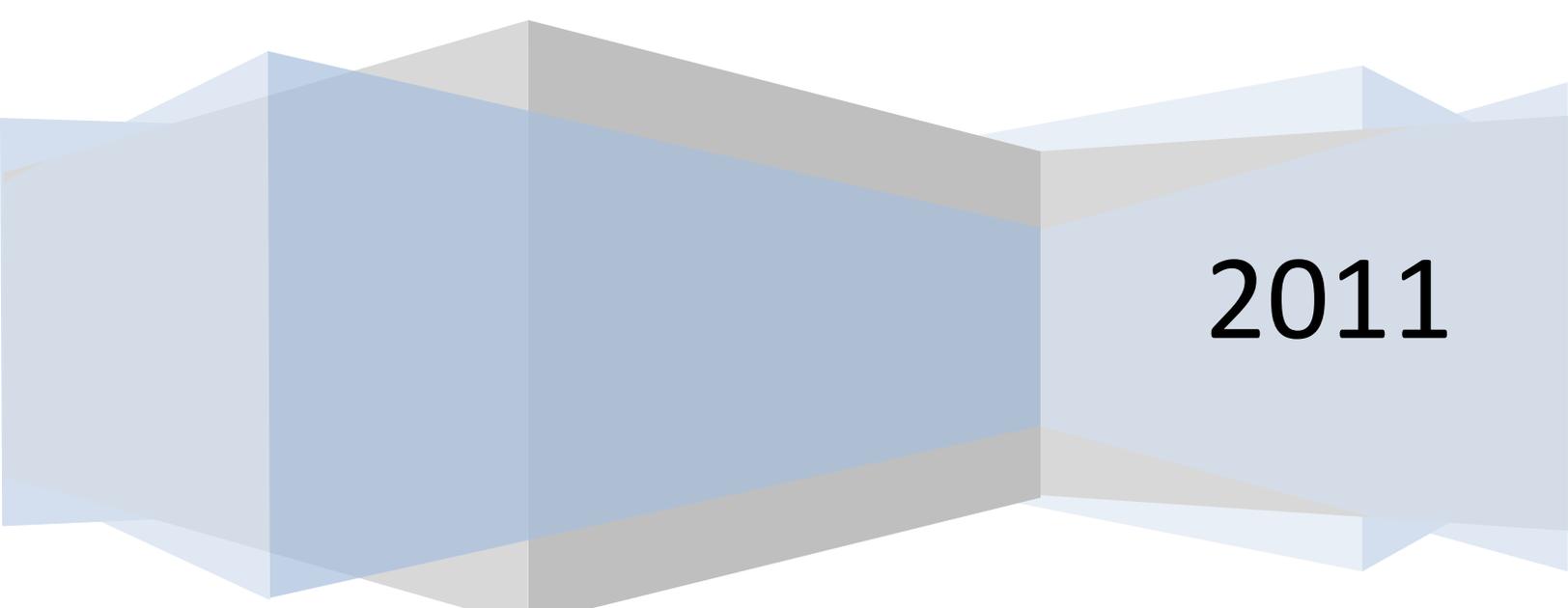


State of Tennessee

2011 Tennessee State Health Plan

Division of Health Care Finance and
Administration

Office of Health Planning



2011

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Table of Contents

	Page
Executive Summary	4
Introduction	5
Health Status of Tennesseans	5
Certificate of Need Revisions	14
Magnetic Radiation Imaging	16
Megavoltage Radiation Therapy	22
Appendices	
❖ Appendix A – Health Services and Planning Policy Statement	
❖ Appendix B – Health and Wellness Task Force Members	

Executive Summary

Status of the State Health Plan:

This report is the third annual update to Tennessee's State Health Plan. The initial State Health Plan approved and adopted in 2009 created the framework Five Principles for Achieving Better Health (drawn from the policy statement set forth in TCA § 68-11-1625(b), (Appendix A)) (<http://tn.gov/finance/healthplanning/Documents/2009TennesseeStateHealthPlan.pdf>). The 2010 update to the State Health Plan focused on proposed goals and strategies (<http://tn.gov/finance/healthplanning/Documents/StateHealthPlanFinal12-24-10.pdf>). Reference is made to these documents for additional background information, the rationale behind developing a State Health Plan, and the public processes involved in developing the State Health Plan and its updates.

Health Status of Tennesseans

Tennessee remains one of the least healthy states in America. In the 2011 United Health Foundation's report, Tennessee ranked as the 39th healthiest state out of the 50 states, an improvement over the previous year's ranking of 42nd.¹ This Update reports on the health status of Tennesseans using the Five Principles for Achieving Better Health framework of the State Health Plan.

Certificate of Need Standards and Criteria

Tennessee's Certificate of Need (CON) program seeks to deliver improvements in access, quality, and cost savings through orderly growth management of the state's health care system. Approving and adopting revisions to the standards and criteria for the CON program is one of the purposes of the State Health Plan. The CON program area standards and criteria that were revised in the 2009 and 2010 documents are found here: <http://tn.gov/finance/healthplanning/>. This 2011 Update to the State Health Plan contains revisions to the standards and criteria for magnetic resonance imaging services, and megavoltage radiation therapy services. Standards and criteria are tied to the State Health Plan's overarching goals and priorities.

Introduction to the 2011 Update to the State Health Plan

The 2011 Update to the State Health Plan

This 2011 Update to the State Health Plan is primarily a technical update that focuses on specific Certificate of Need program areas, which appear beginning on page 14. Recognizing that health and wellness not only impact an individual's quality of life but also have a direct effect on state budgets, the allocation of limited resources, and the attraction of new businesses to Tennessee, Governor Bill Haslam has recently appointed a new Health and Wellness Task Force representing government agencies, health care systems, professional groups, and insurance companies, chaired by John W. Lacey, III, MD, chief medical officer and senior vice president of University of Tennessee Medical Center. The Task Force is charged with garnering resources and forming partnerships to determine the causes behind chronic disease and disability in Tennessee, to determine how to address them, and to advocate for change. The members of the Task Force appear in Appendix B. The Office of Health Planning staff looks forward to receiving direction from the Health and Wellness Task Force on how best to continue its work to improve the health of Tennesseans.

Health Status of Tennesseans

This chapter Reports on the Health Status of Tennesseans, broken out by the State Health Plan's Five Principles for Achieving Better Health

Health Status of Tennesseans

While rising in one ranking to 39th in 2011, Tennessee is one of the least healthy states in America,¹ Though rankings may be considered to be relative, the state's health status is also reflected in the below average life expectancy of our population.² Numerous factors contribute to the health status of Tennesseans including individual behaviors, culture, the environment,

economic and social determinants, and genetics. Tennessee’s lack of an integrated system of health care also contributes to poor health outcomes.

Principle 1: Healthy Lives

“The purpose of the State Health Plan is to improve the health of Tennesseans.”

Background

Our health is affected by many factors such as what we do, where we live, the people that live around us, our income, our education, and the genes we received from our parents. According to the US government’s Healthy People 2020 plan, some of the leading indicators that affect individual health are: Physical Activity, Obesity, Tobacco and Substance Use, Mental Health, Environmental Quality, and Immunizations.³ The description of the current health status of Tennesseans is intended to provide an overview of how the citizens of Tennessee fare in these areas and to initiate dialogue as to how we may improve.

Status of Tennesseans

In *America’s Health Rankings*, an annual report published by the United Health Foundation, Tennessee ranks as the 39th healthiest state out of the 50 states.⁴ Tennessee ranked 42nd in 2010 and 48th in 2009. Though rankings may be considered to be relative, the state’s poor health status is also reflected in the below average life expectancy of our population. Tennesseans are expected to live on average 3 years less than the average US citizen (75 years as compared to 78 years) and 2 more infants die per every 1,000 infants born (approximately 9 deaths per 1,000 live births as compared to 7 deaths per 1,000 live births) as compared to the US average.⁵

How we “live, learn, work, and play” affects our physical and mental health.⁶ As a population, Tennesseans aren’t physically healthy. The lifestyles of Tennesseans are a major determinant of our below-average health, especially in areas such as physical activity, obesity, and smoking. While 23 percent of Americans reported no physical activity within the past month, over 30 percent of Tennesseans stated that they had not been physically active within the same time period. Approximately 68 percent of Tennesseans report being overweight or obese compared to the national average of 65 percent and over 1 out of every 9 Tennesseans has been diagnosed with diabetes.⁷ Though our rates of smoking have decreased slightly since 1999, in 2009 over 1 in 5 Tennesseans still classified themselves as smokers.

Not only is our physical health suffering, our mental health is suffering. Though the number of Tennesseans who are considered binge drinkers is only 1 in 50 people, significantly less than the national average of 1 in 20 people, the mental health of Tennesseans is poorer than that of the national average.⁷ Almost 1 in 10 Tennesseans have recently experienced an episode of depression compared to less than 1 in 12 Americans.⁸

Many Tennesseans are aware of their lack of good health. In a 2009 survey, over 20 percent of Tennesseans said that their health was fair or poor as compared to the national average of almost 15 percent.⁹

Top 10 Leading Causes of Death for Tennessee Residents per 100,000 people, 2010

Source: Tennessee Department of Health, Office of Policy, Planning and Assessment, Division of Health Statistics

<u>Leading Cause</u>	<u>Number</u>	<u>Rate</u>
Total Resident Deaths	59,201	932.9
Heart Diseases	14,489	228.3
Cancer	13,514	212.9
Chronic Lower Respiratory Diseases	3,525	55.5
Accidents and Adverse Effects	3,472	54.7
Stroke and Cerebrovascular Disease	3,178	50.1
Alzheimer’s Disease	2,428	38.3
Diabetes	1,678	26.4
Pneumonia and Influenza	1,347	21.2
Kidney Disease	974	15.3
Suicide	932	14.7

Principle 2: Access to Care

“Every citizen should have reasonable access to health care”

Background

According to the Institute of Medicine, having access to health care means “the timely use of personal health services to achieve the best health outcomes.”¹⁰ In the 2010 National Health Disparities Report (NHDR), attaining good access requires:¹¹

- Gaining entry into the health care system
- Getting access to sites of care where patients can receive needed services
- Finding providers who meet the needs of individual patients and with whom patients can develop a relationship based on mutual communication and trust.

Status of Tennesseans

For most Tennesseans, having health insurance is a key element of access to health care. Those without insurance can face major barriers to accessing health care as outlined by the NHDR. According to the United Health Foundation’s *America’s Health Rankings* report, 15 percent of all Tennesseans are uninsured, ranking Tennessee 30th out of 50 states in the percent of the population who is uninsured.¹²

Access to health care also involves having the right services available within a geographic region, having adequate transportation, and having the service available at the right time. The Health Services and Resources Administration designates areas that may have a shortage of primary medical care, dental or mental health providers as Health Provider Shortage Areas (HPSAs) and areas where residents may have a shortage of personal health services as Medically Underserved Areas (MUAs).¹³ Every county in Tennessee has an HPSA and/or an MUA designation.

Principle 3: Economic Efficiencies

“The state's health care resources should be developed to address the needs of Tennesseans while encouraging competitive markets, economic efficiencies, and the continued development of the state's health care system.”

Background

America’s health care system is one of the most innovative and technologically advanced in the world. It is also expensive. In 2009 the U.S. spent \$2.5 trillion in health expenditures.¹⁴ In fact, the U.S. spends more than double the per capita average of the industrialized countries that make up the Organization for Economic Development and Cooperation (OECD),¹⁵ and Tennessee’s per capita spending is even higher than the US national average. Despite high costs, America’s health outcomes are worse than those of many other industrialized countries on many measures; further, health outcomes in Tennessee tend to be worse than those of other states.¹⁶ Many recognize that our health care system is broken and that “its costs are unsustainable and endanger our nation” and provides “inconsistent quality.”¹⁷ Thus, providing economic efficiencies in health care is a primary concern for state policy makers. Given the inefficiency and fragmentation in the health care delivery system in the United States, as well as the generally acknowledged increases in health care costs, the state health planning process should explore opportunities to improve care while containing cost growth in Tennessee.

Status of Tennesseans

Health care is a major expense in our state. Tennesseans individually spend, on average, \$5,464 annually on health care — \$200 more per person per year than the national average.¹⁸ However, despite this high level of spending, Tennessee ranks 46th worst out of the 50 states for the percentage of adults with Diabetes Mellitus Type 2 and ranks 45th worst in the nation in cardiovascular disease prevalence.¹⁹ As seen in previous sections, Tennesseans fare worse than their counterparts in other states in many other areas of health as well.

In addition to Tennesseans spending more than most people on health care, health care programs consume 52 percent of the state government expenses (by comparison, education represents 28 percent of state government expenses).²⁰ Tennessee’s per capita health care spending is also growing faster than the national average, at 7.4 percent for Tennessee compared to 6.7 percent for the U.S.²¹ Thus, holding back the growing cost of health care and finding cost effective ways to promote health of Tennesseans are primary concerns for state policy makers.

Principle 4: Quality of Care

“Every citizen should have confidence that the quality of health care is continually monitored and standards are adhered to by health care providers.”

Background

The issue of the quality of health care provided in the United States has received increased attention in recent years. The Institute of Medicine, a science-based non-profit organization with a mission to advise the nation on health matters, defines “high quality care” as care that is:

- **Safe** – avoiding injuries to patients from the care that is intended to help them;
- **Effective** - providing services based on scientific knowledge to all who could benefit and refraining from providing services to those not likely to benefit (avoiding under use and overuse, respectively);
- **Patient-centered** – providing care that is respectful of and responsive to individual patient preferences, needs, and values and ensuring that patient values guide all clinical decisions;
- **Timely** – reducing waits and sometimes harmful delays for both those who receive and those who give care;
- **Efficient** – avoiding waste, including waste of equipment, supplies, ideas, and energy; and
- **Equitable** – providing care that does not vary in quality because of personal characteristics such as gender, ethnicity, geographic location, and socioeconomic status.²²

Having an adequate number of physicians and providing health care does not, by itself, ensure quality of care. In a study reported in the New England Journal of Medicine, patient outcomes were not necessarily better – and were sometimes worse – in regions with a very large supply of physicians.²³ Providing quality care is a complex issue involving many facets of the health care system.

Status of Tennesseans

Although there are many examples of the provision of high quality health care in Tennessee, Tennessee has room for improvement. An example is the number of hospitalizations that could have been avoided, which is an outcome indicating not the quality of care in a hospitals but instead the ability of the overall health care system to reach out to people, help them manage their diseases, and avoid problems leading to hospitalization. From 2006 to 2007, Tennessee had approximately 7,500 hospital admissions per 100,000 Medicare recipients that may have been avoided by higher quality in the overall health care system as determined by Medicare. This rate compares unfavorably with a median state 2006/2007 rate of approximately 6,300 per 100,000.²⁴

Hospital readmissions measure the quality of the hospital, the follow-up care patients receive, and coordination between all types of providers. In Tennessee, almost 19 percent of Medicare recipients who are discharged from a hospital are readmitted within 30 days, compared with a 17.5 percent median state rate.

Health care quality is also reflected in adherence to evidence-based procedures. For example in 2008, the proportion of Tennessee diabetics over age 40 who received important screenings such as HbA1C, and foot exams was worse than the national average, and none of these measures have substantially changed when compared with Tennessee's results in 2001. The percentage of adults over the age of 18 who had their blood cholesterol checked annually was at the national average, while the percentage of women who received important cancer screenings such as pap smears and mammograms was rated as average when compared to all other States.²⁵

Principle 5: Health Care Workforce

“The state should support the development, recruitment, and retention of a sufficient and quality health care workforce.”

This State Health Plan recommends that the state consider developing a comprehensive approach to ensuring the existence of a sufficient, qualified health care workforce, taking into account the following issues:

- The number of providers at all levels and in all specialty and focus areas;
- The number of professionals in teaching positions;
- The capacity of medical, nursing, dental, allied health, and other educational institutions;
- State and federal laws and regulations impacting the capacity and funding of programs and the needs of current workforce members.
- The collaboration and consideration of all health professions in creating practices and policies to address workforce issues.

Status of Tennesseans

Through the Workforce Investment Act, workforce training efforts in Tennessee provided over 16,000 new health care workers over the past 3 years, representing approximately 18 percent of all of the Workforce Investment Act training conducted in the state at an investment of over 60 million dollars.²⁶ In 2009 almost 7,000 workers were trained for the health sciences. This number represents 19.5 percent of trainees across all industry sectors.

Physicians

A report from the Council on Graduate Medical Education predicts that by the year 2020 the United States will experience an overall 10 percent shortfall in the number of physicians, and in particular raises the concern of a potential shortage of generalists/primary care physicians.²⁷ Tennessee compares well with the remaining states in the overall number of primary care physicians practicing in the State. Tennessee has approximately 121 actively practicing primary care physicians per 100,000 people, compared with 120 primary care physicians per 100,000 people nationally.²⁸ However, 24 percent of Tennessee's physicians are over the age of 60 and thus nearing retirement age.²⁹ The Rural Partnership in its 2008 Demand Assessment reported, "Primary care physicians continue to be in greatest demand," raising the critical issue of the disproportional primary care workforce distribution within the state.³⁰

Nursing

Nurses fill a wide range of roles in the health care system. In addition to providing direct clinical care, nurses are also better able to perform many administrative and support services than non-clinically trained personnel.³¹ For the near future, Tennessee is predicted to have sufficient associate degree nurses as a result of efforts made by stakeholders comprising the Nursing Education Master Plan Steering Committee.³² However, it is predicted that by 2020 Tennessee will have a shortage of 15,000 registered nurses. The shortage of BSN and MSN graduates is also critical. High level bachelors (BSN) and master's degree (MSN) graduates comprise the nursing faculty pipeline, meaning that without more of these higher degree nurses, a sufficient number of new nurses may not be trained and brought into the workforce.

Dentists

In the US there are over 141,000 dentists.³³ However, 49 million people still lack adequate access to dental care in 4,230 areas and less than ten percent of dentists regularly provide care to these areas.³⁴ Out of the 95 counties in Tennessee, 86 of them are designated as partially or totally lacking adequate access to dental care.³⁵ Currently, Tennessee has 3,614 dentists who are licensed to practice dentistry or approximately 56 dentists per 100,000 people, lower than the national average of 60 dentists per 100,000 people.³⁶ The number of dentists per 100,000 people has been declining since 2000 and this trend is anticipated to continue. Some states have applied for federal grants to improve the workforce shortage of oral health care providers, and Tennessee currently does not participate in the loan repayment program.³⁷

Allied Health Workforce

The effective functioning of the health care system depends on having appropriate numbers of allied health professionals to provide essential services to the public. Allied health professionals encompass a very broad set of disciplines and functions, including rehabilitation professions, medical assisting, emergency medical professions, medical imaging, clinical laboratory services,

dental services, and health information management. In 2010, The Center for Health and Human Services at Middle Tennessee State University updated its report Allied Health in Tennessee: A Supply and Demand Study, which examines the supply and demand for various health care personnel in the state.³⁸ As stated in the report's Executive Summary, from 1997-2007, "Tennessee has experienced a significant increase" in the number of allied health and health science baccalaureate graduates. Associate degrees awarded in the allied health and health sciences increased 29 percent in Tennessee (as compared to 19 percent nationally). According to the study, "These increases have reduced the demand in some occupational areas but have only slightly addressed the fast-growing demands in others." Areas that do not meet the supply demand ratio include: respiratory therapy, health information administration, physical therapy assisting, nursing assisting, laboratory services, occupational therapy assisting, physician assisting, recreation therapy, and dental hygiene.

Public Health Workforce

Critical to the health of Tennesseans is the existence of an adequate public health workforce. Public health professionals focus on improving health outcomes in their states through a wide variety of activities, ranging from HIV/AIDS counseling, testing, and surveillance to bioterrorism and emergency preparedness.³⁹ Tennessee's average age of a state public health employee was over 48 years in 2008, over the national average of 47. The percentage of these Tennessee state employees who are eligible to retire within five years is approximately 48 percent, significantly higher than the 29 percent average of the 28 states reporting this data.⁴⁰

Certificate of Need Standards and Criteria

Introduction

Magnetic Resonance Imaging Services

Megavoltage Radiation Therapy Services

Certificate of Need Standards and Criteria Revisions

Why Certificate of Need

Certificate of Need (CON) laws were developed from the federal Health Planning Resources Development Act of 1974. The aim of CON programs is to help control health care facility costs and allow for meaningful planning of new services and facilities. Under the authority of TCA Title 68, Chapter 11, Part 1, the Tennessee Health Planning and Resource Development Act of 1987, Tennessee has developed a set of guidelines for CON Standards and Criteria. These original CON Standards and Criteria can be found at the Health Services and Development Agency's "Guidelines for Growth" document located at:

<http://health.state.tn.us/statistics/PdfFiles/Guidelines%20for%20Growth.pdf>

Past, Current, and Future Revisions

In 2009, the Office of Health Planning revised the original CON standards for

- Positron Emission Tomography Services
- Cardiac Catheterization Services.

In 2010, the Office of Health Planning updated the CON standards for:

- Open Heart Surgery Services
- External Shock Wave Lithotripsy Services

In this 2011 Update, the Office of Health Planning updates the CON standards for:

- Magnetic Resonance Imaging Services
- Megavoltage Radiation Therapy Services

These 2011 revisions and their corresponding rationale statements are included on the following pages. Future updates will contain updated revisions of other CON Standards and Criteria. The new revisions replace the older versions found in the Health Services and Development Agency's "Guidelines for Growth."

STATE HEALTH PLAN
CERTIFICATE OF NEED STANDARDS AND CRITERIA
FOR
MAGNETIC RESONANCE IMAGING SERVICES

The Health Services and Development Agency (HSDA) may consider the following standards and criteria for applications seeking to provide Magnetic Resonance Imaging (MRI) services. Existing providers of MRI services are not affected by these standards and criteria unless they take an action that requires a new certificate of need (CON) for MRI services.

These standards and criteria are effective immediately as of December 21, 2011, the date of approval and adoption by the Governor of the State Health Plan changes for 2011. Applications to provide MRI services that were deemed complete by HSDA prior to this date shall be considered under the Guidelines for Growth, 2000 Edition.

Definitions

Capacity: The measure of the maximum number of MRI procedures per MRI unit per year based upon the type of MRI equipment.

Dedicated Breast MRI Unit: An MRI unit that is configured to perform only breast MRI procedures and is not capable of performing other types of non-breast MRI procedures.

Dedicated Extremity MRI Unit: An MRI unit that is utilized for the imaging of extremities only and is of open design with a field of view no greater than 25 centimeters.

Magnetic Resonance Imaging (MRI): A noninvasive diagnostic modality in which electronic equipment is used to create tomographic images of body structure. The MRI scanner exposes the target area to nonionizing magnetic energy and radio frequency fields, focusing on the nuclei of atoms such as hydrogen in the body tissue. Response of selected nuclei to this stimulus is translated into images for evaluation by the physician.

MRI Procedure: A single, discrete MRI study performed on a single patient during a single visit. The Health Services and Development Agency (HSDA) shall be responsible for setting reporting requirements consistent with this definition, including the development of a selected set of CPT codes, which shall not include research-only CPT codes for purposes of determining capacity and need.

MRI Study: An MRI scan defined by a CPT procedure code.

MRI Unit: Medical imaging equipment (often referred to as a “scanner”) that uses nuclear magnetic resonance to create tomographic images of body structure. MRI units may be differentiated by magnetic field strength (“tesla” or “T”), and also by construction or orientation. A “closed” scanner typically uses a higher strength magnet and an “open” scanner typically uses a lower strength magnet. There are also “multi-position” or “stand-up” scanners (often used for spine and joint evaluation, where weight-bearing is required) and limited-use scanners, such as those designed only to scan the breast or extremities (e.g., elbows, wrists, toes, etc.).

Mobile MRI Unit: An MRI unit and transporting equipment that is moved or able to be moved to provide services at two or more host facilities, including facilities located in adjoining or contiguous states of the United States.

Mobile MRI Unit Capacity: Total capacity of a mobile MRI unit is 600 annual procedures per day of operation per week and is based upon a daily operating efficiency of 12 procedures per day x 50 weeks per year, multiplied by the number of days per week that the equipment is used. The optimal efficiency of a mobile MRI unit is based upon the number of days per week that it is in operation. For each day of operation per week, the optimal efficiency is 480 procedures per year, or 80 percent of total capacity.

Dedicated Multi-position MRI Unit: An MRI unit that permits the patient to be scanned in various positions, such as sitting, standing, bending, or leaning, as well as lying down, for the purpose of providing weight-bearing scans.

Service Area: The contiguous counties or portions thereof representing a reasonable area in which an applicant intends to provide MRI unit services and in which at least 75% of its service recipients reside. An MRI unit should be located at a site that allows reasonable access for residents of the service area.

Service Area Capacity: The estimate of the number of MRI units needed in a given service area. The estimate is based upon an optimal efficiency of 2,880 procedures per year for a stationary MRI unit and an optimal efficiency of 480 annual procedures per day of operation per week for a mobile MRI unit

Specialty MRI Unit: A Dedicated Breast, Extremity, or Multi-position MRI unit.

Stationary MRI Unit: A non-moveable MRI unit housed at a single permanent location.

Stationary MRI Unit Capacity: Total capacity of a stationary MRI unit is 3600 procedures per year and is based upon a daily operating efficiency of 1.20 procedures per hour, 12 hours per day x 5 days a week x 50 weeks of operation per year. The optimal efficiency for a stationary MRI unit is 80 percent of total capacity, or 2,880 procedures per year.

Standards and Criteria

1. Utilization Standards for non-Specialty MRI Units.
 - a. An applicant proposing a new non-Specialty stationary MRI service should project a minimum of at least 2160 MRI procedures in the first year of service, building to a minimum of 2520 procedures per year by the second year of service, and building to a minimum of 2880 procedures per year by the third year of service and for every year thereafter.
 - b. Providers proposing a new non-Specialty mobile MRI service should project a minimum of at least 360 mobile MRI procedures in the first year of service per day of operation per week, building to an annual minimum of 420 procedures per day of operation per week by the second year of service, and building to a minimum of 480 procedures per day of operation per week by the third year of service and for every year thereafter.
 - c. An exception to the standard number of procedures may occur as new or improved technology and equipment or new diagnostic applications for MRI units are developed. An applicant must demonstrate that the proposed unit offers a unique and necessary technology for the provision of health care services in the Service Area.
 - d. Mobile MRI units shall not be subject to the need standard in paragraph 1 b if fewer than 150 days of service per year are provided at a given location. However, the applicant must demonstrate that existing services in the applicant's Service Area are not adequate and/or that there are special circumstances that require these additional services.
 - e. Hybrid MRI Units. The HSDA may evaluate a CON application for an MRI "hybrid" Unit (an MRI Unit that is combined/utilized with another medical equipment such as a megavoltage radiation therapy unit or a positron emission tomography unit) based on the primary purposes of the Unit.
2. Access to MRI Units. All applicants for any proposed new MRI Unit should document that the proposed location is accessible to approximately 75% of the Service Area's population. Applications that include non-Tennessee counties in their proposed Service Areas should provide evidence of the number of existing MRI units that service the non-Tennessee counties and the impact on MRI unit utilization in the non-Tennessee counties, including the specific location of those units located in the non-Tennessee counties, their utilization rates, and their capacity (if that data are available).
3. Economic Efficiencies. All applicants for any proposed new MRI Unit should document that alternate shared services and lower cost technology applications have been investigated and found less advantageous in terms of accessibility, availability, continuity, cost, and quality of care.

4. Need Standard for non-Specialty MRI Units.

A need likely exists for one additional non-Specialty MRI unit in a Service Area when the combined average utilization of existing MRI service providers is at or above 80% of the total capacity of 3600 procedures, or 2880 procedures, during the most recent twelve-month period reflected in the provider medical equipment report maintained by the HSDA. The total capacity per MRI unit is based upon the following formula:

Stationary MRI Units: $1.20 \text{ procedures per hour} \times \text{twelve hours per day} \times 5 \text{ days per week} \times 50 \text{ weeks per year} = 3,600 \text{ procedures per year}$

Mobile MRI Units: Twelve (12) procedures per day x days per week in operation x 50 weeks per year. For each day of operation per week, the optimal efficiency is 480 procedures per year, or 80 percent of the total capacity of 600 procedures per year.

5. Need Standards for Specialty MRI Units.

- a. Dedicated fixed or mobile Breast MRI Unit. An applicant proposing to acquire a dedicated fixed or mobile breast MRI unit shall not receive a CON to use the MRI unit for non-dedicated purposes and shall demonstrate that annual utilization of the proposed MRI unit in the third year of operation is projected to be at least 1,600 MRI procedures (.80 times the total capacity of 1 procedure per hour times 40 hours per week times 50 weeks per year), and that:
 1. It has an existing and ongoing working relationship with a breast-imaging radiologist or radiology proactive group that has experience interpreting breast images provided by mammography, ultrasound, and MRI unit equipment, and that is trained to interpret images produced by an MRI unit configured exclusively for mammographic studies;
 2. Its existing mammography equipment, breast ultrasound equipment, and the proposed dedicated breast MRI unit are in compliance with the federal Mammography Quality Standards Act;
 3. It is part of or has a formal affiliation with an existing healthcare system that provides comprehensive cancer care, including radiation oncology, medical oncology, surgical oncology and an established breast cancer treatment program that is based in the proposed service area.
 4. It has an existing relationship with an established collaborative team for the treatment of breast cancer that includes radiologists, pathologists, radiation oncologists, hematologist/oncologists, surgeons, obstetricians/gynecologists, and primary care providers.

- b. Dedicated fixed or mobile Extremity MRI Unit. An applicant proposing to institute a Dedicated fixed or mobile Extremity MRI Unit shall provide documentation of the total capacity of the proposed MRI Unit based on the number of days of operation each week, the number of days to be operated each year, the number of hours to be operated each day, and the average number of MRI procedures the unit is capable of performing each hour. The applicant shall then demonstrate that annual utilization of the proposed MRI Unit in the third year of operation is reasonably projected to be at least 80 per cent of the total capacity. Non-specialty MRI procedures shall not be performed on a Dedicated fixed or mobile Extremity MRI Unit and a CON granted for this use should so state on its face.
 - c. Dedicated fixed or mobile Multi-position MRI Unit. An applicant proposing to institute a Dedicated fixed or mobile Multi-position MRI Unit shall provide documentation of the total capacity of the proposed MRI Unit based on the number of days of operation each week, the number of days to be operated each year, the number of hours to be operated each day, and the average number of MRI procedures the unit is capable of performing each hour. The applicant shall then demonstrate that annual utilization of the proposed MRI Unit in the third year of operation is reasonably projected to be at least 80 per cent of the total capacity. Non-specialty MRI procedures shall not be performed on a Dedicated fixed or mobile Multi-position MRI Unit and a CON granted for this use should so state on its face.
6. Separate Inventories for Specialty MRI Units and non-Specialty MRI Units. If data availability permits, Breast, Extremity, and Multi-position MRI Units shall not be counted in the inventory of non-Specialty fixed or mobile MRI Units, and an inventory for each category of Specialty MRI Unit shall be counted and maintained separately. None of the Specialty MRI Units may be replaced with non-Specialty MRI fixed or mobile MRI Units and a Certificate of Need granted for any of these Specialty MRI Units shall have included on its face a statement to that effect. A non-Specialty fixed or mobile MRI Unit for which a CON is granted for Specialty MRI Unit purpose use-only shall be counted in the specific Specialty MRI Unit inventory and shall also have stated on the face of its Certificate of Need that it may not be used for non-Specialty MRI purposes.
7. Patient Safety and Quality of Care. The applicant shall provide evidence that any proposed MRI Unit is safe and effective for its proposed use.
 - a. The United States Food and Drug Administration (FDA) must certify the proposed MRI Unit for clinical use.
 - b. The applicant should demonstrate that the proposed MRI Procedures will be offered in a physical environment that conforms to applicable federal standards, manufacturer's specifications, and licensing agencies' requirements.

- c. The applicant should demonstrate how emergencies within the MRI Unit facility will be managed in conformity with accepted medical practice.
 - d. The applicant should establish protocols that assure that all MRI Procedures performed are medically necessary and will not unnecessarily duplicate other services.
 - e. An applicant proposing to acquire any MRI Unit or institute any MRI service, including Dedicated Breast and Extremity MRI Units, shall demonstrate that it meets or is prepared to meet the staffing recommendations and requirements set forth by the American College of Radiology, including staff education and training programs.
 - f. All applicants shall commit to obtain accreditation from the Joint Commission, the American College of Radiology, or a comparable accreditation authority for MRI within two years following operation of the proposed MRI Unit.
 - g. All applicants should seek and document emergency transfer agreements with local area hospitals, as appropriate. An applicant's arrangements with its physician medical director must specify that said physician be an active member of the subject transfer agreement hospital medical staff.
8. The applicant should provide assurances that it will submit data in a timely fashion as requested by the HSDA to maintain the HSDA Equipment Registry.
 9. In light of Rule 0720-11.01, which lists the factors concerning need on which an application may be evaluated, and Principle No. 2 in the State Health Plan, "Every citizen should have reasonable access to health care," the HSDA may decide to give special consideration to an applicant:
 - a. Who is offering the service in a medically underserved area as designated by the United States Health Resources and Services Administration;
 - b. Who is a "safety net hospital" or a "children's hospital" as defined by the Bureau of TennCare Essential Access Hospital payment program; or
 - c. Who provides a written commitment of intention to contract with at least one TennCare MCO and, if providing adult services, to participate in the Medicare program; or
 - d. Who is proposing to use the MRI unit for patients that typically require longer preparation and scanning times (e.g., pediatric, special needs, sedated, and contrast agent use patients). The applicant shall provide in its application information supporting the additional time required per scan and the impact on the need standard.

Rationale for Revised and Updated Standards and Criteria for Magnetic Resonance Imaging Services

Definitions

Specialty MRI Units. The Office of Health Planning recognizes that certain MRI Units dedicated for breast, extremity, and multi-position purposes do not reach the level of utilization that standard MRI Units do. Consequently, definitions for these Specialty Units have been created and specific standards for each have been developed.

MRI Procedure. To provide for uniform procedure reporting, the Health Services and Development Agency is responsible for setting CPT code reporting requirements consistent with the definition of MRI Procedure. Research CPT codes are excluded from capacity and need calculations.

Capacity. The Office solicited operating schedule information from owners/operators of MRI Units. From this information, while total capacity of a non-Specialty MRI Unit could conceivably be based on an operating schedule of 24 hours per day, 7 days per week, usual practice does not cover such extended hours of operation. It appears that physician offices and outpatient diagnostic centers more usually operate their MRI Units Monday-Friday; inpatient facilities typically operate Monday-Friday, with the potential to operate on Saturdays as needed. There are exceptions, however, with both outpatient and inpatient MRI Units operating more than five days a week. Hours of operation vary and seem to not be dependent upon outpatient or inpatient use, usually from 12 to 16 hours per day. Utilization and operating practices can and do vary widely.

Additionally, from the information received, the length of time per scan varies depending on a variety of circumstances, including protocols in place, whether a patient is sedated or needs longer time to be placed in the unit, whether the scan is with or without contrast, etc. A scan may take as little as 30 minutes or as long as 80 (or more) minutes. Typically, due to sedation and/or contrast requirements, an inpatient facility will take longer to perform its scans. However, Tennessee does not collect sufficient data on these scans in order to develop a total capacity formula based on them.

We are basing a total non-Specialty MRI unit capacity number on the performance of 1.20 scans per hour, Monday through Friday utilization, 12 hours a day, 50 weeks a year, for a total capacity number of 3,600. Using an 80% optimal efficiency number, we arrive at 2,880 as the number of scans a year that a typical stationary non-Specialty MRI Unit should be able to perform.

Standards and Criteria Regarding Certificate of Need Applications for Magnetic Resonance Imaging Services

- 1. Exceptions to Utilization Standards:** Exceptions to the standard number of procedures has been retained for new or improved technology and diagnostic applications, and for mobile MRI Units in operation fewer than 150 days of service per year. Applications for hybrid MRI Units (e.g., MRI Units combined with PET Units or MRT Units) may be assessed under the primary use of the hybrid unit.
- 2. Other Access Issues:** The provision of health care doesn't recognize state boundaries. Accordingly, applicants may include non-Tennessee counties in proposed service areas if that data are available.
- 3. Economic Efficiencies:** To support the goal of reducing health care costs, applicants should document that other options have been investigated and found less advantageous.
- 4. Specialty MRI Units Standards:** Dedicated Breast MRI Units have a proposed total capacity estimate of 2,000 procedures per year. Dedicated Extremity and Dedicated Multi-position MRI Units do not have a defined estimate; an applicant must demonstrate total capacity as well as its estimated annual utilization that, by the third year, will be at least 80% of total capacity.
- 5. Inventories:** Given that there are proposed different standards for Specialty and non-Specialty MRI Units, separate inventories should be maintained. Additionally, a CON granted for the institution of a Specialty MRI Unit should not be permitted to be used for non-Specialty MRI purposes; it is recommended that any CON granted for Specialty MRI purposes so state on its face.
- 6. Quality of Care:** Specific staffing, training, and education standards are included to help ensure patient safety and quality of care provided.

STATE HEALTH PLAN
CERTIFICATE OF NEED STANDARDS AND CRITERIA
FOR
MEGAVOLTAGE RADIATION THERAPY SERVICES

The Health Services and Development Agency (HSDA) may consider the following standards and criteria for applications seeking to provide Megavoltage Radiation Therapy (MRT) Services. Existing providers of MRT services are not affected by these standards and criteria unless they take an action that requires a new certificate of need (CON) for MRT services.

These standards and criteria are effective immediately as of December 21, 2011, the date of approval and adoption by the Governor of the State Health Plan changes for 2011. Applications to provide MRT services that were deemed complete by HSDA prior to this date shall be considered under the Guidelines for Growth, 2000 Edition.

Definitions

External Beam Radiation Therapy (EBRT). Radiation therapy delivered by an MRT Unit from outside the body.

Linear Accelerator. A type of EMRT Unit that delivers a beam of high energy x-rays (photon or electron particles) from an external source to the location of the patient's tumor and/or other tissue being irradiated. Linear accelerators may deliver conventional EBRT, intensity modulated radiation therapy, image-guided radiation therapy, and SRT services. Linear accelerators are the only MRT Unit type specifically listed in Tennessee Code Annotated Section 68-11-1607 (a)(4) as requiring a CON in order for services to be initiated.

Linear Accelerator Service Area Capacity: The estimate of the number of Linear Accelerator MRT units needed in a given service area, based upon an Optimal Capacity of 7,688 procedures per year.

MRT Procedure: Each discrete MRT treatment related to services performed on a single patient during a single visit, designated by CPT code. The Health Services and Development Agency (HSDA) shall be responsible for setting reporting requirements consistent with this definition, including the development of a selected set of CPT codes.

MRT Unit: Medical equipment that performs radiation therapy.

Proton Beam Therapy Unit. A type of EBRT MRT Unit that uses proton beams rather than photon beams. Although not specifically listed as requiring a CON, the cost of initiating proton

beam therapy services likely falls above the capital expenditure threshold set forth in TCA Section 68-11-1607 (2).

Radiation Therapy. A medical procedure that allows non-invasive treatment of tumors and cancer cells using X-rays, gamma rays, and charged particles. The radiation may be delivered by a machine outside the body (external-beam radiation therapy), or it may come from radioactive material placed in the body near cancer cells (internal radiation therapy, also called brachytherapy).

Radiation Therapy is also known as **Stereotactic Radiotherapy (SRT)** when used to target lesions in the brain and as **Stereotactic Body Radiotherapy (SBRT)** when used to target lesions in the body.

Service Area: For linear accelerators that do not perform SRT or SBRT procedures, the contiguous counties representing a reasonable area in which an applicant intends to provide MRT services and in which at least 120,000 people reside and where the applicant is able to reach the optimal capacity set forth below. Otherwise, a Service Area shall be the contiguous counties representing a reasonable area in which an applicant intends to provide MRT services.

Standards and Criteria

1. Utilization Standards for MRT Units.

- a. Linear Accelerators not dedicated to performing SRT and/or SBRT procedures:
 - i. **Full capacity of a Linear Accelerator MRT Unit** is 8,736 procedures, developed from the following formula: 3.5 treatments per hour, times 48 hours (6 days of operation, 8 hours per day, or 5 days of operation, 9.6 hours per day), times 52 weeks.
 - ii. **Linear Accelerator Minimum Capacity:** 6,000 procedures per Linear Accelerator MRT Unit annually, except as otherwise noted herein.
 - iii. **Linear Accelerator Optimal Capacity:** 7,688 procedures per Linear Accelerator MRT Unit annually, based on a 12% average downtime per MRT unit during normal business hours annually.
 - iv. An applicant proposing a new Linear Accelerator should project a minimum of at least 6000 MRT procedures in the first year of service in its Service Area, building to a minimum of 7,688 procedures per year by the third year of service and for every year thereafter.
- b. For Linear Accelerators dedicated to performing only SRT procedures, full capacity is 500 annual procedures.
- c. For Linear Accelerators dedicated to performing only SRT/SBRT procedures, full capacity is 850 annual procedures.
- d. An exception to the standard number of procedures may occur as new or improved technology and equipment or new diagnostic applications for Linear Accelerators develop. An applicant must demonstrate that the proposed Linear

Accelerator offers a unique and necessary technology for the provision of health care services in the proposed Service Area.

- e. Proton Beam MRT Units. As of the date of the approval and adoption of these Standards and Criteria, insufficient data are available to enable detailed utilization standards to be developed for Proton Beam MRT Units.
2. Need Standards for MRT Units.
- a. For Linear Accelerators not dedicated solely to performing SRT and/or SBRT procedures, need for a new Linear Accelerator in a proposed Service Area shall be demonstrated if the average annual number of Linear Accelerator procedures performed by existing Linear Accelerators in the proposed Service Area exceeds 6,000.
 - b. For Linear Accelerators dedicated to performing only SRT procedures, need in a proposed Service Area shall be demonstrated if the average annual number of MRT procedures performed by existing Linear Accelerators dedicated to performing only SRT procedures in a proposed Service Area exceeds 300, based on a full capacity of 500 annual procedures.
 - c. For Linear Accelerators dedicated to performing only SRT/SBRT procedures, need in a proposed Service Area shall be demonstrated if the average annual number of MRT procedures performed by existing Linear Accelerators dedicated to performing only SRT/SBRT procedures in a proposed Service Area exceeds 510, based on a full capacity of 850 annual procedures.
 - d. Need for a new Proton Beam MRT Unit: Due to the high cost and extensive service areas that are anticipated to be required for these MRT Units, an applicant proposing a new Proton Beam MRT Unit shall provide information regarding the utilization and service areas of existing or planned Proton Beam MRT Units' utilization and service areas (including those that have received a CON), if they provide MRT services in the proposed Service Area and if that data are available, and the impact its application, if granted, would have on those other Proton Beam MRT Units.
 - e. An exception to the need standards may occur as new or improved technology and equipment or new diagnostic applications for MRT Units develop. An applicant must demonstrate that the proposed MRT Unit offers a unique and necessary technology for the provision of health care services in the proposed Service Area.
3. Access to MRT Units.
- a. An MRT unit should be located at a site that allows reasonable access for residents of the proposed Service Area.

- b. An applicant for any proposed new Linear Accelerator should document that the proposed location of the Linear Accelerator is within a 45 minute drive time of the majority of the proposed Service Area's population.
 - c. Applications that include non-Tennessee counties in their proposed Service Areas should provide evidence of the number of existing MRT units that service the non-Tennessee counties and the impact on MRT unit utilization in the non-Tennessee counties, including the specific location of those units located in the non-Tennessee counties, their utilization rates, and their capacity (if that data are available).
4. Economic Efficiencies. All applicants for any proposed new MRT Unit should document that lower cost technology applications have been investigated and found less advantageous in terms of accessibility, availability, continuity, cost, and quality of care.
5. Separate Inventories for Linear Accelerators and for other MRT Units. A separate inventory shall be maintained by the HSDA for Linear Accelerators, for Proton Beam Therapy MRT Units, and, if data are available, for Linear Accelerators dedicated to SRT and/or SBRT procedures and other types of MRT Units.
6. Patient Safety and Quality of Care. The applicant shall provide evidence that any proposed MRT Unit is safe and effective for its proposed use.
 - a. The United States Food and Drug Administration (FDA) must certify the proposed MRT Unit for clinical use.
 - b. The applicant should demonstrate that the proposed MRT Units shall be housed in a physical environment that conforms to applicable federal standards, manufacturer's specifications, and licensing agencies' requirements.
 - c. The applicant should demonstrate how emergencies within the MRT Unit facility will be managed in conformity with accepted medical practice. Tennessee Open Meetings Act and/or Tennessee Open Records Act.
 - d. The applicant should establish protocols that assure that all MRT Procedures performed are medically necessary and will not unnecessarily duplicate other services.
 - e. An applicant proposing to acquire any MRT Unit shall demonstrate that it meets the staffing and quality assurance requirements of the American Society of Therapeutic Radiation and Oncology (ASTRO), the American College of Radiology (ACR), the American College of Radiation Oncology (ACRO) or a similar accrediting authority such as the National Cancer Institute (CNI). Additionally, all applicants shall commit to obtain accreditation from ASTRO, ACR or a comparable accreditation authority for MRT Services within two years following initiation of the operation of the proposed MRT Unit.

- f. All applicants should seek and document emergency transfer agreements with local area hospitals, as appropriate. An applicant's arrangements with its physician medical director must specify that said physician be an active member of the subject transfer agreement hospital medical staff.
 - g. All applicants should provide evidence of any onsite simulation and treatment planning services to support the volumes they project and any impact such services may have on volumes and treatment times.
7. The applicant should provide assurances that it will submit data in a timely fashion as requested by the HSDA to maintain the HSDA Equipment Registry.
 8. In light of Rule 0720-11.01, which lists the factors concerning need on which an application may be evaluated, and Principle No. 2 in the State Health Plan, "Every citizen should have reasonable access to health care," the HSDA may decide to give special consideration to an applicant:
 - a. Who is offering the service in a medically underserved area as designated by the United States Health Resources and Services Administration;
 - b. Who is a "safety net hospital" or a "children's hospital" as defined by the Bureau of TennCare Essential Access Hospital payment program; or
 - c. Who provides a written commitment of intention to contract with at least one TennCare MCO and, if providing adult services, to participate in the Medicare program.

Comments:

1. The Office of Health Planning recognizes the need to review MRT Services standards and criteria on a frequent basis due to the evolving nature of the technology involved.
2. It is anticipated that the Tennessee Cancer Registry data, maintained by the Department of Health, will in the future become available for use by applicants to support the need for new MRT Units.

Rationale for Revised and Updated Standards and Criteria for Megavoltage Radiation Therapy Services

Definitions

Linear Accelerator Units. The Office of Health Planning recognizes that Linear Accelerators performing SRT and/or SBRT procedures do not reach the level of utilization of Linear Accelerators that do not perform these procedures. Consequently, standards have been developed that endeavor to recognize these significant differences in utilization.

Proton Beam Therapy Units. Given the increasing interest in proton beam therapy units, surprisingly little data exist on optimal capacity and geographic service areas. However, the Office thought it important to include a specific category for proton beam therapy units to help inform the application and decision-making process.

MRT Procedure. To provide for uniform procedure reporting, the Health Services and Development Agency is responsible for setting CPT code reporting requirements.

Capacity. The Health Services and Development Agency staff solicited operating schedule information from owners/operators of MRT Units and the number of procedures performed annually. The capacity numbers were developed from this information.

Standards and Criteria Regarding Certificate of Need Applications for Magnetic Resonance Imaging Services

1. **Exceptions to Utilization Standards:** Exceptions to the standard number of procedures have been added for new or improved technology and treatment applications. The Office recognizes the rapidly advancing technological changes in this area and the need for flexibility on the part of the HSDA in making its decisions.
2. **Other Access Issues:** The provision of health care doesn't recognize state boundaries. Accordingly, applicants may include non-Tennessee counties in proposed Service Areas if that data are available. Proton Beam Therapy Units are anticipated to require extremely large Service Areas that may include other states' counties.
3. **Economic Efficiencies:** To support the goal of reducing health care costs, applicants should document that other options have been investigated and found less advantageous.
4. **Inventories:** If data are available, separate inventories should be maintained for Linear Accelerators based on procedures performed as well as for other types of MRT Units.

5. **Quality of Care:** Reference to specific recognized authorities' recommendations on staffing, training, and education standards are included to help ensure patient safety and quality of care are provided.

Appendices A and B

Appendix A: Health Services and Planning Policy Statement

Appendix B: Health and Wellness Task Force Members

APPENDIX A

Health Services and Planning Act Policy Statement

The Office of Health Planning is charged by TCA § 68-11-1625 with creating a State Health Plan. The text of the law follows.

- a. There is created the state health planning division of the department of finance and administration. It is the purpose of the planning division to create a state health plan that is evaluated and updated at least annually. The plan shall guide the state in the development of health care programs and policies and in the allocation of health care resources in the state.
- b. It is the policy of the state of Tennessee that:
 1. Every citizen should have reasonable access to emergency and primary care;
 2. The state's health care resources should be developed to address the needs of Tennesseans while encouraging competitive markets, economic efficiencies and the continued development of the state's health care industry;
 3. Every citizen should have confidence that the quality of health care is continually monitored and standards are adhered to by health care providers; and
 4. The state should support the recruitment and retention of a sufficient and quality health care workforce.
- c. The planning division shall be staffed administratively by the department of finance and administration in a manner that the department deems necessary for the performance of the planning division's duties and responsibilities, which may include contracting for the services provided by the division through a private person or entity.
- d. The duties and responsibilities of the planning division include:
 1. To develop and adopt a State Health Plan, which must include, at a minimum, guidance regarding allocation of the state's health care resources;
 2. To submit the State Health Plan to the Health Services and Development Agency for comment;
 3. To submit the State Health Plan to the Governor for approval and adoption;
 4. To hold public hearings as needed;
 5. To review and evaluate the State Health Plan at least annually;
 6. To respond to requests for comment and recommendations for health care policies and programs;
 7. To conduct an ongoing evaluation of Tennessee's resources for accessibility, including, but not limited to, financial, geographic, cultural, and quality of care;
 8. To review the health status of Tennesseans as presented annually to the Division by the Department of Health and the Department of Mental Health and Developmental Disabilities;

9. To review and comment on federal laws and regulations that influence the health care industry and the health care needs of Tennesseans;
10. To involve and coordinate functions with such State entities as necessary to ensure the coordination of State health policies and programs;
11. To prepare an annual report for the General Assembly and recommend legislation for its consideration and study; and
12. To establish a process for timely modification of the State Health Plan in response to changes in technology, reimbursement and other developments that affect the delivery of health care.

Appendix B

Health and Wellness Task Force Members

John Lacey III, MD -- University of Tennessee Chief Medical Officer

Richard Bracken -- Healthcare Corporation of America Chief Executive Officer

Reggie Coopwood, MD -- Regional Medical Center Chief Executive Officer

Pete DeBusk -- DeRoyal Industries Chief Executive Officer

John Dreyzehner, MD, MPH – Department of Health Commissioner

Darrell Freeman -- Zycron Chief Executive Officer

Inga Himelright, MD -- Blue Cross/Blue Shield of Tennessee Chief Medical Officer

Kevin Huffman -- Education Commissioner

Cato Johnson -- Methodist Hospital Vice President

Alan Kohrt, MD - TC Thompson Children's Hospital Medical Director

Wendy Long, MD, MPH -- TennCare Chief Medical Officer

Michael Minch, MD -- Tennessee Medical Association

Randy Wykoff, MD, MPH – Dean, East Tennessee State University College of Public Health

Ed Pershing -- Pershing Yoakley & Associates President

Vickie Shepard -- Healthways, Inc. Senior Vice President

Doug Varney -- Mental Health Commissioner

Dennis Vonderfecht -- Mountain States Health System Chief Executive Officer

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