability, changes of ownership, etc.), shall be filed through the new system, and will allow for users to become familiar with the new system while other components are developed.

(b) Stage two will require all new mandatory reports be filed through the online system. During the implementation of stages one and two, existing projects and older data collections shall continue to be filed via e-mail, to allow for consistency of filings, as well as to allow time for SHPDA staff to add older documentation and data to the system.

(c) Stage three will require that ALL filings with the Agency occur through the new system, as all existing active project files and active data collections are expected to be completely uploaded by this time.

(5) To increase and improve efficiency, SHPDA staff is also working to improve internal processes through the application of technology already available to Agency personnel. These improvements are scheduled to be developed during the development and implementation of the online system, with the goal being the implementation of the online and internal system improvements occurring at the same time. The implementation of both an online filing system and internal improvements undertaken by the Agency are expected to improve the efficiency and effectiveness of staff; provide more transparency to applicants, mandatory reporters, and boards; and to provide a clearer picture of current utilization and need to allow for a more precise decision making process for both the Statewide Health Coordinating Council and the CON Review Board.

(6) In furtherance of the stated desire of the Statewide Health Coordinating Council to have the best possible information available to make the most appropriate decisions for the citizens of Alabama, the Agency is directed to continue to research new technology to allow for a clearer and more accurate picture of existing facility utilization to be presented. Technology such as Business Intelligence or other analytical software would provide additional capability to Agency, Board, and provider representatives seeking to determine potential need. Any technology that provides more efficiency and effectiveness to the health planning process, if cost effective and user friendly, should be investigated and used if appropriate to the stated mission of the Agency and its boards.

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#### ALABAMA STATE HEALTH PLAN 2024-2027 STATE HEALTH PLANNING AND DEVELOPMENT AGENCY

# Chapter 410-2-2 Health Priorities

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# 410-2-2-.01 Introduction

(1) This section of the *Alabama State Health Plan* underscores certain health issues which warrant focused attention. These few issues have been selected for a variety of reasons, including:

(a) Unusual severity in our state, e.g. infant mortality;

(b) Special opportunities, e.g. The Medicaid Omnibus Budget Reconciliation Act (OBRA) option;

(c) Problems of access to health care, e.g. the issue of the uninsured and the vulnerability of rural hospitals.

(2) When resources are limited and needs great, focused attention on the most pressing problems will promote optimal use of any new or additional investments. What follows is a review of the health issues and health concerns, which require priority emphasis in Alabama.

Author: Statewide Health Coordinating Council (SHCC). Statutory Authority: § 22-21-260(4), <u>Code of Alabama</u>, 1975. History: Filed October 18, 2004; Effective November 22, 2004. Amended (SHP Year Only): Filed December 2, 2014; Effective January 6, 2015. Repealed and New: Filed March 16, 2020; Effective May 15, 2020.

## 410-2-2-.02 Maternal and Child Health

## (1) The Problem

(a) Alabama's infant mortality was 9.0 per 1,000 live births in 2005. In 2014 the provisional rate improved to 8.7 deaths per 1,000 live births, a drop from the 2005 rate. Reasons for the improvements include a number of factors related primarily to improved Medicaid coverage.

1. Medicaid has been expanded to serve more children and pregnant women who do not receive cash assistance such as Aid to Families with Dependent Children. This trend started in 1988 with expansion of eligibility to pregnant women and children up to age one (1) with incomes under 100 percent (100%) of the federal poverty level and now up to one hundred thirty-three percent (133%) of the federal poverty level.

2. As of September 1, 1991, Medicaid had workers out-stationed at hospitals, county health departments and other health facilities throughout the state to determine Medicaid eligibility for children and pregnant women who need help with payment for health care but who do not qualify for cash assistance.

3. The Alabama Medicaid Agency received a 1915(b) waiver to create the Alabama Coordinated Care Network for maternity, family planning, children, foster children, and eligible adults beginning October 1, 2019, for three (3) years. The objective is to better coordinate the care, follow-up, and follow-through for Medicaid recipients residing in any one of the seven (7) regions. Each region will have a contracted entity responsible for the coordination of care and services for Medicaid eligibles. Quality measures are key to the success of the waiver.

4. ADPH, in collaboration with the Alabama Department of Human Resources, implemented the Alabama Unwed Pregnancy Prevention Program (AUPPP) in 2001 and the Family Planning Teen Care Coordination Program in 2002. The AUPPP addresses adolescent pregnancy and unwed pregnancy by providing funding support to community-based projects, a statewide teen pregnancy prevention campaign, and media outreach. The teen care coordination program provides medical social support to teens age eighteen (18) and under receiving family planning services in local health departments.

5. Other programs implemented by ADPH that are affecting infant mortality include the Alabama Child Death Review Program legislated in 1997, a campaign addressing "back-to-sleep", a "safety for sleeping babies" brochure, and folic acid outreach. According to the Alabama Child Death Review Program, approximately eighty percent (80%) of infant deaths in Alabama are attributable to unsafe sleeping conditions. (b) Progress has been made in Maternal and Child Health in the state. In 2005, Alabama's infant mortality rate was 0.93%, and in 2014 declined to 0.87%. In "real terms", 517 of Alabama's babies failed to reach their first birthday in 2014. Those at highest risk for infant mortality are infants born to blacks, single mothers, teenagers, and the socio-economically disadvantaged. Over thirty percent (30%) of Alabama's population is black and other. Close to one-half (1/2) of the births in 2014 (43.2%) were to unmarried women, and 8.5% of infants resulted from teenage pregnancies.

(c) Infant death is not the only problem associated with high-risk birth. Research indicates that for every baby who dies, three (3) more are born with handicapping conditions. In 2014, 10.1% of babies were born with a low birth weight, putting them at greater risk for handicapping conditions. Ensure the newborn screening component is followed as it identifies problems in newborns early in their development so interventions and therapies can be applied for long term outcomes.

(d) Alabama's women and children must receive adequate health care -- health care that is primarily preventive, appropriate for the need, and available. Barriers to care include the following:

1. Outreach Efforts. Outreach efforts at the local community level are varied and sometimes nonexistent. Some children do not receive the minimal recommended number of preventive health care visits as outlined by the American Academy of Pediatrics, thus immunization rates for these infants and young children are low, and conditions that could be identified through routine screening exams go untreated.

2. Diminishing Rural Health Services and Delivery Hospitals. Alabama continues to experience a decline in rural population and health providers. Hospitals are financially challenged due to declining population and reductions in federal reimbursement. Only twenty-nine (29) counties have a birthing hospital. Innovative means of delivering care to rural Alabama is needed for primary care, intermediate/interventional, and emergency or hospitalization.

3. Perinatal Services. Several components of the perinatal system are not available in all areas of the state. These components are obstetrical and neonatal outreach education, maternal-fetal and newborn transport systems, and high-risk infant-follow-up. Case management to include tracking and follow-up for women and infants is not available in some areas. There is a need for additional social workers at the local level to provide these services.

4. Child Mental Health. A significant deficit of child mental health professionals, social workers, and residential resources continues for children under age eight (8). The lack of residential resources in Alabama for those with pure mental and behavioral health issues puts pressure on hospitals to retain them or send them several states away for long term rehabilitation or care.

5. Adolescent Mental Health. The resource deficit for adolescent trained professionals should be noted. As important is the lack of adolescent designed residential or mental/behavioral health rehabilitation, and in particular, for those with adolescents mental/behavioral health diagnoses and physical health needs such as gastrointestinal tubes.

#### (2) **Recommendations**

(a) Improve the accessibility of services to maternity and pediatric patients through expansion and improvement of services to women and children.

1. Outreach efforts should be strengthened and targeted to maternity and pediatric patients.

2. Evaluation of case management services should be designed and implemented and management data for the Alabama Department of Public Health should be refined.

(b) Strengthen the Alabama Perinatal Program to implement programs that address recommendations issued by the State Perinatal Advisory Council (SPAC) in 2002. Provide statewide follow-up of all infants identified as high-risk. Improve maternal-fetal and neonatal transport systems.

(c) Maintain and strengthen interagency and private sector efforts directed toward decreasing the amount and effects of substance abuse in women of childbearing age and their children. Efforts to increase intervention and treatments should be encouraged. Child abuse and neglect has risen significantly with the opioid and meth usage. DHR's foster care system is burdened with babies and children of substance abuse mothers. The affected newborns will experience some health care issues long term, though what those issues may be is unknown.

(d) Encourage access in schools for perinatal testing, counseling, prenatal education, and care.

(e) The Statewide Health Coordinating Council (SHCC) is committed to maintaining and strengthening efforts to expand and improve quality pediatric health care throughout Alabama's health care delivery system. This should be achieved through pediatric-trained personnel and systems whose expertise is to care for children -- pediatric-trained physicians (family physicians, pediatricians, pediatric sub-specialists, etc.), nurses (including pediatric and family nurse practitioners), developmental specialists, mental health specialists, and other team members located in health care delivery sites and systems (physicians' offices, multi-specialty ambulatory clinics, health maintenance organizations, children's hospitals, and other service sites).

Author: Statewide Health Coordinating Council (SHCC).

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

History: Filed October 18, 2004; Effective November 22, 2004. Amended (SHP Year Only): Filed December 2, 2014; Effective January 6, 2015. Repeal and New: Filed March 16, 2020; Effective May 15, 2020.

## 410-2-2-.03 Care of the Elderly and Chronically III

## (1) The Problem

(a) The elderly comprise one of the most rapidly growing age groups in the United States. The same is true in Alabama. Since 1900, the state's total population (approximately 4.4 million people) has more than doubled and there are nearly ten times as many senior citizens. In 1900 persons 65 and older accounted for only 3% of the total population compared to 16.8% in 2019. This age group is expected to increase to over 22% by the year 2050.

(b) Improvements in life style, changes in diet, and development of medical technology for identification and treatment of diseases have resulted in increased life expectancy. Because of this increase, a new phenomenon is occurring, aging of the aged. More persons are living well into their 80s and even 90s. Within the ten-(10) year period from 2013 to 2022, the 65 and older segment of the population is expected to increase by fifteen percent (15%). The special needs of these frail elderly will demand increased attention from service providers in the years ahead. The number of people aged 65 and older in Alabama is projected to be almost 900,000 by 2022.

(c) The male population age 65 plus increased by 13.3% from 1990 to 2000 and the female population of the same age group increased by 9.3%, while one-third of the non-institutionalized elderly live alone, 80% of these are women.

(d) As age increases, the incidence of chronic disease and disability, particularly at the lower levels of severity, increases. Another factor affecting the increase of the chronically ill is the projection of an increase in the number of AIDS cases in the state.

(e) Many of our chronically ill live below the poverty level. The current census reflects they do not always seek medical assistance because of out-of-pocket costs. Often they cannot afford required medications. Some live in substandard housing with inadequate plumbing and heating. They do not always practice proper nutrition because of economic concerns and the inability to shop.

(f) Depression, loneliness, alcohol and drug abuse, suicide, and mental health conditions pose problems for many elderly and chronically-ill citizens.

(g) Transportation is not available to all elderly and chronically ill persons. Many who have lived alone in the past will need to be placed in a facility where they can receive assistance. Families, with both husband and wife working, need assistance with parents during work hours and at other times for respite care.

(h) Dental care and audiology are not available at affordable prices for all the elderly and chronically ill, although many more dentists are accepting Medicaid patients.

(i) Recent statistics project an increase in the need for care of the elderly and chronically ill within the next few years. However, much of this care will be linked directly to functional limitations, and only indirectly to illness.

(j) The social, economic, and cultural environment will have important bearing on how well our elderly maintain their overall health status. The support that was once provided by relatives is less feasible in today's society because of scattered families, divorce, single parents, childless couples, and two-income families.

(k) The kind of care and support needed to maintain the health of our elderly and chronically ill population cannot be sustained within the state's current medical framework.

(1) The availability of health care services has increased. Medicaid increased the payment to dentists and physicians in the last two years; the Medicaid drug formulary has been expanded and payments have been increased to nursing homes.

# (2) **Recommendations**

(a) The State should strengthen its existing support services for the elderly and chronically ill and, when appropriate, develop new services, beginning at the community level. These services should include, but not be limited to, the following:

1. Adult day care facilities to assist working families;

2. Assisted living facilities to provide housing for elderly and chronically ill who can no longer live alone;

3. Counseling services that deal with depression, alcohol and drug abuse, suicidal tendencies, mental health, nutrition, appropriate life styles, and self-care;

- 4. Geriatric training and education for caregivers;
- 5. Homemaker and chore services;
- 6. Home delivered meals;
- 7. Transportation services;
- 8. Emergency alert systems;
- 9. Dental care, including prosthodontics;
- 10. Audiology, including hearing aids;
- 11. Optometry services, including glasses;

- 12. Adaptive and assistive equipment;
- 13. Adequate housing for persons living below the poverty level.

14. Nursing Homes to provide housing and/or rehabilitative services for elderly and chronically ill patients who can no longer live alone and who require care at a level above and beyond that available in an assisted living environment.

(b) The success or the breakdown of these support services will determine to a considerable extent the demands made on health care services by the elderly and chronically ill. However, with the success of such support services, the need for more costly health care for our elderly and chronically ill will drastically diminish.

Author: Statewide Health Coordinating Council (SHCC).

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

History: Filed October 18, 2004; Effective November 22, 2004. Amended (SHP Year Only): Filed December 2, 2014; Effective January 6, 2015. Repeal and New: Filed March 16, 2020; Effective May 15, 2020.

#### 410-2-2-.04 Rural Health Care

Alabama has a Rural Health Plan developed with the assistance of the Alabama Department of Public Health's Office of Primary Care and Rural Health, the Alabama Hospital Association, and rural hospitals. The current State Rural Health Plan, published in 2008, was updated in both 2011 and 2016<sup>1</sup>. This plan is incorporated into this State Health Plan by reference hereto.

## (1) The Problem

Rural healthcare providers disproportionately serve individuals who are older, sicker, poorer and underinsured/uninsured as compared to people living in other parts of Alabama. Alabama's uninsured rate (19-64 years) is 15.8%<sup>2</sup>. Policy makers anticipated a rate less than 10% after passage of the Affordable Care Act, but the take up in the Alabama Marketplace/Exchange is only 3%. Rural Alabamians (as well as Americans on the whole) often lack adequate primary care access and have higher rates of diabetes, heart disease, cancer, obesity, tobacco/opioid use, mental health issues and stroke<sup>3</sup>. The health issues plaguing rural Alabamians stress a fragile rural delivery system dealing with lower volumes, rising costs, increased regulations, lower negotiating power and a shortage of healthcare workers. As rural Alabama changes and evolves, so too must rural healthcare delivery in the state. The issues facing Alabama's rural care providers are multifaceted:

(a) Reimbursement and Operational Factors. As a rule, providers in rural areas experience a higher mix of Medicare/Medicaid patients than do the facilities in urban areas; but rural hospitals receive a lower amount of reimbursement per patient from Medicare. Rural providers must have robust volume to thrive. But the healthcare system is shifting away from an inpatient-dominant and volume-driven system and consequently the state's rural delivery system is becoming increasingly brittle. To counter the loss in volume, many rural providers expand their service offerings which is often not ideal because quality is correlated to volume in certain specialties<sup>4</sup>.

As healthcare shifts from volume-based reimbursement to a system based predominately on value, rural providers will continue to struggle if payors do not make a distinction between the unique operating context of a rural hospital and that of suburban and urban providers. Even when a distinction is made, oftentimes it is deleterious to the provider. For example, the Centers for Medicare and Medicaid Services (CMS) implementation of the Prospective Payment System (PPS) assumes hospitals in rural areas will not experience the same labor costs for health personnel services as do urban hospitals. Therefore, the component parts of the prospective payment formula provide for a lower wage allowance for rural hospitals. Another factor that tends to limit reimbursement for rural hospitals is that the PPS system assigns weights related to patient attributes to each diagnosis-related

<sup>&</sup>lt;sup>1</sup> <u>http://alabamapublichealth.gov/ruralhealth/assets/ALRuralHealthPlan2016Update.pdf</u>

 $<sup>^2</sup>$  https://www.alabamapublichealth.gov%2Fhealthrankings%2Faccess-to-care.html&usg=AOvVaw3CCf&n\_LelEqPqpwplkVg

<sup>&</sup>lt;sup>3</sup> https://www.arc.gov/research/researchreportdetails.asp?REPORT\_ID=138

<sup>&</sup>lt;sup>4</sup> https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3336194/

group (DRG). The higher the weight per DRG, the more reimbursement a hospital will receive if that hospital provides services to patients with higher weighted/reimbursed DRGs. Therefore, urban facilities may receive more reimbursement, although the weight assignment per DRG has not been proven as an accurate indicator of the consumption of resources. The bottom line effect of Medicare reimbursement on rural hospitals is the payment rates are generally less for hospitals in rural areas, leading to a less than adequate payment system. According to the Alabama Hospital Association, in recent years approximately eighty-eight percent (88%) of rural hospitals in the state experienced a net operating loss.

(b)Demographic Factors. A low population density, worsened by the emigration of the younger population in search of employment in larger communities, results in a high proportion of the elderly and underinsured/uninsured remaining in rural communities. Alabama's overall population density in 2019 averaged 94.4 people per square mile, ranging from a low of 12.5 persons per square mile in Wilcox County to a high of 586.2 persons per square mile in Jefferson County. In this case a measurement of density may not be an accurate indicator as only 18 counties have a density factor equal to or above the average and 49 counties below the average. Rural facilities thus have a smaller market from which to draw patients and fewer patients who pay adequately as compared to the costs of providing the care. According to the Centers for Medicare and Medicaid Services, in 2014 health care spending per capita for the 65 and older population was over five times higher than health care spending for children, and almost three times higher than for working-age adults<sup>5</sup>. The population 65 and older comprises 16.9% of the state population and 19.2% for the 49 rural counties, further emphasizing the need to develop and implement a rural health plan<sup>6</sup>. In addition, rural Alabama has a high percentage of Veterans and a low percentage of commercially insured residents.

(c) Utilization Factors. Overall use of inpatient services in rural areas continues to decline, while those same services are increasingly used by the elderly who are covered by decreasing Medicare reimbursement. Given that many of the rural hospitals are sole community providers, the leading industry in the community, and one of the major employers in the area, the decreasing use has caused concerns both economically and politically. Leaders are rightly concerned that the demise of the rural hospital leaves a discontinuity of health care services for citizens in their areas.

(d) Insufficient Health Professional Supply. Data from the Alabama Department of Public Health indicates that every county in the state has at least some areas considered to be medically underserved, with fifty-eight (58) counties shown as completely medically underserved. While Alabama has made strides in licensure portability in recent years, there are still barriers to address, including portability within telehealth. Because of the problems attracting specialized professionals and obtaining new technologies, few rural hospitals can provide special services that might increase their revenue. The migration of

<sup>&</sup>lt;sup>5</sup> <u>https://www.cms.gov/research-statistics-data-and-systems/statistics-trends-and-</u>

reports/nationalhealthexpenddata/nhe-fact-sheet.html

<sup>&</sup>lt;sup>6</sup> https://www.census.gov/quickfacts/AL

young people to urban communities, lack of adequate reimbursement, and limited patient resources are other problems hindering the recruitment of professional personnel and fueling the state's health professional shortages. Government reports show that Alabama, like many other parts of the South, is experiencing a physician shortage.

Children living in rural areas have less access to routine primary care and, if they have a chronic condition or medically complex diagnosis, must drive long distances to urban centers for care. Many rural emergency rooms are not equipped for pediatric care, and those cases are often transferred to regional hospitals. In addition, much of the rural emergency care is through a volunteer EMS system, which could be enhanced.

Utilization of nurse practitioners, physician assistants, and nurse midwives meets a real need in addressing the access problem faced by many rural Alabamians. Health planners, providers, policy makers, and communities must approach the recruitment and retention of non-physician health professionals realistically. It is unrealistic to assume that every rural community will be able to recruit and retain a physician. In order to provide access to health care for the citizens of many of the state's most rural areas, the utilization of non-physician health professionals must be seriously encouraged. Also, payment for services provided by these non-physician health professionals must be made by third party payors and self-insured programs in order for their numbers to increase.

(e) No one strategy will solve the state's problems with rural health care. Rural healthcare delivery must evolve and the state must focus on appropriate and adequate access but untether from the idea of access equals an inpatient hospital.

## (2) **Recommendations**

Using the Bipartisan Policy Center's 2018 Report, "Reinventing Rural Health" as a framework, the following are recommendations from the Committee:

(a) Communities should tailor available services to the needs of the community, which for many rural areas are driven by changing demographics. To build tailored delivery services, policies need to be flexible and not just have a "one-size-fits-all" approach.

1. Support Opportunities for Transformation. The healthcare industry nationally continues to move toward the outpatient setting and towards a valuebased approach. Rural hospitals feel the impact of this transformation even more acutely and face unique challenges given both their location and low patient volumes. Many of Alabama's rural hospitals rely on enhanced reimbursement programs (e.g. Critical Access Hospital, Medicare Dependent Hospital, Low Volume Hospital adjustment, etc.) to be able to offer key outpatient services, despite low patient volumes.

2. Overall health improvement and management of disease cannot be done when local access to basic services is lost. Lack of access, either to an

inpatient hospital or to urgent/emergent care, leads to increased time and cost of transportation to healthcare services (particularly among seniors, who experience an average of fourteen (14) additional minutes in an ambulance<sup>7</sup>); reduced per capita income (-4%) and increased unemployment (1.6%) due to the loss of jobs for hospital staff and outward migration of community members<sup>8</sup>.

3. For communities that cannot sustain their current healthcare delivery structure, the SHCC supports state regulatory and statutory allowances for the establishment of new types of access sites that support transformation while maintaining important access points to care. These provider types would provide services critical to any rural community including: primary care; urgent, emergency care and transportation (EMS); observation, outpatient and ambulatory services including basic ancillary services and minor procedures. Emergency services could be enhanced by having several paramedics trained to work alongside and within the volunteer EMS system. In addition, population health approaches, including chronic disease management and care coordination, would be required. Optional services could be provided if they are not locally available (e.g. patients who do not need acute care could be treated and receive skilled nursing and/or rehabilitation services, behavioral health, oral health or home health services).

4. The realities of the health care system are that form follows payment and shifting to more transformative models will require alternative and enhanced reimbursement models, recognizing the unique challenges of low patient volumes coupled with an increasingly large population of Medicare enrollees. All innovation models should ensure adequate reimbursement to support such models.

5. These new provider types would require strong relationships with an inpatient facility or partner organization, as well as a plan to assure emergent and non-emergent transportation in the area between the partner and the smaller entities as well as other service providers in the area.

(b) Maintain Certificate of Need (CON). The CON serves as an important guardrail against reducing access and should not be repealed or limited in scope. Repealing or limiting the scope of CON can reduce access to care for the most vulnerable by destabilizing safety net hospitals. This occurs through a further degradation of the payer mix among patients at safety net providers.

(c) Once the right system and services have been identified for a community, funding mechanisms and payment models should reflect the specific challenges that rural areas face – such as small population size and high operating costs. Sparse populations mean a small number of patients, so reimbursement metrics must consider low patient volumes. Rural health care providers are eager to participate in value-based alternative-

<sup>&</sup>lt;sup>7</sup> https://uknowledge.uky.edu/cgi/viewcontent.cgi?article=1007&context=ruhrc\_reports

<sup>&</sup>lt;sup>8</sup> https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1702512/

payment models, but they need workable approaches and metrics. Policymakers should consider the unique challenges faced in rural areas when developing metrics and funding mechanisms.

1. Exploration and support should continue to identify and increase access to insurance and care for Alabama's uninsured.

2. Addressing Social Determinants of Health. A lack of focus on Social Determinants of Health translates into poor health status, which is borne out in Alabama's consistently low national ranking with respect to issues like obesity, substance use disorder and infant mortality. The SHCC supports the goals of the Alabama Coordinated Health Network (ACHN) and Integrated Care Networks (ICN) and the programs outlined in the Quality Improvement Programs (QIP) to address some of the higher impact health issues affecting many rural residents.

(d) With appropriate services and funding, rural communities can build sustainable and diverse workforces. Rural health can no longer survive on the back of one physician serving an entire community 24/7. Building and supporting the healthcare workforce should be a high priority, and the expectation of care quality should be comparable in rural as in more urban areas of the country. Also, alternative providers practicing at the top of their licenses, such as nurse practitioners and physician assistants, can fill vital primary care roles in the community. Communities should start young and think local for recruitment with pipeline programs that encourage interest in the health care sector in local middle- and high-school students. The State should adopt policies that increase the availability of and participation in rural residency programs. Providers are starting to think creatively by employing case managers, community-health workers and in-home providers to help meet the needs of the community. Policies should support these efforts.

1. Rural Development. The SHCC encourages state policymakers' support and funding (where applicable) of targeted rural initiatives that would assist rural providers.

2. Support Additional Graduate Medical Education ("GME") Funding. Addressing the physician and nurse workforce shortage is a priority for all rural providers. Rural hospitals face unique recruitment challenges but increasing the opportunity for physicians to train in rural hospitals allows medical residents to see the impact they can have and the benefits of rural locations.

3. Promote Rural Practice and Retention. The SHCC encourages state policymakers to pass the Alabama Physician Initiative, which would provide scholarships for certain medical students who are enrolled in and attending any college of medicine in Alabama and who contract with the Alabama Medical Education Consortium to practice for five (5) years after the completion of their residency in rural areas of the state with the greatest need for physicians, with funds allocated through the Alabama Department of Public Health. The SHCC also supports funding and development of workforce development efforts between academic centers (e.g. community colleges, vocational schools, career centers, etc.) and healthcare providers to develop a pipeline of career-ready healthcare professionals.

4. Rural Tax Credits. The SHCC encourages renewal and/or passage of rural tax credits to primary care physicians and advanced practice providers ("APP") who practice in rural areas.

5. Physician Recruitment. The SHCC encourages the secondary school systems to coordinate medical student recruiting efforts with the medical schools.

6. APP Training. The SHCC encourages schools of higher education to develop and expand APP training programs for utilization of such personnel in rural hospital emergency departments and/or rural health clinics. Encourage the continued support and recruitment of nurse practitioners and nurse midwives and expand the number of nurse practitioner programs in the state.

7. APP Utilization. Develop and implement programs to promote the utilization of APPs by:

a. Licensure and physician supervision requirements should be modified where access to care is hindered.

b. Promoting reimbursement by all payors.

(e) Health professionals working in rural areas need the right tools for success. Telemedicine is one tool that can be used to support both rural patients and rural providers. Not only do these services improve access by connecting remote patients with specialists located elsewhere, but they provide much-needed peer support to rural health professionals who often work in professional isolation. Telemedicine may prove to be critical in improving provider recruitment and retention, though challenges remain with broadband availability and reimbursement.

1. Expand Opportunities to Utilize Telehealth. Rural hospitals face unique challenges to provide access to care. Rural facilities are often located an hour or more away from the next closest hospital or clinic. Both providers and patients must travel greater distances to receive face-to-face care. Increasing the utilization of telehealth provides the opportunity to address these barriers to care. Telehealth services can include virtual visits originating at a patient's home or at a medical facility, remote patient monitoring and specialist consults between hospitals. The SHCC encourages policymakers to support innovation in telehealth in the following ways:

a. Support reimbursement of telehealth services at the same rate as face to face services.

b. Expand the definitions to allow patients to receive services in their homes.

c. Continue to invest in high-speed broadband access.

d. Create and invest in communication and marketing materials on the benefits of telehealth and focus distribution of those materials in the rural underserved communities as part of the rural community plan.

e. Financially support, fund and encourage rural community hospitals to provide telehealth education and develop telehealth portal locations for community access.

2. EMS Personnel. The SHCC encourages state stakeholders to determine how EMS personnel and certified paramedics could be utilized in rural areas beyond stabilization/transport and develop policies and reimbursement mechanisms for such paramedical professional utilization.

Author: Statewide Health Coordinating Council (SHCC). Statutory Authority: § 22-21-260(4), <u>Code of Alabama</u>, 1975. History: October 18, 2004; Effective November 22, 2004. Amended (SHP Year Only): Filed December 2, 2014; Effective January 6, 2015. Repeal and New: Filed March 16, 2020; Effective May 15, 2020.

#### 410-2-2-.05 Diseases – Prevention and Management

#### (1) **Preventable Diseases**

(a) Vaccine Preventable Diseases (Measles, Pertussis, HPV, Influenza, Shingles, etc.)

With a more local and global transient population, diseases are resurfacing due to a lack of, and failure to immunize for childhood and seasonal diseases such as influenza.

1. Influenza Problem. Seasonal epidemics of influenza occur every year in the United States, beginning in the fall. Typically, the epidemics cause thousands to tens of thousands of deaths and approximately 200,000 hospitalizations annually.

a. Since the 1940s, a vaccine has been available to prevent influenza; unfortunately, the vaccine is not used as much as it should be. To prevent hospitalizations and deaths caused annually by the influenza virus, the Centers for Disease Control and Prevention ("CDC") has recommended that all U. S. Citizens more than six (6) months of age receive the influenza vaccine.

b. The rate of vaccination is low (25% - 45%).

c. The cost of vaccination is minimal (\$10 - \$18), depending on type (injection vs. nasal).

d. Side effects are minimal.

e. Influenza causes children to miss school, usually up to one week, which in some cases can cause parents to miss work.

f. Recommendations:

- i. Consider adding the influenza vaccine to the required immunization schedule outlined in ALA. ADMIN. CODE r 420-6-1-.03.
- ii. Vaccinating school aged children would keep more kids in school and potentially save the state millions of dollars.

## (2) Adult and Childhood Diseases Preventable with Immunizations

Childhood diseases, such as measles, chicken pox, etc. are once again on the rise due to a mobile society and a failure to vaccinate. Vaccinations continue to be developed to prevent diseases such as shingles, HPV, etc.

(a) The State shall encourage compliance with the recommended vaccination schedules of the American Academy of Pediatrics and the CDC Advisory Council on Immunization Practices ("ACIP") to ensure Alabamians are protected from recognized and costly preventable diseases with a vaccination option.

#### (3) **Obesity**

(a) Discussion (source: <u>www.cdc.gov</u>)

1. In 2016, the prevalence of obesity (BMI> or = 30) among U. S. Adults was 39.8 %. By contrast, the prevalence of obesity in 2000 was 30.5 %.

2. An estimated 300,000 deaths per year in the United States may be attributable to obesity.

3. In 2017, Alabama was one of only seven (7) states with an adult obesity prevalence of over 35%.

4. Even moderate weight excess (10 to 20 pounds for a person of average height) increases the risk of death, particularly among adults aged thirty (30) to sixty-four (64) years.

5. Overweight and obesity are associated with heart disease, certain types of cancer, type 2 diabetes, stroke, arthritis, breathing problems, and psychological disorders, such as depression.

#### (4) **Diabetes**

(a) Discussion (sources: <u>www.adph.org</u> and <u>www.cdc.gov</u>)

1. Twelve percent (12%) of people in Alabama were diagnosed with diabetes in 2015. Thousands are unaware that they have the disease.

2. The increased incidence of diabetes often leads to obesity and kidney disease related issues, requiring additional dialysis centers and services for treatment.

#### (5) Human Immunodeficiency Virus (HIV) and Acquired Immunodeficiency Syndrome (AIDS)

(a) The Problem

1. By December 2019, transmission of the AIDS virus occurs through sexual contact with an infected person, exposure to infected blood or blood products, and perinatally from mother to baby. Transmission patterns of the HIV virus have shifted over time. As of 2017, homosexual/bisexual men account for

66% of adult AIDS cases, with 3% occurring in homosexual/bisexual men who use intravenous drugs. Diagnoses attributable to injectable drug use alone have declined significantly over time and accounted for only 6% of new diagnoses in 2017. Twenty-four percent (24%) of new diagnoses come from among heterosexuals who have had sexual contact with infected partners. Unfortunately, as of 2016, 15% of people infected with HIV are unaware of their status, and 38% of new HIV infections resulted from individuals who were unaware of their HIV-positive status.

2. By the end of 2016, Alabama had reported 13,437 AIDS cases. Of these, 13,397 were in adults and adolescents and 40 were in children less than age 13. Alabama's AIDS cases by reported risk behavior are as follows: 45.3% homosexual/bisexual male; 3.3% homosexual/bisexual with IV drug user; 5.6% IV drug abuse; 0.2% transfusion related/hemophiliac; 19.9% hetero-sexual contact with an infected person; and 24.9% were reported as undetermined. Additionally, according to the Alabama Department of Public Health, an estimated 1 in 6 people living with HIV in Alabama are unaware of their infection. Based on the current prevalence rate, this means that approximately 2,430 Alabama residents may have been infected and unaware of their positive HIV status at the end of 2016.

3. There are at least one million Americans silently infected with HIV. Most of them will get sick during the next decade. Nationally, over 700,000 people with AIDS have died since the beginning of the epidemic. Fifty-two percent (52%) of Alabama's reported AIDS cases have died. The development of antiretroviral therapy (ART) has substantially reduced AIDS-related morbidity and mortality and has improved long-term outcomes for people with HIV. According to the Kaiser Family Foundation, the age-adjusted HIV death rate has dropped by more than 80% since its peak in 1995. Because of this, people already diagnosed with the disease are living much longer. This, combined with the fact that new infections continue to occur, and more people are diagnosed with HIV than die from complications due to the disease, means that more people are living with the HIV virus than ever before.

4. In November 1987, the Alabama Department of Public Health designated HIV infection reportable by provider and patient name and identifiers. By the end of 2016, ADPH had received reports of 7,460 persons who tested positive for HIV and 5,977 additional persons whose infection had advanced to Stage 3 (AIDS). Each one of these individuals is potentially capable of transmitting the virus to someone else and will ultimately have his/her life shortened due to virus infection.

5. The lowest cost has been identified in areas, which have strong outof-hospital support networks to provide services to AIDS and HIV positive patients. In addition to the obvious personal loss experienced by families and friends, the loss of productivity due to deaths of individuals with AIDS represents an economic cost to the state of more than \$800 million. (b) Recommendations

1. The state needs to pursue three primary goals to deal with the problem of HIV/AIDS infection:

a. The elimination of HIV transmission from the infected population of Alabama to the uninfected population.

b. The provision of HIV services, both to prevent infection and to provide care in an environment free of discrimination and stigmatization.

c. The provision of appropriate and necessary health care to infected individuals.

2. The State began participation in seroprevalence surveys with the Center for Disease Control (CDC) in 1987. Data from these surveys indicate that the State needs to continue to monitor the prevalence of infection in targeted at-risk individuals, such as homosexual/bisexual men, IV drug users, clients in Sexually Transmitted Diseases (STD) and Tuberculosis (TB) clinics, and women seeking prenatal and family planning services. Data collected in seroprevalence surveys should be used to target populations and geographic areas in need of HIV/AIDS prevention and educational efforts.

3. The State needs to establish interventions to prevent the transmission of HIV from infected individuals to their sexual and/or needle sharing partners. This need can be addressed by HIV counseling/testing and partner notification services.

4. Since AIDS is only the end of a spectrum of viral infection, the State needs to continue to monitor HIV infection through established reporting mechanisms. Physicians, laboratories, and others required by law to report should do so promptly to the Alabama Department of Public Health.

5. Even if a vaccine were available for HIV/AIDS, efforts to prevent transmission of the HIV virus must rely heavily on education. Educational efforts must be targeted at the general community as well as to designated at-risk individuals and populations. Targeted educational messages must be specific, culturally sensitive and stress how the virus is transmitted and ways to reduce or eliminate the risk of transmission. Information directed at the general populace should not only focus on how the virus is transmitted and ways to reduce individual risk, but also stress how the virus is not transmitted so that discrimination, stigmatization and ostracism of infected individuals are eliminated. The Alabama Department of Public Health should serve as the focal point for HIV/AIDS educational and informational activities.

6. The Alabama Department of Public Health has established a multiagency task force (Alabama AIDS Prevention Network) which should serve to evaluate the effect of HIV/AIDS infection on the health care needs of Alabama and its impact on the state's health care resources. A system of community-based care for infected individuals must be established and maintained utilizing home health services, Medicaid waiver programs, long-term care facilities, hospice programs, and volunteer agencies.

7. Legislation defining the right of access to HIV information for individuals who have a compelling need to know was passed in late 1991. The State needs to continue to monitor and refine this legislation in order to allow exchange of "needed" information, but in a manner, which will protect confidentiality and prevent discrimination against the HIV infected.

Author: Statewide Health Coordinating Council (SHCC).

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

History: Filed October 18, 2004; Effective November 22, 2004. Amended (SHP Year Only): Filed December 2, 2014; Effective January 6, 2015. Repeal and New: Filed March 16, 2020; Effective May 15, 2020.

#### 410-2-2-.06 Health Care for the Medically Indigent

#### (1) The Problem

(a) There have been studies and estimates to determine the number of medically uninsured and underinsured, both in Alabama and nationally. Although the statistics may vary among the various studies, the conclusions are all consistent in that a large percentage of the population has either no health insurance coverage or the coverage is inadequate. According to the July 2018 U. S. Census Bureau's *Quick Fact Sheet on Alabama*, the uninsured population under age 65 is 12.0% of the total population of 4,887,871. Most of the uninsured were found in families where at least one person is employed, and most of the employed worked in small businesses. In 2010, the Congress passed the Patient Protection and Affordable Care Act, which ensured coverage for pre-existing conditions and dependent coverage under a parent's policy through age 25, which reduced the number of uninsured.

Lack of health insurance coverage, including mental health coverage, (b)contributes significantly to uncompensated care provided by those who deliver needed health care. The uninsured and underinsured often fail to seek needed health care services early when treatment is generally less expensive and more effective. The financial impact of the uninsured in Alabama is shown by 2018 data compiled by the Alabama Medicaid Agency. Total uncompensated care in Alabama was estimated to be \$712 million. This number represents the total cost of care for charity care and bad debt, as defined by Medicare, as reported on Medicare Cost Reports filed by the ninety (90) acute care hospitals in Alabama with Medicare, a copy of which is also filed annually with the Alabama Medicaid Agency. This number, however, only reflects the cost for hospital care (not charges) and does not include other uncompensated health care costs from other providers including: Community Mental Health Centers, Psychiatric Hospitals, Nursing Homes, clinics operated by the Alabama Department of Public Health, Federally Qualified Health Clinics (FOHCs), Residential Treatment Facilities, and others. Also, according to the Alabama Medicaid Agency, Medicaid is required to provide to the Centers for Medicare and Medicaid Services (CMS) an audit of uncompensated care, called a DSH (Disproportionate Share Hospital) audit. This audit is used to justify DSH payments from the Federal Government which are used to reimburse hospitals for uncompensated care provided to uninsured patients. The definitions for uncompensated care in this instance are different than those used in the Medicare Cost Reports, but is the amount that Medicaid is accountable for with respect to uncompensated care. Utilizing this measure, the total Uninsured Uncompensated care hospital cost included in the audit for Fiscal Year 2015 was \$510 million. Based upon this audit, hospitals in Alabama did receive a Federal DSH allotment of \$333 million to partially offset the cost. Without Congressional action, however, reductions amounting to approximately forty percent (40%) of the Federal DSH allotments are required to take place in Fiscal Year 2020. According to Medicaid, current expectations are that these scheduled reductions will be deferred for one or two years.

(c) Providers should pursue collections based upon economic-means based policies in order to recover part of the cost of uncompensated care, and according to generally accepted standards. Bad debt is an increasing problem for Alabama providers.

(d) Bad debt is the unpaid charges/rates for services rendered from a patient and/or third-party payer, for which the provider reasonably expected payment.

(e) Charity care is defined as health services for which a provider's policies determine a patient is unable to pay. Charity care could result from a provider's policies to provide health care services free of charge to individuals who meet certain preestablished criteria as required by the 2010 Patient Protection and Affordable Care Act. Charity care is measured as revenue forgone, at full-established rates or charges. Charity care would not include contractual write-offs, but could include partial write-offs for persons unable to pay the full amount of a particular patient's bill.

(f) Uncompensated care is the combination of charity care and bad debt.

(g) Each county is responsible for indigent residents.

1. Article 7 Title 21 – Hospital Service Program for Indigents (§ 22-21-210), et seq.

2. Article 10 Title 21 – Financial Responsibility for Indigent Healthcare (§ 22-21-290), et seq.

#### (2) **Recommendations**

(a) The SHPDA should work with other state agencies to develop a database to determine the nature and extent of uncompensated care in Alabama and to monitor changes in the level of uncompensated care over time.

(b) The State is examining ways to encourage provision of medical insurance through employers and ways to more effectively utilize public funding sources.

(c) The State is examining establishment of a risk pool for small employers and for individuals who lose employer-provided insurance.

(d) The Statewide Health Coordinating Council believes that access to care, which is mandated as a part of the Certificate of Need (CON) Review process shall include the historical and projected charity care provided by each CON applicant and the impact each CON approval will have on access to health care for the medically indigent.

(e) Counties are encouraged to provide adequate resources to fulfill obligations in accordance with the following state statutes:

1. Article 7 Title 21 known as Hospital Service Program for Indigents (§ 22-21-210), et seq.

2. Article 10 Title 21 Financial Responsibility for Indigent Healthcare (§ 22-21-290), et seq.

Author: Statewide Health Coordinating Council (SHCC).

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

History: Filed October 18, 2004; Effective November 22, 2004. Amended (SHP Year Only): Filed December 2, 2014; Effective January 6, 2015. Repeal and New: Filed March 16, 2020; Effective May 15, 2020.

# 410-2-2-.07 Substance Use Disorders

(1) According to the 2018 National Survey on Drug Use and Health nearly one (1) in five (5) people aged 12 or older (19.4%) used some form of illicit drug in 2018, which is an increase from 2015 - 2016. Deaths from opioid overdoses alone were more than 42,000 in 2016.<sup>9</sup> In Alabama the death rate from drug overdoses climbed 82% from 2006 to 2014. The drug crisis affects Alabama hospitals, schools, prisons, and businesses.<sup>10</sup> (Unless otherwise stated, all statistics related to substance use disorders quoted in this section come from the 2018 National Survey on Drug Use and Health).

(2) During 2018, approximately 20.3 million people aged 12 or older had a substance use disorder (SUD) related to use of alcohol or illicit drugs during the previous year, including 14.8 million people with an alcohol use disorder and 8.1 million people with an illicit drug use disorder. The most common illicit drug use disorder reported was the misuse of marijuana (4.4 million people). An estimated 2.0 million people reported an opioid use disorder, including 1.7 million people with a prescription pain reliever use disorder and an additional 500,000 people with a heroin use disorder.

(3) In terms of recent initiates (new users within the previous year) to use or misuse of substances, the substances most used or misused were alcohol (4.9 million new users), marijuana (3.1 million new users), prescription pain relievers (1.9 million new misusers), and cigarettes (1.8 million new users). According to the Substance Abuse and Mental Health Services Administration ("SAMHSA"), in 2018 more than 4 out of 5 people aged 12 or older perceived great risk of harm from weekly use of either cocaine (86.5%) or heroin (94.3%), while less than one-third of people perceived great risk of harm from weekly marijuana usage (30.6%). Approximately 2 out of 3 people perceived a great risk from daily binge drinking (68.5%), and nearly 3 out of 4 people perceived great risk from smoking one or more packs of cigarettes daily (71.8%).

(4) Substance abuse is more common among both adolescents and adults who have a co-occurring mental health issue than among those who do not. Adolescents with a mental health issue were reported as more likely to binge drink (8.5%) or use an illicit drug (32.7%) versus those who do not report a mental health issue (binge drinking 4.1%, illicit drug use 14%). Similar difference in use are reported for adults aged 18 and older.

(5) According to SAMHSA, in 2018 an estimated 21.2 million people aged 12 and older needed substance use treatment in America (7.8%). This includes approximately 3.8% of adolescents aged 12 - 17; 15.3% of young adults aged 18 - 25; and 7% of adults aged 26 and older. Of these, approximately 3.7 million people in America aged 12 and older received treatment for substance use (1.4%), 2.4 million of whom received treatment at a specialty facility. Among the estimated 18.9 million people aged 12 and older who needed substance use treatment but did not receive any, approximately 964,000 perceived a need for treatment. Of those, approximately 40% did not receive treatment because they were not ready to stop using, and approximately one-third had no health care coverage and were not able to afford the cost of treatment.

<sup>&</sup>lt;sup>9</sup> 2018 National Survey of Drug Use and Health, Substance Abuse and Mental Health Services Administration (SAMHSA), Department of Health and Human Services (HHS). 2018.

<sup>&</sup>lt;sup>10</sup> State of Alabama Opioid Action Plan, produced by the Alabama Opioid Overdose and Addiction Council, 2017.

(6) The State should encourage and promote a variety of treatments for SUD. Traditional treatments for SUD include abstinence-based systems such as 12-step programs. Methadone has been used successfully in recent years, especially for severe cases. SAMHSA has recently reported significant success with Medication-Assisted Treatment (MAT) which uses medications (primarily buprenorphine), in combination with counseling and behavioral therapies, to provide a "whole-patient" approach to the treatment of substance use disorders. Research shows that a combination of medication and therapy can successfully treat these disorders, and for some people struggling with addiction, MAT can help sustain recovery.

(7) Marijuana. The primary illicit drug used in 2018 was marijuana, with more than 43.5 million reported users within the previous year. The percentage of people aged 12 or older reporting marijuana usage within the previous year (15.9%) was higher than percentages reported to SAMHSA from 2002 - 2017. The increase is primarily due to increases reported in young adults (aged 18 - 25) as well as in adults (aged 26 or older). By comparison, and in contrast to these numbers, adolescents aged 12 - 17 did not show an increase in usage between 2014 - 2018.

(8) Prescription Drugs. The second most reported form of illicit drug usage in 2018 was misuse of prescription pain relievers, with 3.6% of the population reporting illicitly using prescription pain relievers within the last year. For all people aged 12 or older, and for young adults aged 18 - 25, the percentage of the population reporting illicit usage of prescription pain relievers decreased in 2018 compared to 2015 - 2017. Similar decreases were reported for adolescents aged 12 - 17 and for adults aged 26 or older compared to 2015 - 2016 but are similar to the percentages reported in 2017. Among all people aged 12 or older in 2018 who misused pain relievers in the last year, a significant majority (63.6%) reported that the main reason for misuse was to relieve physical pain. More than half of people who misused pain relievers in the last year (51.3%) reported obtaining the pain relievers from a friend or relative.

(9) According to the Alabama Department of Public Health ("ADPH") 2017 Overdose Surveillance Summary, 836 people in Alabama died of an overdose, 419 of which involved opioids. The top four (4) drugs related to overdose deaths in 2017 were fentanyl (161 deaths); heroin (128 deaths); methamphetamine (110 deaths); and cocaine (98 deaths). Additionally, in 2018 there were 11,081 visits to hospital emergency departments in Alabama related to overdoses, with, 2,180 involving opioids. There was a total of 20,353 overdose-related 911 runs in 2018, with 4,373 involving opioids. In 2017, the rate of drug overdose deaths in Alabama was 17.1 per 100,000 population, an increase from both 2016 (15.4 per 100,000) and 2015 (14.9 per 100,000). The rate for opioid deaths in Alabama in 2017 (8.6 per 100,000 population) was also an increase from both 2016 (7.0 per 100,000) and 2015 (5.7 per 100,000).

## (10) **Opioid Abuse**

(a) Opioids are a class of drugs that include heroin as well as prescription pain relievers such as oxycodone, hydrocodone, morphine and fentanyl. These drugs work by binding to the body's opioid receptors in the reward center of the brain, diminishing pain as well as producing feelings of relaxation and euphoria While most overdose deaths are caused by illegal drugs, many people first become addicted to opioids by using prescription drugs that were legally obtained. (b) According to the Alabama Opioid Overdose and Addiction Council, over 42,000 Americans died from opioid overdoses in 2016. According to SAMHSA, approximately 10.3 million people aged 12 or older misused opioids in 2018. This number corresponds to approximately 3.7 percent of the population. Of these, the vast majority (9.9 million users) misused prescription pain relievers, compared to a much smaller population (808,000) who used heroin. The majority of people who misuse prescription pain relievers (9.4 million) had not used heroin, but a small number (506,000) misused prescription pain relievers and used heroin within the last year. Among those 12 - 17 years old, approximately 699,000 adolescents misused opioids within the last year, with another 1.9 million young adults between the ages of 18 - 25 also misusing opioids.

(c) In the state of Alabama, the number of drug overdose deaths, including opioid deaths, climbed eighty-two percent (82%) from 2006 to 2014. According to the Alabama Department of Mental Health ("ADMH") Substance Abuse Division, in 2018 4,546 individuals were treated by the department, or by entities contracted by the department, for heroin addiction with an additional 7,082 treated for addiction to other opiates and synthetics. These statistics, however, do not include individuals not treated by the department or its contracted entities. These individuals make up approximately thirty-four percent (34%) of the patients that received treatment for substance use related disorders by ADMH or contracted entities.

(d) Currently ADMH works with eighty-three (83) Certified and Contract entities to provide services to individuals suffering from substance use disorders, providing substance abuse treatment, medication assisted therapy and prevention services. An additional eleven (11) providers are certified to provide prevention or treatment services to patients, but do not receive funding from the Department. There are twenty-one (21) Opioid Replacement Therapy (ORT) clinics throughout the state that specifically target individuals suffering from Opioid Use Disorders. Additionally, there are nineteen (19) public, non-profit regional mental health boards, called 310 boards, throughout the state. Of these, fourteen (14) provide substance abuse treatment services. Birmingham and Tuscaloosa have regional boards, with additional mental health centers attached to them.

(e) Governor Ivey created the Alabama Opioid Overdose and Addiction Council through Executive Order 708 on August 8, 2017. The Council, co-chaired by the Commissioner of the Alabama Department of Mental Health, the Attorney General of Alabama, and the State Health Officer, was created to "study the State's current opioid crisis and identify a focused set of strategies to reduce the number of deaths and other adverse consequences of the opioid crisis in Alabama." The Council was given a set of directives related to this purpose, including:

1. Advise and assist the Governor in the development of a comprehensive, coordinated strategy to combat Alabama's opioid crisis;

2. Gather and review data characterizing the opioid crisis facing Alabama, including the threat of synthetic opioids;

3. Review strategies and actions already taken in Alabama to combat the opioid crisis;

4. Review strategies and actions of other States and the National Governor's Association Compact to Fight Opioid Addiction; and

5. Develop a comprehensive strategic plan to abate the opioid crisis in Alabama.

(f) The State of Alabama Opioid Action Plan, created by the Alabama Opioid Overdose and Addiction Council and published December 31, 2017, describes a fourpronged approach to addressing the current opioid crisis in Alabama. The four prongs to the approach described by the council are:

1. Prevention of opioid misuse. Including strategies to modernize the state's Prescription Drug Monitoring Program (PDMP) to fully realize technological improvements in how prescription opioids are prescribed and dispensed, continuing improvements in the education of prescribers and prescribers-in-training, the reduction of stigma attached to opioid addiction, and the development of a centralized data repository that can be used to understand and combat the problem;

2. Intervention within the law enforcement and justice systems. Addressing drug trafficking laws and working with drug courts in Alabama to encourage the use of medication assisted treatment (MAT) for those with Opioid Use Disorders (OUD);

3. Treatment of those with OUDs. Increasing access to care for those with OUD in Alabama and encouraging the use of evidence-based practices to improve the identification and treatment of those with OUD; and

4. Community Response that engages ordinary Alabamians to become involved with finding solutions at a local level. Focus on expanding the availability and usage of naloxone (a potentially life-saving opioid reversal drug); the building of partnerships with businesses, educational institutions and community organizations to improve awareness and involvement; and encouragement for counties to adopt the Stepping Up Initiative, which provides tools to create data driven strategies that work within the judicial system.

(g) ADMH has received several grants in recent years in order to combat substance use disorders, including the State Opioid Response Grant, the Medication Assisted Treatment Prescription Drug Opioid Abuse grant (in specific counties), another grant to expand Drug Courts into specific rural counties, as well as grants from both the USDA (to provide telehealth equipment in specific counties) and the CDC (in partnership with ADPH to provide peer counseling in Emergency Departments).

(h) In 2019, Governor Ivey secured funding in the state's operating budget to improve the Prescription Drug Monitoring Program to, in part, make it easier to use for both physicians and pharmacists. Also, Governor Ivey signed a law making it a crime to traffic in either fentanyl or carfentanil, which are synthetic opioids with a higher potency than heroin. The new law makes it a felony to knowingly possess more than a half gram of fentanyl or a related synthetic opioid. Both Acts were directly recommended by the Alabama Opioid Overdose and Addiction Council.

(i) ADMH recently partnered with Auburn University to create the Opioid Training Institute, providing education to both community members and health care professionals about the current status of opioid abuse in Alabama and to provide strategies and solicit ideas on how to combat the crisis moving forward. The Department has also worked with ADPH to supply naloxone to first responders throughout the state in order to improve access to a potentially life-saving drug to any law enforcement or medical professional who may be called upon to assist an individual suffering from an opioid overdose.

# (11) Methamphetamine Use

(a) Methamphetamine is a potent stimulant with high abuse potential that can be smoked, snorted, injected, or taken orally. The desirable short-term effects of Methamphetamine or initial "rush" is characterized by increased energy and alertness, elevated positive mood state, and decreased appetite.<sup>11</sup>

(b) According to SAMHSA, in 2018 approximately 1.9 million people aged 12 or older used methamphetamines in the past year. This number corresponds to approximately 0.7% of the population. These numbers have not appreciably changed between 2015 and 2018. Among younger users, approximately 43,000 adolescents between the ages of 12 and 17 used methamphetamine in the last year, and approximately 237,000 young adults between the ages of 18 and 25 used methamphetamines in the last year. In both cases, the percentages of the population using methamphetamines in the last year have not appreciably changed between 2015 and 2018.

(c) In the last two years, the number of people abusing methamphetamine in Alabama has outnumbered the number of people abusing other drugs such as cocaine, heroin and marijuana. Most of the users of crystal meth in Alabama are people between 18 and 25 years of age.

(12) Ecstasy. Ecstasy abuse in Alabama continues to increase. Ecstasy, as well as similar drugs such as LSD, GHB, and ketamine are primarily abused in night club settings and are

<sup>&</sup>lt;sup>11</sup> Rawson RA, Gonzales R, McCann MJ, Obert J. *Methamphetamine use among treatment-seeking adolescents in Southern California: participant characteristics and treatment response*. Journal of Substance Abuse Treatment. 2005; 29:67–74.

often referred to as "club drugs." Arrests, overdoses and emergency room visits for club drugs have mirrored the increase in use. Ecstasy remains the leading number one club drug, followed by GHB.<sup>12</sup> GHB overdoses have been reported in several areas of the state.

(13) Cocaine. Cocaine is among Alabama's most significant drug threats. Cocaine is widely available throughout Alabama, as it ranks second for the number of drug addiction treatment admissions. In 2010, 2,108 individuals were treated for smoking cocaine with an additional 842 people treated for using cocaine through other routes of ingestion.

(14) Heroin. Heroin abuse, use, and sales have skyrocketed across the nation. In fall of 2015, police departments across Alabama were expressing concern over the growing number of deaths across all counties.

# (15) Alcohol Abuse

(a) According to SAMHSA, in 2018 approximately 139.8 million Americans aged 12 and older used alcohol in the month prior to being surveyed, 67.1 million were binge drinkers during the same time period, and 16.6 million were heavy drinkers during the same time period. Approximately 2.2 million adolescents aged 12 - 17 drank alcohol within the previous month, with 1.2 million of those binge drinking. For the purposes of the survey, binge drinking was defined having had five (5) or more drinks on the same occasion on at least one (1) of the previous thirty (30) days. Heavy alcohol use is defined as binge drinking on five (5) or more days during the previous thirty (30) days.

(b) SAMHSA data from 2015 - 2016 indicates that approximately 43.94% of Alabamians ages 12 and older reported using alcohol within the previous month. For adolescents aged 12 - 17, the same survey indicates that 8.08% used alcohol within the previous month, and for young adults ages 18 - 25, approximately 50.76% used alcohol within the previous month. Approximately 4.16% of Alabamians ages 12 and over were reported to suffer from alcohol use disorder in 2015 - 2016, with adolescents aged 12 - 17 being affected at a rate of 1.67% and young adults aged 18 - 25 affected at a rate of 9.08%<sup>13</sup>. All of these rates are reported as being lower than the national and regional averages for both alcohol use and alcohol use disorder.

# (16) Tobacco

(a) More people die every year from smoking than from murder, AIDS, suicide, car crashes, and alcohol combined.<sup>14</sup> Alabama has the 8<sup>th</sup> highest adult smoking prevalence rate in the nation.

<sup>&</sup>lt;sup>12</sup> Downloaded from Addictionrecovery.net, November 11, 2019.

<sup>&</sup>lt;sup>13</sup> Alabama Drug Abuse Statistics, 2019, www.recoveryconnection.com: owned and operated by Lakeview Health.

<sup>&</sup>lt;sup>14</sup> Alabama Department of Public Health. 2019

(b) ADPH reports that 21.5% of adults in Alabama are current cigarette smokers. An estimated 23.3% of males and 20.0% of females smoke. From 1996 to 2016 adult smoking prevalence fell on average only 0.2% per year and 10.9% of high school students are current smokers.<sup>15</sup> According to the 2018 National Center for Health Statistics, 10.1% of mothers reported smoking during pregnancy.

(c) A key focus area for the state should be the impact of smoking on Alabama's youth. According to the 2016 Youth Tobacco Survey (YTS), 10.9% of high school students are current smokers. There was a significant difference in smoking prevalence between males (12.9%) and females (8.8%) in high school whereas the prevalence in middle school were very similar (3.4%). Also, the smoking disparity among racial/ethnic groups increased in high school where white students (14.3%) were twice as likely to smoke compared to African American (5.4%) and Hispanic students (7.5%).

(d) Additionally, secondhand smoke creates significant problems for Alabama citizens. Secondhand smoke kills over 750 nonsmoking Alabamians each year. Children exposed to secondhand smoke are at an increased risk for Sudden Infant Death Syndrome, acute respiratory infections, ear problems, severe asthma, and reduced lung function.

(e) The use of tobacco creates an economic burden on the State as well. ADPH estimates that \$5.16 billion in excess personal medical care expenditures were attributable to smoking. There are an estimated \$887.9 million in productivity losses as a result of smoking-attributable premature death. An additional \$1.33 billion in productivity losses were estimated as a result of smoking-attributable illnesses. And \$187.5 million in economic costs were attributed to personal medical costs and productivity losses associated with secondhand smoke. The total annual economic impact of smoking in Alabama is estimated to be \$7.6 billion.<sup>16</sup>

(f) Recent research has shown that youth prevalence rates in Alabama have decreased substantially, although this is known to be somewhat offset by a rise in the use of e-cigarettes among young people in particular. The increase in the state's tobacco tax rate is expected to continue to help reduce young people's initiation of tobacco use and will likely generate an estimated \$62 million of revenue annually.

(g) Efforts to address the tobacco problem in Alabama have been led by ADPH. The Alabama State Plan for Tobacco Prevention and Control is the result of the efforts of the Alabama Tobacco Use Prevention and Control Task Force. The task force is composed of agents of ADPH and its national, state, and local partners. Representatives of task force partner organizations met in March of 2015 to review the state's progress regarding tobacco prevention and control and update the previous plan drafted in 2010.

(h) One of the key partners ADPH is coordinating with is the Tobacco Prevention and Control (TPC) Branch of North Carolina Department of Health and Human

<sup>&</sup>lt;sup>15</sup> 2016 Behavioral Risk Factor Surveillance System (BRFSS), Centers for Disease Control.

<sup>&</sup>lt;sup>16</sup> Dunlap, S.T. & McCallum, D. (2019). *Update: The Burden of Tobacco in Alabama, 2019*. Tuscaloosa, AL: Institute for Social Science Research, University of Alabama.

Services. The TPC works with local coalitions, community agencies, and state and national partners to implement and evaluate effective tobacco prevention and cessation activities that meet the following goals:

- 1. Eliminating environmental tobacco use exposure.
- 2. Promoting quitting among adults and youth.
- 3. Preventing youth initiation.
- 4. Identifying and eliminating disparities among populations.

(i) Another initiative that Alabama should support is the Federal Drug Administration's Youth Tobacco Prevention Plan, a series of actions to stop youth use of tobacco products, especially e-cigarettes, with special focus on three key areas:

- 1. Preventing youth access to tobacco products.
- 2. Curbing marketing of tobacco products aimed at youth.

3. Educating teens about the dangers of using any tobacco product, including e-cigarettes, as well as educating retailers about their key role in protecting youth.

(j) While the ADPH efforts have had some minor success, the state still trails the country in its efforts to reduce tobacco related illness and death. The State Plan for Tobacco Prevention and Control may be seen as an important step in the process of moving the state along the right track toward reaching those goals.

# (17) Vaping

(a) E-cigarettes are battery-powered devices that allow users to inhale aerosolized liquid. E-cigarettes are also called vapes, vape or hookah pens, electronic nicotine delivery systems (ANDS), mods, vaporizers, and tank systems. Even though e-cigarettes do not contain any tobacco, the Food and Drug Administration (FDA) classifies them as "tobacco" products. The amount of nicotine provided by e-cigarettes varies by device.

(b) These devices have become the most used tobacco product among Alabama youth in the past few years. Until recently these devices were not regulated as typical tobacco products. In fact, the e-cigarettes are not currently listed in any sections of the State's statutes included in the definition of "Tobacco Products." Originally e-cigarettes were offered as an alternative to regular tobacco products as a means of assisting in smoking cessation. Their popularity, especially among youth, has overtaken any effort to reduce smoking and tobacco addiction.

(c) According to the American Cancer Society the possible long-term health effects of e-cigarettes aren't yet clear, but there have been recent reports of serious lung disease in some people using e-cigarettes or other vaping devices. Symptoms have included:

- 1. Cough, trouble breathing, or chest pain;
- 2. Nausea, vomiting, or diarrhea; and
- 3. Fatigue, fever, or weight loss

(d) Furthermore, recent reports show nicotine exposure can harm brain development and as a result is more harmful to adolescents. Nicotine can also cause harmful physical effects to the cardiovascular and central nervous system. Eating, drinking, or absorbing nicotine in any way can lead to nicotine poisoning, especially in children. If used during pregnancy, nicotine may also cause premature births and low birthweight babies.

(e) Nicotine, the main drug in tobacco products and e-cigarettes, is known to be highly addictive. Developing adolescent and young adult brains are even more susceptible. In addition to being highly addictive, the American Cancer Society reports that nicotine is a major carcinogen and can cause lung disease, heart disease, and cancer.

(f) Besides nicotine, e-cigarettes and e-cigarette vapor contain propylene glycol and/or vegetable glycerin. These are substances which have been found to increase lung and airway irritation after concentrated exposure.

(g) In addition, e-cigarette and e-cigarette vapor may contain the chemicals or substances listed below:

1. Volatile organic compounds (VOCs): at certain levels, VOCs can cause eye, nose and throat irritation, headaches and nausea, and can damage the liver, kidney and nervous system.

2. Flavoring chemicals: some flavorings are more toxic than others. Studies have shown that flavors contain different levels of a chemical called diacetyl that has been linked to a serious lung disease called bronchiolitis obliterans.

3. Formaldehyde: this is a cancer-causing substance that may form if eliquid overheats or not enough liquid is reaching the heating element (known as a "dry-puff").

(h) The FDA does not currently require e-cigarette manufacturers to stop using potentially harmful substances. And, it is difficult to know exactly what chemicals are in an e-cigarette because most products do not list all of the harmful or potentially harmful substances contained in them.

(i) The Stringer-Drummond Vaping Act, HB41, passed in May 2019. It requires the Alabama Alcoholic Beverage Control Board to regulate retail sales of alternative nicotine devices like sales of tobacco products and prohibits the sale or transfer of alternative nicotine products to minors. The law also prohibits retailers and manufacturers of alternative nicotine products and electronic nicotine delivery systems from advertising the products near schools; and to prohibit specialty retailers of electronic nicotine delivery systems from opening new places of business near schools, child care centers, churches, and other facilities. The law prevents retailers and manufacturers of alternative nicotine products or electronic nicotine delivery systems from advertising those products as tobacco cessation devices as a healthy alternative to smoking. E-cigarettes may only be sold in tobacco, mint, or menthol flavors.

(j) The Stringer-Drummond Act also requires retailers of alternative nicotine products or electronic nicotine delivery systems to obtain a tobacco permit, to comply with FDA regulations governing the retail sale of alternative nicotine products and electronic nicotine delivery systems. Vendors must post warning signs in their stores regarding the dangers of nicotine use and potential risks associated with vaping.

(k) Under the Act, anyone selling e-cigarettes is prohibited to sell or transfer alternative nicotine products or electronic nicotine delivery systems to minors; and in connection therewith would have as its purpose or effect the requirement of a new or increased expenditure of local funds within the meaning of Amendment 621 of the Constitution of Alabama of 1901, now appearing as Section 111.05 of the Official Recompilation of the Constitution of Alabama of 1901, as amended.

(1) ADPH recently recommended that all consumers consider refraining from the use of electronic cigarette and vape products until national and state investigations into vaping-related deaths and illnesses are complete. This recommendation came after the Centers for Disease Control and Prevention reported a cluster of severe pulmonary disease among people who use e-cigarettes or vape products, with more than 800 cases of lung injury reported from forty-six states and one U. S. territory. Two-thirds of cases are 18 - 34 years old, and twelve (12) deaths had been confirmed by September 2019 in ten (10) states.

Author: Statewide Health Coordinating Council (SHCC). Statutory Authority: § 22-21-260(4), Code of Alabama, 1975. History: Repeal and New: Filed March 16, 2020; Effective May 15, 2020.

### 410-2-2-.08 RESERVED

Author: Statewide Health Coordinating Council (SHCC).

Statutory Authority: § 22-21-260(15), Code of Alabama, 1975.

History: Filed February 13, 2014; Effective March 20, 2014. Amended (SHP Year Only): Filed December 2, 2014; Effective January 6, 2015. Repeal and New: Filed March 16, 2020; Effective May 15, 2020.

#### ALABAMA STATE HEALTH PLAN 2024-2027 STATE HEALTH PLANNING AND DEVELOPMENT AGENCY

## 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: § 22-21-260(4), Code of Alabama, 1975.

History: Filed October 18, 2004; Effective November 22, 2004. Amended (SHP Year Only): Filed December 2, 2014; Effective January 6, 2015. Repeal and New: Filed March 16, 2020; Effective May 15, 2020.

### 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; parentsibling-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 preconceptional, 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 childbearing 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: § 22-21-260(4), Code of Alabama, 1975.

History: Filed October 18, 2004; Effective November 22, 2004. Amended (SHP Year Only): Filed December 2, 2014; Effective January 6, 2015. Repeal and New: Filed March 16, 2020; Effective May 15, 2020.

#### 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. 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 openheart 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: § 22-21-260(4), Code of Alabama, 1975.

History: Filed October 18, 2004; Effective November 22, 2004. Amended: Filed February 1, 2013; Effective March 8, 2013. Amended (SHP Year Only): Filed December 2, 2014; Effective January 6, 2015. Repeal and New: Filed March 16, 2020; Effective May 15, 2020.

## 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: § 22-21-260(4), Code of Alabama, 1975.

History: Filed October 18, 2004; Effective November 22, 2004. Amended (SHP Year Only): Filed December 2, 2014; Effective January 6, 2015. Repeal and New: Filed March 16, 2020: Effective May 15, 2020.

#### 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 <u>Code of Alabama</u>, 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, <u>Code of Alabama</u>, 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 x 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		240 Available Dialysis Treatments/Week
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:	$\frac{50}{150}$
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: § 22-21-260(4), Code of Alabama, 1975.

History: 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. Statistical Update: December 3, 2012; August 11, 2014; August 4, 2015. Repeal and New: Filed March 16, 2020; Effective May 15, 2020.

## 410-2-3-.06 RESERVED

Author: Statewide Health Coordinating Council (SHCC).

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

History: Filed October 18, 2004; Effective November 22, 2004. Amended (SHP Year Only): Filed December 2, 2014; Effective January 6, 2015. Repeal and New: Filed March 16, 2020; Effective May 15, 2020.

## 410-2-3-.07 RESERVED

Author: Statewide Health Coordinating Council (SHCC).

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

History: Filed October 18, 2004; Effective November 22, 2004. Amended (SHP Year Only): Filed December 2, 2014; Effective January 6, 2015. Repeal and New: Filed March 16, 2020; Effective May 15, 2020.

### 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, <u>Code of Alabama</u>, 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, <u>Code of Alabama</u>, 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, <u>Code of Alabama</u>, 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: § 22-21-260(4), Code of Alabama, 1975.

History: Filed October 18, 2004; Effective November 22, 2004. Amended (SHP Year Only): Filed December 2, 2014; Effective January 6, 2015. Repeal and New: Filed March 16, 2020; Effective May 15, 2020.

### 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: § 22-21-260(4), Code of Alabama, 1975.

History: Filed October 18, 2004; Effective November 22, 2004; Amended (SHP Year Only): Filed December 2, 2014; Effective January 6, 2015. Repeal and New: Filed March 16, 2020, Effective May 15, 2020.

## 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 = Hospice Deaths by County/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	STREET ADDRESS
(U. S. Postal Service)	(Commercial Carrier)
PO BOX 303025	100 NORTH UNION STREET, SUITE 870
MONTGOMERY, AL 36130-3025	MONTGOMERY, AL 36104
TELEPHONE:	FAX:
(334) 242-4103	(334) 242-4113
EMAIL:	WEBSITE:
data.submit@shpda.alabama.gov	http://www.shpda.alabama.gov

Author: Statewide Health Coordinating Council (SHCC).

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

History: Filed October 18, 2004; Effective November 22, 2004. Amended: Filed February 1, 2010; Effective March 8, 2010. Amended: Filed January 24, 2012; Effective: February 28, 2012. Amended: Filed February 1, 2013; Effective March 8, 2013. Amended: Filed February 13, 2014; Effective March 20, 2014. Amended: Filed: December 2, 2014; Effective: January 6, 2015. Repeal and New: Filed March 16, 2020; Effective May 15, 2020.

# 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: § 22-21-260(4), Code of Alabama, 1975.

History: Filed October 18, 2004; Effective November 22, 2004. Amended (SHP Year Only): Filed December 2, 2014; Effective January 6, 2015. Repeal and New: Filed March 16, 2020; Effective May 15, 2020.

#### ALABAMA STATE HEALTH PLAN 2024-2027 STATE HEALTH PLANNING AND DEVELOPMENT AGENCY

#### Chapter 410-2-4 Facilities

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#### 410-2-4-.01 Introduction.

This chapter focuses on existing health care facilities and the need for additional facilities. Methodologies for many facilities, i.e., general hospitals, nursing homes, specialty care assisted living facilities, rehabilitation, psychiatric and substance abuse, are specific in nature and project a finite number of beds needed. Swing beds, Long Term Acute Care Hospital beds, and Critical Care Access Hospital beds are allowed for hospitals which meet the criteria as specified in the appropriate Federal Directive. The home health methodology is based on upon a minimum level of utilization.

Author: Statewide Health Coordinating Council (SHCC).

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

History: Filed October 18, 2004; Effective November 22, 2004. Amended (SHP Year Only): Filed December 2, 2014; Effective January 6, 2015. Repeal and New: Filed March 16, 2020; Effective May 15, 2020.

# 410-2-4-.02 Acute Care (Hospitals)

# (1) Introduction.

In this section, the methodology for computing acute care bed need will be described, and criteria for making adjustments to the computed bed need will be discussed.

(a) Definition: Hospital

Defined as printed in Rules of Alabama State Board of Health Division of Licensure and Certification Chapter 420-5-7 (effective August 26, 2013):

"Hospital" means a health institution planned, organized and maintained for offering to the public, facilities and beds for use in the diagnosis and treatment of patients requiring in-patient medical care, out-patient medical care, or other care performed by or under the supervision of physicians due to illness, disease, injury, deformity, abnormality, or pregnancy.

# (2) Purpose

(a) The purpose of the bed need methodology is to identify the number of acute general hospital beds needed at least three years into the future to assure the continued availability of quality hospital care for residents of the state of Alabama. Such number, as identified later in this section, shall be the basis for statewide health planning and certificate of need approval, except:

1. in circumstances that pose a threat to public health, and/or

2. when the SHCC makes an adjustment based on criteria specified later in this section.

# (3) Methodology

(a) The planning area used in this methodology is the county with the exception of certain counties which are grouped together into one planning area due to a current or previous lack of an extant hospital in the area: Calhoun/Cleburne, Fayette/Lamar, Houston/Henry, Lee/Macon, Marengo/Choctaw/Perry, Montgomery/Lowndes, and Tallapoosa/Coosa.

(b) The methodology involves:

# applying recent utilization data to projected population and using desired occupancy rates to determine needed beds.

(c) Hospital annual reports (Form BHD 134-A) for the past three years, are used in computing a three-year weighted average daily census (ADC) to provide the utilization measure. The weighted average emphasizes the most current census levels while taking into consideration census for the previous two years.

(d) Desired occupancy rates for each of eight service categories are those which were established under the National Guidelines for Health Planning. These are:

Medical/Surgical (M/S)	80%
M/S in Small Hospitals (under 4,000 total admissions/yr.)	75%
Obstetrics	75%
Pediatrics 0-39 beds 40-79 beds	65% 70%
80 or more beds ICU-CCU	75% 65%
Other	75%

- (e) Computations by Service Category
  - 1. Compute Average Daily Census (ADC) for each of last three years.

ADC = <u>Patient Days in Service Category</u> Days Operational in Year (normally 365)

2. Compute Weighted Average ADC (Weighted ADC).

### (Current Year minus 2 Years ADC x 1) + (Previous Year ADC x 2) + (Current Year ADC x 3)

3. Compute Projected ADC.

# Projected ADC = Weighted ADC x <u>3 Years above Current Year Projected Population</u> Current Year Population

4. Compute Projected Beds Needed.

Beds Needed = <u>Projected ADC in Service Category</u> Desired Occupancy Rate for Service Category

- (f) Summation Across Service Categories
  - 1. Compute Total Beds Needed

Beds Needed = Medical/Surgical Beds Needed + Obstetrical Beds Needed + Pediatric Beds Needed + ICU-CCU Beds Needed Other Beds Needed

2. Compute Net Beds Needed or Excess

Net Beds Needed (Excess) = Beds Needed - Existing Beds

3. All CON Authorized beds shall be considered as Existing Beds for the purposes of need calculations for this section.

# (4) Criteria for Plan Adjustments

(a) The SHCC may make adjustments to the needed beds determined by the methodology described above if evidence is introduced to the SHCC in each of the criteria, which follow, the exception to this is section 410-2-4-.02(5):

1. Evidence that residents of an area do not have access to necessary health services. Accessibility refers to the individual's ability to make use of available health resources. Problems which might affect access include persons living more than 30 minutes travel time from a hospital, the lack of health manpower in some counties, and individuals being without the financial resources to obtain access to healthcare facilities; and

2. Evidence that a plan adjustment would result in health care services being rendered in a more cost-effective manner. The SHCC, by adopting the bed need methodology herein, has decided that beds in excess of the number computed to be needed are not cost-effective. Therefore, the burden of proof that a plan adjustment would satisfy this criteria rests with the party seeking that adjustment; and 3. Evidence that a plan adjustment would result in improvements in the quality of health care delivered to residents of an area. Many organizations, including the Division of Licensure and Certification within the Alabama Department of Public Health, the Professional Review Organization for the State, the Joint Commission on Accreditation of Health Care, and major third-party payers, continually address the issue of the quality of hospital care. Evidence of substandard care in existing hospital(s) within a county and/or evidence that additional hospital beds would enhance quality in a cost-effective way could partially justify a plan adjustment.

a. In applying these three (3) plan adjustment criteria, special consideration should be given to requests from hospitals which have experienced average hospital-wide occupancy rates in excess of 80% for the most recent two-year period. It is presumed that the patients, physicians, and health plans using a hospital experiencing high occupancy rates have rendered positive judgments concerning the accessibility, cost-effectiveness, and/or quality of care of that hospital. Thus, the 80% occupancy standard adds a market-based element of validity to other evidence, which might be given in support of a plan adjustment for an area.

b. Numbers of beds do not always reflect the adequacy of the programs available within hospitals. In applying the three plan adjustment criteria to specific services, consideration should be given to the adequacy of both numbers of beds and programs offered in meeting patient needs in a particular county.

#### (5) Bed Availability Assurance for Acute Care (Hospitals)

(a) On occasion, existing acute care hospitals are located in counties having significant population growth and/or hospitals with broad geographical service areas/statewide missions. These existing acute care hospitals are experiencing a shortage of acute care beds due to population growth and other demographic factors such as the aging baby boomers. The shortage of acute care beds is expected to only worsen. This shortage of acute care beds is causing patient transfers to be refused and ambulances to be turned-away (diverted) to more distant facilities or causing delays in transfers from the ER to an inpatient bed, which is not in the best interests of patients or the provision of quality and cost-effective health care. The Acute Care Bed Need Methodology is based on a county-planning area and is an average of all days of the month and all months of the year. It may not always adequately take into consideration the census level and acute care bed availability of an individual acute care hospital and the significant inpatient bed pressures on the existing hospital, patients, and medical staff.

(b) In order to assist those existing acute care hospitals that are experiencing high census levels, existing acute care hospitals may qualify to add acute care beds if the existing acute care hospital can demonstrate an average weekday acute bed (including

observation patients) occupancy rate/census (Monday through Friday at midnight, exclusive of national holidays) for two separate and distinct periods of thirty (30) consecutive calendar days of the most recent twelve (12) month period at or above the desired average occupancy rate of eighty percent (80%) of total licensed acute care beds for that hospital.

(c) For existing acute care hospitals achieving the occupancy rate in paragraph 2, those hospitals may seek a CON to add up to ten percent (10%) of licensed bed capacity (not to exceed 50 beds), rounded to the nearest whole, or alternatively up to thirty (30) beds, whichever is greater (which shall be at the applicant's option). Such additional beds will be considered an exception to the bed methodology set forth elsewhere in this Section, provided, however, that any additional beds authorized by the CON Board pursuant to this provision shall be considered for purposes of other bed need methodology purposes. In addition to such additional information that may be required by SHPDA, a hospital seeking a CON for additional beds under this section must provide, as part of its CON application the following information:

1. Demonstration of compliance with the occupancy rate in paragraph 2 (average of at least an 80% weekday occupancy rate for two (2) separate and distinct periods of thirty (30) consecutive calendar weekdays of the most recent 12-month period);

2. The application for additional acute care beds does not exceed ten percent (10%) of licensed acute care bed capacity (not to exceed 50 beds), rounded to the nearest whole, or alternatively up to thirty (30) acute care beds, whichever is greater.

3. The existing acute care hospital has not been granted an increase of beds under this section within the preceding twelve-month period, which time begins to run upon the issuance of a certificate of occupancy issued by the Alabama Department of Public Health; and

4. The hospital must have been licensed for at least one year as a general acute care hospital.

(d) Any acute care beds granted under this section can only be added at or/upon the existing campus of the applicant acute care hospital.

#### (6) **Planning Policy.**

In a licensed general acute care hospital, the temporary utilization of inpatient rehabilitation beds, inpatient or residential alcohol and drug abuse beds, or inpatient psychiatric beds for medical/surgical purposes will not be considered a conversion of beds provided that the temporary utilization not exceed a total of twenty percent (20%) in any one specialty unit, as allowed by federal Medicare regulations in a facility's fiscal year.

#### (7) Long Term Acute Care Hospitals (LTAC)

(a) According to the Federal Centers for Medicare and Medicaid Services (CMS), a hospital is an excluded [from the Prospective Payment System] long term acute care hospital if it has in effect an agreement [with CMS] to participate as a general medical surgical acute care hospital and the average inpatient length of stay is greater than twenty-five (25) days. Ordinarily, the determination regarding a hospital's average length of stay is based on the hospital's most recently filed cost report. However, if the hospital has not yet filed a cost report or if there is an indication that the most recently filed cost report does not accurately reflect the hospital's current average length of stay, data from the most recent six-month period is used.

(b) Long term acute care hospitals provide a hospital level of care to patients with an acute illness, injury or exacerbation of a disease process that requires intensive medical and/or functional restorative care for an extended period of time, on average twenty-five (25) days or longer. Generally, high technology monitoring or complex diagnostic procedures are not required. A long-term acute care hospital's primary patient service goal is to improve a patient's medical and functional status so that they can be successfully discharged to home or to a lower level of care. These patients generally do not meet admission criteria for nursing homes, rehabilitation, or psychiatric facilities.

(c) Alabama has an excess of licensed general acute care hospital beds, some of which could be used for long-term hospital care. Therefore, a general acute care hospital may apply for a certificate of need to convert acute care beds to long-term acute care hospital beds if the following conditions are met:

1. The hospital can satisfy the requirements of a long term acute care hospital as outlined above.

2. The long-term acute care hospital can demonstrate that it will have a separate governing body, a separate chief executive officer, a separate chief medical officer, a separate medical staff, and perform basic functions of an independent hospital.

3. The long term acute care hospital has written patient transfer agreements with hospitals other than the host hospital to show that it could provide at least seventy-five percent (75%) of the admissions to the long term acute care hospital, based on the total average daily census for all participating hospitals.

4. The transfer agreements are with other hospitals in the same county and/or with hospitals in a region.

(d) To assure financial feasibility, the conversion of acute care beds to long-term acute care hospital beds shall be for a minimum of twenty-five (25) beds.

(e) Needs Assessment.

1. The bed need for the proposed long term acute care hospital shall be for no more than five percent (5%) of the combined average daily census (ADC) of all the acute care hospitals in the region of the proposed LTACH for the most recent annual reporting period.

2. As an alternative an applicant may justify bed need based on a detailed assessment of patient discharges after stays of twenty-five (25) days or more.

3. An individual hospital's ADC or discharges shall not be used more than once in the computation of need for long term acute care hospital beds.

4. Due to accessibility issues all regions regardless of need methodology shall be permitted one LTACH facility with a maximum of twenty-five (25) beds, which has proven financially feasible.

(f) The hospital must also comply with all statutes, rules, and regulations governing the Certificate of Need Review Program in Alabama.

(8) Pediatric Hospitals. Any licensed freestanding pediatric hospital or wholly owned subsidiary may make application for a Certificate of Need based on the latest obtainable pediatric data. The data submitted as part of the application shall be verified by the SHPDA staff prior to consideration by the Certificate of Need Review Board.

(9) Critical Access Hospitals (CAH).

(a) An existing hospital in Alabama must meet the following criteria to be considered for certification by CMS as a CAH (a new Certificate of Need is not required unless the application is for a new CAH or the hospital where the CAH is to be located has been closed longer than twelve (12) months):

1. Is a public, nonprofit, or for-profit Medicare-certified hospital currently in operation and located in one of the following:

a. A rural area as defined by the Office of Management and Budget (i.e., outside a Metropolitan Statistical area);

b. A rural census tract of a Metropolitan Statistical Area (MSA) determined under the most recent version of the Goldsmith Modification Formula;

c. An area designated as Rural by law or regulation of the State of Alabama or in the state's rural Health Plan as approved by the federal Centers for Medicaid and Medicare Services;

d. A hospital would qualify as a rural referral center or as a sole community hospital if the hospital were located in a rural area.

2. Hospitals, which closed on or after November 29, 1989, or are currently licensed health clinics or health centers that were created by downsizing a hospital, may reopen as a CAH;

3. Is located more than a 35-mile drive (or 15-mile drive in areas with mountainous terrain or with only secondary roads available) from another hospital or CAH, or is designated by the state as being a Necessary Provider of Health Care Services to area residents;

4. Makes available 24-hour emergency care services that the State determines are necessary for ensuring access to emergency care in each community served by the critical access hospital;

5. Provides not more than twenty-five (25) beds for acute inpatient care (which in the case of a swing bed facility can be used interchangeably for acute or SNF-level care) and the hospital may also provide up to ten (10) rehabilitation and ten (10) psychiatric beds so long as these are operated as separate units;

6. Maintains an average annual patient stay of no more than ninety-six (96) hours;

7. Meets critical access hospital staffing requirements;

8. Is a member of a rural health network and has an agreement with at least one full-service hospital (Affiliate) in the network for:

• patient referral and transfer

• development and use of communications systems

• provision of emergency and non-emergency transportation

9. Has an agreement regarding staff credentialing and quality assurance with one of the following:

a. a hospital that is a joint member in the rural health network;

b. a peer review organization or equivalent entity; or

c. another appropriate and qualified entity identified in the state rural health plan.

10. Federal statutes and eligibility requirements governing the CAH Program allow states to designate an existing hospital as a Necessary Provider of Health Care Services for its area residents if it meets all requirements for a CAH except the mileage between hospitals requirement. Alabama will utilize this statutory provision and designate Necessary Provider of Health Care Services for existing hospitals located in a county considered "at risk" for losing primary health care access. Alabama has reviewed numerous indicators of under-service in communities to determine criteria most appropriate for Alabama. Five criteria have been selected.

If the hospital meets one or more of these criteria, Alabama's Bureau of Health Provider Standards, Division of Provider Services, in consultation with the Office of Primary Care and Rural Health, will declare the facility a Necessary Provider of Health Care Services:

Criteria 1. The hospital is located in an area designated as a Health Professional Shortage Area.

Criteria 2. The hospital is located in an area designated as Medically Underserved.

Criteria 3. The hospital is located in a county with an unemployment rate higher than the statewide rate of unemployment.

Criteria 4. The hospital is located in a county with a percentage of population age 65 years and older greater than the state's average.

Criteria 5. The hospital is located in a county where the percentage of families with incomes below 200% of the federal poverty level is higher than the state average for families with incomes below 200% of the federal poverty level.

Any existing hospital, which otherwise satisfies CAH criteria except the mileage requirement but does not meet at least one of the above criteria for certification as a Necessary Provider of Health Services, may appeal to Alabama's State Health Officer. Evaluation of appeals will be based on submission of objective information, which demonstrates the presence of extenuating circumstances which may adversely impact an area's access to health care if the existing hospital is not declared a Necessary Provider of Health Services. Based on evidence presented, the State Health Officer may decide to issue a variance from established criteria and declare the appealing hospital a Necessary Provider of Health Care Services.

a. In order to meet the federal CAH requirements as to the number of beds, an existing hospital may distinguish "authorized" and "licensed" general acute care and swing beds as in the rules established by the ADPH and SHPDA.

b. The "Medicare Prescription Drug, Improvement and Modernization Act" (Public Law H.R. 1 and S. 1 June 27, 2003) is an extensive revision to the Medicare program and contains provisions relating the Critical Access Hospital Program found in Section 405 of the Act. These provisions allow more flexibility for hospitals converting to CAH status.

#### (10) Rural Emergency Hospitals

(a) A Rural Emergency Hospital (REH) is a specialized hospital that provides outpatient services, does not operate any inpatient beds, and meets all of the requirements for licensure under Ala. Admin. Code r. 420-5-23, which is incorporated herein by reference.

(b) Any hospital seeking to convert from either a Critical Access Hospital or a general acute care hospital to an REH shall file a Request for Determination of Reviewability with SHPDA to ensure that no part of their proposed conversion is reviewable under Certificate of Need law.

(c) Any REH seeking to convert back to either a Critical Access Hospital or a general acute care hospital shall require a Certificate of Need to add inpatient beds to its existing outpatient services. For the limited purpose of this conversion, need shall be presumed for that facility to add up to the total number of general acute care beds it possessed Certificate of Need authority to operate as of the date of its conversion to an REH. This presumed need shall exist only for that provider and only for the location at which the REH was operated. Need shall not be presumed for that provider at any other location in the planning area, nor shall it be presumed for any other type of specialized bed defined elsewhere in this plan. Further, need shall not be presumed for any other provider seeking to establish a new facility in the same planning area. This need shall be presumed for an REH through the issuance of a license by the Alabama Department of Public Health.

(11) Birthing Centers

(a) In addition to other applicable criteria, any entity proposing to establish a birthing center must demonstrate, through substantial evidence, that their project will meet all of the requirements for licensure under Ala. Admin. Code r. 420-5-13, which is incorporated herein by reference.

(b) Any entity seeking to establish a birthing center that does not offer any services that would require the entity to be licensed by the Alabama Department of Public Health as a hospital or as an ambulatory surgery center may file a Request for Determination of Reviewability with SHPDA in order to determine if a Certificate of Need is required to establish the facility.

(c) Any entity seeking to establish a birthing center that offers services that would require the entity to be licensed by the Alabama Department of Public Health as a hospital or as an ambulatory surgery center shall constitute a new institutional health service requiring a Certificate of Need under Alabama law. An applicant seeking to establish a birthing center, in this instance, shall not be required to show a need for acute hospital beds or for additional ambulatory surgery center operating rooms, but shall instead provide substantial evidence in its application to demonstrate to the Certificate of Need Review Board that the proposed facility is necessary to the health and welfare of the citizens of the proposed planning area. Specifically, data related to maternal and infant mortality, distances between the proposed location and existing acute care hospitals providing obstetric and maternity care, the policy regarding the types of patients who will be treated versus the types of patients that would automatically be referred to an acute care facility, and copies of transfer agreements regarding the care of high-risk patients and/or patients requiring care above and beyond that available at the proposed facility between the proposed facility and existing acute care providers should all be included as part of the application to create a new birthing center. The grant of a Certificate of Need for the establishment of a birthing center shall not constitute authority for the creation of new acute care beds, other ambulatory surgical services, or any other service requiring a Certificate of Need.

(d) The SHCC is aware that there is currently ongoing litigation between representatives seeking to establish birthing centers and the Alabama Department of Public Health regarding licensure rules for these facilities. Once a final decision is issued in this ongoing litigation, the SHCC will review and revise this section as appropriate based on the ruling issued by the courts.

For a listing of Acute Care, Long Term Acute Care, or Critical Access Hospitals 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

TELEPHONE: (334) 242-4103

EMAIL: data.submit@shpda.alabama.gov 100 NORTH UNION STREET, SUITE 870 MONTGOMERY, AL 36104

FAX: (334) 242-4113

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

Author: Statewide Health Coordinating Council (SHCC). Statutory Authority: § 22-21-260(4), <u>Code of Alabama</u>, 1975. History: Filed October 18, 2004; Effective November 22, 2004. Amended (SHP Year Only): Filed December 2, 2014; Effective January 6, 2015. Repeal and New: Filed March 16, 2020; Effective May 15, 2020.

#### Appendix A

#### **LTACH Regional County Listings**

# **REGION I**

Colbert Franklin Lauderdale Lawrence

#### **REGION II**

Jackson Limestone Madison Marshall Morgan

#### **REGION III**

Bibb Blount Cullman Jefferson Marion Saint Clair Shelby Talladega Walker Winston

#### **REGION IV**

Calhoun Cherokee Clay Cleburne DeKalb Etowah Randolph

## **REGION V**

Fayette Greene Hale Lamar Pickens Sumter Tuscaloosa

#### **REGION VI**

Autauga Bullock Butler Chambers Chilton Coosa Crenshaw Dallas Elmore Lee Lowndes Macon Marengo Montgomery Perry Pike Russell Tallapoosa Wilcox

# **REGION VII**

Baldwin Choctaw Clarke Conecuh Escambia Mobile Monroe Washington

## **REGION VIII**

Barbour Coffee Covington Dale Geneva Henry Houston

### 410-2-4-.03 Nursing Homes

# (1) **Definition**

A Nursing Home is a business entity engaged in providing housing, meals and care to sick or disabled individuals who require medical care, nursing care, or rehabilitative services on a daily or more frequent basis. Hospital swing beds are included in Section 410-2-4-.09.

# (2) Analysis of Existing Facilities

(a) As of October 2019, there were 232 licensed nursing homes, excluding state owned and operated facilities, totaling 27,383 beds operating in the state of Alabama. Average occupancy for the 228 facilities was approximately84.8% for Fiscal Year 2018. Currently, there are approximately 32.9 beds per one thousand persons age 65 and older.

(b) Approximately 84.6 % of nursing home beds in Alabama are occupied by persons age 65 and older. This aged population represents 16.5% of the state's total population and is projected to increase during the coming years.

(c) Nursing homes provide various levels of care for those needing their services. These include:

- 1. Short-term post hospital care (PAC) for those who require specialized rehabilitation after their acute care hospital episodes. Most of these PAC admissions return home.
- 2. Long term care for those with complex chronic conditions requiring care and supervision unavailable in a home setting through available supports and services.
- 3. Palliative care for hospice patients unable to remain in a home environment.
- 4. Memory care in a secured environment for those with complex chronic conditions requiring care and supervision unavailable in a home setting through available supports and services and suffering from Alzheimer's disease and other forms of dementia.

### (3) Long Term Supports and Services

(a) Efforts should be made to maintain an optimum quality of life for long term care residents in their home for as long as possible. The types and amounts of services needed for long term care residents vary. In order to enhance opportunities for residents needing long term care services, which would allow them to remain in their homes for as

long as possible, the health care and social needs of these residents should be evaluated by an independent multidisciplinary team prior to nursing home admission. This team should also evaluate the ability of resources within the local community to meet the needs of these residents.

(b) To foster the ability of Medicaid beneficiaries needing long term care and supports to remain and thrive in their homes, the Alabama Medicaid Agency implemented a home and community-based services (HCBS) program. After consultation with consumers, consumer advocates, and a wide range of health care providers, Medicaid has further enhanced the HCBS program by developing and implementing the integrated care network (ICN) program. The ICN program focuses on bringing medical case management to the home and community-based services (HCBS) population to permit better medical risk assessment of those in the HCBS program which promotes their ability to thrive at home. The ICN also case manages Medicaid beneficiaries in nursing facilities through the existing minimum data set (or MDS) assessments, which includes a return to home assessment. Individuals who might otherwise require admission to a nursing home are now able to remain in their homes because of the home and community-based services provided through this program. Currently, there are nearly 8,200 residents whose long term care needs can be met through the program.

# (4) Financing

(a) The Alabama Medicaid program was started in 1970, and as a result, the nursing home industry grew rapidly during the 70s. Since the 1980 adoption of a more restrictive bed need methodology, the number of beds added have tapered off considerably. Also, with the containment of health care costs as a primary concern, a moratorium on additional nursing home beds was established in August of 1984, and lifted in June of 1989, and was reinstituted in 2005. Medicaid patients account for 53.7% of patient days, private pay patients 20.7%, and Medicare 14.5% as of FY 2018.

# (5) Availability

(a) The 232 licensed nursing homes located in Alabama are generally geographically well distributed and are accessible to the majority of the elderly population within thirty (30) minutes normal driving time. Every Alabama county has a least one nursing home.

### (6) **Continuity**

(a) Discussion

1. Nursing homes should provide care appropriate to resident needs. To ensure that comprehensive services are available and to ensure residents are at a proper level of care, nursing homes should provide, or should have agreements with other health care providers to provide, a broad range of care. When providing these services, or a part of any agreement to provide these services, transfer of residents and support service should be provided as necessary.

(b) Planning Policy

The rendering of complementary long term care services, such as home health care adult day care, senior citizen nutrition programs, hospice, etc., to long term care recipients should be fostered and encouraged. In areas where such services are sufficiently developed, health care facilities should be encouraged to have agreements that increase the availability of such services to residents. In areas where such services are not sufficiently available, facilities should be encouraged to develop and offer such services. The Alabama Department of Public Health, Bureau of Provider Standards, is encouraged to make the appropriate changes to the licensure requirements.

# (7) Quality

(a) Quality care is an obligation of all nursing homes operating in Alabama. Each facility must meet standards of care as established by the federal government (Medicare and Medicaid Requirements of Participation) and the Alabama State Board of Health Rules and Regulations. The Bureau of Provider Standards of the Alabama Department of Public Health is responsible for determining compliance. Additionally, the Quality Improvement Organization (QIO) includes some nursing homes in its review.

# (8) Nursing Home Bed Need Methodology

(a) Purpose. The purpose of this nursing home bed need methodology is to identify, by county, the number of nursing home beds needed to assure the continued availability, accessibility, and affordability of quality nursing home care for residents of Alabama.

(b) General. Formulation of this bed need 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. Only the SHCC, with the Governor's final approval, can make changes to this methodology except that the SHPDA staff shall annually update bed need projections and inventories to reflect more current population and utilization statistics. Adjustments are addressed in paragraph (e).

(c) Basic Methodology. Considering the availability of more home and community-based services for the elderly in Alabama, there should be a minimum of 40 beds per 1,000 population 65 and older for each county.

1. The beds need formula is as follows:

(40 beds per thousand) x (population 65 and older) =Projected Bed Need

2. Due to budgetary limitations of the Alabama Medicaid Agency, additional nursing home beds cannot be funded by Medicaid funds; therefore, applications for additional nursing home beds to be funded by Medicaid should not be approved. Based upon the funding shortage, projects for additional nursing home beds would not be financially feasible. Until further action by the Statewide Health Coordinating Council, there shall be no need for additional skilled nursing beds in the State of Alabama.

(d) Planning Policies

1. The county's annual occupancy for the most recent reporting year should be at least 97% before additional nursing home beds are approved.

2. Conversion of existing hospital beds to nursing home beds should be given priority over new construction when the conversion is significantly less costly and the existing structure can be adapted economically to meet licensure and certification requirements. The conversion shall result in a decrease in the facility's licensed acute care beds equal to or greater than the number of beds to be converted.

3. Bed need projections will be based on a three year planning horizon.

4. Planning will be on a county-wide basis.

5. Subject to SHCC adjustments, no beds will be added in any county where that county's projected ratio exceeds 40 beds per 1,000 population age 65 and older.

6. No new free standing nursing home should be constructed having less than fifty (50) beds.

7. ICF/ IID facilities, state and privately owned, will not be included in the application of the SHCC adopted nursing home bed need methodology.

8. When any nursing home facility relinquishes its license to operate, either voluntarily or involuntarily other than by a Certificate of Need approved transfer, or by obtaining title by a foreclosure as specified in the opinion rendered by the Alabama Attorney General, November 17, 1980, the need for the facility and its resources will automatically be eliminated from the facilities portion of the State Health Plan. The new bed need requirement in the county where the facility was located will be that number which will bring the county ratio up to 40 beds per 1,000 population 65 and older.

(e) Adjustments. The bed need, as determined by the methodology, is subject to adjustments by the SHCC. The nursing home bed need may be adjusted by the SHCC if an applicant can prove that the identified needs of a targeted population are not being met by existing nursing homes in the county of the targeted population.

For a listing of Nursing Homes or the most current statistical need projections in Alabama contact the Data Division as follows:

**MAILING ADDRESS** STREET ADDRESS (U.S. Postal Service) (Commercial Carrier) PO BOX 303025 **100 N. UNION STREET SUITE 870** MONTGOMERY, AL 36130-3025 **MONTGOMERY, AL 36104 TELEPHONE:** FAX: (334) 242-4103 (334) 242-4113 **EMAIL: WEBSITE:** data.submit@shpda.alabama.gov http://www.shpda.alabama.gov

Author: Statewide Health Coordinating Council (SHCC). Statutory Authority: §22 21 260(4), <u>Code of Alabama</u>, 1975. History: Amended August 30, 2005; Amended: Filed August 14, 2012; Effective: September 18, 2012. Amended (SHP Year Only): Filed December 2, 2014; Effective January 6, 2015. Amended: Filed December 18, 2015; Effective February 1, 2016. Repeal and New: Filed March 16, 2020; Effective May 15, 2020.

# 410-2-4-.04 Limited Care Facilities – Specialty Care Assisted Living Facilities

# (1) **Definition**

Specialty Care Assisted Living Facilities ("SCALFs") are intermediate care facilities which provide residents with increased care and/or supervision designed to address the residents' special needs due to the onset of dementia, Alzheimer's disease or similar cognitive impairment in addition to assistance with normal daily activities including, but not limited to, restriction of egress for residents where appropriate and necessary to protect the resident and which require a license from the Alabama Department of Public Health as a Specialty Care Assisted Living Facility pursuant to ALA. ADMIN. CODE r 420-5-20, et seq.

# (2) Specialty Care Assisted Living Facility Bed Need Methodology

(a) Purpose. The purpose of this specialty care assisted living facility bed need methodology is to identify, by county, the number of beds needed to assure the continued availability, accessibility, and affordability of quality care for residents of Alabama.

(b) General. Only the SHCC, with the Governor's final approval, can make changes to this methodology except that the SHPDA staff shall annually update bed need projections and inventories to reflect more current population and utilization statistics. Adjustments are addressed in paragraph (e).

(c) Basic Methodology. Considering the availability of more home and community-based services for the elderly in Alabama, there should be a minimum of six (6) beds per 1,000 population age 65 and older for each county.

The bed need formula is as follows:

(6 beds per thousand) x (population age 65 and older/1,000) = Projected Bed Need

(d) Planning Policies

1. Projects to develop specialty care assisted living facilities or units in areas where there exist medically underserved, low income, or minority populations should be given priority over projects not being developed in these critical areas when the project to develop specialty care assisted living facilities in areas where there exists medically underserved, low income or minority populations is not more costly to develop than other like projects.

- 2. Bed need projections will be based on a three-year planning horizon.
- 3. Planning will be on a countywide basis.

4. Subject to SHCC adjustments, no beds will be added in any county where that county's projected ratio exceeds six (6) beds per 1,000 population age

65 and older, except in the case of any county meeting the conditions delineated in sections (d) 6-8 below.

5. When any specialty care assisted living facility relinquishes its license to operate, either voluntarily or involuntarily other than by a Certificate of Need approved transfer, or by obtaining title by a foreclosure as specified in the opinion rendered by the Alabama Attorney General, November 17, 1980, the beds authorized for use at that facility shall be returned to inventory. The new bed need requirement in the county where the facility was located will be that number which will bring the county ratio up to six (6) beds per 1,000 population age 65 and older, except in the case of any county meeting the conditions delineated in sections (d) 6 - 8 below.

6. Applicants for adjustments have provided evidence to the SHCC that certain counties in the state have a patient base drawn from multiple additional counties for several reasons, including but not limited to: the location of other family members; the difficulties in constructing and operating a financially viable SCALF in rural areas; the location of other medical providers; and the creation of multi-level senior living developments allowing for "aging in place." The SHCC recognizes that an alternative means of assessing need for certain counties is necessary. Any county with a projected population, age 65 and older, of 20,000 or more qualifies for an alternative need projection which shall account for both the projected need and the existing CON authorized bed capacity of that county, and all counties contiguous to that county. The sum of the authorized bed capacity of the target county and all contiguous counties shall be subtracted from the sum of the projected need for the target county and all contiguous counties. This projected net need shall be compared to the projected net need determined under the methodology in section (2)(c) above. The larger of the two projected net need values shall be the need for the target county and shall be reflected on any Statistical Update published by SHPDA.

7. Additional need may be shown in situations involving a sustained high occupancy rate either for a county or for a single facility. An applicant may apply for additional beds, and thus the establishment of need above and beyond the standard methodology utilizing one of the following two policies. Once additional beds have been applied for under one of the policies, that applicant shall not qualify to apply for additional beds under either of these policies unless and until the established time limits listed below have passed. All CON authorized SCALF beds shall be included in consideration of occupancy rate and bed need.

a. If the occupancy rate for a county is greater than 92% utilizing the census data in the most recent full year "Annual Report(s) for Specialty Care Assisted Living Facilities (Form SCALF-1)" published by or filed with SHPDA, an additional need of the greater of either ten percent (10%) of the current total CON Authorized bed capacity of that county or sixteen (16) total beds may be approved for either the creation of a new facility or for the expansion of existing facilities within that county. However, due to the priority of providing the most cost-effective health care services available, a new facility created under this policy shall only be allowed through the conversion of existing beds at an Assisted Living Facility currently in possession of a regular, non-probationary license from the Alabama Department of Public Health. Once additional need has been shown under this policy, no new need shall be shown in that county based upon this rule for twenty-four (24) months following issuance of the initial CON, to allow for the impact of those beds in that county to be analyzed. Should the initial applicant for beds in a county not apply for the total number of beds allowed to be created under this rule, the remaining beds are available to be applied for by other providers in the county meeting the conditions listed in this rule.

b. If the occupancy rate for a single facility is greater than 92% utilizing the census data in the last two (2) most recent full year "Annual report(s) for Specialty Care Assisted Living Facilities (Form SCALF-1)" published by or filed with SHPDA, irrespective of the total occupancy rate of the county over that time period, up to sixteen (16) additional beds may be approved for the expansion of that facility only. Once additional beds have been approved under this policy, no new beds shall be approved for that facility for twenty-four (24) months following issuance of the CON to allow for the impact of those beds at that facility to be analyzed.

8. No application for the establishment of a new, freestanding SCALF shall be approved for fewer than sixteen (16) beds, to allow for the financial feasibility and viability of a project. Need may be adjusted by the Agency for any county currently showing a need of more than zero (0) but fewer than sixteen (16) total beds to a total need of sixteen (16) new beds, but only in the consideration of an application for the construction of a new facility in that county. Need shall not be adjusted in consideration of an application involving the expansion of a currently authorized and licensed SCALF or for the conversion of beds at an existing Assisted Living Facility.

9. Any CON Application filed by a licensed SCALF shall not be deemed complete until, and unless:

a. The applicant has submitted all survey information requested by SHPDA prior to the application date; and

b. The SHPDA Executive Director determines that the survey information is complete.

10. No licensed SCALF filing an intervention notice or statement in opposition in any CON proceeding may cite or otherwise seek consideration by SHPDA of such facility's utilization data until, and unless:

a. The intervenor or opponent has submitted all survey information requested by SHPDA prior to the application date; and

b. The SHPDA Executive Director determines that the survey information is complete.

(e) Adjustments. The bed need, as determined by the methodology, is subject to adjustments by the SHCC. The specialty care assisted living facility bed need may need to be adjusted by the SHCC if an applicant can prove that the identified needs of a targeted population are not being met by existing specialty care assisted living facilities in the county of the targeted population.

(f) Notwithstanding the foregoing, any application for Certificate of Need for specialty care assisted living facility beds for which a proper letter of intent was duly filed with SHPDA prior to the adoption of the bed need methodology shall not be bound by this bed need methodology.

(g) The determination of need for specialty care assisted living facility beds shall not be linked to the number of existing assisted living beds in the county.

(h) In order to determine if this methodology and related planning policies accurately reflect the need for SCALF beds in the state, the SHCC requires additional information to determine the county of residence prior to admission to each SCALF. The SHCC requests that the Health Care Information and Data Advisory Council add a section to the "Annual Report for Specialty Care Assisted Living Facilities (Form SCALF-1)" reporting the county of residence for patients admitted to each SCALF. After the Annual Report is modified by the Health Care Information and Data Advisory Council, the SHCC shall use the information collected to review this methodology at the end of the third mandatory reporting period to determine if additional revisions to this methodology are required to better reflect both the existing utilization of SCALF services and the potential need for additional SCALF beds.

For a listing of Specialty Care Assisted Living Facilities or the most current statistical need projections in Alabama contact the Data Division as follows:

MAILING ADDRESS	STREET ADDRESS
(U. S. Postal Services)	(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).

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

History: Filed October 18, 2004; Effective November 22, 2004. Amended: Filed August 18, 2012; Effective September 18, 2012. Amended (SHP Year Only): Filed December 2, 2014; Effective January 6, 2015. Repeal and New: Filed March 16, 2020; Effective May 15, 2020.

# 410-2-4-.05 Assisted Living Facilities

# (1) **Definition**

Assisted living facilities provide, or offer to provide, any combination of residence, health supervision, and personal care to three (3) or more individuals in need of assistance with daily living activities.

# (2) Existing Assisted Living Facilities

As of September 2019 there were 194 licensed assisted living facilities totaling 7,253 beds operating in the state of Alabama, or approximately 8.7 beds per 1,000 persons age 65 and older. Assisted living is available in Alabama on a private-pay basis only.

# (3) Availability

The 194 licensed assisted living facilities are concentrated in the more populated counties. Three (3) counties contain 35% of the assisted living beds and ten (10) counties contain 65% of the assisted living beds. Forty-eight (48) of the sixty-seven (67) counties have assisted living facilities and nineteen (19) counties have no assisted living facilities.

# (4) Continuity

(a) Discussion. Assisted living facilities should provide assistance appropriate to resident needs. To ensure that comprehensive services are available and to be certain residents are at a proper level of care, assisted living facilities should provide, or should have agreements with health care providers to provide, a broad range of care. When providing these services, transfer of residents and support services should be provided as necessary.

(b) Self-Help Program. Assisted living providers will be encouraged to provide a level of assistance that would help and encourage the residents to be self-sufficient for as long as possible before requiring a change to a more dependent home.

# (5) Quality

Quality assistance is an obligation of all assisted living facilities operating in Alabama. Each facility must meet standards established by the Alabama Department of Public Health (see paragraph 4 above). The Bureau of Health Provider Standards of the Alabama Department of Public Health is responsible for determining compliance.

A current listing of licensed Assisted Living Facilities in Alabama may be found on the Alabama Department of Public Health's website, <u>www.alabamapublichealth.gov</u>.

Author: Statewide Health Coordinating Council (SHCC).

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

History: Filed October 18, 2004; Effective November 22, 2004. Amended: Filed August 18, 2012; Effective September 18, 2012. Amended (SHP Year Only): Filed December 2, 2014; Effective January 6, 2015. Repeal and New: Filed March 16, 2020; Effective \_May 15, 2020.

# 410-2-4-.06 Adult Day Care Programs

# (1) **Definition**

Adult day care programs may be identified as structured, comprehensive programs designed to offer lower cost alternatives to institutionalization for newly or chronically disabled adults who cannot stay alone during the day, but who do not need 24-hour inpatient care. Designed to promote maximum independence, participants usually attend on a scheduled basis. Services may include nursing, counseling, social services, restorative services, medical and health care monitoring, exercise sessions, field trips, recreational activities, physical, occupational and speech therapies, medication administration, well balanced meals, and transportation to and from the facility. Adult day care can provide the respite family members require to sustain healthy relationships while caring for their elderly loved one at home. Adult day care programs provide services to one or more adults not related by blood or marriage to the owner and/or administrator.

# (2) Analysis of Existing Adult Day Care Programs

Adult day care programs are not currently licensed by any department of the state of Alabama. As a consequence, it is extremely difficult to ascertain the actual number of such programs within Alabama. However, Adult Day Care Centers are approved through the Alabama Department of Human Resources, the Alabama Department of Senior Services and the Alabama Medicaid Agency. The Alabama Department of Mental Health also uses adult day care.

### (3) Adult Day Care Programs as Alternatives to Nursing Home Admission

(a) Efforts should be made to maintain an optimum quality of life for individuals who require extended or long-term care. The types and amounts of services needed for these individuals vary. In order to enhance opportunities for individuals needing extended or long-term care services, the needs of these individuals should be evaluated prior to admission to any extended care or long-term care program, including nursing homes, assisted living homes, and adult day care programs.

(b) In an effort to encourage the development and utilization of alternatives to nursing home and assisted living (domiciliary) care, adult day care programs and services for the elderly should be utilized to the greatest extent possible. It is the intent to provide for the establishment of additional adult day care programs in order that: (i) the elderly will be given the opportunity to remain with their families and in their communities rather than being placed in nursing homes or state institutions; (ii) families, particularly those with one or more members working outside of the home, may keep their elderly parents and relatives with them instead of having to place them in impersonal institutions; and (iii) the state of Alabama can deal more effectively and economically with the needs of its elderly citizens.

# (4) Financing

Historically, all adult day care programs have been private pay with some assistance coming from public and community sources.

# (5) Availability

Adult day care programs are concentrated in the more populated counties. Many counties have no adult day care programs.

# (6) Continuity

(a) Discussion. Adult day care programs should provide care appropriate to the needs of their participants. To ensure that comprehensive services are available and that certain participants receive a proper level of care, adult day care programs should provide, or should have agreements with other health care providers to provide, a broad range of care. When providing these services, transportation and support services for participants should be provided as necessary.

(b) Self-Help Program. Adult day care program providers should be encouraged to provide a level of care that will help maintain and improve function and encourage participants to be as independent as they can for as long as possible before the condition of such participants requires a change to a more dependent level of care.

# (7) Quality

Quality care is an obligation of all adult day care programs operating in Alabama. Each program should comply with applicable state and local building regulations, and zoning, fire, and health codes and ordinances. In addition, each program must comply with all requirements of its funding sources, including requirements with respect to a Medicaid Waiver, if applicable.

# (8) **Promotion of Adult Day Care Programs**

The alternate special affordable care offered by adult day care programs should be publicized by responsible agencies using some or all of the following:

- (a) Public Service Announcements
- (b) Physicians (provide literature)
- (c) Hospitals (discharge planners)
- (d) Nursing Homes
- (e) The Alabama Commission on Aging
- (f) The American Association of Retired Persons
- (g) Community Service Agencies/Projects
- (h) Religious Organizations
- (i) The Alabama Department of Human Resources
- (j) The Alabama Department of Senior Services

Author: Statewide Health Coordinating Council (SHCC).

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

History: Filed October 18, 2004; Effective November 22, 2004. Amended (SHP Year Only): Filed December 2, 2014; Effective January 6, 2015. Repeal and New: Filed March 16, 2020; Effective May 15, 2020.

# 410-2-4-.07 Home Health

# (1) **Definitions**

(a) Home Health Agency. A home health agency is an organization that is primarily engaged in providing skilled nursing services and other therapeutic services. Services are provided on an intermittent basis. Each visit must be less than four hours in duration. Any visit made to or procedures performed on a patient at their home must only be made upon a physician's written order. Home health providers shall provide at least the following services, including, but not limited to, skilled nursing care, personal care, physical therapy, speech therapy, medical social services, and medical supplies services.

(b) Home Health Care. Home health care is that component of a continuum of comprehensive health care whereby intermittent health services are provided to individuals and families in their places of residence for the purpose of promoting, maintaining or restoring health, or of maximizing the level of independence, while minimizing the effects of disability and illness, including terminal illness. Services appropriate to the needs of the individual patient and family are planned, coordinated, and made available by providers organized for the delivery of home health care through the use of employed staff, contractual arrangements, or a combination of employed staff and contractual arrangements. There is no licensure requirement for home health agencies in Alabama.

(c) Home Health Services. Home health services are made available based upon patient care needs as determined by an objective patient assessment administered by a multidisciplinary team or a single health professional. Centralized professional coordination and case management are included. These services are provided under a plan of treatment certified by a physician that may include, but are not limited to, appropriate service components, such as medical, nursing, social work, respiratory therapy, physical therapy, occupational therapy, speech therapy, nutrition, homemaker home health aide service, and provision of medical equipment and supplies.

(d) Section 22-21-265, <u>Code of Alabama</u>, 1975, allows an existing home health agency to accept referrals from a county which is contiguous to a county in which the agency holds CON authority. Additional restrictions are provided in statute.

### (2) Inventory of Existing Resources

The State Health Planning and Development Agency annually compiles several home health agency reports and identifies counties which are in need of an additional provider. A current listing of home health agencies is located at http://www.shpda.alabama.gov or http://www.adph.org.

# (3) Availability

Home health visits are scheduled on an intermittent basis and must be available seven days a week at such times as may be ordered by referring physicians. While availability must include provision for weekend and evening services, emergency services are not within the scope or purpose of home health providers.

# (4) Accessibility

(a) Home health services must be obtainable by the general public in every county in the state.

(b) Because physicians and other referral sources are sometimes unfamiliar with the total scope of services offered by home health providers, patients' accessibility is also limited by failure to refer appropriately to home health services. Every agency should provide an active community information program to educate consumers and professionals to the availability, nature, and extent of home health services.

(c) Services are provided in patients' homes, and accessibility to services is not dependent upon physical or geographic accessibility to the home health provider's offices. The essential characteristics are location of home health visiting staff in proximity to patients' places of residence and accessibility of the provider to patients, physicians, and other referral sources.

# (5) Acceptability and Continuity

(a) Acceptability is the willingness of consumers, physicians, discharge planners, and others to use home health services as a distinct component of the health care continuum.

(b) Continuity reflects a case management approach that allows patient entry into the health care continuum at the point that ensures delivery of appropriate services. Home health care provides a balanced program of clinical and social services and may serve as a transitional level of care between inpatient treatment and infrequent physician office visits. Home health also extends certain intensive, specialized treatments into the home setting.

- (c) Planning Guides and Policies
  - 1. Planning Guide

Home health providers shall maintain referral contacts with appropriate community providers of health and social services to facilitate continuity of care and to coordinate services not provided directly by the home health provider.

2. Planning Policy

Home health providers must furnish discharge-planning services for all patients.

## (6) Quality

(a) Quality is that characteristic which reflects professionally appropriate and technically adequate patient services.

(b) The state home health industry, through development of ethical standards and a peer review process, can foster provision of quality home health care services. Each provider must establish mechanisms for quality assurance, including procedures for resolving concerns identified by patients, physicians, families or others involved in patient referral or patient care.

- (c) Planning Policies
  - 1. Planning Policy

The county is the geographic unit for need determination, based upon population.

2. Planning Policy – (New Providers)

When a new provider is approved for a county, that provider will have eighteen (18) months from the date the Certificate of Need is issued to meet the identified need in the county before a new provider may apply for a Certificate of Need to serve a county.

3. Planning Policy – Favorable Consideration

Home health agencies that achieve or agree to achieve Charity Care plus Self Pay at the statewide average percent for all home health providers shall be given favorable CON consideration over home health applicants that do not achieve the statewide average for Charity Care plus Self Pay, but not less than one percent (1%). The latest published SHPDA data report HH-11 shall be used to determine the assets to governmental and non-profit organizations at the individual county level to be considered. See section 410-2-2-.06 for the definition of charity care.

4. Planning Policy – CON Intervention/Opposition

a. Any CON application filed by a health care facility shall not be deemed complete until, and unless:

i. The applicant has submitted all survey information requested by SHPDA prior to the application date; and

ii. The SHPDA Executive Director determines that the survey information is substantially complete.

b. No Home Health Agency or Hospice Agency filing an intervention notice or statement in opposition in any CON proceeding may cite or otherwise seek consideration by SHPDA of such facility's utilization data until, and unless:

i. the intervenor or opponent has submitted all survey information requested by SHPDA prior to the application date; and

ii. the SHPDA Executive Director determines that the survey information is substantially complete.

(7). Home Health Need Methodology

(a). Purpose. The purpose of this home health need methodology is to identify, by county, the number of home health agencies needed to assure the continued availability, accessibility, and affordability of quality home health care for residents of Alabama.

(b). Basic Methodology. In order to perform the calculations for this methodology, population data from the Center for Business and Economic Research (CBER) is utilized. All time frames are based on the year of the latest reported data.

(c) Methodology Terms

The following methodology terms are defined for determining Home Health need by County.

1. Target Year (TY)

The Target Year (TY) as used in this methodology refers to the most recent year of utilization data approved by the Health Care Information and Data Advisory Council and published by SHPDA

Numeric references following "TY" (-1, +1, etc.) refer to a specific number of years before or after the Target Year for either data or population projections.

This methodology shall be based on a three (3) year planning horizon, meaning that the need shall be projected three years ahead of the most recently published home health data, and this methodology shall also use a weighted average of the three (3) most recent sets of annual reports published by SHPDA to determine need.

2. Persons Served (PS)

Persons Served (PS) is defined as the number of patients receiving Home Health services during a reporting year.

3. Population

The ratio of persons served is divided into two (2) cohorts for determination of need as follows:

Patients aged 65 and older (P65O)

Patients aged 64 and under (P64U)

4. Persons Served by County by Year (PSCY)

The ratio of persons served by county by year (PSCY) is determined as follows:

PSCY TY+3 = [PS TY x 0.75 x (P65O TY+3 / P65O TY)] + [PS TY x 0.25 x (P64U TY+3 / P64U TY)]

PSCY TY+2 = [PS TY-1 x 0.75 x (P65O TY+2 / P65O TY-1)] + [PS TY-1 x 0.25 x (P64U TY+2 / P64U TY-1)]

PSCY TY+1 = [PS TY-2 x 0.75 x (P65O TY+1 / P65O TY-2)] + [PS TY-2 x 0.25 x (P64U TY+1 / P64U TY-2)]

5. Average Projected Persons Served per 1,000 Population per Year (APPS)

The average projected persons served per 1,000 population per year (APPS) is determined as follows:

APPS TY+3 = [(SUM PSCY TY+3 x 0.75) / (Statewide TY+3 P65O/1,000)] + [(SUM PSCY TY+3 x 0.25) / (Statewide TY+3 P64U/1,000)]

APPS TY+2 = [(SUM PSCY TY+2 x 0.75) / (Statewide TY+2 P65O /1,000)] + [(SUM PSCY TY+2 x 0.25) / (Statewide TY+2 P64U/1,000)]

APPS TY+1 = [(SUM PSCY TY+1 x 0.75) / (Statewide TY+1 P65O /1,000)] + [(SUM PSCY TY+1 x 0.25) / (Statewide TY+1 P64U/1,000)]

6. Statewide Average Comparative Value (SACV)

The Statewide Average Comparative Value (SACV) is determine as follows: SACV = [((APPS TY+3 x 3) + (APPS TY+2 x 2) + APPS TY+1) / 6)] x 0.85

7. Projected Total Persons Served per 1,000 Population by County (PJPS)

The Projected Total Persons Served per 1,000 Population by County, three (3) years into the future (PJPS), is determined as follows:

PJPS = [(PSCY TY+3 x 0.75) / (P65O TY+3/1,000)] + [(PSCY TY+3 x 0.25) / (P64U TY+3/1,000)]

8. Additional Persons Projected to Need Service to meet SACV Value by County (APNS)

The Additional Persons Projected to Need Service to meet SACV value by County, three (3) years into the future (APNS), is determined as follows:

APNS = (SACV – PJPS) / [(0.75 x (1,000 / P65O TY+3)) + (0.25 x (1,000 / P64U TY+3))]

(d) Need.

Need, by County, based upon the above calculations, will be determined as follows:

If APNS  $\geq$  100, need for one (1) additional home health provider is shown in that county

If APNS  $\leq$  99, no need is shown for any additional home health providers in that county.

(e) Application Approval Limits

No more than one (1) application may be approved in any county showing a need for additional home health services during any approval cycle as defined by the Statewide Health Coordinating Council, or as implemented by SHPDA.

(f) SHPDA Review and Analysis of Utilization Data

During the effective time period of this Plan, SHPDA shall review and analyze existing utilization data to determine if the county should continue to be the planning area for Home Health services in the future or if a regional approach to planning for new Home Health services would be a more accurate means to determine need.

As part of such review, SHPDA shall also determine if a move to a regional planning model would present a detrimental impact on the delivery of services to patients and whether it would present a detrimental impact on existing providers.

Such review and analysis shall be made available to existing Home Health providers in the state, who shall be given an opportunity to provide testimony or written input to the SHCC based on upon the results.

#### (8) Criteria for Plan Adjustments

- (a) The need, as determined by the methodology, is subject to adjustment by the SHCC as provided in Ala. Admin Code 410-2-5-.04, and the additional, specific criteria set forth below. An applicant seeking an adjustment has the burden of demonstrating extraordinary circumstances that result in the identified needs of a target population not being met by existing Home Health Providers, and not able to be met in a timely fashion through application of the methodology, based on each of the following:
  - Evidence that affected residents do not have access to necessary health services that can be met through application of the methodology. Accessibility refers to an individual's ability to make use of available health resources. Problems which might affect access to care include persons living in a county in which no Home Health provider has an existing office, lack of health manpower in certain counties, and individuals being without financial resources to obtain access to care;
  - 2. Evidence of unique, area specific circumstances demonstrating that a plan adjustment would result in health care services being rendered in a more costeffective manner. The SHCC, by adopting the need methodology herein, has determined that services in excess of those computed to be necessary are not cost-effective. Therefore, a party seeking a plan adjustment would have a high burden in establishing such circumstances; and
  - 3. Evidence that a plan adjustment would result in improvements in the quality of health care delivered to residents in the proposed county.
- (b) Applicants seeking an adjustment shall address, and the SHCC shall consider, the potential detrimental financial impact upon existing health care providers in the proposed county.

For a listing of Home Health Agencies or the most current statistical need projections in Alabama please contact the Data Division as follows:

MAILING ADDRESS (U.S. Postal Service)

PO BOX 303025 MONTGOMERY AL 36130-3025 **STREET ADDRESS** (Commercial Carrier)

100 NORTH UNION STREET SUITE 870 MONTGOMERY AL 36104

# **TELEPHONE:** (334) 242-4103

## FAX: (334) 242-4113

E-Mail: data.submit@shpda.alabama.gov Website: http://www.shpda.alabama.gov

Author: Statewide Health Coordinating Council (SHCC).

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

History: Filed October 18, 2004; Effective November 22, 2004. Repealed Filed December 12, 2006; Effective January 16, 2008. Amended (SHP Year Only): Filed December 2, 2014; Effective January 6, 2015. Amended: Filed February 10, 2015; Effective March 17, 2015. Repeal and New: Filed March 16, 2020; Effective May 15, 2020.

#### 410-2-4-.08 Inpatient Physical Rehabilitation

(1) Definition. Inpatient physical rehabilitation services are those designed to be provided on an integrated basis by a multidisciplinary rehabilitation team to restore the disabled individual to the highest physical usefulness of which he is capable. These services may be provided in a distinct part unit of a hospital, as defined in the Medicare and Medicaid Guidelines, or in a free-standing rehabilitation hospital.

(2) General. Rehabilitation can be viewed as the third phase of the medical care continuum, with the first being the prevention of illness, the second, the actual treatment of disease, and the third, rehabilitation or a constructive system of treatment designed to enable individuals to attain their highest degree of functioning. In many cases, all three phases can occur simultaneously. For the purposes of this section of the State Health Plan, only the need for and inventory of inpatient rehabilitation beds will be addressed.

(3) Need Determination. The Statewide Health Coordinating Council (SHCC) has determined that there is a need for 15 rehabilitation beds per 100,000 population for each region.

- (4) Planning Policies
- (a) Planning Policy

Regional occupancy for the most recent reporting year should be at least seventy-five percent (75%) before the SHCC considers any requests for plan adjustments for additional bed capacity.

(b) Planning Policy

Conversion of existing hospital beds to rehabilitation beds should be given priority consideration over new construction when the conversion is significantly less costly, and the existing structure can meet licensure and certification requirements.

(5) Bed Availability Assurance

(a) Over the last three (3) years, on behalf of the SHCC, SHPDA has collected additional data from hospitals with Certificate of Need (CON) authority to operate inpatient rehabilitation beds and from skilled nursing facilities providing inpatient rehabilitation care. This data was collected specifically to review and analyze certain claims made before the SHCC by both groups related to the acuity levels of patients treated in each type of facility. This review and analysis was also to take into account the fact that certain patients can only be treated in one specific type of facility, while others can be treated in either based in large part on the patient's diagnosis.

(b) SHPDA, working under the instruction of the Health Care Information and Data Advisory Council, and in cooperation with the Alabama Hospital Association (AlaHA) and the Alabama Nursing Home Association (ANHA), amended the annual reports for both facility types

to collect additional data on the provision of inpatient rehabilitation services similar in nature to information submitted to the Centers for Medicare and Medicaid Services (CMS) for reimbursement. This data was collected for each of the last three (3) reporting years. SHPDA has reviewed and analyzed the data submitted and has reported the results of that analysis to the SHCC. This bed availability rule is the result of the analysis and recommendation provided to the SHCC by SHPDA, with additional comment and testimony from AlaHA, ANHA, and other interested parties.

(c) An inpatient rehabilitation facility (IRF), or an inpatient rehabilitation unit of an existing acute care hospital, shall qualify to add additional beds above and beyond any need projections shown in this plan should all of the following conditions be met. If any single condition is not met, any application filed to expand under this provision shall be deemed inconsistent with this Plan and shall be removed from the review cycle. For the purposes of this rule, all CON authorized inpatient rehabilitation beds shall be counted in the determination of the provider's occupancy rate.

- (i) The occupancy rate of the applicant shall have been a minimum of 80% for each of the two (2) most recent annual reporting periods as defined by SHPDA;
- (ii) The acuity rate, a value derived by SHPDA using the same formulas and rules used by CMS to determine compliance with the "60% Rule", with the noted exception of those related to BMI (Body Mass Index), shall have been a minimum of 60% for each of the two (2) most recent annual reporting periods as defined by SHPDA; and
- (iii) The average of the occupancy rate and the acuity rate shall be a minimum of 80% for each of the two (2) most recent annual reporting periods as defined by SHPDA.
- (iv) For (i) through (iii) above, the condition defined shall need to have been met for each reporting period separately, and not as a combination of the two reporting periods together.

(d) Should all of the conditions listed in (c) above be met, the applicant may seek to add either 10% of their existing CON authorized bed capacity or up to 10 beds, whichever is greater. Any inpatient physical rehabilitation beds granted under this section shall only be added at or upon the existing campus of the applicant facility and cannot be sold or transferred to another provider or location. The only exception to this rule is in the case of an IRF or acute care hospital with an inpatient rehabilitation unit applying for a Certificate of Need to relocate or otherwise create a replacement facility that is consistent with all other parts of this Plan. Furthermore, once beds are granted to a facility utilizing this policy for a minimum of two (2) years following initial ADPH licensure of those beds to allow for the impact of the addition of those beds to be shown.

(e) The provisions of Bed Availability Assurance shall not become effective until the first statistical update is published for inpatient rehabilitation beds following the effective date of this plan. Furthermore, the provisions of Bed Availability Assurance shall not apply in a region where need is shown for inpatient rehabilitation beds according to the methodology defined in (3) above

The SHCC requires that the Data Council maintain any changes made to the Annual (6) Reports filed by hospitals necessary to capture the data used by Medicare Administrative Contractors to determine presumptive compliance with the inpatient rehabilitation facility compliance threshold requirement, also known as the "60% Rule", including the diagnosis, comorbidities and impairment for each patient. The SHCC requires that the Data Council maintain any changes made to the Annual Reports filed by nursing homes to include comparable patient origin level data to allow for comparison between hospital and nursing home providers. The data supplied should continue to allow for an analysis of current utilization in such a manner as to reflect all inpatient rehabilitative services being offered, regardless of location or facility type, and should therefore be collected from both hospitals and nursing homes. The data collected should not only provide information related to occupancy rate but should also provide information related to the acuity of patients treated at each facility and should, as closely as possible, collect data that is similar in both type and format to allow for as accurate a comparison as possible, while representing as many patients receiving inpatient rehabilitation services as possible. The data collected by SHPDA shall allow for the Agency to produce an analysis of patients served in a manner consistent with the formulas and rules used by CMS to determine compliance with the "60% Rule", with the noted exception of the collection of data related to a patient's BMI (Body Mass Index), which has not been and will continue to not be collected by SHPDA. Further, this data should allow SHPDA to confirm the contention of an applicant for additional beds under section (5) above that they meet each of the individual conditions required to allow for the grant of additional beds under that section.

(a) Any IRF or acute care hospital that does not substantially comply with any data request made on behalf of SHPDA related to this section shall not be allowed to apply for additional beds under the provisions set forth in paragraph (5) above. Any such application shall be deemed to be inconsistent with this Plan.

(b) Any IRF, acute care hospital or nursing home that does not substantially comply with any data request on behalf of SHPDA related to this section shall not be allowed to oppose any application filed on behalf of an IRF or an acute care hospital for additional beds under the provisions set forth in paragraph (5) above.

(c) Such barriers to an application for a Certificate of Need, or inability to intervene or oppose an application for a Certificate of Need, shall be applied in a manner consistent with the provisions set forth in Ala. Admin Code r. 410-1-3-.11.

For a listing of inpatient rehabilitation facilities or the most current statistical need projections in Alabama you may contact the Data Division as follows:

MAILING ADDRESS (U.S. Postal Service)

PO BOX 303025 MONTGOMERY, AL 36130-3025 **STREET ADDRESS** (Commercial Carrier)

100 N. 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).

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

History: Filed October 18, 2004; Effective November 22, 2004: Filed June 30, 2006; Effective August 4, 2006. Amended (SHP Year Only): Filed December 2, 2014; Effective January 6, 2015. Amended: Filed June 30, 2020; Effective August 14, 2020.

#### **INPATIENT REHABILITATION BED REGIONS**

#### REGION I

Lauderdale Limestone Madison Jackson Colbert Franklin Lawrence Morgan Marshall

#### **REGION II**

Lamar Fayette Pickens Tuscaloosa Sumter Greene Hale Bibb

#### **REGION III**

Marion Winston Cullman Blount Walker Jefferson Shelby Chilton Coosa Talladega St. Clair

#### **REGION IV**

DeKalb Etowah Cherokee Calhoun Cleburne Clay Randolph

#### **REGION VI**

Choctaw Washington Mobile Baldwin Escambia Conecuh Monroe Clarke

#### **REGION V**

Perry Marengo Wilcox Dallas Autauga Lowndes Butler Crenshaw Pike Montgomery Elmore Macon Bullock Lee Russell Tallapoosa Chambers

#### **REGION VII**

Covington Coffee Dale Geneva Houston Barbour Henry

#### 410-2-4-.09 Swing Beds

## (1) **Definition.**

A swing bed is a licensed hospital bed that can be used for either a hospital or skilled nursing home patient. A swing bed program is authorized in Alabama to include hospitals that meet the criteria as specified in Federal laws and regulations. In accordance with the appropriate directive and this State Health Plan, a swing bed hospital must meet the following requirements:

(a) must meet the federal requirements addressing the facility size, location, and utilization factors;

(b) must have a valid provider agreement under Medicare;

(c) must meet the discharge planning and social services standards applicable to participating skilled nursing facilities;

(d) must not have a waiver for 24-hour nursing coverage;

(e) must be granted a Certificate of Need by the State Health Planning and Development Agency to provide skilled nursing facility services;

(f) any provider seeking to offer swing beds as a new service is limited to an initial allotment of ten (10) beds;

(g) Subject to the procedure provided in paragraph (2) below, each participating hospital is limited to twenty-five (25) swing beds;

(h) the average length of stay for swing bed patients must not exceed 30 days;

(i) beds authorized as swing beds will remain licensed as general hospital beds and be included in the general acute care inventory and bed need methodology;

(j) critical access hospitals shall be given special consideration in any application for a Certificate of Need for swing beds.

(2) A participating hospital may apply for additional swing beds if it can demonstrate an average occupancy rate for its existing swing beds greater than eighty percent (80%) for the most recent twelve (12) month period. That hospital may apply for no more than five (5) additional swing beds in any given twelve (12) month period, and its application cannot result in a total number of swing beds exceeding the maximum number set forth in paragraph (1)(g) above.

(3) Any hospital certified and operating as a Critical Access Hospital which is located in a county in which only one Nursing Home is licensed and providing service is not required to meet the occupancy rates in paragraph (2) but must adhere to all other requirements set forth in this section in order to apply for additional swing beds.

For a listing of hospitals with CON authorized swing beds contact the Data Division as follows:

MAILING ADDRESS	STREET ADDRESS
(U. S. Postal Service)	(Commercial Carrier)
PO BOX 303025	100 NORTH UNION STREET, SUITE 870
MONTGOMERY, AL 36130-3025	MONTGOMERY, AL 36104
TELEPHONE:	FAX:
(334) 242-4103	(334) 242-4113
EMAIL:	WEBSITE:
<u>data.submit@shpda.alabama.gov</u>	http://www.shpda.alabama.gov

Author: Statewide Health Coordinating Council (SHCC). Statutory Authority: § 22-21-260(4), <u>Code of Alabama</u>, 1975. History: Filed October 18, 2004; Effective November 22, 2004. Amended (SHP Year Only): Filed December 2, 2014; Effective January 6, 2015. Repeal and New: Filed March 16, 2020; Effective May 15, 2020.

#### 410-2-4-.10 Psychiatric Care

#### (1) Background

(a) In the early 1990s, the Alabama Department of Mental Health and Mental Retardation developed a psychiatric bed need methodology that provided for an inventory of 37.1 beds per 100,000 population. Originally, the methodology was calculated using regions; however, in 2003 it was changed to reflect a statewide need methodology. Although the statewide need methodology was helpful in the early years to ensure access to care, it resulted in an uneven distribution of psychiatric beds, with higher concentrations of beds in some regions and shortages of psychiatric beds in other regions of the state.

(b) Over time, the number of psychiatric beds, both private beds and state beds, has declined. States have transitioned funding for mental health services from institutional care to community-based services, as state budgets have been cut and as more is known about the benefits of providing care in a non-institutional, community setting. Alabama mirrors these national trends, as it has closed three state facilities and downsized from 4,000 beds in 2009 to approximately 1,600 beds in 2017. In some areas, community-based services include crisis stabilization and access to timely follow-up care. In other areas, community resources may be limited, and those with psychiatric emergencies often present to a general acute care hospital emergency room for care; some of the more severely mentally ill remain for extended periods of time in private psychiatric facilities, waiting on a state bed to become available.

# (2) Methodology

(a) Discussion.

The Statewide Health Coordinating Council (SHCC) developed a proposal for a new methodology based on the increasing need for psych beds and a better distribution of those beds. Approved by the full SHCC, the purpose of this inpatient psychiatric services need methodology is to identify, by region and by bed type, the number of inpatient psychiatric beds needed to ensure the continued availability, accessibility, and affordability of quality inpatient psychiatric care for residents of Alabama. Only the SHCC, with the Governor's approval, can make changes to this methodology. The State Health Planning and Development Agency (SHPDA) staff shall annually update statistical information to reflect more current utilization through the Hospital Annual Survey.

(b) Bed Need Determined by Region and by Category of Bed.

The new methodology is based upon the regional needs of the state as opposed to a statewide need methodology. It also addresses need based on the category of patients served in the beds being used; the bed categories include: 1. Child/Adolescent; 2. Adult; and 3. Geriatric. Calculation of beds needed will be based on utilization of those beds by category and by region as reported annually in the Hospital Annual Report. The Hospital Annual Report must be amended to accomplish the purposes of this new methodology.

This new methodology will become effective after the certification by the Healthcare Information and Data Advisory Council of the first new Hospital Annual Report following the passage of this amendment. All providers will report their licensed beds, operating beds and patient days by inpatient psychiatric category each year via the new Hospital Annual Report. Operating beds may be the same as or fewer than the total number of licensed psychiatric beds. Providers with unrestricted psychiatric beds obtained prior to the effective date of this new methodology shall be allowed to change the categories of their beds during the first two reporting periods. The bed allocation by category reported on the third Hospital Annual Report following the passage of this amendment shall be considered final for operating beds. Thereafter, any permanent change to a different inpatient psychiatric bed category for an existing operating bed or beds will require the approval of a new CON. This requirement will not apply to licensed beds not currently in use; however, once beds are put into use, the provider will have to declare the category(ies) of the beds.

After this methodology becomes effective, applicants for new inpatient psychiatric beds will be required to select a category (Child/Adolescent, Adult, Geriatric) for which they are seeking inpatient psychiatric beds. Applicants may apply for more than one inpatient psychiatric category if a need is shown. See Section (3)(c), below regarding new beds.

Note: This new methodology is intended for planning purposes. The declaration of psychiatric beds by category on the Hospital Annual Report is not intended to preclude providers from using their psychiatric beds as necessary to address seasonal needs and surge situations. If a hospital determines that it needs to permanently change its psychiatric bed allocation, a new CON will be required. This new methodology, however, does not apply to pediatric specialty hospital providers, and is not intended: to preclude pediatric specialty hospital providers from using their pediatric specialty beds to provide pediatric psychiatric services, as necessary; to require such providers to report or declare via the SHPDA Hospital Annual Report their pediatric specialty beds used for pediatric psychiatric services as psychiatric beds, with related patient days, by inpatient category; or require such providers to obtain a CON for any new or additional use of their pediatric specialty beds for the provision of any pediatric specialty services, including pediatric psychiatric services.

#### (3) **Planning Policies**

(a) Planning on a Regional Basis

Planning will be on a regional basis. Please see attached listing for the counties in each region as designated by the SHCC.

(b) Planning Policies for applicants.

1. An applicant for an inpatient psychiatric bed must be either: 1) an established and licensed hospital provider that has been operational for at least twelve (12) months; or, 2) a new inpatient psychiatric hospital seeking a minimum of at least twenty (20) inpatient psychiatric beds. (Specialty, Free-Standing

Psychiatric Hospitals must have at least twenty (20) inpatient beds pursuant to Rule 420-5-7-.03 Classification of Hospitals, found in Chapter 420-5-7 of the Alabama Department of Public Health Administrative Code.)

2. An applicant for inpatient psychiatric beds in a particular category must demonstrate the ability to comply with state law.

3. In Certificate of Need decisions concerning psychiatric services, the extent to which an applicant proposes to serve all patients in an area should be considered. The problem of indigent care should be addressed by Certificate of Need applicants.

(c) Applying for Additional beds.

Applicants may apply for new psychiatric beds using one of the following occupancy need determinations:

1. Regional occupancy calculation.

Any region that shows an occupancy rate of 75 percent (75%) or greater in any one of the three (3) bed categories shall be eligible for additional beds in that category. The number of additional beds needed shall be calculated by dividing the average daily census for the region by the desired occupancy rate of 70 percent (70%) and then subtracting from this number the current beds in operation. Information for this calculation shall be obtained from the most recent Hospital Annual Report as compiled by SHPDA. Beds granted under the regional methodology shall be deemed part of the official regional bed inventory at time of issuance. See formula below:

To calculate regional occupancy:

Total patient days/(Beds operating x days in Reporting Period)

To calculate beds needed to get the region to 70 percent (70%) occupancy:

- (i) (Total patient days/days in Reporting Period)/.70
  = total beds needed for the region to have a 70 percent (70%) occupancy rate.
  - b. To calculate additional beds needed for the region: Total beds needed to reach 70 percent (70%) occupancy rate minus current beds in operation.

The total patient days and the beds in operation used for the calculations shall come from the information reported to SHPDA through the most recent Hospital Annual Report.

The following is an example of how the regional methodology would be calculated if a single region had 25,000 adult patient days and 90 adult beds:

To calculate the regional occupancy:

25,000 adult days/(90 beds operating x days in Reporting Period) = 76% regional occupancy

To calculate beds needed to have a 70%t occupancy:

(25,000 adult days/days in Reporting Period)/.70 = 98 total beds needed for that occupancy level

Beds needed (98) minus current beds (90) = 8 additional adult beds needed for the region.

2. Individual Provider Occupancy Calculation.

If the average occupancy rate for a single facility within a region is 80 percent (80%) or greater for a continuous period of twelve (12) months in any of the three (3) bed categories, as calculated by the SHPDA using data reported on the most recent Hospital Annual Report, that facility may apply for up to 10 percent (10%) of its current bed capacity or six (6) beds, whichever is greater. An individual facility may demonstrate a need based on occupancy irrespective of the total occupancy for the region in that bed category. Information for this calculation shall be obtained from the most recent Hospital Annual Report as compiled by SHPDA.

Any beds obtained through the Individual Provider Occupancy Calculation shall not be included in the regional bed calculation for a period of three years after the beds are brought into service. After this three-year period the beds shall be included in the regional count. Any provider obtaining beds through this provision shall not be eligible to use the 10 percent rule for 24 months from the date the CON is granted.

# (4) Plan Adjustments

The psychiatric bed need for each region as determined by the methodology is subject to adjustments by the SHCC. The psychiatric bed need may be adjusted by the SHCC if an applicant can prove that the identified needs of a target population are not being met by the current bed need methodology.

For a listing of Hospitals providing inpatient psychiatric services or the most current statistical need projections in Alabama contact the Data Division as follows:

MAILING ADDRESS (U. S. Postal Service)

PO BOX 303025 MONTGOMERY, AL 36130-3025 **STREET ADDRESS** (Commercial Carrier)

100 N. UNION STREET SUITE 870 MONTGOMERY, AL 36104

TELEPHONE: (334) 242-4103

FAX: (334) 242-4113

EMAIL: <u>data.submit@shpda.alabama.gov</u> WEBSITE: http://www.shpda.alabama.gov

Author: Statewide Health Coordinating Council (SHCC). Statutory Authority: § 22-21-260(4), <u>Code of Alabama</u>, 1975. History: Filed October 18, 2004; Effective November 22, 2004. Amended (SHP Year Only): Filed December 2, 2014; Effective January 6, 2015. Amended: Filed June 21, 2018; Effective: August 5, 2018. Repeal and New: March 16, 2020; Effective: May 15, 2020.

#### <u>Appendix</u> A <u>Psychiatric Care Regions</u>

#### **North Central Region**

Blount Calhoun Cherokee Chilton Clay Cleburne Coosa DeKalb Etowah Jefferson Randolph Shelby St. Clair Talladega Tallapoosa Walker

#### Southeast Region

Autauga Barbour Bullock Butler Chambers Coffee Covington Crenshaw Dale Dallas Elmore Geneva Henry Houston Lee Lowndes Macon Montgomery Pike Russell Wilcox

## North Region

Colbert Cullman Franklin Jackson Lauderdale Lawrence Limestone Madison Marshall Morgan

## Southwest Region

Baldwin Clarke Conecuh Escambia Mobile Monroe Washington

## West Region

Bibb Choctaw Fayette Greene Hale Lamar Marengo Marion Perry Pickens Sumter Tuscaloosa Winston

## 410-2-4-.11 Substance Use

## (1) Discussion

(a) The National Household Survey on Drug Abuse (NHSDA) estimated 22.2 million Americans age twelve (12) or older in 2012 were classified with dependence on or use of either alcohol or illicit drugs, a figure significantly higher than in 2000 – about 14.5 million. Most of these persons (14.9 million) were dependent on or used alcohol only. Another 2.8 million were dependent on or used both alcohol and illicit drugs, while 4.5 million were dependent on or used illicit drugs but not alcohol. Persons age eighteen (18) to twenty-five (25) had the highest rates of alcohol dependence or use (14.8%). (Source: www.samhsa.gov)

(b) There are more deaths and disabilities each year in the United States from Substance use than from any other cause. One-quarter of all emergency room visits, onethird of all suicides, and more than one half of all homicides and incidents of domestic violence are alcohol-related. (Source: www.ncadd.org)

(c) Alcohol and drug use costs the American economy an estimated \$276 billion per year in lost productivity, health care expenditures, crime, motor vehicle crashes and other conditions. (Source: <u>www.ncadd.org</u>)

## (2) Background

(a) Substance use services for treating indivituals with substance use disorders or those who misuse substances is provided through an array of private and public providers throughout the state. The array of services ranges from inpatient medical detoxification services to residential treatment services to a variety of outpatient types of services including various affiliated support groups.

(b) In the past few years the technology for treating individuals with dependence and use problems has changed rather dramatically from a traditional inpatient/residential mode to outpatient treatment. This has occurred for a variety of reasons including financial considerations. These phenomena can be verified through analysis of current utilization of both inpatient and residential services.

# (3) Methodology

(a) The Alabama Department of Mental Health (DMH) has developed a substance use bed need methodology, which is based upon a formula utilized in other states, commonly referred to as the "Mardin Formula". This prevalence base formula was selected in lieu of utilization-based formulas due to the lack of comprehensive statistical information on the current utilization of residential treatment centers. Calculation of needed beds is performed as follows:

(b) Step 1: Multiply the population ages 10-17 by 19%, which is the proportion assumed to have problems with chemical dependency;

(c) Step 2: Multiply the population ages 18 and over by 7%, which is the proportion assumed to have problems with chemical dependency;

(d) Step 3: Multiply the sum of steps 1 and 2 by 12%, which is the proportion who will seek treatment annually;

(e) Step 4: Multiply the product in step 3 by 60% which is the proportion of those seeking treatment who will require detoxification services for 3 days. Calculate total number of patient days;

(f) Step 5: Multiply those receiving detoxification services by 50%, which is the proportion who will need residential treatment for 10 days. Calculate total number of patient days;

- (g) Step 6: Add the patient days in steps 4 and 5 to arrive at total patient days;
- (h) Step 7: Divide by 365 to determine average daily census (ADC);
- (i) Step 8: Divide by 80% occupancy to arrive at total needed beds;
- (j) Step 9: Subtract existing public beds to arrive at total private bed need;
- (k) Step 10: Subtract existing private beds to determine need or excess.

The Statewide Health Coordinating Council (SHCC) is aware that the Alabama (4) Department of Mental Health (ADMH) currently utilizes multiple different classifications for residential and inpatient substance use treatment beds, differentiated based on the level, type and amount of medical care provided in each classification. It is the position of the SHCC that an accurate definition of substance use treatment beds for the purposes of health planning is required in order to be able to provide a more appropriate set of planning policies for these facilities moving forward. Therefore, the State Health Planning and Development Agency (SHPDA) is hereby directed to work with ADMH along with any interested parties to create a formal definition of substance use treatment beds, based on the classifications already utilized by ADMH, to determine which types of these beds would require a Certificate of Need under current law. SHPDA shall, within one (1) year of the effective date of this plan, provide to the SHCC a definition of a substance use treatment bed that would require a Certificate of Need under current law as well as a proposed amendment to this section reflecting that definition. SHPDA is further directed to analyze the existing planning methodology established in this section utilizing the proposed definitions defined above to determine whether the methodology should be amended to more accurately and appropriately determine need for these providers in the state.

For a listing of Substance Use Treatment Centers 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

TELEPHONE: (334) 242-4103

EMAIL: data.submit@shpda.alabama.gov 100 N. UNION STREET SUITE 870 MONTGOMERY, AL 36104

FAX: (334) 2424-4113

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

#### (4) Methadone Treatment

(a) Definition. Methadone is an opioid agonist medication used to treat heroin and other opiate addiction. Methadone reduces the craving for heroin and other opiates by blocking receptor sites that are affected by heroin and other opiates.

(b) Background

1. Prior to June 1991 Alabama operated two methadone clinics in Birmingham and in Mobile, both of which were operated through a DMH contract. These clinics are part of the UAB Mental Health Center and the Mobile Mental Health Center. The average number of clients served in any given month never exceeded 380 of which fewer than 5% were clients from out of state.

2. As of April 2015, Alabama has twenty-two (22) certified methadone treatment programs.

(c) Recommendations

1. A methadone treatment program should provide adequate medical, counseling, vocational, educational, mental health assessment, and social services to patients enrolled in the opioid treatment program with the goal of the individual becoming free of opioid dependency, with oversight by the Alabama Department of Mental Health.

2. The Methadone Advisory Committee suggests the following information be submitted with Certificate of Need applications:

a. The number of arrests for the previous year regarding the sale and possession of opioids by county for the area to be served.

b. Data from the Medical Examiner regarding all deaths related to overdose from opioids by county for the area to be served during the previous year.

c. Data from all hospital emergency rooms regarding the number of persons diagnosed and treated for an overdose of opioids by county for the area to be served.

d. The number of clients within specific geographic areas who, out of necessity, must travel in excess of 50 miles round-trip for narcotic treatment services.

e. The name and number of existing narcotic treatment programs within 50 miles of the proposed site.

f. Number of persons to be served by the proposed program and the daily dosing fee.

g. Applicant shall submit evidence of the ability to comply with all applicable rules and regulations of designated governing authorities.

- (d) Need
  - 1. Basic Methodology

a. The purpose of this need methodology is to identify, by region, need for additional treatment facilities to ensure the continued availability, accessibility, and affordability of quality opioid replacement treatment services for residents of Alabama.

b. A multi-county region shall be the planning area for methadone treatment facilities. A listing of the counties in each region is attached as part of this section. These were derived from the regions used by the Alabama Department of Mental Health (ADMH), Division of Mental Health and Substance Abuse Services.

c. The Center for Business and Economic Research, University of Alabama, (CBER) population data shall be used in any determination of need for methadone treatment facilities in Alabama.

d. Data from the National Survey on Drug Use and Health (NSDUH) shall be used in the calculation of national rates of dependency on heroin or prescription pain relievers in Alabama.

e. Data from ADMH shall be used in the determination of the number of current patients seen by each clinic within a region. ADMH shall supply, on an annual basis, an Annual Report to SHPDA with rates of prevalence, service utilization and epidemiological data to assist with implementation of the methodology and publication of statistical updates to this plan.

f. For each region, need shall be calculated using the following methodology:

- (i) For each county in the region, list the population, ages 18 and over, as reported by CBER, for the year matching the year for which need is being projected.
- (ii) Using NSDUH data for the same time period, determine the rate of dependency on heroin and prescription pain relievers nationally.

- (iii) For each county in the region, multiply the population from step (i) above by the dependency rate in step (ii) above to determine the projected number of residents in that county addicted to heroin or prescription pain relievers.
- (iv) Multiply the estimate from step (iii) above by 20% (0.2) to determine the projected number of residents of that county likely to seek Medication Assisted Therapy for opioid dependency.
- (v) Add the county totals determined in step (iv) above to determine the regional totals.
- (vi) Using data supplied by ADMH, determine the current census of each treatment center in the region on the last day of the year matching the year of population and NSDUH dependency data used in step (i) and step (ii) respectively.
- (vii) Add the facility census totals determined in step (vi) above to determine regional totals.
- (viii) If the number of residents projected to seek treatment in a region as determined in step (v) is greater than the current census of all treatment centers in the region as determined in step (vii) by more than 10%, a need shall be shown for a new methadone treatment facility in that region.
  - (ix) Only one methadone treatment facility may be approved in any region showing a need under this methodology during any application cycle, defined here as the period of time between the date of publication of one statistical update and the date of publication of a successive update.
  - (x) Upon the issuance of a Certificate of Need for a new methadone treatment facility in a region, no additional CONs shall be issued for the development of a new methadone treatment facility in that region for a period of eighteen (18) months to allow for the impact of a new provider in the region to be shown and reflected in the next statistical update.

2. The provisions of subsection 1 above shall not prohibit the grant of a Certificate of Need for the relocation and replacement of an existing methadone treatment facility within the same planning region.

3. All methadone clinic applications shall be site specific. No CON shall be granted for a new methadone treatment facility to be located within fifty (50) linear miles of an existing methadone treatment facility.

(e) Adjustments.

Need for additional methadone treatment facilities, as determined in subsection 1 above, is subject to adjustment by the SHCC as provided below. The SHCC may adjust the need for a new methadone treatment facility only upon demonstration of one or more of the following conditions listed in 1 through 3 below. Applicants seeking an adjustment under this section shall include, as part of the application, supporting documentation from ADMH.

1. The opioid-related arrest or death rate in the region exceeds the national average, and there are no methadone treatment facilities within fifty (50) miles of the county for which the proposed adjustment applies.

2. Hospital emergency room admissions for opioid-overdose related conditions in the region exceed the national average, and there are no methadone treatment facilities within fifty (50) miles of the county for which the proposed adjustment applies.

3. Admissions to drug-free programs specifically treating opioid dependency in the region exceed the national average, and there are no methadone treatment facilities within fifty (50) miles of the county for which the proposed adjustment applies.

(f) Preference for Indigent Patients.

In considering CON applications filed under this section, whether pursuant to the regular need methodology or an adjustment, preference shall be given to those applicants demonstrating the most comprehensive plan for treating patients regardless of their ability to pay.

Region I	Region II	Region III	<b>Region IV</b>
Cherokee Colbert Cullman DeKalb Etowah Fayette Franklin Jackson Lamar Lauderdale Lawrence Limestone Madison Marion Marshall Morgan Walker	Bibb Blount Calhoun Chilton Clay Cleburne Coosa Jefferson Pickens Randolph Shelby St. Clair Talladega Tuscaloosa	Autauga Bullock Chambers Choctaw Dallas Elmore Greene Hale Lee Lowndes Macon Marengo Montgomery Perry Pike Russell Sumter	Baldwin Barbour Butler Clarke Coffee Conecuh Covington Crenshaw Dale Escambia Geneva Henry Houston Mobile Monroe Washington
Winston		Tallapoosa Wilcox	

#### Methadone Treatment Facility Regional County Listings

Author: Statewide Health Coordinating Council (SHCC).

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

History: Filed October 18, 2004; Effective November 22, 2004. Amended: Filed August 16, 2012; Effective September 20, 2012. Amended: Filed November 20, 2013; Effective December 25, 2013. Amended (SHP Year Only): Filed December 2, 2014; Effective January 6, 2015. Amended: Filed: September 9, 2015; Effective October 14, 2015. Repeal and New: Filed March 16, 2020; Effective May 15, 2020.

#### 410-2-4-.12 Ambulatory Surgery

#### (1) Discussion

An evolution in the provision of surgical care provided in ambulatory surgery centers has taken place. As a result of cost containment measures and advances in medical technology, many surgical procedures which previously required inpatient care (both before and after the procedures) are now done on an outpatient basis.

## (2) **Definitions**

For the purposes of this section, the following definitions shall be used:

- (a) Ambulatory Surgery Center (ASC) a health care facility, licensed by the Alabama Department of Public Health, with the primary purpose of providing medically necessary or elective surgical care on an outpatient basis and in which the patient stays less than 24 hours. Excluded from this definition are the offices of private physicians and dentists, including those organized as professional corporations, professional associations, partnerships, or individuals in sole proprietorship. Also excluded from this definition are health care facilities licensed as hospitals.
- (b) Hospital-owned Ambulatory Surgery Center (HASC) a facility either owned and operated exclusively by an existing acute care hospital or where the hospital holds majority ownership in conjunction with other entities and which is operated as a separately licensed entity distinct from the hospital, containing operating rooms which are solely and exclusively used for the provision of outpatient surgical services that, due to licensure, practice standards or other reasons, are not performed in a physician's office or in an office-based lab (OBL).
- (c) Hospital Surgical Department (HSD) operating rooms specifically designated by a hospital for performing surgical procedures, on an inpatient, outpatient, or "mixed-use" basis.
- (d) Multi-Specialty Ambulatory Surgery Center (MASC) an ASC established for the provision of outpatient surgical procedures in a variety of specialties. MASCs allow for physicians from multiple disciplines to perform surgical procedures in a centralized location that, due to licensure, practice standards or other reasons, are not performed in a physician's office or in an office-based lab (OBL).
- (e) Operating Room rooms used for the performance of surgical procedures requiring one or more incisions and which must comply with licensure standards for an operating room. Operating Rooms are not to include procedure rooms.
- (f) Procedure Room rooms designated for the performance of special procedures that do not require a restricted environment and are not considered to be operating rooms.

(g) Single-Specialty Ambulatory Surgery Center (SASC) – an ASC established for the provision of outpatient surgical procedures of a single specialty only. SASCs allow for surgical procedures to be performed that, due to licensure, practice standards or other reasons, are not performed in a physician's office or in an office-based lab (OBL).

# (3) **Purpose**

- (a) The purpose of this need methodology is to identify the number of Ambulatory Surgery Center operating rooms needed at least three (3) years into the future to assure the continued availability of quality ambulatory surgical care for the residents of the state of Alabama. Such number, as identified later in this section, shall be the basis for statewide health planning and certificate of need approval, except:
  - 1. In circumstances that pose a threat to public health, and/or
  - 2. When the SHCC makes an adjustment based on criteria specified later in this section

## (4) **Planning Policies**

For the purposes of this section, the following planning policies shall apply regarding the provision of ambulatory surgical services:

- (a) The methodology in (5) below shall not apply to the expansion of an existing HSD, nor shall it apply to any hospital seeking to establish an outpatient surgical department internal to the existing hospital.
- (b) The methodology in (5) below shall not apply to any hospital seeking to convert up to four (4) of its existing operating rooms in a HSD for use in the creation of a HASC, provided that said conversion does not seek to add any additional operating rooms to its existing complement as reported to SHPDA on the Annual Report for Hospitals and Related Facilities for the most recent reporting period. However, the methodology in (5) below shall apply if the applicant seeks to add additional rooms to its existing complement, as reported, as a part of any conversion. Any application to create a new HASC through the conversion of existing HSD rooms shall only be allowed in the same county in which the HSD is currently located. Once a Certificate of Need is issued related to the conversion of the operating rooms in a HSD to a HASC, those rooms will be counted as a part of the CON authorized inventory for the purposes of future statistical updates to this plan. Once CONs are issued for the conversion of the maximum number of operating rooms allowed to be converted through the use of this policy, that hospital shall not qualify to apply to convert additional operating rooms through the use of this policy for a minimum of twenty-four (24) months following the licensure by the Alabama Department of Public Health of all facilities created by that applicant through this policy to allow for the impact of any new ASC created through this policy to be shown.

1. Any ORs converted using this policy shall be removed from the hospital inventory upon licensure of any ASC established through this policy by ADPH. These converted ORs shall not be reopened by the hospital after licensure of the ASC created under this policy unless and until additional action is taken by the hospital, either through the granting of a CON or a determination by SHPDA that the reopening of said converted ORs is not reviewable under CON law.

2. Furthermore, any applicant seeking to establish a HASC through the use of this provision shall affirm, as a part of their application, that the hospital shall maintain majority ownership of the HASC for a minimum of five (5) years following its initial licensure to ensure financial viability for the project.

- (c) The methodology in (5) below shall apply to any hospital seeking to construct and/or operate a HASC that is not to be created through the conversion of operating rooms in an existing HSD.
- (d) An HASC created through these planning policies shall be considered a MASC once established, and the methodology in (5) below shall apply to any existing HASC seeking to expand through the addition of new operating rooms.
- (e) The methodology in (5) below shall not apply to any applicant seeking to establish a new SASC consisting of no more than four (4) operating rooms. The methodology in (5) below shall apply, however, to any operating rooms beyond the four (4) allowed under this policy. Applicants seeking to establish a new SASC consisting of no more than four (4) operating rooms shall need to provide, as part of their application, evidence that the SASC is needed in the service area. Once a Certificate of Need is issued related to the establishment of a SASC, those rooms will be counted as a part of the CON authorized inventory for the purposes of future statistical updates to this plan.
- (f) The methodology in (5) below shall not apply to any applicant seeking to convert an existing SASC into either a MASC or a SASC of a different specialty without adding additional operating rooms, but shall apply to any applicant seeking to establish a new MASC, to expand an existing MASC, or to an applicant seeking to convert an existing SASC into a MASC that also seeks to add additional operating rooms. Any provider seeking to convert an SASC either to a MASC or to a SASC of a different specialty shall still be required to file for a CON even if the applicant does not seek to add additional operating rooms to its existing CON authorized capacity.
- (g) Irrespective of (a)-(f) above, any applicant seeking to offer any service listed elsewhere in this plan which contains its own statistical need methodology or planning policies shall be required to adhere to the need criteria of that section in addition to the need criteria established in this section.

- (h) An application for a Certificate of Need for an ambulatory surgical center that is exempt from the methodology in (5) below shall remain subject to the remaining criteria set forth in Alabama's Certificate of Need laws and regulations.
- (i) While reviewing any application for the construction of a new Ambulatory Surgery Center, the Certificate of Need Review Board shall consider the physical location of the proposed new ASC in relation to any existing health care facilities in the same planning area to determine whether the proposed new location would create a detrimental impact upon existing providers that might negatively impact the provision of care to existing patients.
- (j) The methodology in (5) below shall not apply to any applicant seeking to create or add procedure rooms to an existing facility or to create an ambulatory surgery center that only consists of procedure rooms. Any applicant seeking to create or add procedure rooms shall, in the alternative, provide as a part of any application evidence that the additional rooms are necessary for the delivery of quality outpatient surgical care to patients.

## (5) Methodology

- (a) The county shall be the planning area for the determination of need for additional outpatient surgery rooms in Ambulatory Surgery Centers.
- (b) For the purposes of this methodology, only those ORs utilized and patient cases treated in Ambulatory Surgery Centers shall be used. ORs utilized and patient cases treated at any other location shall not be included as a part of this methodology.
- (c) No application for the establishment of a new MASC shall be approved for fewer than four (4) operating rooms to allow for the financial feasibility and viability of a project. Need may be adjusted, therefore, by the Agency for any county currently showing need of more than zero (0) but fewer than four (4) operating rooms to a total of four (4) operating rooms, but only in the consideration of an application for the construction of a new facility in that county, and in situations in which no MASC currently exists in that county. Need shall not be adjusted in consideration of an application involving the expansion of an existing MASC or SASC, nor shall it be adjusted in consideration of an application involving the creation of a new MASC in a county wherein a MASC already exists.
- (d) For the purposes of this methodology, the following values will be used to perform the necessary calculations: Average Time of Outpatient Surgery – 1.5 hours; Average Hours of Operation – 8 hours/day 5 days/week, 50 weeks/year; Maximum Cases per OR in one year – 1,350.
- (e) In counties in which an existing CON Authorized ASC already exists, need shall be shown for additional Ambulatory Surgery Center operating rooms should the average number of cases per room in the county projected three (3) years from the most recent

reported year and considering the growth of population of that county over the three (3) year planning horizon exceed 70% of the maximum, or 945 operations/room/year. Should a need for additional operating rooms be determined, the need shall be the total number of operating rooms required to decrease the average number of cases per room in the county to 70%, or 945 cases/room/year.

- (f) In counties in which an existing CON Authorized ASC does not exist, need shall be shown for Ambulatory Surgery Center operating rooms based upon the projected number of cases for residents of that county in ASC's located elsewhere and the growth in population of that county over a three year planning horizon. The total number of operating rooms shown to be needed will be that number required to sustain a utilization rate of 70%, or 945 cases/room/year.
- (g) Need for new operating rooms/suites shall be determined using the following formula:

County Net OR need = 
$$\left(\frac{\left(\frac{(Y1 * 3) + (Y2 * 2) + Y3}{6}\right) * \left(\frac{P3}{P1}\right)}{945}\right)$$
 – Existing County ORs

\*For counties with existing ASCs:

Y1 = total operations, ASCs in county, current reporting year

Y2 = total operations, ASCs in county, current reporting year -1

Y3 = total operations, ASCs in county, current reporting year -2

\*For counties without existing ASCs:

Y1 = total operations, county residents in ASCs, current reporting year

Y2 = total operations, county residents in ASCs, current reporting year - 1

Y3 = total operations, county residents in ASCs, current reporting year -2

P1 = current reporting year's population as projected by CBER<sup>17</sup>

P3 = population 3 years from current reporting year as projected by CBER

\*\* Due to the impact of COVID-19 on the delivery of ambulatory surgical services, the SHCC, in consultation with the Health Care Information and Data Advisory Council, has determined that data from the 2020 reporting period shall NOT be utilized in the determination of need for additional ASC operating rooms. SHPDA is hereby directed to omit FY2020 data, if necessary, and utilize FY2019 data in its place.

Once a CON is issued for the provision of ASC services in a county in which an ASC did not previously exist, or should all ASCs in a county cease to operate AND lose CON authority, the appropriate methodology shall be applied on the next issued statistical update.

<sup>&</sup>lt;sup>17</sup> Centers for Business and Economic Research, University of Alabama

- (h) The current need for additional operating rooms/suites can be found as a statistical update to this section
- (i) Additional need may be shown in situations involving a sustained high utilization rate for a single facility in a county. An applicant may apply for additional ORs, and thus the establishment of need above and beyond the standard methodology, utilizing one of the following two policies. A provider obtaining a Certificate of Need under either of the two following policies may not submit another application under either such policy for a period of twenty-four (24) months following the date the additional ORs are licensed/become operationalized to allow for the impact of those additional ORs to be shown.
  - a. If the utilization rate for an ASC is greater than 80% for each of the two (2) most recent "Annual Report(s) for Ambulatory Surgery Centers" published by or filed with SHPDA, an additional need of the greater of either ten percent (10%) of the current total CON authorized OR capacity of that provider, or four (4) total ORs may be approved for the expansion of that facility, irrespective of the total utilization rate of ASC ORs of the county over that time period.
  - b. If an ASC is seeking to add the services of additional surgeons treating cases in a service line not currently offered at that ASC, an additional need of the greater of either ten percent (10%) of the current total CON authorized OR capacity of that provider, or four (4) total ORs, may be approved for the expansion of that facility, irrespective of the total utilization rate of ASC ORs of the county over that time period. However, these additional ORs may be added ONLY if the projected number of additional cases to be treated in this new service line for the first two (2) years following implementation of the service would cause the utilization rate of the existing ORs at that facility to increase to 80% or higher according to the calculations used to determine utilization rate as defined above.

As a part of any application seeking to expand based upon this specific policy, additional information shall be submitted showing both the current volume of cases treated by the additional surgeons currently at any other surgery locations for the previous two (2) years along with the current volume of cases treated by the ASC seeking expansion for the previous two (2) years AND the projected number of cases to be treated at the ASC for the first two (2) years following implementation of the new service line. No application shall be accepted under this policy in which the underlying utilization data for the previous two (2) years following implementation of the new service does not support a projected utilization rate of the existing ORs at that ASC of 80% or greater for the first two (2) years following implementation of the new service line.

(j) Any ASC or Hospital that does not substantially comply with any data request made on behalf of SHPDA shall not be allowed to apply for a Certificate of Need under any provision in this section of the Plan, nor shall they be allowed to intervene in or oppose any application filed on behalf of another ASC or Hospital under any provision in this section of the Plan. Such barriers to an application for a Certificate of Need, or inability to intervene or oppose an application for a Certificate of Need, shall be applied in a manner consistent with the provisions set forth in Ala. Admin. Code r. 410-1-3-.11.

- (k) The SHCC finds that a minimum of three (3) years is needed to evaluate the effectiveness of the need methodology in this section. To facilitate such review:
  - 1. On the date this new methodology becomes effective, SHPDA shall memorialize the total number of ambulatory surgery centers, including both single- and multi-specialty, and the total number of outpatient surgery rooms including all hospitals, HASCs, SASCs, and MASCs for future use. This memorialization shall also be used by SHPDA to establish and maintain the CON authorized OR capacity for each ambulatory surgery center currently licensed and operational, as well as all CON projects still active and under development, which will establish the existing state inventory of CON authorized ORs for the purposes of this methodology moving forward.
  - 2. SHPDA shall consult with the Health Care Information and Data Advisory Council to make such amendments to the existing Annual Report for Ambulatory Surgery Centers as needed to more accurately determine the utilization of ASCs as defined by the methodology in this section. The SHCC specifically requests that any amendments to the existing Annual Report for Ambulatory Surgery Centers include the collection of additional information related to the amount of available time for all operating rooms at a facility and the total amount of surgical time (including any necessary preparatory or cleanup) the operating rooms at a facility are in use, as well as a specific breakdown of cases treated in operating rooms versus cases treated in procedure rooms.
  - 3. SHPDA shall compile and summarize the information for the three-year period defined above, and shall provide a report to the SHCC showing the growth or decline in outpatient surgery rooms, HASCs, SASCs, and MASCs and in the total number of outpatient surgeries/procedures performed in these locations. SHPDA shall identify potential causes for such changes including population and demographic changes. Such information shall also be distributed to any interested parties, which shall be given an opportunity to provide testimony or written input to the SHCC regarding the impact of the methodology.
  - 4. As part of the analysis of the impact of this new methodology, SHPDA shall review the number of cases in which patients travel outside of their county of residence to receive services. This information shall be used by SHPDA to provide to the SHCC information allowing for future discussions related to both the ability for an HASC to be created in a contiguous county of an existing hospital and whether the county is the appropriate planning area for ASCs. Furthermore, SHPDA shall specifically review the information collected

regarding the total time available for surgeries in operating rooms and the total time the operating rooms are in use to determine if this would be a more accurate mechanism to determine need for additional operating rooms under the utilization exemption defined in (5)(i) above. Such information shall also be distributed to any interested parties, which shall be given an opportunity to provide testimony or written input to the SHCC regarding this analysis as part of those discussions.

5. Following receipt of such input, SHCC shall review the methodology to consider any needed changes.

## (6) Criteria for Plan Adjustments

- (a) The need, as determined by the methodology, is subject to adjustment by the SHCC as provided in Ala. Admin Code 410-2-5-.04, and the additional, specific criteria set forth below. An applicant seeking an adjustment has the burden of demonstrating extraordinary circumstances that result in the identified needs of a target population not being met by existing ambulatory surgery providers, and not able to be met in a timely fashion through application of the methodology, based on each of the following:
  - 1. Evidence that affected residents do not have access to necessary health services that can be met through application of the methodology. Accessibility refers to an individual's ability to make use of available health resources. Problems which might affect access to care include persons living more than thirty (30) minutes travel time from a facility providing ambulatory surgical services, lack of health manpower in certain counties, and individuals being without financial resources to obtain access to care;
  - 2. Evidence of unique, area specific circumstances demonstrating that a plan adjustment would result in health care services being rendered in a more cost-effective manner. The SHCC, by adopting the need methodology herein, has determined that services in excess of the number computed to be needed are not cost-effective. Therefore, a party seeking a plan adjustment would have a high burden in establishing such circumstances; and
  - 3. Evidence that a plan adjustment would result in improvements in the quality of health care delivered to residents in the proposed county.
- (b) Applicants seeking an adjustment shall address, and the SHCC shall consider, the potential detrimental financial impact on existing health care facilities in the proposed county.

# (7) Inventory of Existing Resources

For a listing of Ambulatory Surgery Centers contact the Data Division as follows:

STREET ADDRESS
(Commercial Carrier)
100 NORTH UNION STREET, SUITE 870
MONTGOMERY, AL 36104
FAX:
(334) 242-4113
WEBSITE:
http://www.shpda.alabama.gov

Author: Statewide Health Coordinating Council (SHCC). Statutory Authority: § 22-21-260(4), <u>Code of Alabama</u>, 1975. History: Filed October 18, 2004; Effective November 22, 2004. Amended (SHP Year Only): Filed December 2, 2014; Effective January 6, 2015. Repeal and New: Filed March 16, 2020; Effective May 15, 2020.

#### 410-2-4-.13 Renovations

(1) Renovation is defined as a project for modernization, improvement, alteration and/or upgrading of an existing physical plant and/or equipment. Renovation does not include the modernization or construction of a non-clinical building, parking facility, or any other non-institutional health services capital item on the existing campus of a health care facility, provided that construction or modernization does not allow the health care facility to provide new institutional health services subject to review and not previously provided on a regular basis.

# (2) Planning Policies

(a) The applicant must demonstrate that the proposed renovation is the most cost effective or otherwise most appropriate alternative to provide patients with needed health care services and/or facility improvements.

(b) The applicant must provide evidence that the proposed square footage, construction cost per square foot, and cost of fixed equipment is appropriate and reasonable for the types and volumes of patients to be served.

(c) The applicant must demonstrate how the disruption of normal operations will be minimized during the period of construction.

## (3) Needs Assessment.

(a) For the renovation of a health care facility an applicant must submit significant evidence of need for the project. Evidence of need for the project should include, but is not limited to, one or more of the following:

1. The service being provided by the applicant requires additional space or the facility requires renovation to meet minimum licensure and certification requirements.

2. There are operating problems which can best be corrected by renovation of the existing facility.

3. The renovation will correct deficiencies that place the health and safety of patients and/or employees at significant risk.

Author: Statewide Health Coordinating Council (SHCC).

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

History: Filed October 18, 2004; Effective November 22, 2004. Amended (SHP Year Only): Filed December 2, 2014; Effective January 6, 2015. Repeal and New: Filed March 16, 2020; Effective May 15, 2020.

## 410-2-4-.14 Replacements

(1) Replacement is defined as a project for the erection, construction, creation or other acquisition of a physical plant or facility where the proposed new structure will replace an existing structure and will be located in the same planning area and market area. Replacement does not include the modernization or construction of a non-clinical building, parking facility, or any other non-institutional health services capital item on the existing campus of a health care facility, provided that construction or modernization does not allow the health care facility to provide new institutional health services subject to review and not previously provided on a regular basis.

# (2) Planning Policies

(a) The applicant must demonstrate that the proposed replacement is the most cost effective or otherwise most appropriate alternative to provide patients with needed health care services and/or facility improvements.

(b) The applicant must provide evidence that the proposed square footage, construction cost per square foot, and cost of fixed equipment is appropriate and reasonable for the types and volumes of patients to be served.

(c) The applicant for the proposed replacement must be the same as the owner of the facility to be replaced.

# (3) Needs Assessment

(a) For replacement of a health care facility an applicant must submit significant evidence of need for the project. Evidence of need for the project should include, but is not limited to, one or more of the following:

1. The existing structure requires replacement to meet minimum licensure and certification requirements.

2. There are operating problems, which can best be corrected by replacement of the existing facility.

3. The replacement of the existing structure will correct deficiencies that place the health and safety of patients and/or employees at significant risk.

(b) For replacement of hospitals, the occupancy rate for the most recent annual reporting period should have been at least 60%. If this occupancy level was not met, the hospital should agree to a reduction in bed capacity that will increase its occupancy rate to 60 percent. For example, if a 90-bed hospital had an average daily census (ADC) of 45 patients, its occupancy rate was 50%. (The ADC of 45 patients divided by 90 beds equals 50 percent). To determine a new bed capacity that would increase the hospital's occupancy rate to 60%, divide the ADC of 45 patients by 0.60 (a fraction of a bed should be rounded

upward to the next whole bed). The hospital's new capacity should be 75 beds, a 15 bed reduction to its original capacity of 90 beds.

Author: Statewide Health Coordinating Council (SHCC).

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

History: Filed October 18, 2004; Effective November 22, 2004. Amended (SHP Year Only): Filed December 2, 2014; Effective January 6, 2015. Repeal and New: Filed March 16, 2020; Effective May 15, 2020.

## 410-2-4-.15 Inpatient 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.

(b) It is the intent of this section to address health planning concerns relating to hospice services provided on an inpatient basis. For coverage of hospice services provided primarily in the patient's place of residence, please see Section 410-2-3-.10.

(c) A hospice program is required by federal statutes as a Condition of Participation for hospice care (Title 42- Public Health; Chapter IV – CMS, Department of Health and Human Services; Part 418 – Hospice care; Section 418.98 or successors) and state statutes and regulations (Alabama State Board of Health, Department of Public Health; Administrative Code, Chapter 420-5-17; Section 420-5-17-.01 or successors) to provide general inpatient level of care and inpatient respite level of care as two of the four levels of hospice care. As per the Medicare Condition of Participation (418.108), the total number of inpatient days used by Medicare beneficiaries who elected hospice coverage in a 12-month period in a particular hospice may not exceed twenty percent (20%) of the total number of hospice days consumed in total by this group of beneficiaries.

(d) A hospice program per federal statute must provide the inpatient levels of care that meets the conditions of participation specified. The approved locations for inpatient hospice care are a hospital, a skilled nursing facility ("SNF"), or an inpatient hospice facility.

(e) A hospice program may provide the inpatient levels of care in a freestanding inpatient facility/unit which the hospice program owns and manages; through beds owned by either a hospital or a skilled nursing facility ("SNF") but leased and managed by a hospice program; or through contracted arrangements with another hospice program's inpatient facility/unit.

# (2) **Definitions**

(a) All definitions included in Section 410-2-3-.10 are incorporated herein by reference.

(b) Inpatient hospice facility. An "Inpatient Hospice Facility" is defined as a freestanding hospice facility or a designated unit, floor or specific number of beds located in a skilled nursing facility or hospital leased or under the management of a hospice services provider.

(c) General Inpatient Level of Care. The general inpatient ("GIP") level of hospice care is intended for short term acute care for pain control and symptomatic management. It is not intended for long term care, residential or rehabilitation.

(d) Inpatient Respite Level of Care. The inpatient respite level of care is limited per Medicare and Medicaid to a maximum of five (5) days per episode for the purpose of family respite.

## (3) Availability and Accessibility

(a) Hospice services must be obtainable by all of the residents of the State of Alabama.

(b) Physicians and other referral sources may be unfamiliar with the total scope of services offered by hospice; accessibility may be limited due to 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.

(c) In order for a SNF to provide the inpatient levels of care for hospice patients, the SNF must meet the standards specified by CMS regarding items such as required staffing of facilities.

(d) Hospice agencies are limited in establishing contracts with hospitals for the inpatient levels of care. This is due to (a) the increased number of hospice providers that request contracts from the same hospitals in the same service areas; and (b) the reimbursement hospitals receive from the hospice providers for the hospice inpatient levels of care.

# (4) Inventory

(a) The establishment of an inpatient hospice facility does not eliminate the need for contractual arrangements with hospitals or SNF for inpatient levels of care. If the inpatient hospice facility is at full capacity and a hospice patient is eligible for/requires inpatient care, the hospice remains responsible to provide that level of care at a contracted facility.

# (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 the most cost effective service delivery.

(c) Hospice programs are required to meet the most stringent 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) Inpatient Hospice Facility Need Methodology

(a) Purpose. The purpose of this inpatient hospice services need methodology is to identify, by region, the number of inpatient hospice beds needed to assure the continued availability, accessibility, and affordability of quality of care for residents of Alabama.

(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. The purpose of this need methodology is to identify, by region, the number of inpatient hospice beds needed to assure the continued availability, accessibility, and affordability of quality hospice care for residents of Alabama.

2. The need methodology shall be calculated by aggregating the reported average daily censuses (ADC) for all licensed hospices in the designated Region, as reported annually to SHPDA, and multiplying that aggregate regional ADC by 3%. The resulting figure shall be the regional need.

3. Any increase in regional need shall be limited to no more than five percent (5%) per year with the sole exclusion of any need determined under Planning Policy 7 of this section.

(d) Planning Policies

1. Planning will be on a regional basis. The attached listing defines the regional descriptions designated by the SHCC.

2. An applicant for an inpatient hospice facility must be an established and licensed hospice provider and operational for at least thirty-six (36) months in Alabama.

3. An applicant for an inpatient hospice facility must demonstrate the ability to comply with Medicare/Medicaid regulations.

4. An applicant for an inpatient hospice facility must demonstrate that existing inpatient hospice beds in the region cannot meet the community demand for inpatient hospice services.

5. An applicant for an inpatient hospice facility must demonstrate that sharing arrangements with existing facilities have been studied and implemented when possible.

6. An applicant for an inpatient hospice facility may provide supplemental evidence in support of its application from other data reported by licensed hospices on an annual basis to the State of Alabama or the Federal Government.

7. Additional need may be shown in situations involving a sustained high occupancy rate either for a region or for a single facility. An applicant may apply for additional beds, and thus the establishment of need above and beyond the standard methodology, utilizing one of the following two policies. Once additional beds have been applied for under one of the policies, that applicant shall not qualify to apply for additional beds under either of these policies unless and until the established time limits listed below have passed. All CON Authorized Inpatient Hospice beds shall be included in consideration of occupancy rate and bed need.

a. If the total combined occupancy rate for all CON Authorized Inpatient Hospice facilities in a region is above 90% as calculated by SHPDA using data reported on the most recent full year "Annual Report for Hospice Providers (Form HPCE-4)" published by or filed with SHPDA, an additional need of the greater of five percent (5%) of the current total CON Authorized bed capacity of that region or five (5) total beds may be approved for the expansion of an existing facility within that region. Once additional bed need has been shown under this policy, no new need shall be shown in that region based upon this rule for twenty-four (24) months following issuance of the initial CON to allow for the impact of those beds in that region to be analyzed. Should the initial applicant for beds in a region not apply for the total number of beds allowed under this rule, the remaining beds would then be available to be applied for by other providers in the region meeting the conditions listed in this rule.

b. If the occupancy rate for a single facility within a region is greater than 90% as calculated by SHPDA using data reported on the most recent full year "Annual Report for Hospice Providers (Form HPCE-4)" published by or filed with SHPDA, irrespective of the total occupancy rate for all CON Authorized Inpatient Hospice facilities in that region, up to five (5) additional beds may be approved within that region for the expansion of that facility only. Once additional beds have been approved under this policy, no new beds shall be approved for that facility for twenty-four (24) months following issuance of the CON to allow for the impact of those beds at that facility to be analyzed.

8. No application for the establishment of a new, freestanding Inpatient Hospice facility shall be approved for fewer than ten (10) beds to allow for the financial feasibility and viability of a project. Need may be modified by the Agency for any county currently showing a need of more than zero (0) but fewer than ten (10) total beds to a total need of ten (10) new beds, but only in the consideration of an application for the construction of a new, freestanding facility in a region in which no freestanding Inpatient Hospice currently exists. Need shall not be adjusted in consideration of an application involving the expansion of a CON Authorized Inpatient Provider, nor shall need be adjusted according to this rule in any region wherein a CON Authorized freestanding Inpatient Hospice facility already exists.

#### (e) Adjustments

The need for inpatient hospice beds, as determined by the methodology, is subject to adjustments by the SHCC. The SHCC may adjust the need for inpatient hospice beds in a region if an applicant documents the existence of at least one of the following conditions:

1. Absence of available inpatient beds for a hospice certified for Medicaid and Medicare in the proposed region, and evidence that the applicant will provide Medicaid and Medicare-certified hospice services in the region; or

2. Absence of services by a hospice in the proposed region 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.

3. A community need for additional inpatient hospice services greater than those supported by the numerical methodology.

#### (7) Inpatient Hospice Regions

The attached "Inpatient Hospice Regional County Listing" is hereby adopted as an Appendix "A" to Section 410-2-4-.15.

For a listing of Inpatient Hospice Facilities or the most current statistical need projections in Alabama contact the Data Division as follows:

MAILING ADDRESS	STREET ADDRESS
(U. S. Postal Service)	(Commercial Carrier)
PO BOX 303025	100 NORTH UNION STREET, SUITE 870
MONTGOMERY, AL 36130-3025	MONTGOMERY, AL 36104
TELEPHONE:	FAX:
(334) 242-4103	(334) 242-4113
(334) 242-4103	(554) 242-4115
EMAIL:	WEBSITE:
<u>data.submit@shpda.alabama.gov</u>	http://www.shpda.alabama.gov

Author: Statewide Health Coordinating Council (SHCC).

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

History: Filed February 1, 2010; Effective March 8, 2010. Amended: Filed January 24, 2012; Effective: February 28, 2012. Amended: Filed November 2, 2012; Effective: December 7, 2012. Amended: Filed December 2, 2014; Effective January 6, 2015. Repeal and New: Filed March 16, 2020; Effective May 15, 2020.

# Appendix A

# **Inpatient Hospice Regional County Listings**

<u>REGION 1</u>	REGION 5	<b>REGION 9</b>	<u>RE</u>
Colbert	Jefferson	Chambers	Lee
Franklin		Clay	Mac
Lauderdale		Randolph	Rus
Marion	<u>REGION 6</u>	Talladega	
		Tallapoosa	
	Calhoun		RE
REGION 2	Cherokee		
	Cleburne	<u>REGION 10</u>	Balo
Jackson	Saint Clair		Mol
Limestone		Choctaw	Was
Madison	REGION 7	Dallas	
		Marengo	
	Bibb	Perry	RE
REGION 3	Fayette	Sumter	
	Greene	Wilcox	Clar
Cullman	Hale		Con
Lawrence	Lamar	<u>REGION 11</u>	Cov
Morgan	Pickens		Esca
Walker	Tuscaloosa	Autauga	Mor
Winston		Bullock	
		Butler	
	<u>REGION 8</u>	Crenshaw	REC
REGION 4		Elmore	
	Chilton	Lowndes	Barl

Blount DeKalb Etowah Marshall

Chilton Coosa Shelby

Montgomery Pike

# EGION 12

e icon ssell

# EGION 13

ldwin obile ashington

## EGION 14

arke necuh vington cambia onroe

# EGION 15

Barbour Coffee Dale Geneva Henry Houston Author: Statewide Health Coordinating Council (SHCC).

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

History: New Rule: Filed January 24, 2012; Effective: February 28, 2012. Amended: Filed November 2, 2012; Effective: December 7, 2012. Amended (SHP Year Only): Filed December 2, 2014; Effective January 6, 2015. Repeal and New: Filed March 16, 2020; Effective May 15, 2020.

# 410-2-4-.16 Freestanding Emergency Departments (FEDs)

A "Freestanding Emergency Department" or "FED" is a new institutional health service requiring a Certificate of Need under Alabama law. In addition to other applicable criteria, all proposed FEDs must demonstrate, through substantial evidence, that their project will meet all the requirements for licensure under ALA. ADMIN. CODE r 420-5-9, which is incorporated herein by reference.

Author: Statewide Health Coordinating Council (SHCC). Statutory Authority: §§ 22-21-260(13), (15), <u>Code of Alabama</u>, 1975. History: Filed June 5, 2015; Effective July 10, 2015. Repeal and New: Filed March 16, 2020; Effective May 15, 2020.

## ALABAMA STATE HEALTH PLAN 2024-2027 STATE HEALTH PLANNING AND DEVELOPMENT AGENCY

## Chapter 410-2-5

#### **Alabama Health Statistics and Revision Procedures**

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## 410-2-5-.01 Introduction

This chapter contains information that is pertinent to the *State Health Plan*, but of such detail that it is best included in this Appendix. Population is based on Center for Business and Economic Research (CBER) The University of Alabama.

Author: Statewide Health Coordinating Council (SHCC).

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

History: Filed October 18, 2004; Effective November 22, 2004. Amended (SHP Year Only): Filed December 2, 2014; Effective January 6, 2015. Repeal and New: Filed March 16, 2020; Effective May 15, 2020.

## 410-2-5-.02 **Population**

The most current population data supplied to SHPDA by the Center for Business and Economic Research (CBER), University of Alabama, is available by contacting the Data Division as follows:

MAILING ADDRESS	STREET ADDRESS
(U. S. Postal Service)	(Commercial Carrier)
PO BOX 303025	100 NORTH UNION STREET, SUITE 870
MONTGOMERY, AL 36130-3025	MONTGOMERY, AL 36104
TELEPHONE:	FAX:
(334) 242-4103	(334) 242-4113
EMAIL:	WEBSITE:
Data.submit@shpda.alabama.gov	http://www.shpda.alabama.gov
Author: Statewide Health Coordina	ating Council (SHCC)

Author:Statewide Health Coordinating Council (SHCC)Statutory Authority:§ 22-21-260(4), Code of Alabama, 1975History:Filed October 18, 2004; Effective November 22, 2004. Repeal and New: FiledMarch 16, 2020; Effective May 15, 2020.

# 410-2-5-.03 Vital Events

The most recent publicly available information on Vital Events can be obtained from the Center for Health Statistics, Alabama Department of Public Health, at <u>www.alabamapublichealth.gov</u>/healthstats/index.html, or at (334) 206-5429.

For additional assistance with any data related to this section contact the Data Division as follows:

MAILING ADDRESS (U. S. Postal Service)	STREET ADDRESS (Commercial Carrier)
PO BOX 303025	100 NORTH UNION STREET, SUITE 870
MONTGOMERY, AL 36130-3025	MONTGOMERY, AL 36104
TELEPHONE:	FAX:
(334) 242-4103	(334) 242-4113
EMAIL:	WEBSITE:
<u>data.submit@shpda.alabama.gov</u>	http://www.shpda.alabama.gov

Author: Statewide Health Coordinating Council (SHCC). Statutory Authority: § 22-21-260(4), <u>Code of Alabama</u>, 1975. History: Filed October 18, 2004; Effective November 22, 2004. Amended (SHP Year Only): Filed December 2, 2014; Effective January 6, 2015. Repeal and New: Filed March 16, 2020; Effective May 15, 2020.

#### 410-2-5-.04 Plan Revision Procedures

#### (1) Introduction

The Statewide Health Coordinating Council (SHCC) is responsible for the development of the State Health Plan (SHP) with final approval required by the Governor. The SHCC desires (a) a process that will maintain a viable and current SHP; (b) a coordinated system of revising the SHP; and (c) required information to be provided as outlined in ALA. ADMIN CODE r 410-2-5-.05 by individuals, groups, or other entities seeking a specific revision to the SHP commonly called an adjustment.

(2) There are three types of plan revisions:

(a) Plan Adjustment. In addition to such other criteria that may be set out in the SHP, a requested modification or exception to the SHP of limited duration, to permit additional facilities, beds, services, or equipment to address circumstances and meet the identified needs of a specific planning area, or part thereof, that is less than statewide and identified in the State Health Plan. A Plan Adjustment is not of general applicability and is thus not subject to the AAPA's rulemaking requirements. Unless otherwise provided by the SHCC, a Plan Adjustment shall be valid for only one (1) year from the date the Plan Adjustment becomes effective, subject to the exceptions provided in this paragraph. If an Application is not filed with SHPDA seeking a Certificate of Need for all or part of the additional facilities, beds, services or equipment identified in the Plan Adjustment within one (1) year of the Governor's approval of the Plan Adjustment, the Plan Adjustment shall expire and be null and void. If an Application(s) seeking a Certificate of Need for all or part of the additional facilities, beds, services or equipment identified in the Plan Adjustment is filed prior to the expiration of the one (1) year period, the Plan Adjustment shall remain effective for purposes of such pending Certificate of Need Application(s). Such one (1) year period shall be further extended for the duration of any deadline provided by SHPDA for the filing of applications as part of a batching schedule established in response to a letter of intent filed within nine (9) months of the effective date of the adjustment. Upon the expiration of such deadlines, no Certificate of Need Applications shall be accepted by SHPDA which are based, in whole or in part, upon the expired Plan Adjustment.

(b) Statistical Update – An update of a specific section of the SHP to reflect more current population, utilization, or other statistical data.

(c) Plan Amendment – The alteration or adoption of rules, policies, methodologies, or any other plan revision that does not meet the plan adjustment or statistical update definition. An amendment is of "general applicability" and subject to the AAPA's rulemaking requirements.

## (3) Application Procedures

(a) Application Procedure for Plan Adjustment. Any person may propose an adjustment to the SHP, which will be considered in accordance with the provisions of SHPDA Rule 410-2-5-.04(4). The proposal will state with specificity the proposed language of the adjustment and shall meet the electronic filing requirements of SHPDA Rule 410-1-3-.09 (Electronic Filing).

(b) Procedure for Statistical Update. SHPDA staff shall make statistical updates to the SHP as needed. The SHCC shall be informed at its next regularly scheduled meeting of such updates.

(c) Application Procedure for Plan Amendment. Any person may propose an amendment to the SHP by submitting a detailed description of the proposal to the SHPDA in accordance with the electronic filing requirements of SHPDA Rule 410-1-3-.09 (Electronic Filing). Such amendment shall be considered in accordance with the provisions of Rule 410-2-5-.04(4). The proposal will state with specificity the proposed language of the amendment. If it is to amend a methodology, the exact formula will be included, as well as the results of the application of the formula. The SHCC may also consider Plan Amendments on its own motion.

# (4) **Review Cycle**

(a) Within fifteen (15) days from the date of receipt of an application for an amendment or adjustment, the SHPDA staff shall determine if the applicant has furnished all required information for SHCC review and may thus be accepted as complete. The SHCC Chairman and the applicant will be notified when the application is accepted as complete.

Within forty-five (45) days after the application is deemed complete, the (b)application will be added to the SHCC calendar for review. SHPDA shall provide notice of the application for an amendment or adjustment when the application is deemed complete to: (1) all certificated health care facilities known to provide similar services in the county or planning region where the adjustment is requested; (2) all certificated health care facilities known to provide similar services in adjacent counties when the planning area is the county; and (3) such health care associations, state agencies and other entities that have requested to be placed on SHPDA's general notice list for such planning area or service. Once an application is deemed complete, persons other than the applicant will have thirty (30) days from the date of completion to electronically file statements in opposition to or in support of the application, as well as any other documentation to be considered by the SHCC. All such documentation shall be filed with SHPDA in accordance with the provisions of Rule 410-1-3-.09 (Electronic Filing), together with a certification that it has been served on the applicant and/or any other persons that have filed notices of support or opposition to the application. No documentation may be submitted beyond the deadlines in this subsection and subsection (3) unless authorized by written

order issued by the Chairperson. All persons shall adhere to SHPDA's rules governing electronic filing.

(c) Procedure for Consideration of Plan Adjustments. Proposed Plan Adjustments deemed complete will be placed on the SHCC agenda (individually or collectively) for a public hearing without further action by the SHCC. Unless otherwise provided herein, all written documentation to be considered by the SHCC at the public hearing shall be filed with the State Agency and served on the applicant and any intervenors and opponents of record not less than fourteen (14) days prior to the public hearing. Interested parties may address the proposed Plan Adjustments at the SHCC meeting, subject to such time limits and notice requirements as may be imposed by the SHCC Chairman. If the SHCC approves the Plan Adjustment in whole or in part, the adjustment, along with the SHCC's favorable recommendation, will be sent to the Governor for consideration and approval/disapproval. A Plan Adjustment shall be deemed disapproved by the Governor if not acted upon within fifteen (15) days. SHPDA, upon the approval of a Plan Adjustment, shall publish a copy of the Adjustment to its website, www.shpda.alabama.gov.

(d) Procedure for Consideration of Plan Amendments. A proposed Plan Amendment deemed complete will be placed on the SHCC agenda (individually or along with other proposed amendments) for an initial determination if the proposed amendment should be published in accordance with the AAPA and set for public hearing. At the Chairman's discretion, interested parties may be allowed to address the SHCC regarding the proposed amendments prior to such initial consideration. If the SHCC accepts the amendment for publication and hearing in accordance with the AAPA, SHPDA shall cause such publication and notice to be issued in accordance with the AAPA and the provisions of Rule 410-1-3-.10. Interested parties may address the proposed Plan Amendment at the SHCC meeting, subject to such time limits and notice requirements as may be imposed by the SHCC Chairman.

(e) If approved by the SHCC, a Plan Amendment, along with the SHCC's favorable recommendation, will be sent to the Governor for approval or disapproval. A Plan Amendment shall be deemed disapproved by the Governor if not acted upon within fifteen (15) days. Upon approval by the Governor, a Plan Amendment shall be filed with the Legislative Services Agency for further review in accordance with the AAPA. No party shall have any rights of administrative review, reconsideration or appeal of the approval or denial of a Plan Amendment except as may be specifically provided in the AAPA. SHPDA, upon final approval of a Plan Amendment, shall publish a copy of the amended section of the Plan to its website, <u>www.shpda.alabama.gov</u>, including the effective date of the Amendment.

(f) MEDIATION. At the discretion of the Chairman of the SHCC, non-binding mediation may be used to resolve differences between interested parties in regard to any pending matter before the SHCC. Said mediation will be conducted by the Chairman of the SHCC or his or her designee. Any modification or compromise relating to a pending proposal resulting from the mediation shall be sent to all interested parties as defined in

paragraph (4)(b). No statement, representation or comment by any party to the Mediation shall be used, cited to, referenced or otherwise introduced at the SHCC's hearing on the proposal in question. Any proposed compromise or other agreement between the parties shall not be binding upon the SHCC.

# (5) Filing Fees

Any person proposing a Plan Adjustment shall be required to pay an administrative fee equal to the minimum fee set by SHPDA for the filing of a Certificate of Need Application. Such fees shall be non-refundable and shall be used to defray costs associated with the processing and consideration of Plan Adjustment requests. All required filing fees must be submitted to the State Agency via overnight mail or other delivery method and marked in such a way as to clearly identify the fee with the electronic submission; or the fee may be submitted electronically via the payment portal available through the State Agency's website.

Author: Statewide Health Coordinating Council (SHCC).

Statutory Authority: §§ 22-21-260 (13), (15), Code of Alabama, 1975.

History: Filed October 18, 2004; Effective November 22, 2004. Amended: Filed February 1, 2013; Effective: March 8, 2013. Amended: Filed September 8, 2014; effective October 13, 2014. Amended (SHP Year Only): Filed December 2, 2014; Effective January 6, 2015. Amended: Filed December 22, 2016; Effective: February 5, 2017. Amended: Filed: February 6, 2018; effective: March 23, 2018. Repeal and New: Filed March 16, 2020; Effective May 15, 2020.

## 410-2-5-.05 Application for State Health Plan Adjustment

## (1) **Requirements**

(a) Applicant Identification. An application for a Plan Adjustment must be filed in accordance with SHPDA Rule 410-1-3-.09, and accompanied by the administrative fee specified in Rule 410-2-5-.04(c)(5). The application must include the name of the applicant, physical address, telephone number, the contact person and mailing address, telephone number, and e-mail address.

(b) Project Description. Provide a narrative statement explaining the nature of the request, with details of the plan adjustment desired. (If the request is for additional beds, indicate the number and type, i.e., Psychiatric, Rehabilitation, Pediatric, Nursing Home, etc.) The narrative should address availability, accessibility, cost, quality of the health care in question, and state with specificity the proposed language of the adjustment.

(c) Service Area. Describe the geographical area to be served. (Provide an  $8\frac{1}{2}$ " x 11" map of the service area. The map should indicate the location of other similar health care facilities in the area.)

(d) Population Projections. Provide population projections for the service area. In the case of beds for a specific age group, such as pediatric beds or nursing home beds, document the existence of the affected population. An example for nursing home beds is the number of persons 65 and older. The applicant must include the source of all information provided.

(e) Need for the Adjustment. Address the current need methodology. If the application is to increase beds or services in a planning area, give evidence that those beds or services have not been available and/or accessible to the population of the area.

(f) Current and Projected Utilization. Provide current and projected utilization of similar facilities or services within the proposed service area.

(g) If additional staffing will be required to support the additional need, indicate the availability of such staffing.

(h) Effect on Existing Facilities or Services. Address the impact this plan adjustment will have on other facilities in the area both in occupancy and manpower.

(i) Community Reaction. Give evidence of project support demonstrated by local community, civic and other organizations. (Testimony and/or comments regarding plan adjustment provided by community leaders, health care professionals, and other interested citizens.)

(j) Provide any other information or data available in justification of the plan adjustment request.

Author: Statewide Health Coordinating Council (SHCC).

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

History: Filed October 18, 2004; Effective November 22, 2004. Amended (SHP Year Only): Filed December 2, 2014; Effective January 6, 2015. Amended: Filed February 6, 2018; Effective: March 23, 2018. Repeal and New: Filed March 16, 2020; Effective May 15, 2020.

#### 410-2-5-.06 Open Meetings Act

All meetings of the Statewide Health Coordinating Council (SHCC) shall be held in compliance with the provisions of the "Alabama Open Meetings Act" ("Act") ALA. CODE §§ 36-25A-1 through -11 (1975 as amended), which requires public notice of any gathering, whether or not prearranged, of a quorum of a governmental body, committee or subcommittee during which the members deliberate specific matters expected to come before the body, committee or subcommittee at a later date. To ensure compliance with the letter and spirit of the Act, entities seeking to sponsor inspection or educational sessions for multiple SHCC members relating, directly or indirectly, to a pending or contemplated plan adjustment or amendment must first file a written request for approval from the Chairman, with a copy to all other entities that have filed comments or pleadings relating to the matter. Such requests will only be granted in extraordinary circumstances, and will be publicized and conducted in accordance with the provisions of the Act relating to meetings involving a quorum of the SHCC.

Author: Statewide Health Coordinating Council (SHCC).

Statutory Authority: § 22-21-260(13), (15), Code of Alabama, 1975.

History: Filed September 9, 2010; Effective: October 14, 2010. Amended (SHP Year Only): Filed 2, 2014; Effective January 6, 2015. Repeal and New: Filed March 16, 2020; Effective May 15, 2020.

## 410-2-5-.07 Electronic Notice

SHPDA shall provide any written notice required under these rules in electronic PDF format, which shall be considered delivered upon the date of transmission. All health care providers holding a certificate of need from SHPDA, as well as other interested parties seeking to be included in SHPDA's general distribution list, shall maintain with the agency a current e-mail address for purposes of this rule.

Author: Statewide Health Coordinating Council (SHCC).

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

History: Filed February 1, 2013; Effective March 8, 2013. Amended (SHP Year Only): Filed December 2, 2014; Effective January 6, 2015. Repeal and New: Filed March 16, 2020; Effective May 15, 2020.

#### 410-2-5-.08 SHCC Committee Responsibilities

#### (1) Discussion.

In order to assist the SHCC with the process of reviewing and revising the State Health Plan, the Chair of the SHCC may create committees tasked with the purpose of reviewing certain assigned sections of the Plan. The Chair of the SHCC shall assign various members to individual committees based on their knowledge and experience and shall have the authority to nominate chairs of the individual committees at the time of the committee assignments. Historically, the SHCC has kept six (6) standing committees, with additional committees and/or task forces created by the Chair as needed. The six (6) standing committees of the SHCC, and the current sections of the Plan assigned to each committee are as follows:

## (a) General Items

The General Items Committee shall have responsibility over the section(s) of the Plan related to an introduction to health planning, as well as any healthcare or health-related priorities set forth by the Governor. The section(s) of the Plan the General Items Committee are responsible for include:

1.	410-2-1	Introduction to Health Planning

- 2. 410-2-1-.01 Statutory Authority
- 3. 410-2-1-.02 Overview of Chapters
- 4. 410-2-1-.03 Health Planning Structure in Alabama
- 5. 410-2-1-.04 Alabama Health Policy Analysis
- 6. 410-2-1-.05 Data Collection and Publication
- 7. 410-2-2 Health Priorities
- 8. 410-2-2-.01 Introduction
- 9. 410-2-2-.02 Maternal and Child Health
- 10. 410-2-2-.03 Care of the Elderly and Chronically III
- 11. 410-2-2-.04 Rural Health Care
- 12. 410-2-2-.05 Diseases Prevention and Management
- 13. 410-2-2-.06 Health Care for the Medically Indigent
- 14. 410-2-2-.07 Substance Use Disorders
- 15. 410-2-2-.08 RESERVED

## (b) Home Health

The Home Health Committee shall have responsibility over the section(s) of the Plan related to Home Health Care. The section of the Plan the Home Health Committee is responsible for includes:

1. 410-2-4-.07 Home Health

#### (c) Hospital

The Hospital Committee shall have responsibility over the section(s) of the Plan related to Hospitals, whether general acute care facilities or specialized facilities, and any or all related functions separately governed by Certificate of Need that are offered as a part of a general acute care hospital's overall institutional health services. The section(s) of the Plan the Hospital Committee are responsible for include:

1.	410-2-303	Cardiac Services
2.	410-2-4	Facilities
3.	410-2-401	Introduction
4.	410-2-402	Acute Care (Hospitals)
5.	410-2-408	Inpatient Physical Rehabilitation
6.	410-2-409	Swing Beds
7.	410-2-410	Psychiatric Care
8.	410-2-411	Substance Abuse
9.	410-2-413	Renovations
10.	410-2-414	Replacements
11.	410-2-416	Freestanding Emergency Departments

#### (d) Long Term Care

The Long Term Care Committee shall have responsibility over the section(s) of the Plan related to providers that serve patients over an extended period of time, especially in regard to elder care. The section(s) of the Plan the Long Term Care Committee are responsible for include:

- 1. 410-2-4-.03 Nursing Homes
- 2. 410-2-4-.04 Limited Care Facilities, Specialty Care Assisted Living Facilities

- 3. 410-2-4-.05 Assisted Living Facilities
- 4. 410-2-4-.06 Adult Day Care Programs

#### (e) Special Needs and Assessments

The Special Needs and Assessments Committee shall have responsibility over the section(s) of the Plan related to information required by applicants, health planners, and SHCC members to make the health planning process function, and shall have responsibility for reviewing current health planning mechanisms to provide for a more efficient and effective health planning process. The section(s) of the Plan the Special Needs and Assessments Committee are responsible for include:

1.	410-2-412	Ambulatory Surgery
2.	410-2-5	Alabama Health Statistics and Revision Procedures
3.	410-2-501	Introduction
4.	410-2-502	Population
5.	410-2-503	Vital Events
6.	410-2-504	Plan Revision Procedures
7.	410-2-505	Application for State Health Plan Adjustment
8.	410-2-506	Open Meetings Act
9.	410-2-507	Electronic Notice
10.	410-2-508	SHCC Committee Responsibilities

#### (f) Specialty Services

The Specialty Services Committee shall have responsibility over the section(s) of the Plan that are not specific to the responsibilities of the other committees. These usually involve various services that are unique to health planning, and do not conveniently tie in with other sections of the Plan assigned to other committees. The section(s) of the Plan the Specialty Services Committee are responsible for include:

1. 410-2-3	Specialty Services
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- 2. 410-2-3-.01 Introduction
- 3. 410-2-3-.02 Neonatal Services
- 4. 410-2-3-.04 Oncology-Radiation Therapy Services

- 5. 410-2-3-.05 End Stage Renal Disease Services
- 6. 410-2-3-.0 New Technology
- 7. 410-2-3-.09 Transplantation Services
- 8. 410-2-3-.10 Hospice Services
- 9. 410-2-3-.11 Air Ambulance
- 10. 410-2-4-.15 Inpatient Hospice Services

Author: Statewide Health Coordinating Council (SHCC) Statutory Authority: § 22-21-260(4), <u>Code of Alabama</u>, 1975. History: Filed March 16, 2020; Effective May 15, 2020.

# 410-2-5-.09 State of Emergency Provisions

# 1. Finding of Emergency Need and Waiver.

A. The Statewide Health Coordinating Council recognizes that additional health care resources may be required, on an urgent and temporary basis, to address public health needs of the citizens of Alabama during a State of Emergency declared by the Governor (a "Declaration"). Accordingly, upon the issuance of a Declaration authorizing temporary waivers to Certificate of Need ("CON") requirements, the State Health Planning and Development Agency (the "Agency") may grant waivers for:

(1) Any proposed expansion of institutional health services, beds, facilities, equipment and other resources (hereafter "institutional health services") by existing providers to meet the declared emergency, regardless of existing need methodology and without respect to health planning areas otherwise provided in the State Health Plan ("SHP"); and

(2) The establishment of emergency alternate care sites, or their equivalent, as may be approved by ADPH for the duration of the declared emergency.

## 2. <u>Waiver Filing Requirements</u>.

A. Any provider seeking a waiver from CON authority under this provision shall provide the State Health Planning and Development Agency ("the Agency") in writing, on abbreviated forms to be prescribed by the Agency, an application containing the following information, as applicable:

(1) Name and address of the provider;

(2) Expanded institutional health services or any other services to be provided;

(3) Number of beds or additional hemodialysis stations requested exceeding the current CON authorized capacity;

(4) A description of any equipment being acquired;

(5) The date that the proposed expanded facilities, equipment or services will be in service and available to address the emergency;

(6) Projected cost;

(7) Information demonstrating that the project is required to address the public health emergency identified in the Declaration; and

(8) An unqualified commitment, by an authorized officer of the applicant, to comply with the requirements and limitations of this rule and any similar rule adopted by the CON Board.

B. The application shall be signed by an authorized officer of the applicant under oath.

3. <u>Waiver Term</u>. Any waiver issued pursuant to this rule shall automatically terminate on the earlier of: (i) as applicable, the discontinuation of services subject to the waiver; or (ii) sixty (60) days following the termination of the State of Emergency identified in the Declaration. Any continued operation of institutional health services authorized under a waiver granted pursuant to

this section shall require a CON, subject to regular CON criteria and procedures, including compliance with the SHP, without regard to this rule.

4. <u>New Health Care Facility</u>. Except as specifically provided in Ala. Admin. Code §410-2-5-.09.1(A)(1) and (2), the construction, development or other establishment of a new health care facility, as defined in Section 410-1-2-.05, shall not be eligible for a waiver under this rule.

5. <u>Subsequent Relocation</u>. The grant of a waiver under this rule for the temporary relocation of beds, equipment or other resources shall automatically authorize the return of such beds, equipment or other resources to their original location after the emergency, without the need for further authorization. Providers shall notify SHPDA of the effective date of such relocation in such manner as prescribed by the Executive Director.

6. <u>No Impact on Regular Need Methodology</u>. Expanded health services authorized on a temporary basis pursuant to a waiver granted under this rule shall not be considered for purposes of the permanent need methodology in the SHP.

7. <u>Conflict.</u> The provisions of this rule shall be subject to additional restrictions or conditions as may be imposed in a Declaration. In the event of a conflict between any provision of this rule and a Declaration, the Declaration shall prevail. Waivers previously issued under Ala. Admin. Code §§ 410-2-5-.09-E and 410-1-10-.05-E shall remain in force in accordance with their terms. The provisions of Ala. Admin. Code §410-1-10-.01, <u>Emergency Review</u>, are unaffected by this rule.

Author: Statewide Health Coordinating Council Statutory Authority: §§ 41-22-5, 22-21-260(6), -264 and -275, <u>Code of Alabama</u> (1975) History: Filed: September 17, 2020; Effective: November 14, 2020.