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# Tennessee State Health Plan

## 2009

Division of Health Planning  
Department of Finance and Administration

November 2009

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State of Tennessee



**STATE OF TENNESSEE**

**PHIL BREDESEN**  
GOVERNOR

18 November 2009

Mr. Jefferson H. Ockerman  
Director, Division of Health Planning  
Department of Finance and Administration  
William R. Snodgrass Building  
312 Rosa L. Parks Boulevard, Suite 2100  
Nashville, TN 37243

Dear Mr. Ockerman:

I have received and reviewed the first edition of the State Health Plan, submitted by you to my office on October 7, 2009. Pursuant to Tennessee Code Annotated, Section 68-11-1625(d)(3), this letter shall serve as notice of my approval and adoption of the first edition of the State Health Plan.

Thank you for your work on this important project.

Warmest regards,

A handwritten signature in black ink, appearing to read "Phil Bredeesen".

Phil Bredeesen



**STATE OF TENNESSEE  
DEPARTMENT OF FINANCE AND ADMINISTRATION  
DIVISION OF HEALTH PLANNING  
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**M.D. GOETZ, JR.  
COMMISSIONER**

**JEFF OCKERMAN  
DIRECTOR**

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October 7, 2009

Governor Phil Bredesen  
The Capitol  
Nashville, TN

Re: First edition of the State Health Plan

Dear Governor Bredesen:

Included with this letter for your review is the first edition of the State Health Plan, the purpose of which is to “guide the state in the development of health care programs and policies and in the allocation of health care resources in the state.”

TCA § 68-11-1625 (d) requires that the State Health Plan be submitted to the Health Services and Development Agency for comment (accomplished during June, 2009) and then to the Governor “for approval and adoption.”

The Division of Health Planning has worked with Deputy Governor Morgan as well as with the Commissioners and staff of the Departments of Health and of Mental Health and Developmental Disabilities (as well as staff of other departments and agencies and the members of the State Health Plan Advisory Committee) in the development of this document. This first edition of the State Health Plan accomplishes the following:

- Revises the standards and criteria for two Certificate of Need program areas (PET and Cardiac Catheterization services);
- Establishes Five Principles for Achieving Better Health (based on the statutory health planning policy statements set out in TCA § 68-11-1625(b));
- Provides data on the current status of the health of Tennesseans;
- Establishes guidelines for revising the CON program’s standards and criteria; and
- Sets the stage over the course of the next year for public involvement in the creation of goals and objectives for achieving better health in Tennessee.

Attached to this letter is a summary of the applicable statutory requirements, the opportunities for comment provided to the public (as well as to the HSDA and an Advisory Committee), and the next steps for the continued development of the State Health Plan.

Governor Bredeesen  
October 7, 2009  
Page Two

Please let me know if you have any questions, comments, or desired changes regarding this first edition of the State Health Plan.

Sincerely,

A handwritten signature in black ink, appearing to read "Jefferson H. Ockerman". The signature is fluid and cursive, with a large initial "J" and "H".

Jefferson H. Ockerman

Attachment

Cc: Commissioner Dave Goetz  
Deputy Governor John Morgan  
Assistant Commissioner Mike Morrow  
HSDA Executive Director Melanie Hill

Additional information on applicable statutory requirements, what is included in the first edition of the State Health Plan, the process followed for receipt of comments on the State Health Plan draft:

Statutory Charge. In 2004, the Tennessee General Assembly (General Assembly) passed Public Chapter 942, an act relating to “health services and health planning” (codified as Tennessee Code Annotated § 68-11-1625). This Public Chapter created the Division of Health Planning within the Department of Finance and Administration and charged it with developing a state health plan that “is updated at least annually” and that “shall guide the state in the development of health care programs and policies and in the allocation of health care resources in the state.” This Division has worked to develop this first edition of the State Health Plan over the past 21 months.

What is included in the first edition of the State Health Plan. According to TCA § 68-11-1602 (18), the State Health Plan “shall include clear statements of goals, objectives, criteria and standards to guide the development of health care programs administered or funded by the state of Tennessee through its departments, agencies or programs, and considered as guidance by the Health Services and Development Agency when issuing certificates of need.” TCA § 68-11-1625(d)(1) requires “at a minimum,” that the State Health Plan must include “guidance regarding allocation of the state’s health care resources.”

This first edition establishes Five Principles for Achieving Better Health (derived from the statutory health policy statement in TCA § 68-11-1625(b)), provides data on the current status of the health of Tennesseans, establishes guidelines for revising the CON program’s standards and criteria, sets new standards and criteria for two Certificate of Need (CON) program areas (PET and Cardiac Catheterization Services), and sets the stage for a public process to take place over the next year to create goals and objectives to guide the development of the state’s health care programs.

Process for Approval and Adoption by the Governor. Tennessee Code Annotated § 68-11-1625(d) requires that the State Health Plan be submitted to the Health Services and Development Agency (HSDA) for comment by its members and staff and then submitted to the Governor for approval and adoption. This first edition of the State Health Plan was submitted to the HSDA for comment on June 1, 2009, and the Agency members and staff have provided their comments to this Division. The State Health Plan was also provided to the general public, via the Division’s website and an email address list, and to the State Health Plan Advisory Committee for comment. Previously, the new standards and criteria for the two CON program areas were submitted to the HSDA and to the general public for comment via the Division’s website and the email address list. Additional statutory obligations placed on the Division of Health Planning regarding the State Health Plan are to hold public hearings as needed and to provide 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.

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# Tennessee State Health Plan

**2009**

## **Sections**

- 1 State Health Plan
- 2 Certificate of Need Standards and Criteria  
(Appendices A and B to the State Health Plan)
- 3 Appendices C – H to the State Health Plan
- 4 Certificate of Need Work Papers  
(Attachments to the State Health Plan)

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# **Tennessee State Health Plan**

**2009**

## **Section 1**

**Tennessee State Health Plan**

## **Notes on this first edition of the State Health Plan**

This document is the foundation for a public dialogue between the Division of Health Planning and the public to develop the vision and goals for future editions of the State Health Plan. While this document presents the status of Tennesseans' health today in many areas, it also points out many information gaps on the issues of health care quality, access, economic efficiencies, and workforce development. This first edition is meant to provide a basis to inform the discussions the Division of Health Planning plans to hold over the next year among consumers, providers, the health care sector, the public health sector, and the broader community so that updated editions of the State Health Plan can establish goals for the future of Tennesseans' health that stakeholders can embrace.

On a more particular note, this first edition of the State Health Plan describes the process for creating new standards and criteria for the Certificate of Need Program categories and sets out new standards and criteria for positron emission tomography units and cardiac catheterization services.

The Division of Health Planning recognizes that the current health care reform discussions and potential legislation at the federal level, if implemented, will directly impact the health of and the delivery of health care to Tennesseans. Funds made available through the Health Information Technology for Economic and Clinical Health Act and the American Recovery and Reinvestment Act of 2009 will also directly impact the health of and the delivery of health care to Tennesseans.

The Division of Health Planning expressly thanks the members of the State Health Plan Advisory Committee and the Tennessee Department of Health and the Tennessee Department of Mental Health and Developmental Disabilities and their dedicated and talented staffs for their invaluable assistance in developing this draft first edition of the State Health Plan.



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# Executive Summary

## **The Beginnings of a State Health Plan**

In 2004, the Tennessee General Assembly (General Assembly) passed Public Chapter 942, an act relating to “health services and health planning.” This Public Chapter created the Division of Health Planning within the Department of Finance and Administration and charged it with developing a state health plan that “shall guide the state in the development of health care programs and policies and in the allocation of health care resources in the state.”<sup>1</sup>

## **Why a State Health Plan?**

Tennessee has been called one of the least healthy states in America: in one recent report, we rank as the 47<sup>th</sup> healthiest state out of the 50 states and the District of Columbia.<sup>2</sup> Tennessee is improving on some measures of health outcomes. For example, our rates of tobacco use are falling, and our life expectancies are increasing. However, Tennessee is failing to keep up with the rest of the nation in improving its population’s health: in 1990, Tennessee was ranked the 37<sup>th</sup> healthiest state. In addition, Tennessee’s health system performance has ranked below average as well, though Tennessee improved to 39<sup>th</sup> in 2009 from 41<sup>st</sup> in 2007.<sup>3</sup>

Once developed, the State Health Plan will provide a collective vision for coordination among state departments and agencies to work to improve the health of Tennesseans and the performance of our health system. As conceived by the General Assembly, the State Health Plan includes a vision for moving our current largely episodic health care system to an integrated system of care, providing opportunities for economic efficiencies while addressing the need for health promotion, health education, disease prevention, better nutrition, and chronic disease management.

## **Purpose of this First Edition and Next Steps**

This document is the beginning of a comprehensive and participatory health planning process to coordinate Tennesseans’ efforts to improve our health. Over the next year, the Division of Health Planning plans to hold several public meetings and convene focus groups across the state to gather public input that will be incorporated into a new edition of the State Health Plan. What we Tennesseans choose to value in terms of changing the Tennessee system of health care delivery and in how we approach improving the health of our citizens will be determined in this process.

## **The Planning Model: Public Input for the Updated Edition**

In order to decide on a collective vision for improving health, we first need to identify and understand the current status of health and health care delivery in Tennessee. This first edition of the State Health Plan describes the current status of our health and healthcare to establish benchmarks for measuring our progress over time. On a more particular note, this first edition of the State Health Plan describes the process for creating new standards and criteria for the Certificate of Need Program categories and sets out

new standards and criteria for positron emission tomography units and cardiac catheterization services.

Over the next year, the Division of Health Planning plans to provide individuals, consumers, providers, the health care sector, the public health sector, and the broader community opportunities to participate in the development of the State Health Plan. The process, as envisioned, should seek input from these stakeholders through email, letters, and a series of public meetings across the state to gather their views on improving the health of Tennesseans. From this public input, the Division of Health Planning plans to prepare an updated edition of the State Health Plan that will set forth a collective vision of health goals and values for Tennessee.

### **The Framework for Tennessee’s Comprehensive State Health Plan – Five Principles for Achieving Better Health**

The following Five Principles for Achieving Better Health, based on the statutory health planning policy statement created by the General Assembly, codified in Tennessee Code Annotated § 68-11-1625 (b) and appearing in Appendix C, serve as the basic framework for the State Health Plan. Through the public participatory process described above, the Division of Health Planning plans for specific goals and policy directives related to each of these areas, as well as to any others that are developed, to be established.

1. The purpose of the State Health Plan is to improve the health of Tennesseans. Every person’s health is the result of the interaction of individual behaviors, society, the environment, economic factors, and our genetic endowment. Although not all determinants of health are discussed herein, this first edition of the State Health Plan will present Tennessee’s current state of the following key determinants of health: nutrition and exercise; chronic conditions; mental health and substance abuse; preventive health care; and maternal and prenatal care. The description of the current status of our health determinants is intended to support an informed public discussion of how we as Tennesseans should work together to achieve our common goal of improving our health.
2. Every citizen should have reasonable access to health care. Many elements impact one’s access to health care, including existing health status, employment, income, geography, and culture. In addition, many questions surround what constitutes “reasonable” access to different types of health care, including primary, emergency and trauma, mental health and substance abuse, dental, and specialty care. The State Health Plan can provide standards for reasonable access and offer policy direction to improve access. In addition, the State of Tennessee currently seeks to expand access to health care through its Safety Net initiative, Cover Tennessee, and multiple other programs and services. The State Health Plan can serve a coordinating role to expand health care access through these efforts, increasing both the effectiveness and the efficiency of the state’s resources.

3. 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. The United States health care system is economically inefficient in the sense that it is more expensive and does not necessarily produce better health outcomes than those of many other countries. Moreover, the provision of health care does not function like most other capitalist markets for a variety of reasons, including the fact that studies have shown that a greater supply of health care services can actually increase demand for services, the existence of a lack of pricing and quality transparency, and a misalignment of economic incentives. A State Health Plan should work to identify opportunities to improve the efficiency of the state's health care system, and to encourage innovation and competition. However, while competition can increase the efficiency of Tennessee's health care system, the State Health Plan must also consider the issue of ensuring that the health care industry is able to make essential health care services accessible to every person in Tennessee, regardless of ability to pay.
4. Every citizen should have confidence that the quality of health care is continually monitored and standards are adhered to by health care providers. As a starting point, the State Health Plan adopts the definition of "high quality care" used by The Institute of Medicine of the National Academies, private nonprofit institutions providing science, technology, and health policy advice under a congressional charter.<sup>4</sup> That definition of "high quality care" is care that is safe, effective, patient-centered, timely, efficient, and equitable. Yet, there has been widespread recognition that much of the U.S. health care system is not meeting high quality standards. While Tennesseans can be assured that health care providers are held to certain professional standards by the state's licensure system, the federal Agency for Healthcare Research and Quality rated Tennessee's overall health care quality as "weak" in its 2007 report. In response to high variability in the quality of care being provided, many health care stakeholders are working to improve their quality of care through greater adoption of best practices and data-driven evaluation. The State Health Plan will define Tennessee's strategy for measuring and improving the quality of care our citizens receive.
5. The state should support the development, recruitment, and retention of a sufficient and quality health care workforce. In the short term, Tennessee appears to have a sufficient number of primary care physicians<sup>5</sup> and nurses (although they are not necessarily proportionately distributed throughout the state, meaning patient access to primary care is not uniformly available). Whether or not in the future Tennessee will experience a health care workforce shortage, as has been predicted for the United States as a whole, is an issue for further research and discussion. However, the anticipated retirement of a large number of providers and workforce professionals as well as the increasing health needs of the aging Baby Boom generation indicate that the topic should be addressed sooner rather

than later. The state should consider developing a comprehensive approach to ensure the existence of a sufficient, qualified health care workforce, taking into account issues regarding the safety net system, 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, allied health and other educational institutions, state and federal laws and regulations impacting capacity programs, and funding. At the time of publication of this document, the current economic recession, for a variety of reasons, has alleviated some of the nursing workforce shortage pressures.

### **Using Data to Make Decisions: the Health Planning Decision Support System**

Health-related data within state government are dispersed across multiple state departments and agencies. The Health Planning Decision Support System (HPDSS), currently under development by the Division of Health Planning, will bring data from a variety of sources into a central system so users can retrieve, summarize, and analyze data relevant to policy and programmatic decisions. The HPDSS will begin by bringing county and zip-code level population health information together to support information-seekers, analysts, and decision-makers in government agencies and health-related organizations throughout Tennessee. The HPDSS will significantly enhance the ability of the State Health Plan to guide the development of health-related programs and policies and the allocation of health-related resources.

### **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. State law directs the Health Services and Development Agency (HSDA) to use the State Health Plan as guidance in issuing CONs. Currently, the HSDA relies on the standards and criteria contained in *Tennessee's Guidelines for Growth, 2000 Edition*. These standards and criteria have not been updated since 2000. As a result of research performed by the staff of the Division of Health Planning in conjunction with a public input process over the past year, this first edition of the State Health Plan contains updates to the standards and criteria for positron emission tomography (PET) services and for cardiac catheterization services. Each update to the certificate of need standards will go through its own public review process, including submission to the HSDA and to the public for comment, before being adopted by the Governor and included in future editions of the State Health Plan. Standards and criteria will be tied to the State Health Plan's overarching goals and priorities.

# Chapter 1: Introduction and Overview

*In this chapter we present some background information regarding the State Health Plan – why it is needed and its history, purpose, and future. We also present highlights of the state’s current health initiatives.*

## The State Health Plan

The Tennessee General Assembly has recognized that a coordinated state health plan is needed to direct the appropriate use of the state’s resources in improving the health of Tennesseans. In this chapter, the rationale for a state health plan and the incremental approach to its creation are discussed first. The Division of Health Planning acknowledges the extensive work performed by many stakeholders in the past to develop a health planning framework in Tennessee. This State Health Plan builds on their efforts.

## The State’s Health Priorities

Brief highlights are then presented regarding the state’s focused efforts on driving improvements in the health and mental health of its citizens by reducing the incidence of chronic diseases and risk factors, improving access to health care through more access to health insurance and to community-based long term care, and improving health care quality and delivery through eHealth initiatives.

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## Why a State Health Plan?

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Health is a complex issue with many determinants and influences, including our individual behaviors, our cultures, the environment, the economy, and our own genes. Given these complexities and the recognized need for a coordinated and participatory approach to creating an effective State Health Plan, we must begin with a proposed definition for “health.”

Since 1946, the World Health Organization (WHO) defines health as “a state of complete physical, mental, and social well being, and not merely the absence of disease.”<sup>6</sup> As an initial step for creating the foundation for the State Health Plan, the Division of Health Planning will use this widely recognized definition of health.

Evidence points to there being a strong need to improve Tennesseans’ health. While Tennessee has shown improvement in certain health outcome measurements, nationally, Tennessee is ranked 47th out of 51 jurisdictions (including all states and the District of Columbia) in terms of the overall health of its citizens.<sup>7</sup> In 1990, it was ranked 37th and in 2007 it was ranked 46th.<sup>8</sup> In other words, in comparison to these other political jurisdictions, Tennessee is not keeping up. The comparatively poor health of

Tennesseans negatively impacts not only the quality of life of our citizens, but a wide variety of other issues, including the economy of the state.

The Division of Health Planning recognizes that Tennessee's lack of an integrated system of health care contributes to poor health outcomes. Instead of a cohesive system with a common vision and goals, Tennessee has a collection of services provided, with some levels of cooperation, by the public health sector, communities, and the private health care sector. The Commonwealth Fund, a respected national health care think tank, ranked Tennessee's health system performance 39<sup>th</sup> in 2009 – an improvement from 41<sup>st</sup> in 2007 – based on benchmarks for 38 indicators of access, quality, costs, and health outcomes.<sup>9</sup> The Division of Health Planning believes that providing a process through which we can create a common vision among all sectors of the health system will enable the state's departments and agencies in a coordinated fashion to move towards meeting key policy area goals for improving the health of Tennesseans.

This document, the first edition of Tennessee's State Health Plan, is the foundation for a public process that is planned to develop the vision and goals for future editions of the State Health Plan. While this document presents the status of Tennesseans' health today in many areas, it also recognizes many information gaps on the issues of quality, access, economic efficiencies, and workforce development. This first edition is meant to provide a basis to inform the discussions planned to be held over the next year among consumers, providers, the health care sector, the public health sector, and the community so that updated editions of the State Health Plan can establish goals and objectives for the future of Tennesseans' health that stakeholders can embrace.

### **Statutory Policy Statement for the State Health Plan.**

In 2004, Public Chapter 942 passed by the General Assembly created the Division of Health Planning in the Department of Finance and Administration and charged it with developing a State Health Plan. According to this law, the State Health Plan “shall include clear statements of goals, objectives, criteria and standards to guide the development of health care programs administered or funded by the state of Tennessee through its departments, agencies or programs, and considered as guidance by the Health Services and Development Agency when issuing certificates of need....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.”<sup>10</sup> Tennessee Code Annotated § 68-11-1625(b) provides a statement of policy that is the basis for the Five Principles for Achieving Better Health, discussed in Chapter 3.<sup>11</sup> This policy statement appears in Appendix C.

Tennessee Code Annotated § 68-11-1625(d) requires that the State Health Plan be submitted to the Health Services and Development Agency for comment by its members and staff and then submitted to the Governor for approval and adoption.<sup>12</sup> Additional statutory obligations placed on the Division of Health Planning regarding the State Health Plan are to evaluate and update the State Health Plan at least annually, to hold public hearings as needed, and to provide 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.<sup>13</sup>

### **The Incremental Approach to Creating a State Health Plan**

The Division of Health Planning, with the advice of its Advisory Committee,<sup>14</sup> recognizes that the creation of a complete and meaningful state health plan is a dynamic, ongoing enterprise. Consequently, this first edition of the State Health Plan is neither all inclusive nor final. Additionally, there are numerous plans mandated by the General Assembly or funding agencies that are currently in place or in development. Appendix D lists many of these, and all of them should be considered as specific components of the Tennessee State Health Plan.

Not only does the Tennessee Health Services and Planning Act anticipate annual updates to the State Health Plan in response to changes in technologies, reimbursement methods, and circumstances, but the Division of Health Planning believes that this document should represent a launching pad for further discussions, education, and policy changes. Consequently, the State Health Plan is being developed incrementally, focusing in this edition on: 1) establishing the state's current specific health priorities; 2) identifying the initial Five Key Policy Areas of the State Health Plan; 3) providing the process for revising standards and criteria of the Certificate of Need program areas, as well as newly revised standards and criteria for positron emission tomography services and cardiac catheterization services; and 4) explaining the need for and the process for developing the Health Planning Decision Support System.

### **Planning Model**

The health planning process is modeled after those of many other states. These models seek ideas and comments from a wide range of identified stakeholders. After reviewing many of these health plans, the Division of Health Planning initially has identified the following stakeholder groups, which are referred to throughout this document:

- Individuals/Health Care Consumers
- Providers (health care/health professionals and specialists, including mental health and substance abuse professionals, hospitals, ambulatory care organizations, and other health care professionals)
- Health Care Sector (including, but not limited to, health insurance plans, purchasers of health insurance, durable medical equipment and other suppliers and ancillary businesses, pharmaceutical companies, and health care educators)
- Public Health Sector (including government health care employees and social workers)
- Community (other stakeholders who may not be included in the above groups)



## **—————An Overview of the State’s Current Focus Areas—————**

This section highlights state government’s current priority initiatives designed to improve the health of Tennesseans, centering on three areas, set forth below. It should be noted that progress on these initiatives is directly impacted by the ability of the state to provide resources to them and that reductions in the state’s budget as a result of the current economic recession may negatively impact these initiatives as well as other health and health care programs of the state.

- Driving improvements in the health of Tennesseans by addressing the complexities of chronic diseases and their risk factors, coordinated school health, and providing mental health resources;
- Ensuring Tennesseans have improved access to health care through more access to health insurance and a new emphasis on expanding access to and utilization of cost-effective home and community-based alternatives to institutional care for Medicaid-eligible individuals through the Long-Term Care Community Choices Act of 2008 (<http://tennessee.gov/tenncare/forms/pc1190.pdf/>); and
- Improving health care quality and delivery through eHealth initiatives to provide for the exchange of electronic health information in Tennessee, ensuring that providers have complete patient information at the point of care.

### **Addressing the Complexities of Chronic Diseases and Risk Factors Associated with Them**

In the United States and in Tennessee chronic health conditions such as diabetes, heart disease, and cancer are the leading cause of death and disability.<sup>15</sup> There are several state government initiatives to address chronic disease, including smoking cessation, a new State Healthcare Report Card on Diabetes and Hypertension, and Coordinated School Health programs.

#### **Smoking Cessation.**

Smoking is a major risk factor for heart disease, stroke, and lung cancer, and is the single most preventable cause of disease and death in the United States.<sup>16</sup> Tennessee has one of the highest rates of smoking in the United States and also, not surprisingly, one of the highest rates of heart disease, stroke, and lung cancer. Additionally, smoking during pregnancy can lead to pregnancy complications and serious health problems in newborns.<sup>17</sup> The State’s Smoking Cessation initiative is a combination of two programs overseen by the Tennessee Department of Health (TDOH) and an increase in the tobacco sales tax:

**Tennessee Non-Smokers Protection Act** – Beginning October 1, 2007, Tennesseans were able to breathe smoke free at numerous restaurants, hotels, and many other establishments as a result of the Tennessee Non-Smokers Protection Act. This law, enforced by the TDOH, makes it illegal to smoke in most places where people work (<http://health.state.tn.us/smokefreetennessee/>).

**Tennessee Tobacco QuitLine** – The Tennessee Tobacco QuitLine is a toll-free telephone service that provides personalized support for Tennesseans who want to quit smoking or chewing tobacco. Participants are assigned “quit coaches” who assist them in developing individualized quitting plans and work with them for an entire year. This free program has a 25 percent successful quit rate after 12 months. (<http://health.state.tn.us/tobaccoquitline.htm>; 1-800-QUIT NOW)

**Increase in the Tobacco Sales Tax** – Effective July 1, 2007, the state tax on cigarettes increased from \$0.20 to \$0.62 per pack. Additional annual revenues from the increase are earmarked for education (estimate: \$195 million), agricultural enhancements (estimate: \$21 million) and trauma centers statewide (estimate: \$12 million) (<http://tennessee.gov/revenue/misc/cigtaxincrease.htm>).

### **State Healthcare Report Card on Diabetes and Hypertension**

The Health Quality Initiative, a study group of state government health, health care, and health planning experts and private sector volunteers convened by M. D. Goetz, Jr., the Commissioner of Finance and Administration for the state, produced the State Healthcare Report Card Version 1.1 – Diabetes and Hypertension in March 2009 (available at the Division of Health Planning’s website: [www.state.tn.us/finance/HealthPlan/dhpshtml](http://www.state.tn.us/finance/HealthPlan/dhpshtml)). This report, for the first time, provides information on these two conditions at county and regional levels within Tennessee. The Health Quality Initiative will build on the lessons learned in creating this report for increased analysis of the quality of health care at the local level. This document is included as an attachment to the State Health Plan.

### **Coordinated School Health**

Healthy habits begin in childhood, so the time that children spend in school is an opportunity to create healthy behaviors that will last into adulthood. In 2006, the General Assembly passed and Governor Phil Bredesen signed into law funding for coordinated school health for every Local Education Agency (LEA) in every school district in Tennessee. The statewide coordinated school health program is the first of its kind in the nation, and builds upon a five-year pilot project at ten sites in Tennessee. In addition, coordinated mental health assistance has been added to the program. The General Assembly has further shown its commitment to encouraging healthy behaviors in schools with a 2004 law mandating healthy food in vending machines in public schools.

#### **Physical Health in Public Schools**

The Office of Coordinated School Health within the Tennessee Department of Education (TDOE) has made Tennessee a national leader in implementing the Centers for Disease Control’s coordinated school health model. The Office of

Coordinated School Health works with local education departments on the following eight components of school health: nutrition; physical education, activity, and wellness; healthy school environment; mental health and school counseling; school staff wellness; student, family, and community partners; health services; and health education. Coordinated school health programs create partnerships at the state and local level with county health departments, universities, businesses, hospitals, and non-profit organizations. The project has brought in four million dollars in grants and in-kind contributions at the local level as a result of its partnerships.<sup>18</sup>

Tennessee law requires all public schools to include 90 minutes of physical education per week during school hours from kindergarten to 12<sup>th</sup> grade. All local education agencies (LEAs) are also required to screen students in grades K, 2, 4, 6, and 8 for vision, hearing, body mass index (BMI), and blood pressure. In the 2007-2008 academic year, the first year of implementation, 80.6 percent of schools were compliant.<sup>19</sup> Some LEAs also conducted dental screenings (39 percent), BMI and blood pressure screenings in high school, and/or scoliosis screenings in 6<sup>th</sup> grade (41 percent).<sup>20</sup> As a result of the required and optional screenings, 104,532 students were referred to doctors, with most referrals for BMI (45 percent), vision (27 percent), and dental (14 percent). Without these screening these children might not have received care for their conditions.<sup>21</sup>

### **Mental Health in Schools**

The TDOE Office of Schools and Mental Health has a \$301,010 18-month grant from the United States Department of Education Office of Safe and Drug Free Schools for Coordinated School Health coordinators to integrate schools' health and mental health systems. School staff, from teachers to administrators to bus drivers, will be trained to recognize signs of mental health problems and know how to make referrals to the appropriate person.

In addition, in Project BASIC (Better Attitudes and Skills in Children) the Tennessee Department of Mental Health and Developmental Disabilities (TDMHDD) places child development consultants in elementary schools to identify and refer children with severe emotional disturbance. TDMHDD also oversees and supports school based mental health services by providing liaisons who train teachers to provide positive behavioral supports and behavior plans. Liaisons also see youth for brief interventions and guide groups of children in anger management and communication skills enhancement.

### **Healthy Food Sold in Schools**

In 2004 the General Assembly passed and Governor Bredesen signed into law new nutritional guidelines for food sold during school hours on public school grounds in Tennessee. As a result, Tennessee selectively prohibits, as set forth below, the sale of sodas, other high calorie beverages, high fat snack foods, salty snack foods, and other unhealthy foods at public schools (only water, 100 percent fruit juice, low-fat or no-fat milk, and low calorie drinks can be sold as

beverages). The law applies fully to grades k-5; schools of grades 6-8 must implement 50 percent of the nutritional quality standards; schools of grades 9-12 are exempt.<sup>22</sup>

## **Mental Health Resources**<sup>23</sup>

### **Behavioral Health Safety Net**

The TDMHDD provides essential mental health services to 19,716 impoverished and uninsured severely and/or persistently mentally ill people through the Behavioral Health Safety Net. The program was created to help mentally ill people who were disenrolled from TennCare, Tennessee's Medicaid program, during the reforms of 2005.

The Behavioral Health Safety Net is a partnership between the TDMHDD and 19 local mental health agencies. The Behavioral Health Safety Net provides assessment, evaluation, diagnostic, and therapeutic sessions; case management; psychiatric medication management; lab work related to medication management; and pharmacy assistance and coordination.

The Behavioral Health Safety Net partners with the Cover Tennessee Cover Rx program for pharmacy services including discounts on generic and brand name drugs plus one atypical antipsychotic drug per month with a \$5.00 co-pay. In 2007 the program was expanded so that lithium and Depakote could be available with a \$5.00 co-pay.

An additional 12,000 very low income Tennesseans diagnosed with severe and persistent mental illness were transferred from TennCare to the Behavioral Health Safety Net in January 2009.

### **Access to Recovery**

The TDMHDD administers the U.S. Department of Health and Human Services (HHS) Substance Abuse and Mental Health Services Administration (SAMHSA) Access to Recovery (ATR) Grant to provide an array of treatment and recovery services for Tennesseans with substance abuse problems. This grant provides enhanced referral collaboration with the criminal justice system; expands a statewide culturally competent provider network of both faith and community-based agencies; and develops a strengths-based case management model that allows individuals to achieve and maintain recovery by offering consumer choice while improving access to clinical treatment and recovery support. TDMHDD staff provides guidance, monitoring and oversight of this important recovery program.

### **Crisis Stabilization Units**

The TDMHDD in collaborative funding with the Bureau of TennCare has established regional crisis stabilization units (CSUs) across Tennessee. The CSUs provide 24-hour, seven days a week, walk-in and short-term stabilization services for individuals with mental health and substance abuse issues. They provide assessment, triage, medication management, and group and individual therapy as well as opportunities for clients to work with a wellness recovery consumer specialist. CSUs offer care in a less restrictive setting than a psychiatric hospital or other residential treatment resource and are short

term focused services. There are currently crisis stabilization units operating in Nashville, Chattanooga, Cookeville, Jackson, Knoxville, Memphis, and Johnson City, which also serve residents of surrounding counties.

### **Improving Access to Health Care through More Access to Health Insurance**

**Cover Tennessee** – Through the Cover Tennessee Act of 2006,<sup>24</sup> Governor Bredesen and the General Assembly authorized the Department of Finance and Administration to establish the Cover Tennessee program to provide health insurance options to certain uninsured individuals in Tennessee (please go to this website, or call the telephone number shown, for details on all Cover Tennessee programs: <http://www.covertn.gov/>; 1-866-COVERTN). Cover Tennessee is an umbrella initiative designed for affordability and portability that includes four health insurance products and pharmacy assistance. These programs are:

- CoverTN is a limited (non-catastrophic event), portable health insurance plan for employees of small businesses and self-employed individuals. It emphasizes low front-end costs to encourage preventive care, including free checkups, free mammograms, and low co-pays. Premiums are split 1/3 each by the individual, the employer, and the state.
- CoverKids is Tennessee’s program under the federal State Children’s Health Insurance Program for families with incomes that are too high to qualify for TennCare coverage. The program provides coverage for children 18 and under and maternity coverage for pregnant women. It features no monthly premiums, but each participant pays reduced co-payments for services. The coverage includes an emphasis on preventive health services and coverage for physician services, hospitals, vaccinations, well-child visits, healthy babies program, developmental screenings, mental health vision care, and dental services. Qualifying for enrollment for CoverKids is based on a household income of up to 250% of the federal poverty level (FPL), the number of persons in the household and also on the age of the child you wish to enroll. Household income includes income earned and income received. Children in families with a household income greater than 250% FPL may buy into the CoverKids plan.
- AccessTN provides comprehensive health insurance options for uninsurable Tennesseans – those with sufficient incomes but who can’t purchase health insurance due to certain pre-existing conditions. There is no income test for this program, which is one of 34 State high-risk pools in the country that perform this function. Funding comes from several sources, including individual premiums, some state assistance, and assessments on the insurance industry.<sup>25</sup>
- A CoverTN category, Tennesseans Between Jobs, is open to those who have worked at least one 20-hour week in the last six months and earned an annual

income of \$43,000 or less, or who have had their work hours reduced to below 20 hours. The state will pay one-third of eligible workers' insurance premiums.

- CoverRx is designed to help those who have no pharmacy coverage, but have a critical need for medication. It pays for up to five prescriptions per month. Insulin and diabetic supplies are excluded from the prescription limit.<sup>26</sup> Because CoverRx is not insurance, there are no monthly premiums and no cost to join. Members are responsible for affordable, income-based co-pays when they fill prescriptions. Participants will pay a discounted price for any drugs that are not covered. Please see Appendix E for income requirements and the co-pay sliding scale based on income or go to [http://www.covertn.gov/web/faq\\_rx.pdf](http://www.covertn.gov/web/faq_rx.pdf).

### **Simplifying the Eligibility and Application Process for Assistance Programs**

In September of 2009, Governor Bredesen unveiled FindHelpTN, a Web-based eligibility screening tool designed to connect Tennesseans with social service programs and resources. FindHelpTN is a centralized source of information for state and federal assistance programs that includes eligibility screening, application instructions and localized location information for the administering agency.

Created to help community-based service providers connect those in need to the appropriate state programs and services, FindHelpTN takes users through a 10-step questionnaire that covers eligibility criteria ranging from household income and employment status to insured and disability status. In most cases, the survey takes less than 15 minutes to complete.

When the user completes the process, FindHelpTN generates a printable report that lists programs for which each member of the household may be eligible along with detailed information about how to apply and where to learn more. FindHelpTN cannot enroll individuals in any program. However, the site does link users to websites where they may apply, lists information needed for any application, and provides directions to offices that may assist users.

FindHelpTN provides eligibility information on the following programs:

- Families First/Temporary Assistance for Needy Families
- TennCare
- QMB (Qualified Medicare Beneficiary)
- QI (Qualified Individual) and SLMB (Special Low Income Medicare Beneficiary)
- Food Stamps
- CoverKids
- CoverTN
- CoverRx
- AccessTN
- SSI (Supplemental Security Income)

- Free/Reduced School Lunch
- LIHEAP (Low Income Home Energy Assistance)
- WIC (Women, Infants and Children) supplemental food program

FindHelpTN can be accessed directly at [www.tn.gov/FindHelpTN](http://www.tn.gov/FindHelpTN) or through the [TN.gov](http://TN.gov) main page.

**Improving Access to Health Care through More Access to and Utilization of Cost-Effective Home and Community-Based Alternatives to Institutional Care for Medicaid-Eligible Individuals through the Long-Term Care Community Choices Act of 2008** (<http://tennessee.gov/tenncare/forms/pc1190.pdf>)

The Tennessee Long-Term Care Community Choices Act of 2008 calls for an expansion of home and community based services through a program re-design that will make access to these basic in-home services faster and easier for people who qualify. The state Bureau of TennCare has special permission from the federal government that allows Medicaid members who qualify for nursing home care to get help at home as long as the cost is the same or less than a non-skilled nursing home. More than 4,300 TennCare members have received care through the Home and Community Based Services (HCBS) program during the current program year. Elderly and physically disabled Tennesseans who believe they might qualify can call the HCBS hotline toll free at 1-866-836-6678.

**Improving the Health Care Quality and Delivery of Tennesseans through e-Health Initiatives**

The Tennessee Office of e-Health Initiatives under the Department of Finance and Administration serves as the single coordinating authority for the exchange of electronic health information in Tennessee. It works to improve the health of Tennesseans by ensuring providers have complete patient information at the point of care, enabling providers to create a more comprehensive treatment plan for patients. The Office of e-Health Initiatives spearheads the Tennessee e-Health Network, the state's mechanism for statewide health information exchange, administers the Physician Connectivity Grant program, and initiates various projects to advance e-Health and health information technology in Tennessee.

It is recognized that providers are ultimately responsible for the security and confidentiality of their patients' protected health information. Thus, the Office of e-Health Initiatives is currently finalizing policies and creating stringent technical requirements to make sure patient privacy is protected by:

- Giving patients the right to “opt-out” or choose for their information not to be shared under any circumstance;
- Allowing patient information to be shared ONLY for treatment purposes; and

- Putting technical infrastructure in place to share patient information that is secure, follows state and federal law, keeps logs of activities and audits of any transactions it handles, and follows the same opt-out guidelines.

As a result, Tennessee has established some of the most promising pilot projects in the nation for the development of portable electronic medical records. By leveraging state and federal funds, Tennessee is accomplishing leading edge changes in the health information technology sector. Key projects underway include: the Tennessee e-Health Network, the state's Physician Connectivity Grant program (providing up to \$3,500 per physician and \$2,500 per clinician, to help health care providers offset the costs of purchasing hardware, software and peripherals associated with connecting to e-health resources), and the state's e-Prescribing program. Please go to the section on "Technology and Access" beginning on page 34 for further details on the state's Office of e-Health Initiatives programs and projects.



# Chapter 2: Purpose of this First Edition and Opportunities for Public Input

*In this chapter we present the steps to be taken by the Division of Health Planning to develop subsequent editions of the State Health Plan.*

The first edition of the State Health Plan: The intent of the first edition of the State Health Plan is to provide a foundation for a comprehensive health planning process.

Opportunities for Public Input: The Division of Health Planning will hold public and focus group meetings across the state to gather input that will be incorporated into future editions of the State Health Plan. Stakeholders will be involved in setting the goals and objectives for the State Health Plan and the revision of standards and criteria for the Certificate of Need program.

## **————— The First Edition of the State Health Plan —————**

This first edition of the State Health Plan is designed to provide a focused approach to improving the health of Tennesseans and the effectiveness of our health care system; it is also designed to provide a foundation for informed public and expert input. Subsequent editions of the State Health Plan can then establish specific goals and objectives stakeholders can embrace. The Division of Health Planning welcomes input from the public on all components of this first edition of the State Health Plan.

The complexity of health challenges facing Tennessee requires an incremental process to the development of a truly comprehensive State Health Plan, which the Division of Health Planning anticipates will take several years to produce. Participation by stakeholders from all parts of Tennessee is necessary to develop priorities for consideration and to guide the overall development of the State Health Plan. The following section outlines the process that will lead to subsequent editions of the State Health Plan.

## **————— Opportunities for Public Input —————**

The creation of a state health plan is a dynamic, ongoing enterprise. The Tennessee Health Services and Planning Act requires the State Health Plan to be updated at least annually. The ongoing dialogue of the planning process will engage all stakeholders to work towards common policies, principles, and priorities that will lead to better health for Tennesseans.

Over the next year, the Division of Health Planning plans hold public and focus group meetings to receive input on the first edition of the State Health Plan. The Division of Health Planning's website, <http://www.state.tn.us/finance/HealthPlan/dhp.shtml>, will provide announcements of the date, location, and format of these meetings. At the website, members of the public may sign up to be notified when meetings are announced. This input will become the basis for the development of goals and objectives relating to the Five Principles for Achieving Better Health discussed in Chapter 3.

The State Health Plan will also gather input from the many task forces – made up of diverse interests that include the public, the government, and for-profit and nonprofit entities – that are focusing on specific issues and areas of health in Tennessee.

Each edition of the State Health Plan will also include updates to the standards and criteria for the Certificate of Need program. The process for engaging the medical community and the general public in creating revisions to the Certificate of Need category standards and criteria is discussed in detail in Chapter 5. This public process also allows the Division of Health Planning to consult with experts representing the diversity of geography and opinion in Tennessee to create necessary specific, technical changes to Certificate of Need standards and criteria.

## **Chapter 3: Five Principles for Achieving Better Health**

*Based on the statutory health planning policy statement contained in Tennessee Code Annotated § 68-11-1625 (b) and with the help of the State Health Plan Advisory Committee, the Division of Health Planning has developed an initial framework for the State Health Plan organized around Five Principles for Achieving Better Health. In this chapter we provide background information and observations related to the Five Principles for Achieving Better Health underlying the State Health Plan:*

1. The purpose of the State Health Plan is to improve the health of Tennesseans.
2. Every citizen should have reasonable access to health care.
3. 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.
4. Every citizen should have confidence that the quality of health care is continually monitored and standards are adhered to by health care providers.
5. The state should support the development, recruitment, and retention of a sufficient and quality health care workforce.

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## Healthy Lives

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*Principle for Achieving Better Health Number 1: The purpose of the State Health Plan is to improve the health of Tennesseans.*

### **Overview**

Every person's health is the result of the interaction of individual behaviors, society, the environment, economic factors, and one's genetic endowment. Health determinants discussed in this section are nutrition and exercise; management of chronic health conditions, mental health and substance abuse, preventive health care, and maternal and prenatal care. The description of our current health outcomes is intended to support an informed public discussion of how we as Tennesseans should work together to achieve our common goal of improving our health. Future editions of the State Health Plan may include more subject areas as a result of public input.

### **Observations**

#### **Life Expectancy**

One source of information about Tennesseans' health is life expectancy. According to this measure, Tennesseans are not doing as well as we could be. In 2004, the most recent year available, Tennesseans' average life expectancy was 75.2 years. Tennessee has added 0.8 years of life average expectancy since 1991, but during this time period other states have improved more, so that currently Tennessee has the fifth shortest average life expectancy of all U.S. states. For comparison purposes, the highest ranking states, Minnesota and Hawaii, have life expectancies of 80.3 and 81.3 years, respectively.<sup>27</sup> Among Tennessee's neighbors, North Carolina has the highest life expectancy at 76.5 years and Mississippi has the lowest (in fact, the lowest in the nation) at 74.2 years.<sup>28</sup>

Exhibit 1 lists the top ten causes of death that reduce Tennesseans' life expectancies. Please note, however, that recent research conducted by The Commercial Appeal and Scripps Howard News service, using data provided by the Centers for Disease Control and Prevention and reported in July, 2009, questions the accuracy of reported causes of death due to low autopsy rates, causing, for example, some counties in Tennessee to report fatal coronary diseases at twice the rate of other Tennessee counties<sup>29</sup>.

## Exhibit 1. Leading Causes of death in Tennessee, 2006

Cause of Death (data from 2006)	Years of Reduced Life Expectancy*	Number of Deaths
ALL CAUSES	556,454	28,090
1 Cancer (malignant neoplasms)	113,319	7,926
2 Heart diseases	96,050	6,169
3 Accidents and adverse effects	92,311	2,625
4 Certain perinatal conditions <sup>30</sup>	27,667	372
5 Suicide	25,453	807
6 Assault (homicide)	19,102	466
7 Chronic lower respiratory diseases	15,922	1,376
8 Stroke (cerebrovascular disease)	15,652	1,089
9 Diabetes (diabetes mellitus)	14,443	926
10 Birth defects (congenital anomalies)	13,412	233

\* Years of reduced life expectancy is the total years of life lost by Tennesseans who did not live to the average life expectancy of 75 years.

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

We also know that Tennessee ranks 47<sup>th</sup> in the nation in the rate of deaths before age 75 from causes considered at least partially treatable or preventable with timely and appropriate medical care. Out of every 100,000 Tennesseans, 118 will die before age 75 from one of these conditions, 28 more deaths per 100,000 people than the average state.<sup>31</sup>

### Nutrition and Exercise

Good nutrition and exercise are vital to healthy growth and development of children, disease prevention, and good health of adults. As a whole, we Tennesseans need to improve our nutrition and exercise habits. Last year, 31.5 percent of Tennesseans reported that they had no physical activity in the last 30 days, compared to a national average of 22.6 percent. Only Mississippians had higher levels of inactivity.<sup>32</sup> Lack of exercise combined with poor nutrition contributes to Tennessee's high levels of obesity and diabetes. Tennessee ranks 47<sup>th</sup> in the nation in obesity, with 30.7 percent of adults being obese compared to a 25.1 percent average for the nation.<sup>33</sup>

### Chronic Health Conditions

Chronic health conditions are defined as health conditions that last a year or longer and limit what one can do and/or that require ongoing medical care.<sup>34</sup> Chronic diseases include many forms of cancer, diabetes, stroke, heart disease, and disabilities, among others. Mental health problems are often chronic conditions and are discussed in the following section.

Tennessee has high levels of chronic disease. Six of the top ten causes of reduced life expectancy in Tennessee are chronic health conditions. Only four states have higher rates of cancer deaths than Tennessee.<sup>35</sup> Among Tennessee adults, 10.6 percent have type 2 diabetes – worse than all but one other state.<sup>36</sup> Tennessee is 47<sup>th</sup> in the nation in cardiovascular disease prevalence.<sup>37</sup>

Many chronic health conditions are preventable. Nutrition and exercise can help prevent diabetes. Nutrition, exercise, and avoiding tobacco use can prevent heart disease and stroke.<sup>38</sup> Lung cancer and many other cancers can be caused by tobacco use (in fact, 30 percent of cancer deaths are attributable to tobacco use).<sup>39</sup>

Early detection allows for early treatment of many chronic health conditions. Breast cancer and cervical cancer are examples of cancers that can be treated more effectively if they are found early through routine screenings. Detection of diabetes is important for behavior change and treatment to slow the progression of the condition. Detection of hypertension is important for behavior change and treatment that may prevent heart disease and stroke.

A chronic health care model exists that is based on evidence from research and practice, developed by a national program of The Robert Wood Johnson Foundation called “Improving Chronic Illness Care” (ICIC). ICIC works to better the health of chronically ill patients by helping health systems, especially those that serve low-income populations, improve their care through implementation of its chronic health care model. This model has been implemented successfully by many providers and has been used as guidance by state and community health programs.<sup>40</sup> The model combines the elements of the community, the health system, self-management support, delivery system design, decision support, and clinical information systems. While this model is resource-intensive, Tennessee providers may want to consider adopting it.

### **Tobacco Cessation**

Tobacco use is the single most preventable cause of death and disease in the United States.<sup>41</sup> Tobacco use is a major risk factor for cancer, heart disease, emphysema, and generally diminished health.<sup>42</sup> Tennessee has made some progress in reducing the use of tobacco, but the rate of Tennesseans who use tobacco is still high. In the past decade, Tennesseans’ smoking rate has fallen from 26.9 percent to 24.3 percent.<sup>43</sup> Tennessee took major steps in recent years toward reducing tobacco use through the Tennessee Non-Smoker Protection Act, the Tobacco QuitLine, and an increase in the tobacco tax (for descriptions of these programs, see page 11). However, in the rate of adult smokers, Tennessee still exceeds all but five states.<sup>44</sup>

Each year, Tennessee conducts random unannounced inspections of retail stores that sell tobacco. In 2007, the most recent year available, 16 percent of Tennessee stores sold tobacco to a child under age 18. Only four states had a higher rate of selling tobacco to minors. However Tennessee has made tremendous progress in this area. A decade ago, 63 percent of stores in the survey sold tobacco to minors.<sup>45</sup>

The Tennessee Tobacco Use Prevention and Control Program of the TDOH has a strategic plan to reduce tobacco use based on recommendations contained in the Centers for Disease Control and Prevention (CDC) report “Best Practices for Comprehensive Tobacco Control Programs-2007.”

## **Mental Health**

Mental health is an integral part of our overall health. The more we learn about mental health, the more we realize that mental health issues are inseparable from all other health issues. For example, studies show that depression in people who have had a heart attack triples the risk of death from a subsequent heart attack or other heart condition.<sup>46</sup> Unfortunately, the prevalence of mental health problems and illnesses is often underestimated. Furthermore, despite improvements in our understanding of mental health problems and illnesses, people with mental health problems and illnesses often do not get treatment, and mental health issues continue to be stigmatized.

The Surgeon General has defined mental health as “the successful performance of mental function, resulting in productive activities, fulfilling relationships with other people, and the ability to adapt to change and to cope with adversity; from early childhood until late life, mental health is the springboard of thinking and communication skills, learning, emotional growth, resilience, and self-esteem.”<sup>47</sup> Mental illness is “the term that refers collectively to all mental disorders. Mental disorders are health conditions that are characterized by alterations in thinking, mood, or behavior (or some combination thereof) associated with distress and/or impaired functioning.”<sup>48</sup>

Mental health problems are more prevalent in Tennessee than the national average. 14 percent of Tennesseans reported at least one episode of what is clinically defined as serious psychological distress in the past year, compared with 11 percent nationally. Among Tennessee adults, 10 percent reported a two week or longer major depressive episode in the past year, compared with an average of 7 percent of adults in the U.S. Tennessee teens ages 12-18 reported a rate of major depressive episode of 8 percent, the same as the national average.<sup>49</sup> In Exhibit 1 on page 23, we can see that suicide is a major cause of lost years of life in Tennessee, reflecting the young ages of many people who commit suicide. Suicide is the third leading cause of death among teenagers ages 13-19 in Tennessee, after accidents (including automobile accidents), and homicide.<sup>50</sup> Recent evidence indicates that people with serious mental illnesses die on average 25 years earlier than the general population because of risk factors such as smoking, obesity, substance abuse, psychotropic medication side effects, and inadequate access to medical care.

Mental health problems often go untreated. Fewer than half of Americans who experienced psychological distress receive mental health services. Teens and young adults are less likely to receive services.<sup>51</sup> A major reason that mental health issues are undertreated is that stigma continues to be attached to mental health issues. Fear, hopelessness, and lack of understanding make it difficult for people to take care of themselves and others dealing with mental illness, depression, and substance abuse. Many health insurers have limited benefits for mental health and substance abuse services. In October 2008, Congress addressed mental health insurance parity and required large group insurers to have the same copays, out-of-network benefits, and medical necessity criteria for mental health and substance abuse coverage as for medical/surgical benefits. Annual and lifetime dollar limits for mental health and medical/surgical coverage are already required to be set at the same level by a previous

law. However, these laws do not apply to health insurance plans for small businesses and individuals or health insurance plans that do not offer mental health coverage at all.<sup>52</sup>

Substance abuse is closely tied to mental health problems. In 2005 and 2006, 8.9 percent of Tennesseans reported illicit drug use in the previous month, compared with an 8.2 percent national average. The rate of Tennesseans who used marijuana in the past month was close to the national rate at 6.1 percent. However, Tennesseans used other illicit drugs at a higher rate than the national average. Use of illicit drugs other than marijuana in the previous month was 4.7 percent in Tennessee, compared to a rate of 3.6 percent for the nation.<sup>53</sup> Also, 20.5 percent of Tennessean teens and adults reported at least one episode of binge drinking in the previous month (defined as 5 or more drinks on the same occasion). This number is lower than the national average of 22.8 percent. In Tennessee, like most states, prevalence of binge drinking is especially high among young adults. Among Tennesseans age 18-25, 39.9 percent reported binge alcohol use in the past month.

### **Prenatal Care and Infant Mortality**

Infant mortality is a serious problem in Tennessee. In 2006, Tennessee's infant mortality rate of 8.7 out of 1,000 live births exceeded the provisional national rate of 6.6 by 31.8 percent. Only two states have higher infant mortality rates. There is also a significant racial disparity in infant mortality in Tennessee. The rate among African-Americans (16.7 per 1,000 live births) is 2.5 times the rate for whites (6.6 per 1,000 live births). Infant mortality rates are also higher in certain areas of the state. Tennessee's infant mortality by region is shown in Exhibit 2, below.

#### **Exhibit 2. Tennessee Infant Mortality Rate by Region 1997-2006, Aggregate**

Shelby	13.1
Madison	11.5
Southwest	10.9
Northwest	9.9
Hamilton	9.4
Sullivan	8.9
Davidson	8.7
Northeast	8.3
South Central	7.8
Upper-Cumberland	7.0
Southeast	6.9
East	6.5
Mid-Cumberland	6.2
Knox	6.0

*Source: Office of Policy, Planning and Assessment (2009). Infant Mortality in Tennessee, 1997-2006. Tennessee Department of Health, Nashville, TN.*

Major risk factors for infant mortality include low birth weight; preterm birth; lack of prenatal care; maternal smoking, alcohol, and drug abuse. In Tennessee between 2001 and 2005, low birth weight babies (less than five pounds eight ounces) were 20 times as likely to die in the first year as normal birth weight infants, and premature babies were 15



times more likely to die as normal gestation babies.<sup>54</sup> Infants who survive prematurity after being in a hospital's neonatal intensive care unit are at higher risk for cerebral palsy, blindness, and chronic conditions.<sup>55</sup> Children born prematurely have both physical and mental challenges depending on weeks premature.<sup>56</sup> Some studies have found that babies born with low birth weight are at higher risk for the adult health problems of high blood pressure, type 2 diabetes, and heart disease.<sup>57,58</sup>

In Tennessee from 2001 and 2005, the mortality rate for infants whose mothers received no prenatal care was almost six times higher than infants whose mothers received adequate care. Also, infants born to mothers who smoked during pregnancy were 74 percent more likely to die in the first year than those born to non-smoking mothers.<sup>59</sup> In Tennessee in 2006, 15.6 percent of white mothers and 7.4 percent of black mothers reported smoking during pregnancy.<sup>60</sup>

### **Preventive Care**

Immunizations and well-child checkups are important elements of preventive health care. Childhood immunizations are a safe and cost-effective method of preventing disease in a population.<sup>61</sup> Tennessee performs well in this area, ranking 22<sup>nd</sup> in the nation in early childhood immunization coverage, with 80.5 percent of children ages 19 to 35 months receiving age appropriate immunization.<sup>62</sup> Local TDOH offices in all 95 counties in Tennessee provide well child screenings for infants age zero to one, which include immunizations.

The Nurses for Newborns project is funded by TDMHDD, Division of Alcohol and Drug Abuse Services to provide funding for registered nurses to make home visits to provide health-care assessments, education and positive parenting skills in effort to prevent infant mortality and child abuse/neglect. Services are provided to new and pregnant mothers and continue through the child's second birthday in six Tennessee counties and are focused on mothers with mental health, substance abuse, and developmental disabilities disorders.

Tennessee does slightly better than the national average on recommended screenings and preventative care for older adults, although the national average is quite low. Tennessee ranks 24<sup>th</sup>, with 40 percent of adults over 50 receiving recommended screenings and preventative care.<sup>63</sup>

For people who already have chronic diseases such as heart disease or diabetes, comprehensive and evidence-based treatment can prevent serious problems in future years. Unfortunately, the federal agency with the mission of improving the nation's health care system (the Agency for Healthcare Research and Quality), terms Tennessee's diabetes care "very weak." While Tennessee has improved the rate of patients with diabetes who get regular screenings of their HgA1C level to above that of the national average,<sup>64</sup> the rate of foot and eye tests is below average,<sup>65</sup> and avoidable hospitalizations for diabetes are worse than the national average as well.<sup>66</sup>

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## Access to Health Care

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*Principle for Achieving Better Health Number 2: Every citizen should have reasonable access to health care*

### **Overview**

The State Health Plan Advisory Committee took particular interest in the policy area of ensuring that all Tennesseans have “reasonable access” to health care. While the statutory policy statement refers only to emergency and primary care,<sup>67</sup> this broader focus in the State Health Plan raises the concerns of all facets of “access” that are important for improving health care – not just access to a specific type of provider. Some of these facets discussed by the Advisory Committee, and which will provide a basis for public discussion for an updated State Health Plan, include:

- Economic access – how the financial/insured status of the individual impacts access to health care
- Disparities/inequalities in access to health care
- Access to emergency and primary care
- Geographic access – the distance one has to travel to receive comprehensive care; also, a regional analysis of health care “watersheds” – the clusters of comprehensive health care services that draw patients in from outlying areas
- How to obtain and analyze data for the purpose of learning how access impacts known health care needs
- The impact of access to transportation on access to health care
- The role of technology, such as telemedicine, in meeting health care access needs

Defining “reasonable access” is a primary determinant in meeting this Principle Number 2 and can be expected to change depending on the type of access under consideration.<sup>68</sup> As a result, public input on the definition of “reasonable access” will be critical in the development of the State Health Plan. The Division of Health Planning is currently gathering data and reports concerning the facets of access listed above, though it is likely that the current availability of data is not sufficient to provide a comprehensive analysis.

### **Observations**

#### **Access and Health Insurance**

Approximately half of Tennesseans are enrolled in health insurance through their employers, and another one in twenty purchases health insurance individually.<sup>69</sup> According to a 2009 survey by the University of Tennessee Center for Business and Economic Research, ten percent of Tennesseans are uninsured.<sup>70</sup> The remaining group has some form of public health insurance. The major public programs are:

Medicare – a federal social insurance program for seniors and certain disabled individuals; it provides a Medicare part A which covers hospital bills, Medicare

Part B which covers medical insurance coverage, and Medicare Part D which covers prescription drugs.

TennCare (Medicaid) – a program funded jointly by the federal government and states but administered at the state level that covers certain very low income children and their families (see TennCare discussion on page 30); and

Children’s Health Insurance Program (CHIP) – also a federal-state partnership that serves certain children and families who do not qualify for Medicaid but who cannot afford private coverage (see discussion on page 30).

Other public programs include military health benefits provided through TRICARE and the Veterans Health Administration and benefits provided through the Indian Health Service.

Individuals without adequate health insurance – meaning both the uninsured and the underinsured – have difficulty accessing the health care system, frequently do not participate in preventive care programs, and add to the cost of health care due to delayed care and emergency department treatment. The testimony of The Commonwealth Fund Senior Vice President Cathy Schoen before the United States Senate Health, Education, Labor and Pensions Committee in February, 2009 supports this assertion. In her testimony, Ms. Schoen stated: “Compared with adults with more adequate coverage, underinsured and uninsured adults were far more likely to go without needed care because of costs—over half of the underinsured and two-thirds of the uninsured went without recommended treatment, follow-up care, or medications, or did not see a doctor when sick. Half of both groups faced financial stress, including medical debt. Indeed, experiences among the underinsured and the uninsured were often similar.”<sup>71</sup>

Further, a 2004 report from The Commonwealth Fund found that small businesses that provide health insurance for their employees consistently suffer faster premium increases and steeper jumps in deductibles over time than large firms. Employees in small firms also pay more of their premium costs and have higher deductibles. They also pay more for family coverage—but less for single coverage—than employees in large firms.<sup>72</sup>

### **Disparities/Inequality and Access**

Vulnerable populations of Tennesseans as defined by race/ethnicity, socio-economic status, geography, age, disability status, and sex are especially at risk for certain health problems and lower health status. The TDOH Division of Minority Health & Disparity Elimination is in the process of creating a Tennessee Strategic Plan to Eliminate Health Disparities. See Appendix D for more information on this plan.

### **The Health Safety Net**

Several components of the state’s health care system can be considered part of the health “safety net,” a group of providers, services, and programs that ensure a minimum level of access to low-income citizens. While many providers will waive charges for uninsured and low-income patients, the primary components of the safety net include TennCare, CoverKids, emergency care at hospital emergency departments, health care at faith-

based, community-based, rural health, and federally funded centers, and the TDOH local health department clinics. Please see page 14 for a discussion of the Behavioral Health Safety Net. Note, also, that what basic level of health care services all people in Tennessee should have access to – sometimes referred to as “essential services” – is a topic that deserves extensive discussion. For example, hospitals tend to define “essential services” more broadly, including high level specialty services such as neonatal intensive care unit Levels 3 and 4 and Level 4 trauma centers.

### TennCare

The TennCare program is the state of Tennessee’s Medicaid program. The Bureau of TennCare within the Tennessee Department of Finance and Administration is the state agency charged with the responsibility for administering the TennCare program.<sup>73</sup>

TennCare covers a wider range of health care services than does Medicare, providing health insurance coverage to certain categories of low-income individuals, including infants age 0-1 with a household income below 185 percent of Federal Poverty Level (FPL), children age 1-5 with household income below 133 percent of FPL, children age with household income below 100 percent of FPL, pregnant women with household below 185 percent of the FPL, parents of eligible children with household income below 73 percent of FPL if the parent is jobless and 134 percent of FPL if the parent has a job, and low income people with disabilities.<sup>74</sup> However, having a low or no income does not in itself make a person eligible for TennCare.<sup>75</sup>

TennCare services are offered through managed care entities. Medical and behavioral services are covered by “at risk” managed care organizations (MCOs) in each region of the state. Enrollees have their choice of MCOs serving the areas in which they live, except that some enrollees are assigned to TennCare Select. TennCare Select is a managed care plan for certain populations, such as children in state custody and enrollees who may be living temporarily out-of-state. In addition to the MCOs, there is a Pharmacy Benefits Manager for coverage of prescription drugs and a Dental Benefits Manager for provision of dental services to children under age 21. Coordination of care is the responsibility of the enrollee’s primary care provider in his or her MCO.

Long-term care services are provided in Nursing Facilities (NFs) and Intermediate Care Facilities for persons with Mental Retardation (ICFs/MR), as well as under Home and Community Based Services waivers for persons who would otherwise require care in a NF or ICF/MR. These services have historically been “carved out” of TennCare and paid for by the state through a fee-for-service arrangement. The state is bringing long-term care services for persons who are elderly and disabled into the managed care program, in the summer of 2009.

### CoverKids (CHIP)

The United States Department of Health and Human Services Centers for Medicare and Medicaid Services administers the Children’s Health Insurance Program (CHIP), which provides federal matching funds to help states expand health care coverage to their

uninsured children. CHIP is jointly financed by the Federal and State governments and is administered by the States. Within broad Federal guidelines, each State determines the design of its program, eligibility groups, benefit packages, payment levels for coverage, and administrative and operating procedures. CoverKids is Tennessee's CHIP program for families with incomes below 250 percent of the FPL but above thresholds for TennCare coverage. The program provides coverage for children 18 and under and maternity coverage for pregnant women. It features no monthly premiums, but each participant pays reduced co-payments for services. The coverage includes an emphasis on preventive health services and coverage for physician services, hospitals, vaccinations, well-child visits, healthy babies program, developmental screenings, mental health, vision care, and dental services. The Division of Benefits Administration within the Tennessee Department of Finance and Administration administers this program.

### Emergency Care Access

Access to emergency care is directly impacted by the *Emergency Medical Treatment and Active Labor Act* (EMTALA), enacted in 1986 by Congress to ensure that all members of the public have access to emergency treatment, regardless of ability to pay.<sup>76</sup> EMTALA imposes specific health care provision obligations on Medicare-participating hospitals that offer emergency services.<sup>77</sup> Hospitals must screen patients who enter the emergency department, and then must provide stabilizing treatment for patients with emergency medical conditions. If a hospital is unable to stabilize a patient within its capability, or if the patient requests, an appropriate transfer to another facility should be performed.<sup>78</sup> Emergency care is the only kind of care that hospitals are required to provide to an individual regardless of ability to pay. Preventative care and care for chronic diseases, for example, are not covered by EMTALA.

According to the 2007 Joint Annual Report of Hospitals, Tennessee has 126 hospitals providing emergency services.<sup>79</sup>

### Community Health Centers

Community health centers are community-based and patient-directed organizations that serve populations with limited access to health care. These populations include low income individuals, the uninsured, those with limited English proficiency, migrant and seasonal farm workers, individuals and families experiencing homelessness, and those living in public housing.<sup>80</sup> In 2007, nearly 40 percent of patients at health centers that receive grant funds under the federal Health Center Consolidation Act (Section 330 of the Public Health Service Act), known as "federally qualified health centers" (FQHCs), were uninsured; approximately 36 percent of patients were children. Also in 2007, 27 percent of FQHC patients were African-American and 34 percent were Hispanic/Latino — more than twice the proportion of African-Americans and over two times the proportion of Hispanics/Latinos reported in the overall U.S. population. FQHCs provide comprehensive primary care and preventive care, including health, oral, and mental health/substance abuse services to persons of all ages, regardless of their ability to pay.<sup>81</sup>

## TDOH Local Clinics

The TDOH partners with each county to staff a local health department. The TDOH directly administers 89 local health departments and contracts with six “metro” counties to provide a variety of public health services, including nutritional services, prenatal care, emergency preparedness, and communicable disease prevention. Several local health department clinics also provide comprehensive primary and dental care. Such services are typically provided in areas of the state where private providers cannot meet the needs of the low-income and uninsured population.

## **Geographic Access**

Access to health care can also be characterized by the proximity of services to where people live. Several programs and providers seek to ensure that rural populations have access to essential health care services, including the Critical Access Hospitals (CAHs), trauma centers, and emergency dental care. Please see Appendix H for State of Tennessee maps showing counties with FQHCs, CAHs, and rural health clinics.

## Critical Access Hospitals (CAH)

The federal Medicare Rural Hospital Flexibility Program (MRHFP) supports the conversion and designation of small rural hospitals to Critical Access Hospital status. CAH status allows a community to maintain access to primary care and emergency care when the maintenance of a full service acute care hospital is no longer feasible. To convert to CAH status, an acute care hospital must obtain written designation from the Tennessee Commissioner of Health that it is eligible to become a CAH and also obtain approval from the Health Services and Development Agency through its Certificate of Need program (or exemption therefrom) set forth in Tennessee Code Annotated § 68-11-1607 (j).<sup>82</sup> According to the TDOH Division of Health Care Facilities, as of June 30, 2009, Tennessee had 17 CAHs.<sup>83</sup> A Tennessee CAH must receive approval from the Health Services and Development Agency through its Certificate of Need program to close the hospital or eliminate any service in the hospital which required a certificate of need.<sup>84</sup>

## Trauma Centers

Tennessee’s trauma center system was created in 1988 to provide comprehensive emergency medical services to patients suffering traumatic injuries, beyond what an emergency department can provide. Trauma centers require a host of resources beyond those provided by emergency departments, including specialized physicians and nurses, state-of-the-art equipment and space, available 24 hours a day, seven days a week.<sup>85</sup> Tennessee currently has six Level I trauma centers (the most advanced level), one Level II center, and three Level III trauma centers<sup>86</sup> (two Level II centers and one Level III center have closed since 2002). Currently, there is a trauma center within 100 air miles of every Tennessee community.<sup>87</sup>

## Emergency Dental Care

The U.S. Surgeon General in 2000 stated in the first-ever report on oral health in the United States that oral health is “essential to overall general health.” However, despite marked improvements since 1950, there remains a “silent epidemic of oral disease affecting our most vulnerable citizens.”<sup>88</sup> Tennessee’s Medicaid program, TennCare, covers comprehensive dental services for children as is medically necessary.<sup>89</sup> Regarding the adult population, however, Tennessee in general experiences a very poor state of oral health (e.g., Tennessee ranks 48<sup>th</sup> in the nation in the percentage of adults 65 years and older who have had all permanent teeth extracted – 34.9 percent).<sup>90</sup> Tennessee, like many other states, has data from statewide dental surveys of school aged children but at this time does not have its own statewide dental data on adult populations.

As reported by the TDOH in its “Adult Emergency Oral Health Care 2008 Report to the Legislature,” submitted January 15, 2009, “Tennessee’s Medicaid and Medicare programs do not provide adult dental services, and many persons with private health insurance do not have dental coverage. National estimates suggest that for every person without health insurance, 2.3 persons do not have dental insurance coverage. Behavioral Risk Factor Surveillance System (BRFSS) data (2006) published by the CDC estimated that 606,686 Tennessee adults lacked health insurance, translating into an estimated 1,395,378 Tennesseans without dental insurance coverage. There are some dental resources available to Tennesseans. TDOH has 54 dental clinics located in 53 rural counties, and 3 mobile dental clinics providing care to children in school settings. Rural dental clinics are staffed by 30.9 FTE dentists who provide comprehensive care to children and emergency care to adults. Five metro health departments have 8 dental clinics; 13 Federally, Qualified Health Centers (FQHCs) sites, and 7 Safety Net sites also offer adult dental services. In FY 2007-2008, TDOH allocated additional Health Access and Safety Net dollars to address adult emergency oral health needs; however, dental services are not a required function of public health, and there is no consistent source of state funding specifically for adult emergency oral health.”<sup>91</sup>

### **Cost as Access**

The problems of cost and access to health care are inextricably linked. According to the Center for Studying Health System Change’s 2007 Health Tracking Household Survey, for the 59 million United States citizens reporting not getting or delaying treatment in 2007, cost was the most frequently cited and growing obstacle to care. The proportion of Americans reporting going without or delaying needed medical care increased sharply between 2003 and 2007, from 14 percent in 2003 to 20 percent in 2007. Insured and uninsured people reported increasing access problems, but insureds reported a larger relative increase in access problems compared with uninsured people. The fact that, over the past ten years, the amounts charged to and paid by consumers for health care services have increased more rapidly than have personal incomes has resulted in increases in cost-related access problems. These rising costs are passed on to individuals and families in the form of higher premiums, deductibles, coinsurance, and copayments.<sup>92</sup>

The current economic recession is only likely to exacerbate this problem. There is at this time insufficient Tennessee data available on this issue.

### **Workforce and Access**

Issues regarding the number and location of Tennessee's health care workforce are discussed in *Principle for Achieving Better Health Number 5* beginning on page 44 of this Chapter. Issues surrounding provider insurance reimbursement impact access to health care as well.

### **Technology and Access**

In April, 2006, Governor Bredesen established the Office of e-Health Initiatives to coordinate e-Health initiatives across the state. Tennessee now has established some of the most promising pilot projects in the nation for the development of a portable electronic medical record, for connecting physicians to pharmacists through e-Prescribing, and for telemedicine connections to rural hospitals. By leveraging state and federal funds, Tennessee is accomplishing leading edge changes in the health information technology sector.

The Office of e-Health Initiatives implements e-health initiatives in Tennessee to ensure interoperability, facilitate the definition of uniform standards, eliminate duplication of effort, and reduce competition for resources. Its primary programs include:

The Tennessee e-Health Network. Tennessee opened its statewide broadband network – the network the state uses to conduct its business – for the benefit of health care providers and created the Tennessee e-Health Network as a physical home for the sharing of health information for treatment purposes only. The Tennessee e-Health Network is a private “backbone” that exists in all of the state's 95 counties; information travelling the network is not transmitted across the World Wide Web. The Tennessee e-Health Network offers secure, high-speed broadband capabilities to practitioners at state-negotiated rates. The e-Health Network is tailored to the particular security concerns related to health information transfer and uses layers of security features to ensure that health care providers only are using the information for the purposes of treatment. By design, the e-Health Network is only to be used to offer key information to medical professionals in the process of making clinical decisions. Authorized e-Health Network users can exchange files and messages securely and access registries from the TDOH for domestic violence, immunizations, and controlled substance database. In the near future, the Office of e-Health Initiatives expects to add a master patient index (MPI) and record locator services (RLS) to the e-Health Network's application features.

Physician Connectivity Grant Program. The Office of e-Health Initiatives also administers the state's Physician Connectivity Grant program, providing up to \$3,500 per physician and \$2,500 per clinician, to help health care providers offset the costs of purchasing hardware, software, and peripherals associated with connecting to e-health resources. To receive the grants, health care providers



must agree to electronically prescribe (“e-prescribe”) for at least two years. The Office of e-Health Initiatives has approved a total of 1,961 health care providers and more than 420 treatment sites in Tennessee as grant recipients. Additionally, the Office of e-Health Initiatives provides e-prescribing training and education programs to support grant recipients and has trained more than 350 grant recipients as of April 2009.

Surescripts, the nation’s largest electronic prescribing network, recognized Tennessee’s e-prescribing effort in June 2009 with a Safe-Rx Award as a top five most improved e-prescribing state in 2008. According to Surescripts, Tennessee moved to #18, up from #27 in 2007, in the company’s state-by-state ranking of e-prescribing activity. In 2008, Tennessee health care providers issued more than 2 million electronic prescriptions, representing 3 percent of all prescriptions written in the state. Currently, Tennessee has 2,238 active electronic prescribers, with 1,110 pharmacies in the state accepting prescriptions electronically.

Regional Health Information Organizations (RHIOs). RHIOs are designed to share specific health information among their participants in a secure fashion. There are several RHIO projects in place and in the planning stages in Tennessee:

The Mid-South e-Health Alliance is a RHIO that shares clinical encounter data among 24 emergency departments and ambulatory clinics in the Memphis area. It has had approximately 2.1 million records from 880,000 unique patients and adds approximately 30,000 records daily.

Innovation Valley Health Information Network, located in the greater Knoxville area, is a community-based, non-profit collaborative of local consumers, physicians, hospitals, employers, payers and other healthcare providers and provides a collaborative, consumer-centric health information network that provides consumers and their permitted caregivers real-time access to consumers’ current and historic medical records.

CareSpark is a regional, community-based non-profit organization serving northeast Tennessee and southwest Virginia. CareSpark has developed a secure network that enables exchange of information for the purpose of patient care and treatment among physicians, hospitals, pharmacies, laboratories, imaging centers, public health departments and other facilities serving approximately 750,000 patients in the region.

In the West Tennessee, Middle Tennessee, and the Upper Cumberland regions, projects are in start-up mode to create health information exchanges to serve these areas of the State.

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## Economic Efficiencies

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*Principle for Achieving Better Health Number 3: 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.*

### **Overview**

This section sets the stage for an initial discussion on encouraging competition, economic efficiencies, and the continued development of the state's health care system. During the next year, the Division of Health Planning plans to hold public and focus group meetings throughout the state, engage stakeholders, and solicit comments from the public in order to develop goals and priorities under *Principle for Achieving Better Health Number 3*.

### **Observations**

Health care is a major expense in our state. Tennesseans individually spend, on average, \$5,464<sup>93</sup> annually on health care, and 51 percent of the state government's budget is for health care spending.<sup>94</sup> Thus, providing economic efficiencies in health care is a primary concern for state policy makers.

The health care sector of the economy is complex and includes a wide variety of stakeholders. Tensions arise in this sector in part from the expectation that stakeholders should compete against each other and yet also cooperate with each other to provide quality health care when required by law – even if these services are unprofitable. Given the inefficiency and fragmentation in the health care delivery system in the United States,<sup>95</sup> as well as the generally acknowledged dramatic increases in health care costs, the state health planning process should explore opportunities to improve care and contain spiraling cost growth in Tennessee.

### **The Effects of Inefficiency in Tennessee's Health Care System**

#### High cost of care v. poor health outcomes.

America's health care system is the most expensive in the world<sup>96</sup> and Tennessee's per capita spending is even higher than the 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.<sup>97</sup> For example, among Tennessee adults, 10.6 percent have type 2 diabetes – a higher rate than all but one state<sup>98</sup> – and Tennessee ranks 47<sup>th</sup> in the nation in cardiovascular disease prevalence.<sup>99</sup> And out of 50 states and the District of Columbia, Tennessee claims the second highest spending per capita on prescription and over-the-counter drugs and other medical nondurables (\$983/person in 2004).<sup>100</sup> Such poor health conditions may contribute to higher prescription drug usage in Tennessee, illustrating significant inefficiency in our health care system (for more discussion on the health status

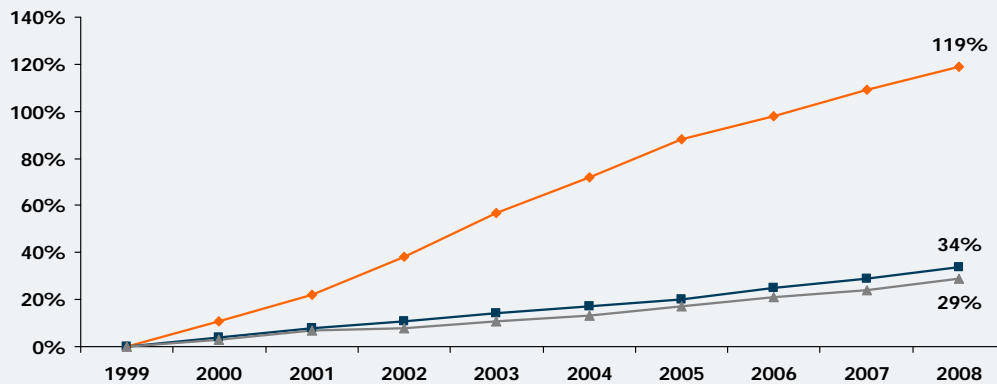
of Tennesseans, see *Principle for Achieving Better Health Number 1* beginning on page 22).

Health Insurance and Rising Health Costs.

Another driver of economic inefficiency both in Tennessee and nationwide is the gradually decreasing access to health insurance and health services for an increasing number of citizens. Health care costs in Tennessee continue to rise each year, making it more difficult for Tennesseans to afford health care (this concern is also discussed in *Principle for Achieve Better Health Number 2* on page 28). Since 1999, cumulative costs for the average family health insurance premium have risen more than three times faster than workers’ earnings and inflation (see Exhibit 4, below). In a 2008 survey conducted by the University of Tennessee Center for Business and Economic Research, 97 percent of uninsured respondents reported that the inability to pay for health insurance is the primary reason for being uninsured.<sup>101</sup> According to the Kaiser Commission on Medicaid and the Uninsured, the uninsured are significantly less likely to receive timely preventive care and are more likely to be hospitalized for avoidable reasons.<sup>102</sup> Thus, rising costs and an increasing lack of access to health insurance further contribute to economic inefficiency.<sup>103, 104</sup>

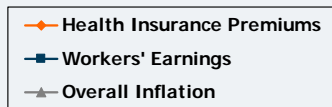
**Exhibit 4.**

**Cumulative Changes in Health Insurance Premiums, Inflation, and Workers’ Earnings, 1999-2008**



Note: Due to a change in methods, the cumulative changes in the average family premium are somewhat different from those reported in previous versions of the Kaiser/HRET Survey of Employer-Sponsored Health Benefits. See the Survey Design and Methods Section for more information, available at <http://www.kff.org/insurance/7790/index.cfm>.

Source: Kaiser/HRET Survey of Employer-Sponsored Health Benefits, 2000-2008. Bureau of Labor Statistics, Consumer Price Index, U.S. City Average of Annual Inflation (April to April), 2000-2008; Bureau of Labor Statistics, Seasonally Adjusted Data from the Current Employment Statistics Survey, 2000-2008 (April to April).



## Variations in Health Care Cost, Quality, and Outcomes.

Finally, the Dartmouth Atlas of Health Care (Dartmouth Atlas) reveals wide-ranging variations in health care cost, quality, and outcomes within U.S. states, regions, and communities.<sup>105</sup> The Dartmouth Atlas has continually found that higher spending does not necessarily lead to increased access to health care or to higher quality of care and, in fact, it reports that patient outcomes can actually suffer from a lack of coordination of care and overutilization of care.<sup>106</sup> Thus, it appears that a greater “supply” of health care (specialists, hospital beds, imaging equipment, etc.) may not always lead to better outcomes — instead, it could lead to more expensive, yet less effective care. While national studies<sup>107, 108</sup> have examined the relationship between the distribution of health care resources, cost, quality, and outcomes, the Division of Health Planning seeks to promote further study specific to Tennessee’s health care system and communities. For more discussion on the relationship between cost and quality, see the discussion on *Principle for Achieving Better Health Number 4* at page 41.

Given the above examples, opportunities may exist to streamline costs and improve care in Tennessee. For example, the Commonwealth Fund predicts that Tennessee’s economy could potentially save hundreds of millions of dollars by improving primary care services and reducing avoidable hospitalizations (see the chart “Comparison of Tennessee Health System Performance with Top-Performing Systems in Other States” (Appendix F) for more details on this potential cost-savings).

### **Competition in the Health Care System**

Several features distinguish the health care market from more traditional capitalist economic markets. The supply sensitivity of health care services, the lack of price and quality transparency, and the unique arrangement of economic incentives produce a market where competition works differently than other markets and where factors other than consumer (i.e., patient) decisions frequently drive market forces. These issues present both significant challenges and opportunities for Tennessee as the health planning process considers how to promote competitive markets in our health care system while using competition to address the health needs of Tennesseans. In the future, the Division of Health Planning hopes to utilize data from a database comprised of de-identified health insurance claims data to analyze these issues.

### The Supply Sensitivity of Health Care Services

In addition to studying variations in the quality and cost of care, the Dartmouth Atlas and many other studies have demonstrated the supply sensitivity of health care services. The Dartmouth Atlas defines supply sensitive care as “discretionary care that is provided more frequently when a population has a greater per capita supply of medical resources.”<sup>109</sup> In other words, a greater supply of many health care services will result in higher utilization of those services, even if this additional utilization is not medically necessary. In fact, several studies have shown that higher spending on health care frequently does not lead to better outcomes and higher quality of care.<sup>110, 111, 112</sup>

The Dartmouth Atlas reports that “in a payment system where provider incomes depend upon the volume of services they provide, patients in regions with more physicians and hospital beds have more frequent visits to physicians and more hospitalizations.”<sup>113</sup> Interestingly, several studies have examined the role that discretionary decisions play in creating higher regional utilization. “These studies found that physicians’ decisions in higher-spending regions were similar to those in low-spending regions in cases where there was strong evidence for a specific treatment. But physicians in high-spending regions were much more likely to intervene in cases where judgment was required (such as whether to admit a patient with heart failure to the hospital or whether to refer a patient with heartburn to a specialist). In other words, the local ‘ecology’ of health care—local capacity, local social norms and the current payment environment—profoundly influences clinical decisions.”<sup>114</sup>

### Lack of Transparency

The lack of transparency in health care makes it difficult, if not sometimes impossible, for consumers to know how much a service costs or what level of quality one provider offers in comparison to others – and if having this information would influence patient provider choice. Certainly, the quality of care health care providers provide can be difficult to measure accurately given different risk levels presented by each patient.<sup>115</sup> Moreover, interpreting quality reports often requires technical expertise, and easy-to-understand rating systems may not support meaningful comparisons among providers; a number of standardized quality of care measures have been introduced into the industry, but the role of quality information remains low in consumers’ health care decision-making.<sup>116</sup> See page 41 for a discussion of quality of care measures.

In addition, it may be difficult for patients to learn in advance the price of a health care procedure. The pay rates of providers are negotiated between health insurers and providers, meaning that different health insurers may pay different amounts to providers for performing the same procedure.<sup>117</sup> While price information is typically considered to be confidential, there may be opportunities for the health planning process in Tennessee to address the lack of price transparency in the state’s health care system, and learn to what extent, if any, it is a barrier to a more competitive market.

### Economic Incentives and Choice

The financial relationships that exist among providers, payers, and consumers may reduce overall efficiency and inhibit traditional market competition.<sup>118</sup> Under the current fee-for-service system, an economic incentive exists for providers to provide more compensated services, which could lead to overutilization of certain health care services. Additionally, contracts and prices are decided by large public and private bureaucracies (i.e., governments and insurance companies), reducing opportunities for innovation and entrepreneurship.<sup>119</sup>

Health care choices are also frequently limited for patients and purchasers of health insurance. For instance, Tennesseans who receive their health insurance through their employers may not have many options from which to choose: eighty-five percent of national firms offering health benefits offer only one health plan type.<sup>120</sup> In addition, a 2007 study by the American Medical Association found a high concentration of market share by a small number of health insurance plans in most metropolitan statistical areas, including most in Tennessee.<sup>121</sup> Consequently, employees and businesses rarely have the opportunity to choose among insurance plans to find one that works best for them.

In response to rising premiums and their fear of litigation, national research indicates that physicians may practice defensive medicine in certain clinical situations, resulting in an over-utilization of medical services; however, the overall prevalence and costs of such practices have not been reliably measured. Recent national surveys of physicians indicate that many practice defensive medicine, but limitations to these surveys suggest caution in interpreting and generalizing the results.<sup>122</sup> More data is needed in this area.

### **Improving Competition in Tennessee's Health Care System While Addressing Health Needs**

In order to improve efficiencies in health care markets, all barriers to competition should be examined. The Commonwealth Fund, for example, suggests that encouraging the implementation of electronic medical records, making accurate provider quality information widely available and encouraging its use, and restructuring provider reimbursement streams to enable innovation could all help improve the effectiveness of the state's health care system by making the ground more fertile for competition.<sup>123</sup>

While improving competition in health care is a stated policy of Tennessee law, a tension does exist between encouraging competition and ensuring the availability of some level of essential health care services. The Certificate of Need (CON) program is the state's primary tool to accomplish the orderly and economic development of health care projects to meet health care needs of Tennesseans. While it has not been used as a tool to promote competition, the state health planning process should consider how the CON program could promote competition while providing greater access to essential health care services. As stated by Tennessee law,<sup>124</sup> the three primary criteria on which a CON application is judged are need, economic feasibility, and the orderly development of the health care system. The state health planning process will consider how the CON program can further all of the principles of the State Health Plan while ensuring that community health needs are met.

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## Quality of Care

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*Principle for Achieving Better Health Number 4: Every citizen should have confidence that the quality of health care is continually monitored and standards are adhered to by health care providers.*

### **Overview**

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.<sup>125</sup>

Tennessee upholds professional standards through its system of licensing health care providers and facilities. Many different organizations and stakeholders in Tennessee are working on improving quality in health care.

### **Observations**

While Tennesseans can be assured that health care providers are held to certain professional standards by the state’s licensure system, they should also be concerned about variation in quality of care. Beginning with a 1999 Institute of Medicine study entitled “To Err is Human” (available at: <http://www.iom.edu/CMS/8089/5575.aspx>), there has been a growing, widespread recognition that much of the U.S. health care system is not meeting the quality standards the public expects and desires. Tennessee is not excluded from this concern: the federal Agency for Healthcare Research and Quality rated Tennessee’s overall health care quality as “weak” in its 2007 report.<sup>126</sup>

The State of Tennessee enforces a minimum standard of quality through the state licensure process and the health related boards. There are 26 boards, committees, councils, and one

registry that grant licenses to health care professionals. In addition, there are 21 types of facilities that require licenses. The requirements for individual licensure generally include:

- Being of good moral character and professional ethics
- Passing certain examinations or possessing a certain degree
- Having performed a certain number of hours of classroom training and supervised clinical training at specified types of institutions.
- Fulfilling continuing education requirements

There are numerous organizations dedicated to working with health care providers on a national level. In Tennessee, QSource is the statewide Quality Improvement Organization that contracts with the federal Centers for Medicare and Medicaid Services to work with providers to implement quality of care improvements. Its web site is found at: <http://www.qsource.org/about.htm>.

There has been rapid increase in the availability of quality of care measures and scorecards put out by a variety of groups.<sup>127</sup> These measures and scorecards assess quality of care based on one or more of the following domains:

- **Process measures**—whether or not the provider followed evidence-based guidelines, such as performing important blood tests on diabetic patients;
- **Outcome measures**—the number of times that a provider’s intervention is successful versus unsuccessful events (such as an injury to the patient). With outcome measures it is important to adjust the results based on the severity of a patient’s illness so that it does not bias a provider’s results;
- **Capacity measures**—whether a provider has the right equipment and facilities to perform procedures, for example a neonatal intensive care unit in a hospital;
- **Volume Measures**—Outcomes of some procedures improve when the providers regularly repeat the procedure; and
- **Patient experience measures**—the impressions patients have of the quality of care, such as whether the provider listened, and whether the provider understood the patient.

Quality of care measures are publicly available from insurance companies, employers, the federal government, and state governments.<sup>128</sup> Many health insurance plans measure their quality of care and service using the HEDIS measures developed by the National Committee for Quality Insurance ([www.ncqa.org](http://www.ncqa.org)). The Leapfrog Group is a national coalition of employers that rates hospitals on quality of care ([www.leapfroggroup.org](http://www.leapfroggroup.org)). In Tennessee, the Memphis Business Group on Health ([www.memphisbusinessgroup.org](http://www.memphisbusinessgroup.org)) is working with Memphis hospitals to increase the number of hospitals that report to the Leapfrog Group and to encourage quality improvements in those hospitals. On the United States Department of Health and Human Services “Hospital Compare” website ([www.hospitalcompare.hhs.gov](http://www.hospitalcompare.hhs.gov)), Medicare has begun publicly comparing the quality of hospital care experienced by its members. Many states have initiated ranking or grading systems for their health care providers and institutions, but Tennessee has not. Quality measures usually evaluate either hospitals or health plans, because their data is the most readily available.



A recent Robert Wood Johnson Foundation report concluded the following regarding quality information:

- **Availability:** Virtually all publicly reported quality information is for hospitals and health plans, not individual physicians or groups. Most information is disseminated almost exclusively through the Internet.
- **Awareness:** Knowledge of publicly available quality information is not widespread. Awareness is higher among consumers who are more educated and in good health.
- **Use:** Even among consumers who are aware of the information, use of publicly reported quality information is low.
- **Reasons:** Lack of relevance, not lack of interest or understanding, is the biggest reason consumers do not use publicly reported information.<sup>129</sup>

Finally, relating to information, health care consumers seek health care because they need services and expertise they cannot provide themselves. The practice of medicine is complex and patients rely heavily on the advice and orders of their health care providers. While some sources, such as WebMD,<sup>130</sup> offer consumers basic information about health conditions and symptoms, these sources do not replace the need for health care providers to properly diagnose and treat patients.

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## Health Care Workforce

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*Principle for Achieving Better Health Number 5: The state should support the development, recruitment, and retention of a sufficient and quality health care workforce.*

### **Overview**

In its World Health Report of 2008, the World Health Organization called for a “return to primary care,” arguing that values, principles and approaches of primary care are more relevant now than ever before.<sup>131</sup> In the short term, Tennessee appears to have a sufficient number of primary care physicians<sup>132</sup> and nurses (although they are not necessarily proportionately distributed throughout the State, meaning patient access to primary care is not uniformly available). In fact, the current economic recession has encouraged a sufficient number of retired nurses to re-enter the workforce, preventing the estimated nursing shortage that had been predicted. Whether or not this trend will continue, or if in the future Tennessee will experience an overall health care workforce shortage, as has been predicted by some, is an issue for further research and discussion. At this time, however, the anticipated retirement of a large number of providers and workforce professionals as well as the increasing health needs of the aging Baby Boom generation indicate that the topic should be addressed sooner rather than later. The state should consider developing a comprehensive approach to ensure the existence of a sufficient, qualified health care workforce, taking into account issues regarding the safety net system, 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, allied health and other educational institutions, state and federal laws and regulations impacting capacity programs, and funding.

This overview presents selected available data on the current state of the health care workforce in Tennessee. It should also be noted that the quality of care provided by the health care workforce is discussed in *Principle for Achieving Better Health Number 4*, beginning on page 41.

### **Observations**

The Tennessee Department of Labor and Workforce Development (“TDLWD”) reports that educational and health services industries experienced the highest percentage growth of service-producing industries in Tennessee in 2007; short term employment increased 2.3 percent and projected overall industry growth is the highest of all industry sectors. Further, most jobs in the health services industry require postsecondary vocational training or a Bachelor’s or higher degree, placing increased importance on the state’s public and private education systems.<sup>133</sup> The current economic recession will most certainly impact this industry’s growth numbers.

A wide array of professionals form the backbone of the health care system, and ensuring there are sufficient numbers of these different types of professionals is essential to the provision of quality care. Health care professionals range from doctors and nurses to

allied health workers and public health officials; each category faces unique challenges, including higher education resources, impending retirement of existing professionals, and the distribution of professionals throughout the state.

### **Physicians**

Given an aging U.S. population, one of the greatest challenges facing the health care system is maintaining an adequate number of 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.<sup>134</sup> A separate report shows that the supply of physicians varies dramatically – by more than 50 percent -- by region of the country,<sup>135</sup> raising the related issues of physician location and consumer access, and suggesting the need for careful consideration whether an increase in the number of physicians alone is needed to solve regional inequities in supply and cost, or whether the issue of location of physicians is the larger one. Tennessee, through the work of the TDOH’s Office of Rural Health and The Rural Partnership,<sup>136</sup> is able to analyze its primary care physician practice location data to assess its intrastate regional differences; however, at this time the state is unable to do so with specialty or “focus” practice areas.

Whether or not it has a sufficient number of primary care physicians, Tennessee compares well with the remaining states and the District of Columbia in the overall number of primary care physicians practicing in the State. It has approximately 121.6 actively practicing primary care physicians per 100,000 people, compared with 120 primary care physicians per 100,000 people nationally.<sup>137</sup> However, 20 percent of Tennessee’s physicians are over the age of 60 and thus nearing retirement age. In 2008, as reported by The Rural Partnership in its 2008 Demand Assessment, health care employers in Tennessee's 91 non-metropolitan counties had more than 770 openings for health professionals (physicians, nurses, and advanced practice nurses/physician assistants).<sup>138</sup> In its Executive Summary, this report states: “Primary care physicians continue to be in greatest demand,” raising the critical issue of the disproportional primary care workforce distribution within the state.

It should be noted that the presence of more physicians does not necessarily translate into better care. As reported by a study published by The New England Journal of Medicine, patient outcomes are not necessarily better – and are sometimes worse – in regions with a very large supply of physicians.<sup>139</sup> Consequently, ensuring that physicians receive proper initial training and can participate in ongoing quality enhancement efforts is equally important as ensuring an adequate number of physicians.

### **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.<sup>140</sup> There are several levels of nurses that correspond to a certain level of education, including associate, bachelors, masters, and doctoral degrees. 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 (the “Nursing Education Steering Committee”). In fact, In January 2008 the Nursing Education Steering Committee released a follow-up report and found that Tennessee will over-produce associate degree nurses.<sup>141</sup>

However, there is a risk that Tennessee will continue to under-produce higher level bachelors (BSN) and masters degree (MSN) nursing graduates. The shortage of BSN and MSN graduates is critical, according to the report. BSN/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. A variety of reasons contribute to this shortage, including a wave of expected retirements and competition between nursing schools and clinical practices for advanced degree nurses. The salaries paid to nurses working in clinical practices tend to be higher than those paid to nursing school faculty members, providing an economic disincentive to teaching. According to the American Association of Colleges of Nursing, the average salary of a master's prepared nurse practitioner working in a clinical setting is \$72,480, while master's prepared faculty members across all ranks earn an annual average salary of \$55,712.<sup>142</sup>

### **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 2004, 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.<sup>143</sup> As stated in the report's Executive Summary, from 1995-2000, “Tennessee has experienced a 3.6 percent decline” in the number of allied health and health science baccalaureate graduates. Associate degrees awarded in the allied health and health sciences declined 24.7 percent in Tennessee (as compared to 13.9 percent nationally). The report states: “This decline in the number of health care workforce graduates has implications for decreased access to health care by Tennessee residents.

The study finds that the shortage of physical therapists trained in Tennessee has been “significantly decreased” and that occupational therapists are now being educated at a rate that balances demand. However, the study notes several professions where current graduation levels do not meet demand: respiratory therapy, health information administration, health information management, medical assisting, surgical technology, nursing assistance, EMT-paramedic training, and medical imaging (radiography and diagnostic medical sonography). Information provided by this study will inform the state's work in this area.

### **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.<sup>144</sup> As reported by the Association of State and Territorial Health Officials, most states continue to be affected by shortages of nurses in public health, as well as in other public health classifications, including epidemiologists, laboratorians, dentists, social workers, and environmental health workers. Tennessee's average age of a state public health employee was over 48.7 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 48.3 percent, significantly higher than the 29 percent average of the 28 states reporting this data. The percentage of these Tennessee state employees who are eligible to retire immediately is 26.7 percent.<sup>145</sup>

### **More Information Needed**

Further research and analysis are needed to develop information on the access of Tennessee's population to additional health professionals, including physician specialists, mental health professionals, dentists, advanced practice nurses/physician assistants, dental hygienists and assistants, and allied health workforce members. The Division of Health Planning is working with the TDOH and related stakeholder groups to identify data, trends, and other information that will help the State support the development, recruitment, and retention of a sufficient and quality health care workforce.

### **Expansion of Workforce Services Using Health Information Technology**

Rapid changes in technology are presenting new opportunities for delivering medical care to rural areas. Telemedicine is one innovation that may be used to strengthen the likelihood of access to and continued health care in rural communities and isolated populations. As already demonstrated by several providers in Tennessee, telemedicine can spread the reach of specialists and other professionals in short supply, such as public health dentists and psychiatrists. In addition, the American Recovery and Reinvestment Act (ARRA) of 2009 provides almost \$50 billion of federal investment in health information technology.<sup>146</sup> Investment in Tennessee's health information infrastructure could greatly improve the efficiency and of the state's health workforce and possibly reduce the negative effects of variation in the distribution of health professionals.

## Chapter 4: Data Driven Policy

*In this chapter we describe two critical infrastructure initiatives led by the Division of Health Planning. Both are designed to provide a dynamic fact-based foundation for moving forward with the five Principles for Achieving Better Health described in Chapter 3, and to support the standards developed for the Certificate of Need program described in Chapter 5.*

### Data Driven Decision Support

The Division of Health Planning is constructing a Health Planning Decision Support System (HPDSS), enabling the Division of Health Planning to bring data from a variety of sources into a central computer-based system.

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### Decision Support System

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#### HEALTH PLANNING DECISION SUPPORT SYSTEM (HPDSS)

##### **Project Goals**

The State of Tennessee’s Division of Health Planning is charged by [statute](#) with “guid(ing) the state in the development of health care programs and policies and in the allocation of health care resources in the state.” Data development and the ability to analyze data in a variety of ways are key components of meeting this charge. Developing policy guidance for and an assessment of Tennessee’s health care resources and the health outcomes of Tennesseans (including health status, access, quality, and cost); developing specific strategies relating to disease prevention, disease management, and health care infrastructure; and utilizing the strategies to update the Certificate of Need (CON) criteria and standards in alignment with both evidence and comprehensive statewide health planning all require accurate, consistent, and comprehensive databases and the ability to engage them.

To aid in developing these programs and policies, the HPDSS is being developed. The HPDSS will bring data from a variety of sources into a central secure computer-based system through which authorized users can retrieve, summarize, and analyze decision-relevant data. It is anticipated that, through data-sharing agreements, HPDSS will also be made available to assist information-seekers, analysts, and decision-makers across government departments and agencies.

##### **Project Objectives**

The Division of Health Planning intends to develop the following capabilities through the HPDSS:

- Support Certificate of Need (CON) decisions and guide use of state health resources
- Track and project supply and demand for resources and facilities

- Report on geographic access to health care
- Report on financial and cultural access to health care
- Track and project health care workforce development and demand for health care workers
- Track and project health status of Tennesseans
- Report quality of health care
- Supply health data needs of other areas of state government
- Track the performance of health initiatives
- Report on the health care market and the financial status of the health care safety net

### **Source Data**

Identifying source data and adding data to HPDSS will be an on-going process. Sources for data come from the TDOH, the TDMHDD, the Health Services and Development Agency, and other state agencies. Other data are expected to come from sources outside of state government.

### **Scope**

The HPDSS can be thought of either as a series of projects or as phases of a single large project. Each phase will follow the stages and yield deliverables as their descriptions are developed. At the same time, these phases will build upon the overall project chartered herein.

# Chapter 5: Certificate of Need Program

*In this chapter we present a brief background on the Certificate of Need program, the steps utilized by the Division of Health Planning to develop revised standards for CON categories, the status of CON categories undergoing review, and an overarching Policy Statement Regarding Certificates of Need. The revised and updated standards and criteria for positron emission tomography (PET) services and for cardiac catheterization services can be found in Appendix A and Appendix B, respectively.*

## Certificate of Need

A Certificate of Need (“CON”) is a permit for the establishment or modification of a health care institution, facility or service, purchase of major medical equipment, or establishment of certain services at a designated location. A brief background on CON and the list of institutions, services, and actions for which a CON is required are presented.

## Process for Revising Standards and Criteria

The publicly-participatory process for revising CON standards and criteria is presented along with a prioritized schedule of CON categories to be revised.

## Policy Statement Regarding Certificates of Need

An overarching Policy Statement Regarding Certificates of Need is presented that ties the current three criteria of need, economic feasibility, and orderly development of health care to the Five Health Planning Principles of the State Health Plan.

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## **Certificate of Need**

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A Certificate of Need (“CON”) is a permit for the establishment or modification of a health care institution, facility or service, purchase of major medical equipment, or establishment of certain services at a designated location. The CON program is intended to serve as a growth management and cost savings tool, since it requires certain health care providers to establish the need for new services and facilities before the providers will be allowed to build facilities, become licensed, or conduct certain business. Tennessee Code Annotated § 68-11-1603 declares that it is the policy of the State that “the establishment and modification of health care institutions, facilities and services shall be accomplished in a manner that is orderly, economical and consistent with the effective development of necessary and adequate means of providing for the health care of the people of Tennessee.” Thus, the three primary criteria for a CON are need, economic feasibility, and the contribution to the orderly development of the health care system.



The Tennessee Health Services and Development Agency (HSDA) administers the CON program.

**Institutions, Services, and Actions Requiring a CON per Tennessee Code Annotated § 68-11-1607**

As of the date of this edition of the State Health Plan, the following institutions require a Certificate of Need prior to establishment, licensure, or certification:

- Hospital
- Nursing home
- Recuperation center
- Ambulatory surgical treatment center (“ASTC”)
- Mental health hospital
- Mental retardation institutional habilitation facility
- Home care organization (home health and hospice)
- Outpatient diagnostic center (“ODC”)
- Rehabilitation facility
- Residential hospice
- Non-residential methadone treatment facility
- Birthing Center

As of the date of this edition of the State Health Plan, the following services require a Certificate of Need before they are initiated:

- Burn unit
- Neonatal intensive care unit (“NICU”)
- Open heart surgery
- Positron emission tomography (“PET”)
- Swing beds
- Home health
- Psychiatric (inpatient)
- Rehabilitation (inpatient)
- Hospital-based alcohol and drug treatment for adolescents provided under a program of care longer than 28 days
- Extracorporeal lithotripsy
- Magnetic resonance imaging (“MRI”)
- Cardiac catheterization
- Linear accelerator
- Hospice
- Methadone treatment provided through a facility licensed as a non-residential methadone treatment facility

As of the date of this edition of the State Health Plan, the following actions require a Certificate of Need:

- Modification, renovation, or addition to a hospital in excess of \$5 million and other health care institutions in excess of \$2 million.

- Any change in the bed complement of a health care institution which:
  - a) Increases by one or more the total number of licensed beds;
  - b) Redistributes beds from acute to long-term care;
  - c) Redistributes from any category to acute, rehabilitation, child and adolescent psychiatric, or adult psychiatric; and/or
  - d) Relocates beds to another facility or site.
- Change in location or replacement of existing or certified facilities providing health care services, major medical equipment, or health care institutions.
- Change of parent office of a home health or hospice agency from one county to another county.
- Acquisition of major medical equipment in which the cost exceeds \$2 million.
- Discontinuation of obstetrical services.

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### **Process for Revising Standards and Criteria**

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Tennessee Code Annotated § 68-11-1609 directs the HSDA to use the current *Guidelines for Growth, 2000 Edition* as the standards and criteria for granting a CON until the Division of Health Planning produces an updated State Health Plan. Many of the current standards were last updated well before 2000. Given the large number of categories requiring revised standards and criteria, the Division of Health Planning intends to adopt new standards and criteria incrementally and in consideration of the priorities identified by the State Health Plan Advisory Committee with the advice of public input. The *Guidelines for Growth, 2000 Edition* shall be considered part of this and subsequent State Health Plan editions, and as the State Health Plan is approved and adopted to include revised standards and criteria for each category, the revised standards shall replace each respective category of *Guidelines for Growth* standards and criteria.

#### **Public Process for Revising CON Standards and Criteria**

To ensure a publicly-participatory process that is as efficient as possible, the Division of Health Planning will endeavor to revise each category of Certificate of Need Standards and Criteria by pursuing the following steps:

1. The Division of Health Planning will conduct background research on the institution/service/action in question, including in this process interviews with and data provided by relevant state department and agency personnel, including the Health Services and Development Agency, the TDOH, and the TDMHDD. This research will result in an informational packet containing the current standards and criteria used; pertinent news and research literature; and Division of Health Planning analysis as needed.
2. If the Division of Health Planning deems it necessary, it will select a reasonable number of recognized experts (depending on the institution/service/action in question) to interview, for the express purpose of ensuring that Division of Health Planning staff achieves a full understanding of

the issues involved. The Division of Health Planning will endeavor to ensure that these experts help the Division of Health Planning understand the diversity of providers, needs, and circumstances in Tennessee. Prior to meeting with them, the Division of Health Planning will submit questions to the selected experts in addition to the informational packet.

3. The Division of Health Planning will interview the selected experts to outline broad concerns, discuss specific technical issues, and receive their professional advice on the drafting of revised standards and criteria.

4. After meeting with these experts, if the Division of Health Planning deems it necessary, the Division of Health Planning will develop a questionnaire to seek written input on specific draft standards and criteria under consideration by the Division of Health Planning. The questionnaire will be emailed to all known providers of the institution/service/actions in question in Tennessee, known statewide associations, and anyone who has expressed directly with the Division of Health Planning an interest in receiving this questionnaire; additionally, it will be made available to the public via the Division of Health Planning's web site and that of the Health Services and Development Agency.

5. The Division of Health Planning will utilize initial input from the interviewed experts and feedback from the questionnaire to draft proposed standards and criteria.

6. The Division of Health Planning will submit the proposed standards and criteria to the HSDA, to its Advisory Committee, to the TDOH, and to the TDMHDD, and to the public for comment.

7. The Division of Health Planning will facilitate a public meeting prior to the due date for public comments. This meeting will allow providers of differing opinions to interact with each other and offer evidence for their respective positions.

8. The Division of Health Planning will receive and consider written comments from all who provide them, making any changes to the proposed standards and criteria deemed necessary.

9. The Division of Health Planning will submit the proposed standards and criteria to the Governor for approval and adoption in the next edition of the State Health Plan.

### **Schedule of Priorities for Revising CON Standards and Criteria**

The following schedule lists priorities for revising CON category standards and criteria and the status of each. The former Health Planning and Advisory Board initiated work on categories 1-3 below, thus the Division of Health Planning began work on these categories first. Please note that revised standards and criteria for positron emission

Tomography (PET) services and for cardiac catheterization laboratory services are included in Appendix A and Appendix B, respectively.

In addition to revising standards and criteria for existing categories, the Division of Health Planning is considering which categories should continue to be regulated by the CON program; whether non-regulated institutions, services, and actions should be regulated by the CON program; and the processes required to address these considerations.

**Exhibit 5. Priorities for Revising CON Standards and Criteria**

<b>Category</b>	<b>Status</b>
1. Positron Emission Tomography (PET) Services	Revised
2. Cardiac Catheterization Laboratory Services	Revised
3. Open Heart Surgery Services	Under revision
4. Home Health/Hospice Services	Research and planning
5. Magnetic Resonance Imaging	Research and planning
6. Ambulatory Surgical Treatment Centers	Research and planning
7. Next categories to be determined by Advisory Committee with the advice of public input	Ongoing

**———— Policy Statement Regarding Certificates of Need ————**

As discussed in this Plan, the health needs of Tennesseans are complex and working to meet them requires a multifaceted approach. No policy or program can single-handedly change unhealthy behaviors, enhance the efficiency of health care delivery, ensure the adequacy of health care services and professionals, and plan to meet future health needs. However, because the Certificate of Need program impacts so many facets of our health care system, and thus the delivery of health care to Tennesseans, it offers a significant opportunity to address many of these challenges in a coordinated way.

For many years, the CON program in Tennessee has operated without an overarching set of principles relating the goals of the CON program to the health needs of the state as identified by a comprehensive health planning process. Through the State Health Plan, the Division of Health Planning aims to tie together the current criteria of CON — need, economic feasibility, and orderly development of health care — with the goals and objectives to be established under the Five Health Planning Principles discussed in detail in Chapter 3. This effort will be accomplished through overarching directives for the CON program and through specific standards and criteria pertaining to each CON category. The result will be a State Health Plan that orients all of state government towards common health policies and principles.

### **Role of the Division of Health Planning in the Certificate of Need Program**

The Division of Health Planning was created by statute in 2004 (Tennessee Code Annotated § 68-11-1625). As set forth therein, the Division of Health Planning's purpose is "(t)o 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." The statute more specifically states that a principal responsibility of the Division of Health Planning is "to develop and adopt a state health plan, which must include, at a minimum, guidance regarding allocation of the state's health care resources." "Guidance regarding allocation of the state's health care resources," a broad statement covering a variety of areas, directly refers to the development of standards and criteria for the Certificate of Need program.

These standards and criteria are integral to the CON program. Tennessee Code Annotated § 68-11-1608 directs the Departments of Health and of Mental Health and Developmental Disabilities to review each CON application for consistency with the State Health Plan. Moreover, Tennessee Code Annotated § 68-11-1609 (b) states: "No certificate of need shall be granted unless the action proposed in the application is necessary to provide needed health care in the area to be served, can be economically accomplished and maintained, and will contribute to the orderly development of adequate and effective health care facilities or services. In making such determinations, the agency shall use as guidelines the goals, objectives, criteria and standards in the state health plan." Consequently, the State Health Plan created by the Division of Health Planning is foundational to the CON program.

### **Policies for the Certificate of Need Program**

In addition to the three criteria prescribed by Tennessee Code Annotated § 68-11-1609 (b) used to review CON applications, this Plan also incorporates the Five Principles for Achieving Better Health into the CON program. The guidance of these policy areas will help ensure consistency between the CON program and the decisions and priorities of all other state government departments and agencies. As a result of the priorities identified through the health planning process, future editions of this State Health Plan will establish more specific goals and objectives relating to each of the principles that will help inform the HSDA in granting CONs.

The Five Principles for Achieving Better Health are:

1. The purpose of the State Health Plan is to improve the health of Tennesseans. The State Health Plan will identify and prioritize the health needs of Tennesseans through public input and data collection and analysis. Consequently, the State Health Plan will inform the HSDA regarding the types of health care services and facilities that are most needed. In addition, through more comprehensive data collection and analysis made possible by the HPDSS, health status will be monitored throughout the state. Finally, health may be improved through better coordination among providers throughout the continuum of care. Where appropriate, specific CON standards and criteria will address a service's position in the continuum of care.

2. Every citizen should have reasonable access to health care. Given the community-based orientation of the Certificate of Need program, the HSDA already considers access to health care under its first criterion of need. However, there are legitimate questions surrounding what constitutes “reasonable” access to different types of health care, including, for example, primary, emergency and trauma, mental health, dental, and specialty care. As a result of a publically participatory health planning process, the State Health Plan will provide benchmarks for reasonable access and offer policy direction to the HSDA to improve access.
3. While addressing health care needs, the State should encourage competitive markets, economic efficiencies, and development of a robust statewide health care system. As discussed in this State Health Plan, as part of the overall United States health care system, Tennessee’s health care system experiences economic inefficiencies and functions without traditional market-based competition. The State Health Plan will encourage greater efficiency through transparency, thus enabling greater competition that can itself lead to a more efficient distribution of resources. However, given many of the characteristics that distinguish health care from other economic sectors, the Certificate of Need program plays a role in maintaining essential health care services in communities as well as supporting institutions that predominantly serve the elderly, categorically needy, and indigent persons.
4. Every citizen should have confidence that the quality of health care is continually monitored and standards are adhered to by health care providers. Many categories included in the CON program in Tennessee are of particular interest regarding health care quality. Through various channels, the State Health Plan will encourage the measurement and improvement of the quality of care provided to Tennesseans. Through the CON program, the allocation of health care resources in Tennessee will be based on sound research and will be designed to maximize patient outcomes and safety. Thus, specific standards and criteria will be designed to ensure that outcomes of care are measurable, measured, and publicly reported.
5. The State should support the development, recruitment, and retention of a sufficient and quality health care workforce. The allocation of health care resources includes the allocation — or addressing shortages — of health care professionals and providers. Staffing is always a key issue for CON applicants. The State Health Plan will seek to orchestrate the development of a comprehensive health care workforce development strategy that will coordinate the health needs of the state with workforce development and placement initiatives. In addition, the State Health Plan will include in this strategy opportunities for the CON program to contribute to a sufficient and quality health care workforce.

The Rules of the HSDA, 0720-11-.01, further detail the three general criteria for CON:

1. Need. The health care needed in the area to be served may be evaluated upon the following factors:
  - a) The relationship of the proposal to any existing applicable plans (e.g., the State Health Plan and the Guidelines for Growth, 2000 Edition);
  - b) The population served by the proposal;
  - c) The existing or certified services or institutions in the area;
  - d) The reasonableness of the service area;
  - e) The special needs of the services area population, including the accessibility to consumers, particularly women, racial and ethnic minorities, and low-income groups;
  - f) Comparison of utilization/occupancy trends and services offered by other area providers;
  - g) The extent to which Medicare, Medicaid (TennCare), and medically indigent patients will be served by the project.
  
2. Economic Feasibility. The probability that the proposal can be economically accomplished and maintained may be evaluated upon the following factors:
  - a) Whether adequate funds are available to the applicant to complete the project;
  - b) The reasonableness of the proposed project costs;
  - c) Anticipated revenue from the proposed project and the impact on existing patient charges;
  - d) Participation in state/federal revenue programs;
  - e) Alternatives considered;
  - f) The Availability of less costly or more effective alternative methods of providing the benefits intended by the proposal.
  
3. Contribution to the Orderly Development of Adequate and Effective Health Care Facilities and/or Services. The contribution which the proposed project will make to the orderly development of an adequate and effective health care system may be evaluated upon the following factors:
  - a) The relationship of the proposal to the existing health care system (for example: transfer agreements, contractual agreements for health services, affiliation of the project with health professional schools);
  - b) The positive or negative effects attributed to duplication or competition;
  - c) The availability and accessibility of human resources required by the proposal, including consumers and related providers;
  - d) The quality of the proposed project in relation to applicable governmental or professional standards.

**Inclusion of Data Reporting Requirements for Health Care Facilities or Services with an Approved Certificate of Need.**

Through its research the Division of Health Planning has determined that, in order to develop the State Health Plan and to perform the Division of Health Planning's other

duties set out in Tennessee Code Annotated § 68-11-1625, purposeful changes must be made to the quantity and quality of health-related information currently available to the state. The Division of Health Planning further has determined that the Certificate of Need program can and should assist in the assembly of needed data to inform the ongoing development of the State Health Plan. As a result, the Division of Health Planning will strive to include new data reporting requirements for successful certificate of need applicants, as well as existing providers of CON program areas, in the standards and criteria as they are developed. The Division of Health Planning will incorporate this data along with data from other sources into its developing centralized data warehouse, the Health Planning Decision Support System (HPDSS). Over time through the health planning process the Division of Health Planning anticipates developing a rational and consistent data reporting system with common definitions for all providers in the State of Tennessee. Readily accessible, reliable, and timely data will enhance the CON program through greater transparency and better informed analysis.



## **Chapter 6: Advisory Committee**

### **The State Health Plan Advisory Committee**

In order to receive expert advice on the “big picture” elements of the health planning process, the Division of Health Planning has created the State Health Plan Advisory Committee. Members of the Committee include government officials and private sector individuals with health data and policy expertise. Membership from the private sector will change over time, while the membership of government officials is tied to their office. For a complete membership list, please refer to Appendix G.

The Committee held its first meeting on October 23, 2008 and affirmed the Five Health Planning Principles that form the basis for this Plan. Similar to its discussion of the Five Principles, the Committee will continue to act as a sounding board for the overarching direction of the health planning process. Members of the Committee have individually reviewed and commented extensively on this draft first edition of the State Health Plan.

## References

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- <sup>1</sup> Tennessee Code Annotated §§ 68-11-1602(15) and 1625(a).
- <sup>2</sup> United Health Foundation's "America's Health Rankings 2008," <http://www.americashealthrankings.org/2008/index.html>.
- <sup>3</sup> Douglas McCarthy, et al, "Aiming Higher: Results from a State Scorecard on Health System Performance, 2009," The Commonwealth Fund, October 8, 2009, <http://www.commonwealthfund.org/Content/Publications/Fund-Reports/2009/Oct/2009-State-Scorecard.aspx>.
- <sup>4</sup> Four organizations comprise the Academies: the [National Academy of Sciences](#), the [National Academy of Engineering](#), the [Institute of Medicine](#), and the [National Research Council](#).
- <sup>5</sup> The definition of "primary care physician" varies somewhat depending on the data source. Family physicians, general internists, pediatricians, internal medicine practitioners and general practitioners are normally included in the definition; United Health Foundation also includes OB-GYN practitioners in its data analyses. The practitioners included in specific data reports are so noted in the corresponding endnotes later on in this document.
- <sup>6</sup> World Health Organization. Basic Documents, Forty-fifth edition, Supplement, October 2006, [http://www.who.int/governance/eb/who\\_constitution\\_en.pdf](http://www.who.int/governance/eb/who_constitution_en.pdf).
- <sup>7</sup> United Health Foundation, "America's Health Rankings 2008," <http://www.americashealthrankings.org/2008/index.html>.
- <sup>8</sup> United Health Foundation, "America's Health Rankings 2008," <http://www.americashealthrankings.org/2008/index.html>; note that the state improved one place in both 2006 and in 2007, to 47<sup>th</sup> and 46<sup>th</sup>, respectively, but that it dropped back to 47<sup>th</sup> in 2008.
- <sup>9</sup> Douglas McCarthy, et al, "Aiming Higher: Results from a State Scorecard on Health System Performance, 2009," The Commonwealth Fund, October 8, 2009, <http://www.commonwealthfund.org/Content/Publications/Fund-Reports/2009/Oct/2009-State-Scorecard.aspx>.
- <sup>10</sup> Tennessee Code Annotated §§ 68-11-1602(15) and 1625(a).
- <sup>11</sup> See Appendix A for the full text of the statute.
- <sup>12</sup> Codified in Tennessee Code Annotated § 68-11-1625(d)(2) and (3).
- <sup>13</sup> Codified in Tennessee Code Annotated § 68-11-1625(d)(4), (5) and (12).
- <sup>14</sup> The Advisory Committee is discussed in Chapter 6 on page 55; its members are listed in Appendix G.
- <sup>15</sup> United States Department of Health and Human Services Centers for Disease Control and Prevention, "Chronic Disease Prevention and Health Promotion." <http://www.cdc.gov/nccdphp/>.
- <sup>16</sup> United States Department of Health and Human Services, "HealthyPeople 2010: Understanding and Improving Health." 2nd ed. Washington, DC: U.S. Government Printing
- <sup>17</sup> Tennessee Department of Health, "Smoking During Pregnancy," <http://health.state.tn.us/FactSheets/smoking.htm>
- <sup>18</sup> Tennessee Department of Education Office of Coordinated School Health, "Office of Coordinated School Health Annual Data and Compliance Report," [http://www.tennessee.gov/education/schoolhealth/data\\_reports/doc/DataandComplianceReport2008FINAL.pdf](http://www.tennessee.gov/education/schoolhealth/data_reports/doc/DataandComplianceReport2008FINAL.pdf).
- <sup>19</sup> Tennessee Department of Education Office of Coordinated School Health, "Office of Coordinated School Health Annual Data and Compliance Report," [http://www.tennessee.gov/education/schoolhealth/data\\_reports/doc/DataandComplianceReport2008FINAL.pdf](http://www.tennessee.gov/education/schoolhealth/data_reports/doc/DataandComplianceReport2008FINAL.pdf).
- <sup>20</sup> Tennessee Department of Education Office of Coordinated School Health, "Office of Coordinated School Health Annual Data and Compliance Report," [http://www.tennessee.gov/education/schoolhealth/data\\_reports/doc/DataandComplianceReport2008FINAL.pdf](http://www.tennessee.gov/education/schoolhealth/data_reports/doc/DataandComplianceReport2008FINAL.pdf).
- <sup>21</sup> Tennessee Department of Education Office of Coordinated School Health, "Office of Coordinated School Health Annual Data and Compliance Report," [http://www.tennessee.gov/education/schoolhealth/data\\_reports/doc/DataandComplianceReport2008FINAL.pdf](http://www.tennessee.gov/education/schoolhealth/data_reports/doc/DataandComplianceReport2008FINAL.pdf).

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<sup>22</sup> Rules of the State Board of Education, Chapter 0520-1-6, Child Nutrition Programs.

<http://www.tennessee.gov/sos/rules/0520/0520-01/0520-01-06.pdf>.

<sup>23</sup> Please note that the listing of current initiatives doesn't include the five Regional Mental Health Institutes (RMHIs) operated by the TDMHDD. Lakeshore Mental Health Institute (Knoxville), Moccasin Bend Mental Health Institute (Chattanooga) and Memphis Mental Health Institute provide in-patient psychiatric services for adults; Middle Tennessee Mental Health Institute (Nashville) and Western Mental Health Institute (Bolivar) provide in-patient psychiatric services for both adults and children/youth. Most RMHI admissions are on an emergency involuntary basis, with a variety of court-ordered inpatient evaluation and treatment services also provided. The RMHIs provide psychiatric services based upon the demonstrated and emerging best practices of each clinical discipline.

<sup>24</sup> Tennessee Code Annotated §§ 56-7-3001 to 56-7-3028.

<sup>25</sup> Cover Tennessee AccessTN, "FAQs About the AccessTN Company Assessment,"

[http://www.covertn.gov/web/access\\_assess\\_faq.pdf](http://www.covertn.gov/web/access_assess_faq.pdf).

<sup>26</sup> Cover Tennessee "CoverRx," [http://www.covertn.gov/web/cover\\_rx.html](http://www.covertn.gov/web/cover_rx.html).

<sup>27</sup> Frank Lichtenberg, "Why Has Longevity Increased More in Some States Than in Others? The Role of Medical Innovation and Other Factors." *Medical Progress Report* (July 2007) The Manhattan Institute.

<sup>28</sup> Frank Lichtenberg, "Why Has Longevity Increased More in Some States Than in Others? The Role of Medical Innovation and Other Factors." *Medical Progress Report* (July 2007) The Manhattan Institute.

<sup>29</sup> Bartholomew Sullivan, "Study Finds Significant Disparities on Cause of Death in Tennessee,"

Commercial Appeal, July 27, 2009, <http://www.commercialappeal.com/news/2009/jul/27/report-causes-of-death-skewed/>.

<sup>30</sup> The category "certain perinatal conditions" includes:

- Fetus and newborn affected by maternal factors and by complications of pregnancy, labor and delivery
- Disorders related to length of gestation and fetal growth
- Birth trauma
- Respiratory and cardiovascular disorders specific to the perinatal period
- Infections specific to the perinatal period
- Hemorrhagic and hematological disorders of fetus and newborn
- Transitory endocrine and metabolic disorders specific to fetus and newborn
- Digestive system disorders of fetus and newborn
- Conditions involving the integument and temperature regulation of fetus and newborn
- Other disorders originating in the perinatal period

<sup>31</sup> Commonwealth Fund, "Aiming Higher: Results from a State Scorecard on Health System Performance 2009," <http://www.commonwealthfund.org/Content/Publications/Fund-Reports/2009/Oct/2009-State-Scorecard.aspx>.

<sup>32</sup> United States Department of Health and Human Services Centers for Disease Control and Prevention, National Centers for Chronic Disease Control and Prevention Behavioral Risk Factor Surveillance System Annual Survey Data 2007.

<http://apps.nccd.cdc.gov/brfss/page.asp?cat=EX&yr=All%20Years&qkey=4347&state=TN#EX>

<sup>33</sup> United Health Foundation, "America's Health Rankings 2008,"

<http://www.americashealthrankings.org/2008/index.html>.

<sup>34</sup> Partnership for Solutions. "Chronic Conditions,"

<http://www.partnershipforsolutions.org/problem/index.html>.

<sup>35</sup> United Health Foundation, "America's Health Rankings 2008,"

<http://www.americashealthrankings.org/2008/index.html>.

<sup>36</sup> Trust for America's Health, "F as in Fat 2008."

<sup>37</sup> United Health Foundation, "American's Health Rankings 2008"

<http://www.americashealthrankings.org/2008/index.html>.

<sup>38</sup> Centers for Disease Control and Prevention, "Heart Disease and Stroke Prevention; Addressing the Nation's Leading Killers" <http://www.cdc.gov/nccdphp/publications/AAG/dhdsp.htm>.

<sup>39</sup> American Cancer Society, "Tobacco-Related Cancers Fact Sheet,"

[http://www.cancer.org/docroot/PED/content/PED\\_10\\_2x\\_Tobacco-Related\\_Cancers\\_Fact\\_Sheet.asp?sitearea=PED](http://www.cancer.org/docroot/PED/content/PED_10_2x_Tobacco-Related_Cancers_Fact_Sheet.asp?sitearea=PED).

<sup>40</sup> Improving Chronic Illness Care, "The Chronic Care Model," <http://www.improvingchroniccare.org>.

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- <sup>41</sup> Centers for Disease Control and Prevention. Best Practices for Comprehensive Tobacco Control Programs—2007. Atlanta: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health; October 2007.  
[http://www.cdc.gov/tobacco/tobacco\\_control\\_programs/stateandcommunity/best\\_practices/index.htm](http://www.cdc.gov/tobacco/tobacco_control_programs/stateandcommunity/best_practices/index.htm).
- <sup>42</sup> The Office of the Surgeon General, “The Health Consequences of Smoking: A Report of the Surgeon General,” May 27, 2004, <http://www.surgeongeneral.gov/library/smokingconsequences/index.html>.
- <sup>43</sup> United States Department of Health and Human Services Centers for Disease Control and Prevention, National Centers for Chronic Disease Control and Prevention Behavioral Risk Factor Surveillance System Annual Survey Data.
- <sup>44</sup> United Health Foundation, “America’s Health Rankings 2008,”  
<http://www.americashealthrankings.org/2008/index.html>.
- <sup>45</sup> Department of Health and Human Services Substance Abuse and Mental Health Services Administration, “Tobacco/Synar,” <http://prevention.samhsa.gov/tobacco/01synartable.aspx>.
- <sup>46</sup> DE Bush et al. *Post-Myocardial Infarction Depression*. Summary, Evidence Report/Technology Assessment: Number 123. AHRQ Publication Number 05-E018-1, May 2005. Agency for Healthcare Research and Quality, Rockville, MD. <http://www.ahrq.gov/clinic/epcsums/midepsum.htm>.
- <sup>47</sup> The Office of the Surgeon General, “Mental Health: A Report of the Surgeon General,” 1999  
<http://www.surgeongeneral.gov/library/mentalhealth/home.html>.
- <sup>48</sup> The Office of the Surgeon General, “Mental Health: A Report of the Surgeon General,” 1999  
<http://www.surgeongeneral.gov/library/mentalhealth/home.html>.
- <sup>49</sup> Office of Applied Studies. “State Estimates of Substance Use and Mental Health from the 2005-2006 National Surveys on Drug Use and Health. Substance Abuse and Mental Health Services Administration,” <http://www.oas.samhsa.gov/2k6/State/AppC.htm#TabC-24>.
- <sup>50</sup> Tennessee Department of Health Office of Vital Records.
- <sup>51</sup> Office of Applied Studies. Results from the 2007 National Survey on Drug Use and Health: National Findings (DHHS Publication No. SMA 08-4343, NSDUH Series H-34). Rockville, MD: Substance Abuse and Mental Health Services Administration. <http://oas.samhsa.gov/2k9/SPDtx/SPDtx.htm>.
- <sup>52</sup> Centers for Medicaid and Medicare Services. “The Mental Health Parity Act,”  
[http://www.cms.hhs.gov/healthinsreformforconsume/04\\_thementalhealthparityact.asp](http://www.cms.hhs.gov/healthinsreformforconsume/04_thementalhealthparityact.asp).
- <sup>53</sup> Office of Applied Studies. State Estimates of Substance Use and Mental Health from the 2005-2006 National Surveys on Drug Use and Health. Substance Abuse and Mental Health Services
- <sup>54</sup> Office of Policy, Planning and Assessment (2009). Infant Mortality in Tennessee, 1997-2006. Tennessee Department of Health, Nashville, TN.
- <sup>55</sup> M Hack et al., “Outcomes in young adulthood for very-low-birth-weight infants.” *The New England Journal of Medicine*. 346 (2002):149-157.
- <sup>56</sup> Bhutta et al., “Cognitive and behavioral outcomes of school-aged children who were born preterm.” *JAMA* 288 (2002):728-737.
- <sup>57</sup> G. Valsmakis et al., “Causes of Intrauterine Growth Restriction and the Postnatal Development of the Metabolic Syndrome.” *Annals of the New York Academy of Sciences*, 1092 (2006): 138-147.
- <sup>58</sup> D.J.P Barker, “Type 2 (Non-Insulin-Dependent) Diabetes Mellitus, Hypertension and Lyperlipidaemia (Syndrome X): Relation to Reduced Fetal Growth.” *Diabetologia*, 36, no. 1 (1993): 62-67.
- <sup>59</sup> Office of Policy, Planning and Assessment (2009). Infant Mortality in Tennessee, 1997-2006. Tennessee Department of Health, Nashville, TN.
- <sup>60</sup> Tennessee Department of Health, “Infant Mortality Stats and Facts,”  
[http://health.state.tn.us/infantmortality/stats\\_facts.htm](http://health.state.tn.us/infantmortality/stats_facts.htm).
- <sup>61</sup> United Health Foundation, “America’s Health Rankings 2008,”  
<http://www.americashealthrankings.org/2008/index.html>.
- <sup>62</sup> United Health Foundation, “America’s Health Rankings 2008,”  
<http://www.americashealthrankings.org/2008/index.html>.
- <sup>63</sup> Commonwealth Fund, “Aiming Higher: Results from a State Scorecard on Health System Performance 2009,” <http://www.commonwealthfund.org/Content/Publications/Fund-Reports/2009/Oct/2009-State-Scorecard.aspx>.
- <sup>64</sup> Hemoglobin A1C levels reflect a patient’s success in maintaining healthy blood sugar levels over the past two or three months, and is a complement to daily blood sugar tests performed by the patient.
- <sup>65</sup> Diabetics are at a high risk of foot amputation or blindness.

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<sup>66</sup> Agency for Healthcare Research and Quality, “2007 State Snapshots,” [http://statesnapshots.ahrq.gov/snaps07/meter\\_metrics.jsp?menuId=4&state=TN&level=15&region=0&compGroup=N](http://statesnapshots.ahrq.gov/snaps07/meter_metrics.jsp?menuId=4&state=TN&level=15&region=0&compGroup=N).

<sup>67</sup> See Chapter 1: Introduction and Overview, page 8; Tennessee Code Annotated § 68-11-1625(b)(1)

<sup>68</sup> The Certificate of Need program in Tennessee impacts “reasonable access.” See “Chapter 5 Certificate of Need Program” at page 46 as well as the discussion of the CON program in Principle for Achieving Better Health Number 3: “Develop health care resources to address needs while encouraging competitive markets, economic efficiencies, and development of the health care industry,” at page 32.

<sup>69</sup> Urban Institute and Kaiser Commission on Medicaid and the Uninsured estimates based on the Census Bureau’s March 2007 Current Population Survey (CPS: Annual Social and Economic Supplements).

<sup>70</sup> Christopher Carty and William F. Fox, “The Impact of TennCare: A Survey of Recipients 2009,” University of Tennessee Center for Business and Economic Research, Knoxville, August 2009.

<sup>71</sup> C. Schoen, Insurance Design Matters: Underinsured Trends, Health and Financial Risks, and Principles for Reform, Hearing on “Addressing the Underinsured in National Health Reform,” U.S. Senate Health, Education, Labor and Pensions Committee, February 24, 2009.

<sup>72</sup> Risky Business: When Mom and Pop Buy Health Insurance for Their Employees, Jon R. Gabel, M.A., and Jeremy D. Pickreign, M.S., The Commonwealth Fund, April 2004.

<sup>73</sup> The TennCare program operates under a Section 1115 waiver from the Centers for Medicare and Medicaid Services (CMS) in the United States Department of Health and Human Services. It is a demonstration program. Medicaid waiver programs are time-limited. The first TennCare waiver ended on June 30, 2002. The waiver under which TennCare is now operating is called “TennCare II.” It began on July 1, 2002, and has been extended through June 30, 2010. In the summer of 2009, the state will begin preparing the next extension request. In addition to overseeing the contracts with the managed care entities and overseeing the long-term care program, the Bureau of TennCare is responsible for payment of Medicare premiums, deductibles, and/or coinsurance for certain low-income Medicare beneficiaries.

<sup>74</sup> The Kaiser Family Foundation, State Health Facts, [www.statehealthfacts.org](http://www.statehealthfacts.org).

<sup>75</sup> According to the CMS website, “Medicaid does not provide medical assistance for all poor persons. Even under the broadest provisions of the Federal statute (except for emergency services for certain persons), the Medicaid program does not provide health care services, even for very poor persons, unless they are in one of the designated eligibility groups.” US Department of Health and Human Services, Centers for Medicare and Medicaid Services website <http://www.cms.hhs.gov/MedicaidGenInfo/>.

<sup>76</sup> Section 1867 of the Social Security Act

<sup>77</sup> Primarily, a medical screening examination within the capability of the hospital’s emergency department (including ancillary services routinely available to the emergency department) to determine whether or not an emergency medical condition (EMC) exists when such a request is made, including active labor.

<sup>78</sup> 42 U.S.C. 1395dd; [http://www.ssa.gov/OP\\_Home/ssact/title18/1867.htm#t](http://www.ssa.gov/OP_Home/ssact/title18/1867.htm#t).

<sup>79</sup> Tennessee Department of Health, 2007 Joint Annual Report of Hospitals.

<sup>80</sup> “[The Health Center Program](http://www.bphc.hrsa.gov/about/): What is a Health Center?”, Health Resources and Services Administration, U.S. Department of Health and Human Services, <http://www.bphc.hrsa.gov/about/>.

<sup>81</sup> “[The Health Center Program](http://www.bphc.hrsa.gov/about/): What is a Health Center?”, Health Resources and Services Administration, U.S. Department of Health and Human Services, <http://www.bphc.hrsa.gov/about/>.

<sup>82</sup> 42 U.S.C. 1395i-4; [http://www.ssa.gov/OP\\_Home/ssact/title18/1820.htm](http://www.ssa.gov/OP_Home/ssact/title18/1820.htm); The United States Department of Health and Human Services oversees the Rural Hospital Flexibility Grant Program (Flex Program) to help qualifying rural hospitals obtain designation as a CAH. Grants are awarded to States for: 1) development and implementation of Rural Health Plans with broad collaboration; 2) stabilizing rural hospitals by helping them consider, plan for, and obtain designation as a CAH; 3) supporting CAHs, other providers and communities as they develop networks of care; 4) helping improve and integrate emergency medical services; and 5) improving the quality of care in rural communities; <http://ruralhealth.hrsa.gov/funding/flex.htm>.

<sup>83</sup> Tennessee Department of Health, Division of Health Care Facilities: <http://health.state.tn.us/HCF/critical.pdf>

<sup>84</sup> Tennessee Code Annotated § 68-11-1607(a)(9)

<sup>85</sup> Tennessee Trauma Alliance, <http://www.tntrauma.org/basic%20facts.htm>

<sup>86</sup> Tennessee Trauma Alliance, <http://www.tntrauma.org/basic%20facts.htm>; Trauma centers vary in their specific capabilities and are identified by “Level” designation: Level-I, being the highest, to Level-III being the lowest (some states have four designated levels, in which case Level-IV is the lowest). Level I: Regional Medical Center at Memphis; Vanderbilt University Medical Center ; UT Medical Center Trauma Center ;

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Erlanger Medical Center; Wellmont Holston Valley; Johnson City Medical Center ; Level II: Wellmont Bristol Regional Medical Center; Level III; Blount Memorial Hospital ; Athens Regional Medical Center; Woods Memorial Hospital District.

<sup>87</sup> Tennessee Trauma Alliance, <http://www.tntrauma.org/basic%20facts.htm>.

<sup>88</sup> U.S. Surgeon General, “Oral Health,” <http://www.surgeongeneral.gov/library/oralhealth/>.

<sup>89</sup> Bureau of TennCare, “TennderCare,” <http://tennessee.gov/tenncare/tenndercare/dentalkids.html>.

<sup>90</sup> 2006 Behavioral Risk Factor Surveillance System, Centers for Disease Control; source: TDOH

<sup>91</sup> State of Tennessee Department of Health “Adult Emergency Oral Health Care 2008

Report to the Legislature,” January 15, 2009, <http://health.state.tn.us/Downloads/adultemoralth08.pdf>.

<sup>92</sup> “Falling Behind: Americans’ Access to Medical Care Deteriorates, 2003-2007”; Center for Studying Health System Change, June 2008; <http://www.hschange.com/CONTENT/993/>.

<sup>93</sup> Kaiser State Health Facts, “Tennessee: Health Care Expenditures per Capita by State of Residence, 2004,” Kaiser Family Foundation, <http://www.statehealthfacts.org/profileind.jsp?ind=596&cat=5&rgn=44>.

<sup>94</sup> State Of Tennessee, Comprehensive Annual Financial Report Year Ending June 30, 2007.

<sup>95</sup> Anthony Shih, Karen Davis, et. al., “Organizing the U.S. Health Care Delivery System for High Performance”, The Commonwealth Fund (2008), [http://www.commonwealthfund.org/publications/publications\\_show.htm?doc\\_id=698139](http://www.commonwealthfund.org/publications/publications_show.htm?doc_id=698139).

<sup>96</sup> Health spending in the United States is projected to increase from 16 percent of gross domestic product (GDP) in 2006 to 20 percent in 2016, increasing from \$2 trillion to \$4 trillion during these 10 years. According to the Commonwealth Fund: “The U.S. spends twice per capita what other industrialized nations spend on health care but ranks 19th out of 19 countries on mortality amenable to medical care. There are wide variations in health care outlays across the U.S., with no apparent relationship to quality or health outcomes. Over 100,000 lives could be saved if all states in the U.S. performed at the level of the best state, at considerably lower cost. The U.S. could learn from best practices within the nation and from other countries on how to simultaneously improve quality and efficiency.” Karen Davis, “Health and Wealth: Measuring Health System Performance,” Invited Testimony, Senate Committee on Commerce, Science, and Transportation, Subcommittee on Interstate Commerce, Trade, and Tourism, Hearing on “Rethinking the Gross Domestic Product as a Measurement of National Strength,” March 12, 2008,

[http://www.commonwealthfund.org/publications/publications\\_show.htm?doc\\_id=673038](http://www.commonwealthfund.org/publications/publications_show.htm?doc_id=673038).

<sup>97</sup> Kaiser State Health Facts, “Health Care Expenditures per Capita by State of Residence, 2004,” Kaiser Family Foundation,

<http://statehealthfacts.org/comparetable.jsp?ind=596&cat=5&sub=143&yr=14&typ=4&o=a&sort=n>.

<sup>98</sup> Trust for America’s Health, “F as in Fat, 2008,” <http://healthyamericans.org/reports/obesity2008/>.

<sup>99</sup> United Health Foundation, “America’s Health Rankings, 2008,”

<http://www.americashealthrankings.org/2008/index.html>.

<sup>100</sup> State Health Facts: “Health Care Expenditures per Capita by Service by State of Residence, 2004,” Kaiser Family Foundation,

<http://statehealthfacts.org/comparetable.jsp?ind=597&cat=5&sub=143&yr=14&typ=4&sort=1025>.

<sup>101</sup> Christopher Carty and William Fox, “The Impact of TennCare: A Survey of Recipients, 2008,” University of Tennessee Center for Business and Economic Research, <http://cber.utk.edu/tnicare/tnicare08.pdf>.

<sup>102</sup> Kaiser Commission on Medicaid and the Uninsured, “The Uninsured: A Primer, 2008,” Kaiser Family Foundation, <http://www.kff.org/uninsured/upload/7451-04.pdf>.

<sup>103</sup> According to the Center for Studying Health System Change, a nonpartisan policy research organization, 20 percent of Americans reported in 2007 that they had delayed or forgone needed medical care due to costs, up from 14 percent in 2003. Cunningham, Peter J. and Laurie E. Felland, “Falling Behind: Americans’ Access to Medical Care Deteriorates, 2003-2007,” June 2008, Center for Studying Health System Change, <http://www.hschange.org/CONTENT/993/>.

<sup>104</sup> As conditions become more severe and complex, they consume greater resources and become more expensive to treat. Thus, failing to provide needed preventive care directly contributes to greater economic inefficiency through avoidable hospital admissions, emergency department use, and complications of chronic and acute disease. Davis, Karen, Cathy Schoen, et al., “Slowing the Growth of Health Care Expenditures: What are the Options?,” Prepared for The Commonwealth Fund/Alliance for Health Reform 2007 Bipartisan Congressional Health Policy Conference, January 2007, [http://www.commonwealthfund.org/usr\\_doc/Davis\\_slowinggrowthUSHltcareexpenditureswhatareoptions\\_989.pdf?section=4039](http://www.commonwealthfund.org/usr_doc/Davis_slowinggrowthUSHltcareexpenditureswhatareoptions_989.pdf?section=4039).

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<sup>105</sup> The 2008 edition of the Atlas studied the records of more than four million Medicare beneficiaries, who between 2001 and 2005 received care at an estimated 3,000 hospitals nationwide during the last two years of their lives. The study found tremendous unwanted variation in care. “The dramatic differences in costs and the absence of any evidence of benefit from higher spending points to important opportunities and challenges for U.S. policy makers. The opportunity lies in the potential gains in efficiency that could be achieved if higher spending regions or hospitals adopted the practice patterns of the most efficient U.S. regions. For example, if all U.S. regions could safely adopt the practice patterns observed for the most efficient regions (such as Madison, Wisconsin; Sioux Falls, South Dakota; or Des Moines, Iowa), spending during 2005 for patients with severe chronic illness would have declined by over 25%.” John E. Wennberg, Elliott S. Fisher, et. al., “Tracking the Care of Patients with Severe Chronic Illness: The Dartmouth Atlas of Health Care 2008,” Executive Summary, The Dartmouth Institute for Health Policy and Clinical Practice, pgs. 4-5,

[http://www.dartmouthatlas.org/atlas/2008\\_Atlas\\_Exec\\_Summ.pdf](http://www.dartmouthatlas.org/atlas/2008_Atlas_Exec_Summ.pdf).

<sup>106</sup> Elliot Fisher, David Goodman, et. al., “Health Care Spending, Quality, and Outcomes: More Isn’t Always better,” The Dartmouth Institute for Health Policy and Clinical Practice, February 2009,

[http://www.dartmouthatlas.org/atlas/Spending\\_Brief\\_022709.pdf](http://www.dartmouthatlas.org/atlas/Spending_Brief_022709.pdf).

<sup>107</sup> Cindy L. Bryce and Kathryn Ellen Cline, “The Supply and Use of Medical Technologies,” *Health Affairs* 17, no. 1 (1998): 213.

<sup>108</sup> Laurence Baker, Howard Birnbaum, et. al., “The Relationship Between Technology Availability and Health Care Spending,” *Health Affairs*, Web Exclusive (2003).

<sup>109</sup> Elliot Fisher, David Goodman, et. al., “Health Care Spending, Quality, and Outcomes: More Isn’t Always better,” The Dartmouth Institute for Health Policy and Clinical Practice, February 2009,

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<sup>113</sup> Elliot Fisher, David Goodman, et. al., “Health Care Spending, Quality, and Outcomes: More Isn’t Always better,” The Dartmouth Institute for Health Policy and Clinical Practice, February 2009,

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<sup>114</sup> Elliot Fisher, David Goodman, et. al., “Health Care Spending, Quality, and Outcomes: More Isn’t Always better,” The Dartmouth Institute for Health Policy and Clinical Practice, February 2009,

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<sup>115</sup> J. William Thomas, “Book Review,” review of “Risk Adjustment for Measuring Health Care Outcomes, 3rd edition,” edited by Lisa Iezzoni, *International Journal for Quality in Health Care* 16, no. 2 (2004): 181–182.

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# Tennessee State Health Plan

**2009**

## **Section 2**

### **Certificate of Need Standards and Criteria**

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**APPENDIX A. Revised and Updated Standards and Criteria for Positron Emission Tomography (PET) services**



**STATE OF TENNESSEE**

**STATE HEALTH PLAN  
CERTIFICATE OF NEED STANDARDS AND CRITERIA**

*FOR*

**POSITRON EMISSION TOMOGRAPHY SERVICES**

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

These standards and criteria are effective immediately as of November 18, 2009, the date of approval and adoption by the governor of the State Health Plan. Applications to provide PET services that were deemed complete by HSDA prior to this date shall be considered under the Guidelines for Growth, 2000 Edition.

**Definitions**

**Positron Emission Tomography (PET):** A noninvasive diagnostic imaging procedure that assesses the level of metabolic activity and perfusion in various organ systems of the human body (source: The Centers for Medicare and Medicaid Services). PET differs from other nuclear medicine modalities in the type of radiation emitted and in the type of scanner required to detect it. By measuring the distributions of certain radiotracers in the body some time after they have been administered, PET can be used to diagnose physical abnormalities and to study body functions in normal subjects.

**PET Unit:** Diagnostic equipment (often referred to as a “scanner”) that uses a positron camera (tomograph) to produce cross-sectional tomographic images (this process is often referred to as a “scan”). The images are obtained from positron emitting radioactive tracer substances (radiopharmaceuticals) such as 2-(F-18) Fluoro-D-Glucose (FDG) which are administered intravenously to the patient. The radioactive tracers may be

produced on-site, e.g. with a cyclotron, or may be ordered from commercial distributors. As a result, factors such as equipment cost, geographic distribution and availability of distributors, and other related factors (regulatory compliance/certification) should be considered by the Agency in its review of all PET applications.

First developed in the 1970s, initial PET scanners were dedicated machines performing only that service. PET scanners can be either fixed (stationary) or mobile. Current technological adaptations include hybrid machines, such as combined PET-CT (computed tomography) scanners that are capable of performing a variety of nuclear medicine studies.

**PET Procedure:** A PET diagnostic scan or combination of scans 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.

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

**Mobile PET Unit:** A PET unit and transporting equipment that is moved to provide services at two or more host facilities, including facilities located in adjoining or contiguous states of the Continental United States.

**Capacity:** The measure of the maximum number of PET scans per PET unit per year based upon the type of PET equipment to be used (i.e., stationary or mobile).

**Stationary PET Unit Capacity:** Total capacity of a stationary PET unit is 2,000 procedures per year and is based upon a daily operating efficiency of eight procedures per day x 250 days of operation per year. The optimal efficiency for a stationary PET unit is 80 percent of total capacity, or 1,600 procedures per year.

**Mobile PET Unit Capacity:** Total capacity of a mobile PET scanner is 400 annual procedures per day of operation per week and is based upon a daily operating efficiency of at least eight (8) procedures per day x number of days in operation per week x approximately 50 weeks per year. The optimal efficiency of a mobile PET 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 320 procedures per year, or 80 percent of total capacity.

**PET Unit Service Area:** The counties, or portions thereof, representing a reasonable area in which a health care institution intends to provide PET unit services, including, but not limited to, oncology and cardiology diagnostic and treatment services, and in which at least 75% of its service recipients reside. A PET 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 PET units needed in a given service area. The estimate is based upon an optimal efficiency of 1,600 procedures per year for a stationary PET unit and an optimal efficiency of 320 annual procedures per day of operation per week for a mobile PET unit, and the quantitative estimate of the number

of patients who potentially could benefit from PET diagnostic services, especially those patients pertaining to the following categories:

- those patients where the use of PET unit services is essential to the diagnosis, treatment, or surveillance of cancer, including, but not limited to, diagnosis codes approved by the Centers for Medicare and Medicaid Services (CMS);
- those patients who are either non-emergent candidates for open heart surgery or therapeutic cardiac catheterization procedures;
- those patients with a diagnosis of partial complex epilepsy for whom surgical intervention is being considered; and
- any other patient population that may benefit from the accessibility to stationary or mobile PET unit services as a result of expanded clinical applications and changes in the reimbursement of PET service by third party payors, including those pertaining to programs administered by the CMS.

In addition to the above determinants of service area capacity, applicants should consider demographic patterns, including the results of estimates of population health risk factors and population-based cancer, heart disease, or other applicable clinical incidence rates. The data should be consistent with data prepared by the Tennessee Department of Health. Applicants should also document the extent, if any, of diagnostic oncology, cardiac and neurological medical services in the proposed service area in its determination of the need for PET unit services.

## **Standards and Criteria**

1. Applicants proposing a new stationary PET unit should project a minimum of at least 1,000 PET procedures in the first year of service, building to a minimum of 1,600 procedures per year by the second year of service and for every year thereafter. Providers proposing a mobile PET unit should project a minimum of at least 133 mobile PET procedures in the first year of service per day of operation per week, building to an annual minimum of 320 procedures per day of operation per week by the second year of service and for every year thereafter. The minimum number of procedures for a mobile PET unit should not exceed a total of 1600 procedures per year if the unit is operated more than five (5) days per week. The application for mobile and stationary units should include projections of demographic patterns, including analysis of applicable population-based health status factors and estimated utilization by patient clinical diagnoses category (ICD-9).

For units with a combined utility, e.g., PET/CT units, only scans involving the PET function will count towards the minimum number of procedures.

2. All providers applying for a proposed new PET 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 PET units that service the non-Tennessee counties and the impact on PET 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.

3. All providers 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. Any provider proposing a new mobile PET unit should demonstrate that it offers or has established referral agreements with providers that offer as a minimum, cancer treatment services, including radiation, medical and surgical oncology services.
5. A need likely exists for one additional stationary PET unit in a service area when the combined average utilization of existing PET service providers is at or above 80% of the total capacity of 2,000 procedures during the most recent twelve-month period reflected in the provider medical equipment report maintained by the HSDA. The total capacity per PET unit is based upon the following formula:

Stationary Units: Eight (8) procedures/day x 250 days/year = 2,000 procedures/year

Mobile Units: Eight (8) procedures /day x 50 days/year= 400 procedures/year

The provider should demonstrate that its acquisition of an additional stationary or mobile PET unit in the service area has the means to perform at least 1,000 stationary PET procedures or 133 mobile PET procedures per day of operation per week in the first full one-year period of service operations, and at least 1,600 stationary PET procedures or 320 mobile PET procedures per day of operation per week for every year thereafter.

6. The applicant should provide evidence that the PET unit is safe and effective for its proposed use.
  - a. The United States Food and Drug Administration (FDA) must certify the proposed PET unit for clinical use.
  - b. The applicant should demonstrate that the proposed PET 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 PET unit facility will be managed in conformity with accepted medical practice.

- d. The applicant should establish protocols that assure that all clinical PET procedures performed are medically necessary and will not unnecessarily duplicate other services.
  - e. The PET unit should be under the medical direction of a licensed physician. The applicant should provide documentation that attests to the nature and scope of the duties and responsibilities of the physician medical director. Clinical supervision and interpretation services must be provided by physicians who are licensed to practice medicine in the state of Tennessee and are board certified in Nuclear Medicine or Diagnostic Radiology. Licensure and oversight for the handling of medical isotopes and radiopharmaceuticals by the Tennessee Board of Pharmacy and/or the Tennessee Board of Medical Examiners—whichever is appropriate given the setting—is required. Those qualified physicians that provide interpretation services should have additional documented experience and training, credentialing, and/or board certification in the appropriate specialty and in the use and interpretation of PET procedures.
  - 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.
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 0720-4-.01 (1), which lists the factors concerning need on which an application may be evaluated, 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 documents that the service area population experiences a prevalence, incidence and/or mortality from cancer, heart disease, neurological impairment or other clinical conditions applicable to PET unit services that is substantially higher than the State of Tennessee average;
    - c. Who is a “safety net hospital” or a “children’s hospital” as defined by the Bureau of TennCare Essential Access Hospital payment program and/or is a comprehensive cancer diagnosis and treatment program as designated by the Tennessee Department of Health and/or the Tennessee Comprehensive Cancer Control Coalition; or

- d. 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.

## APPENDIX B. Revised and Updated Standards and Criteria for Cardiac Catheterization services



STATE OF TENNESSEE

# STATE HEALTH PLAN CERTIFICATE OF NEED STANDARDS AND CRITERIA

*FOR*

## CARDIAC CATHETERIZATION SERVICES

The Health Services and Development Agency (HSDA) may consider the following standards and criteria for applications seeking to provide cardiac catheterization services. Rationale statements for each standard are provided in an appendix. Existing providers of cardiac catheterization services are not affected by these standards and criteria unless they take an action that requires a new certificate of need (CON) for such services.

These standards and criteria are effective immediately as of November 18, 2009, the date of approval and adoption by the governor of the State Health Plan. Applications to provide cardiac catheterization services that were deemed complete by HSDA prior to this date shall be considered under the Guidelines for Growth, 2000 Edition.

### Definitions

**Cardiac Catheterization:** An invasive medical procedure performed within a cardiac catheterization laboratory and used as a diagnostic or therapeutic tool for heart and circulatory conditions. During a catheterization procedure a catheter is inserted into a blood vessel and is manipulated by a physician to travel along the course of the vessel in the chambers or vessels of the heart. Imaging equipment is used as an aid in placing the catheter tip in the desired position. Once in place the physician is able to perform various diagnostic and/or therapeutic procedures. Cardiac catheterization services include diagnostic cardiac catheterizations, therapeutic cardiac catheterizations, and electrophysiological (EP) studies, both diagnostic and therapeutic.

**Cardiac Catheterization Laboratory:** A room or suite of rooms in a hospital, freestanding facility, or a mobile laboratory that has the equipment, staff, and support services to function as an integrated unit for the purposes of performing cardiac catheterization procedures.



**Diagnostic Cardiac Catheterization:** The performance of cardiac catheterization for the purpose of detecting and identifying defects in the great arteries or veins of the heart, or abnormalities in the heart structure, whether congenital or acquired. Diagnostic cardiac catheterization services include, but are not limited to, left heart catheterizations, right heart catheterizations, left ventricular angiography, coronary procedures, and other cardiac catheterization services of a diagnostic nature. Post-operative evaluation of the effectiveness of prostheses also can be accomplished through a diagnostic catheterization procedure.

**Therapeutic Cardiac Catheterization:** The performance of cardiac catheterization for the purpose of correcting or improving certain conditions that have been determined to exist in the heart or great arteries or veins of the heart. This includes Percutaneous Coronary Interventions (PCI) or any catheter-based treatment procedures for relieving coronary artery narrowing. Included within this definition are procedures such as rotational atherectomy, directional atherectomy, extraction atherectomy, laser angioplasty, implantation of intracoronary stents, brachytherapy, and other catheter treatments for treating coronary atherosclerosis.

**Cardiac Catheterization Procedure:** A medical diagnostic or therapeutic intervention during which a catheter is manipulated by a physician to travel along the course of a blood vessel into the chambers or vessels of the heart. When the catheter is in place, the physician is able to perform various diagnostic studies and/or therapeutic procedures in the heart. For the purposes of measuring operator/physician volume under Standard 7, each procedure performed during a cardiac catheterization case following the catheterization shall count toward that operator/physician's volume.

**Electrophysiological (EP) Study:** An invasive procedure that tests the heart's electrical system through a catheter typically from the groin to the heart. Once the catheter is placed in the heart by the physician, electrical signals are sent through the catheter to the heart tissue to evaluate the electrical conduction system contained within the heart muscle tissue. An EP study can be performed solely for diagnostic purposes to pinpoint the exact location of electrical signals (cardiac mapping) or in conjunction with a therapeutic procedure called catheter ablation. The procedures (both diagnostic and therapeutic studies) are performed in a specially equipped laboratory and under controlled clinical circumstances by cardiologists and nurses who sub-specialize in electrophysiology.

**Diagnostic Electrophysiological Study:** An invasive test performed that allows an electrophysiologist to determine the details of abnormal heartbeats, or arrhythmias. Measurements related to the electrical system within the heart are made at baseline and during stimulation to provide information about the exact location and type of arrhythmia so that specific treatment can be given. During this testing, cardiac mapping through the use of catheter manipulation or 3-dimensional systems may take place. The arrhythmia may start from any area of the heart's electrical conduction system.

**Therapeutic Electrophysiological Study:** In conjunction with the diagnostic electrophysiological study, a therapeutic procedure called catheter ablation may be performed. Catheter ablation is most commonly done through the delivery of radio-frequency energy or cryo-energy to an area of the heart to selectively destroy cardiac tissue.

**Peripheral Vascular Catheterization:** An invasive medical procedure that may be performed within a cardiac catheterization laboratory. The procedure involves the insertion of a catheter into a peripheral artery or vein for diagnostic or therapeutic purposes. This procedure is used to evaluate the presence of plaque build-up (Atherosclerosis) in the peripheral arteries – meaning the arteries to the lower abdomen, kidneys, arms, legs, head, neck and feet.

**Diagnostic Peripheral Vascular Catheterization:** An invasive diagnostic test in which a catheter is inserted into a peripheral vein or artery to inject dye (contrast medium). X-rays are taken of the dye within the arteries, allowing clear visualization of the blood flow inside the artery where peripheral vascular disease can occur. This test may be performed within a cardiac catheterization laboratory.

**Therapeutic Peripheral Vascular Catheterization:** A procedure that can be used to dilate (widen) narrowed or blocked peripheral arteries or to remove a clot or plaque from arteries. In conjunction with or subsequent to peripheral vascular catheterization, a therapeutic procedure may be performed by various means that include balloon angioplasty, stenting, and atherectomy or other mechanical intervention to restore blood flow to the effected organ or tissue. These procedures may be performed within a cardiac catheterization laboratory.

- a) **Balloon Angioplasty:** A thin tube called a catheter with a deflated balloon on its tip is passed into the narrowed artery segment. The balloon is then inflated, compressing the plaque and dilating the narrowed artery so that blood can flow more easily. The balloon is then deflated and the catheter is withdrawn.
- b) **Peripheral Stenting:** A cylindrical, wire mesh tube that expands and locks open - may be placed in the narrowed artery with another catheter to keep the diseased artery open.
- c) **Catheter-based Atherectomy:** A procedure for opening up an artery using a specialized catheter inserted into a blocked artery to remove a buildup of plaque. The catheter may contain a sharp rotating blade (“burr” device), dissectional device (grinding bit), or laser filament to remove the plaque. It may be used as a complement to angioplasty and stenting.

Note: Additional procedures may be added as technology evolves.

**Cardiac Catheterization Case:** For the purposes of measuring a facility’s volume of cardiac catheterization procedures under Standards 11, 14, 19, and 22, a “case” shall mean one visit to a cardiac catheterization laboratory or another procedure room by one patient, regardless of the number of procedures performed during that visit.

**Cardiac Catheterization Weighted Case:** For the purposes of these standards and criteria and for measuring laboratory capacity, a “weighted case” shall mean one visit to a cardiac catheterization laboratory or another procedure room by one patient. If multiple procedures are performed between admission and discharge to the laboratory or procedure room, the weighted case is equal to the highest weighted diagnostic–equivalent procedure performed during the case.

**Diagnostic-Equivalent Procedure and Weights:** For the purposes of measuring laboratory capacity, the following weights will be assigned to each of the following procedure categories. All procedures that fall under the following categories shall count towards measuring laboratory capacity, but only diagnostic and therapeutic cardiac catheterization procedures as defined in these Standards and Criteria may count towards Standards 11, 14, 19, and 22 regarding minimum volume.

Category	Procedures Included	Weight
Diagnostic Cardiac Catheterization	Left heart catheterization, right heart catheterization, left/right heart catheterization, intravascular ultrasound, endomyocardial biopsy	1.0
Diagnostic Peripheral Vascular Catheterization	Abdominal angioplasty with runoff, carotid, renal, bilateral extremity	1.5
Therapeutic Cardiac Catheterization	PCI, atherectomy, ASD/PFO closures, Impella, IABP, valvuloplasty	2.0
Therapeutic Peripheral Vascular Catheterization	All of the procedures in the diagnostic peripheral category with either angioplasty, stent placement, atherectomy, thrombolysis	3.0
Diagnostic Electrophysiological Studies	Atrial and ventricular pacing and recording, device placement	2.0
Therapeutic Electrophysiological Studies	Ablations, lead revision	4.0
Pediatrics	Any cardiac catheterization procedure performed on a person less than 18 years of age	Double the adult weight

**Cardiac Catheterization Laboratory Capacity:** The capacity of dedicated and multipurpose cardiac catheterization laboratories is equal to 2000 weighted cases per year. This number is based on 50 weeks of 40 hours each, assuming an average case time, including room turnover and setup, of 60 minutes.

**Pediatric Cardiac Catheterization Laboratory:** A room or suite of rooms in an acute care hospital that has the equipment, staff, and support services to function as an integrated unit for the purposes of performing cardiac catheterization procedures on a person under 15 years of age. Pediatric cardiac catheterization laboratories should only

be situated in facilities offering full pediatric cardiac medical and cardiac surgical capabilities, including pediatric open heart surgery.

**Mobile Cardiac Catheterization Laboratory:** A cardiac catheterization laboratory and transporting equipment that is moved to provide services at two or more host acute care campuses, including facilities located in adjoining or contiguous states of the Continental United States. Mobile cardiac catheterization laboratories shall perform diagnostic procedures only, unless they are permanently fixed at an acute care hospital with on-site open heart surgery capability. However, facilities approved to perform therapeutic cardiac catheterizations without on-site open heart surgery backup may temporarily perform these procedures in a mobile laboratory on the hospital's campus during construction impacting the fixed laboratories.

**Mobile Cardiac Catheterization Laboratory Capacity:** The capacity measures of a mobile cardiac catheterization laboratory are the same as a regular dedicated or multipurpose cardiac catheterization laboratory; however, capacity shall be measured on a pro-rated schedule per week day of operation (400 weighted cases per week day of operation).

**Freestanding Facility:** Any professional or business undertaking, whether for profit or not for profit, which offers or proposes to offer any clinical health service in a setting which is not on the campus of an acute care facility. Freestanding facilities may perform diagnostic procedures only.

**Service Area:** The geographic area defined in terms of counties represented by the applicant as the reasonable area to which the cardiac catheterization laboratory intends to provide services and in which at least 75% of its recipients reside. At least 75% of the population of a service area for cardiac catheterizations should reside within 60 miles driving distance of the facility.

**Age Group-Specific Historical State Utilization Rate:** For the purposes of defining need in areas with no existing cardiac catheterization services, applicants should base their projected utilization on age group-specific historical state utilization rates. The age group-specific historical state utilization rates shall be calculated as follows based upon information from the Hospital Discharge Data System and the population estimates maintained by the Department of Health:

- Each age group is defined by the following age intervals: <18, 18-29, 30-39, 5 year intervals for 40-84 (i.e., 40-44, 45-49), and >85.
- For each age group, multiply the number of state residents in that age category by the corresponding number of cardiac catheterization procedures performed on patients in that age category.
- Determine the age group-specific historical state utilization rate based upon the average of single-year rates calculated from the most recent three years of available data.

The age group-specific historical state utilization rate will be calculated separately for diagnostic and therapeutic catheterization cases and will be a running average. The

Department of Health shall maintain the ongoing age group-specific historical state utilization rate to avoid breaches of patient confidentiality.

## Standards and Criteria Regarding Certificate of Need Applications for All Cardiac Catheterization Services

Applicants proposing to provide any type of cardiac catheterization services must meet the following minimum standards:

1. **Compliance with Standards:** The Division of Health Planning is working with stakeholders to develop a framework for greater accountability to these Standards and Criteria. Applicants should indicate whether they intend to collaborate with the Division and other stakeholders on this matter.
2. **Facility Accreditation:** If the applicant is not required by law to be licensed by the Department of Health, the applicant should provide documentation that the facility is fully accredited or will pursue accreditation by the Joint Commission or another appropriate accrediting authority recognized by the Centers for Medicare and Medicaid Services (CMS).
3. **Emergency Transfer Plan:** Applicants for cardiac catheterization services located in a facility without open heart surgery capability should provide a formalized written protocol for immediate and efficient transfer of patients to a nearby open heart surgical facility (within 60 minutes) that is reviewed/tested on a regular (quarterly) basis.
4. **Quality Control and Monitoring:** Applicants should document a plan to monitor the quality of its cardiac catheterization program, including, but not limited to, program outcomes and efficiency. In addition, the applicant should agree to cooperate with quality enhancement efforts sponsored or endorsed by the State of Tennessee, which may be developed per Policy Recommendation 2.
5. **Data Requirements:** Applicants should agree to provide the Department of Health and/or the Health Services and Development Agency with all reasonably requested information and statistical data related to the operation and provision of services and to report that data in the time and format requested. As a standard of practice, existing data reporting streams will be relied upon and adapted over time to collect all needed information.
6. **Clinical and Physical Environment Guidelines:** Applicants should agree to document ongoing compliance with the latest clinical guidelines of the American College of Cardiology/Society for Cardiac Angiography and Interventions Clinical Expert Consensus Document on Cardiac Catheterization Laboratory Standards (ACC Guidelines). As of the adoption of these Standards and Criteria, the latest version (2001) may be found online at:  
<http://www.acc.org/qualityandscience/clinical/consensus/angiography/dirIndex.htm>.

Where providers are not in compliance, they should maintain appropriate documentation stating the reasons for noncompliance and the steps the provider is taking to ensure quality. These guidelines include, but are not limited to, physical facility requirements, staffing, training, quality assurance, patient safety, screening patients for appropriate settings, and linkages with supporting emergency services.

7. **Staffing Recruitment and Retention:** The applicant should generally describe how it intends to maintain an adequate staff to operate the proposed service, including, but not limited to, any plans to partner with an existing provider for training and staff sharing.
8. **Definition of Need for New Services:** A need likely exists for new or additional cardiac catheterization services in a proposed service area if the average current utilization for all existing and approved providers is equal to or greater than 70% of capacity (i.e., 70% of 2000 cases) for the proposed service area.
9. **Proposed Service Areas with No Existing Service:** In proposed service areas where no existing cardiac catheterization service exists, the applicant must show the data and methodology used to estimate the need and demand for the service. Projected need and demand will be measured for applicants proposing to provide services to residents of those areas as follows:

**Need.** The projected need for a service will be demonstrated through need-based epidemiological evidence of the incidence and prevalence of conditions for which diagnostic and/or therapeutic catheterization is appropriate within the proposed service area.

**Demand.** The projected demand for the service shall be determined by the following formula:

- A. Multiply the age group-specific historical state utilization rate by the number of residents in each age category for each county included in the proposed service area to produce the projected demand for each age category;
- B. Add each age group's projected demand to determine the total projected demand for cardiac catheterization procedures for the entire proposed service area.

10. **Access:** In light of Rule 0720-4-.01 (1), which lists the factors concerning need on which an application may be evaluated, 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 documents that the service area population experiences a prevalence, incidence and/or mortality from heart and cardiovascular diseases or other clinical conditions applicable to cardiac catheterization services that is substantially higher than the State of Tennessee average;
- c. Who is a “safety net hospital” as defined by the Bureau of TennCare Essential Access Hospital payment program; or
- d. 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.

### **Specific Standards and Criteria for the Provision of Diagnostic Cardiac Catheterization Services Only**

If an applicant does not intend to provide therapeutic cardiac catheterization services, the HSDA should place a condition on the resulting CON limiting the applicant to providing diagnostic cardiac catheterization services only. Applicants proposing to provide only diagnostic cardiac catheterization services should meet the following minimum standards:

- 11. **Minimum Volume Standard:** Such applicants should demonstrate that the proposed service utilization will be a minimum of 300 diagnostic cardiac catheterization cases per year by its third year of operation. Annual volume shall be measured based upon a two-year average which shall begin at the conclusion of the applicant’s first year of operation. If the applicant is proposing services in a rural area where the HSDA determines that access to diagnostic cardiac catheterization services has been limited, and if the applicant is pursuing a partnership with a tertiary facility to share and train staff, the Agency may determine that a minimum volume of 200 cases per year is acceptable. Only cases including diagnostic cardiac catheterization procedures as defined by these Standards and Criteria may count towards meeting this minimum volume standard.
- 12. **High Risk/Unstable Patients:** Such applicants should (a) delineate the steps, based on the ACC Guidelines, that will be taken to ensure that high-risk or unstable patients are not catheterized in the facility, and (b) certify that therapeutic cardiac catheterization services will not be performed in the facility unless and until the applicant has received Certificate of Need approval to provide therapeutic cardiac catheterization services.



13. **Minimum Physician Requirements to Initiate a New Service:** The initiation of a new diagnostic cardiac catheterization program should require at least one cardiologist who performed an average of 75 diagnostic cardiac catheterization procedures over the most recent five year period. All participating cardiologists in the proposed program should be board certified or board eligible in cardiology and any relevant cardiac subspecialties.

## **Specific Standards and Criteria for the Provision of Therapeutic Cardiac Catheterization Services**

Applicants proposing to provide therapeutic cardiac catheterization services must meet the following minimum standards:

14. **Minimum Volume Standard:** Such applicants should demonstrate that the proposed service utilization will be a minimum of 400 diagnostic and/or therapeutic cardiac catheterization cases per year by its third year of operation. At least 75 of these cases per year should include a therapeutic cardiac catheterization procedure. Annual volume shall be measured based upon a two-year average which shall begin at the conclusion of the applicant's first year of operation. Only cases including diagnostic and therapeutic cardiac catheterization procedures as defined by these Standards and Criteria shall count towards meeting this minimum volume standard.
15. **Open Heart Surgery Availability:** Acute care facilities proposing to offer adult therapeutic cardiac catheterization services shall not be required to maintain an on-site open heart surgery program. Applicants without on-site open heart surgery should follow the most recent American College of Cardiology/American Heart Association/Society for Cardiac Angiography and Interventions Practice Guideline Update for Percutaneous Coronary Intervention (ACC/AHA/SCAI Guidelines). As of the adoption of these Standards and Criteria, the latest version of this document (2007) may be found online at:  
<http://circ.ahajournals.org/cgi/reprint/CIRCULATIONAHA.107.185159>

Therapeutic procedures should not be performed in freestanding cardiac catheterization laboratories, whether fixed or mobile. Mobile units may, however, perform therapeutic procedures provided the mobile unit is located on a hospital campus and the hospital has on-site open heart surgery. In addition, hospitals approved to perform therapeutic cardiac catheterizations without on-site open heart surgery backup may temporarily perform these procedures in a mobile laboratory on the hospital's campus during construction impacting the fixed laboratories.

16. **Minimum Physician Requirements to Initiate a New Service:** The initiation of a new therapeutic cardiac catheterization program should require at least two cardiologists with at least one cardiologist having performed an average of 75

therapeutic procedures over the most recent five year period. All participating cardiologists in the proposed program should be board certified or board eligible in cardiology and any relevant cardiac subspecialties.

17. **Staff and Service Availability:** Ideally, therapeutic services should be available on an emergency basis 24 hours per day, 7 days per week through a staff call schedule (24/7 emergency coverage). In addition, all laboratory staff should be available within 30 minutes of the activation of the laboratory. If the applicant will not be able to immediately provide 24/7 emergency coverage, the applicant should present a plan for reaching 24/7 emergency coverage within three years of initiating the service or present a signed transfer agreement with another facility capable of treating transferred patients in a cardiac catheterization laboratory on a 24/7 basis within 90 minutes of the patient's arrival at the originating emergency department.
18. **Expansion of Services to Include Therapeutic Cardiac Catheterization:** An applicant proposing the establishment of therapeutic cardiac catheterization services, who is already an existing provider of diagnostic catheterization services, should demonstrate that its diagnostic cardiac catheterization unit has been utilized for an average minimum of 300 cases per year for the two most recent years as reflected in the data supplied to and/or verified by the Department of Health.

## **Specific Standards and Criteria for the Provision of Pediatric Cardiac Catheterization Services**

Applicants proposing to provide pediatric cardiac catheterization services should meet the following minimum standards:

19. **Minimum Volume Standard:** Such applicants should demonstrate that the proposed service utilization will be a minimum of 100 cases per year by its third year of operation. Annual volume shall be measured based upon a two-year average which shall begin at the conclusion of the applicant's first year of operation. Only cases that include diagnostic and therapeutic cardiac catheterization procedures as defined by these Standards and Criteria shall count towards meeting this minimum volume standard.
20. **Minimum Physician Requirements to Initiate a New Service:** The initiation of a new pediatric cardiac catheterization program should require at least two cardiologists with at least one cardiologist having performed an average of 50 pediatric cardiac catheterization procedures over the most recent five year period. Pediatric cardiac catheterization procedures should be performed only by board certified or board eligible physicians specializing in pediatric cardiac care.

21. **Open Heart Surgery Availability:** Such applicants should offer full pediatric cardiac medical and cardiac surgical capabilities, including pediatric open heart surgery.

## **Specific Standards and Criteria for the Offering of Mobile Cardiac Catheterization Services**

The need for mobile cardiac catheterization services should be based upon the following minimum standards:

22. **Minimum Volume Standard:** Such applicants should demonstrate that the proposed service utilization will be a minimum of 60 cardiac catheterization cases per day of operation per year by its third year of operation. Annual volume shall be measured based upon a two-year average which shall begin at the conclusion of the applicant's first year of operation. If the applicant is proposing services in a rural area where the HSDA determines that access to diagnostic cardiac catheterization services has been limited, and if the applicant is pursuing a partnership with a tertiary facility to share and train staff, the Agency may determine that a minimum volume of 40 cases per day of operation per year is acceptable. Only cases that included diagnostic cardiac catheterization procedures may count towards meeting this minimum volume standard.
23. **Limitations on Procedure Types in Mobile Facilities:** No therapeutic or pediatric cardiac catheterization procedures should be performed using a mobile laboratory unless the mobile unit is located on a hospital campus with on-site open heart surgery capability and, in the case of a pediatric procedure, offers full pediatric cardiac medical and cardiac surgical capabilities. On a temporary basis, however, the same scope of services offered in a fixed laboratory may be offered in a mobile laboratory only for the duration of construction impacting the fixed laboratory.
24. **Non-Cardiologist Physician and Staff Competence:** In cases where attending cardiologists live more than 30 minutes from the mobile laboratory and/or typically leave after performing a procedure, the applicant should document that a sufficient number of physicians and support staff at the facility have an understanding of the potential complications of cardiac catheterization and are an integral part of the program's management process.

# Rationale for Revised and Updated Standards and Criteria for Cardiac Catheterization Services

## Definitions

**Diagnostic-Equivalent Procedure and Weights:** The Division recognizes that a variety of procedures may be performed in a cardiac catheterization laboratory, including procedures not specifically defined as cardiac catheterization procedures. Thus, in order to allow for a consistent measurement of cardiac catheterization laboratory capacity, the Division includes the above procedure weighting system in these Standards and Criteria. The weighting system was developed in consultation with the Tennessee Hospital Association, which in turn consulted with its member hospitals.

## Standards and Criteria Regarding Certificate of Need Applications for All Cardiac Catheterization Services

1. **Compliance with Standards:** Meetings with providers throughout Tennessee revealed widespread agreement on the need for greater ongoing enforcement of CON standards and criteria. Providers felt that applicants should be held accountable for the promises they make in an application. The Division of Health Planning is currently in discussions with the Department of Health, the HSDA, and other CON stakeholders on the subject of how to devise a reasonable system of CON accountability. The specifics of increased accountability for providers offering CON-regulated services should be developed through a public process that includes all interested stakeholders.
2. **Facility Accreditation:** As a condition of licensure, hospitals must be inspected by a Department of Health surveyor. While accreditation is not a condition of hospital licensure in Tennessee, freestanding cardiac catheterization laboratories in Tennessee are not required to be licensed and, subsequently, are not surveyed by a quality review panel. In order to promote a safe environment for a high-risk procedure such as cardiac catheterization, the Division believes that all facilities providing cardiac catheterization services should be surveyed by a proper authority, such as the Department of Health or a nationally recognized accrediting body such as the Joint Commission. Ensuring that each facility meets high performance standards is particularly relevant to the policy statement concerning quality found in TCA § 68-11-1625(b): “Every citizen should have confidence that the quality of health care is continually monitored and standards are adhered to by health care providers.” This standard seeks to hold all applicants seeking to provide cardiac catheterization services to a similar standard of accountability.

3. **Emergency Transfer Plan:** Responses to the Questionnaire indicated widespread agreement on the importance of this standard. While this standard is included in the most recent ACC/AHA/SCAI Practice Guideline Update for Percutaneous Coronary Intervention, the Division believes that patient safety issues necessitate greater scrutiny during the CON application process.
4. **Quality Control and Monitoring:** The Division had considered requiring applicants to participate in the National Cardiovascular Data Registry (NCDR). Respondents to the Questionnaire agreed with the intent of such a requirement, however most respondents indicated that the costs of participation in the NCDR are burdensome, especially for new cardiac catheterization programs. Consequently, this standard seeks to ensure that applicants will develop a comprehensive quality control system that best fits their circumstances and that applicants participate in ongoing efforts to improve the overall quality of cardiac care in Tennessee.
5. **Data Requirements:** Currently, the Hospital Joint Annual Report (JAR) does not contain the level of detail needed by the HSDA to consider properly cardiac catheterization CON applications. As stated in Policy Recommendation 5, the Division is committed to working with CON stakeholders to modify existing data reporting streams to meet the data needs of the CON process.
6. **Clinical and Physical Environment Guidelines:** Respondents to the Questionnaire agreed that the ACC Guidelines should serve as the State's standard for quality. Respondents also agreed that it is reasonable for facilities to demonstrate where they are not in compliance with the ACC Guidelines and the subsequent measures the facility is taking to ensure quality. Maintaining compliance could be incorporated into existing licensure and accreditation review processes by the Department of Health and the Joint Commission. Through discussions concerning Policy Recommendation 2, the Division will work with the Department of Health to develop a reasonable review process.
7. **Staffing Recruitment and Retention:** As stated in TCA § 68-11-1625(b), "The state should support the recruitment and retention of a sufficient and quality health care workforce." Moreover, maintaining and developing an adequate staff is essential to the quality and ongoing availability of the proposed service. This standard is also intended to ensure that applicants will not significantly affect the ability of existing providers to maintain an adequate staff.
8. **Definition of Need for New Services:** Respondents to the Questionnaire agreed that this standard is reasonable. This standard is comparable to other states' standards defining need for additional cardiac catheterization services.
9. **Proposed Service Areas with No Existing Service:** For proposed service areas with no existing services, precisely determining need and demand may be difficult. Several other states rely both on existing utilization rates and

epidemiological evidence to help project need and demand. The age groups were determined based upon recommendations from and data provided by the Department of Health. This standard sets clear guidelines for demonstrating need and demand while giving the HSDA flexibility to consider appropriately each application. Over time, as utilization data is reported and more actively analyzed by the Department of Health and the Division of Health Planning, this standard may be revised to predict more accurately need and demand.

10. **Access:** One of the five Principles for Achieving Better Health contained in the State Health Plan is that “Every citizen should have reasonable access to health care.” Thus, issues affecting access to health care should be considered in the CON process. These criteria build upon the overarching CON criterion of need to provide the HSDA with clearer guidance on improving access to health care. Respondents to the Questionnaire mostly agreed that subsection (d) is reasonable and would not disadvantage providers in negotiations with MCOs.

### **Specific Standards and Criteria for the Provision of Diagnostic Cardiac Catheterization Services Only**

11. **Minimum Volume Standard:** Questionnaire respondents generally agreed that 300 weighted cases per year is an appropriate minimum volume standard for a diagnostic catheterization program. Such a standard is consistent with nationally recognized guidelines. For the rural exception, given the requirement that the applicant share staff with a tertiary facility, a proper amount of experience to maintain competency should be maintained. In addition, provided that other procedures may be performed in a cardiac catheterization laboratory, this standard sets a minimum volume only for diagnostic cardiac catheterizations per nationally recognized guidelines. Finally, this standard addresses a concern raised by a Questionnaire respondent—an applicant should not rely predominantly on projected EP study and peripheral vascular procedures to demonstrate the need for a cardiac catheterization laboratory.
12. **High Risk/Unstable Patients:** This standard is consistent with nationally recognized guidelines. Moreover, given the increased resources and clinical expertise needed to provide therapeutic cardiac catheterization services and in order to promote the orderly development of the health care system, the Division proposes that it is appropriate to require CON approval to initiate such services.
13. **Minimum Physician Requirements to Initiate a New Service:** It may be financially difficult for applicants seeking to provide a diagnostic cardiac catheterization service in a rural area to initiate the service with two full-time cardiologists. Given the lower level of risk associated with diagnostic-only programs, this standard allows an applicant to build more easily a diagnostic cardiac catheterization program over time. This standard is consistent with the

recommendations of the ACC Expert Consensus Document on Cardiac Catheterization Laboratory Standards.

## **Specific Standards and Criteria for the Provision of Therapeutic Cardiac Catheterization Services**

14. **Minimum Volume Standard:** Questionnaire respondents generally agreed that 400 weighted cases per year is an appropriate minimum volume standard for a diagnostic and therapeutic catheterization program and is consistent with nationally recognized guidelines. In addition, this standard addresses a concern raised by a Questionnaire respondent—an applicant cannot rely predominantly on projected EP study and peripheral vascular procedures to demonstrate the need for a cardiac catheterization laboratory.
15. **Open Heart Surgery Availability:** The Division is sensitive to the disagreement in the provider community on the availability of on-site open heart surgery to perform therapeutic cardiac catheterizations. However, given national trends to expand the accessibility of therapeutic services and the protocols recommended by the ACC/AHA/SCAI to provide such services in an appropriate setting, the Division proposes that this standard is appropriate for Tennessee. Moreover, a more organized, statewide approach to quality as proposed in Policy Recommendation 2 will contribute to more accessible, high quality services.
16. **Minimum Physician Requirements to Initiate a New Service:** In meetings with providers throughout Tennessee, the Division heard a concern that new therapeutic programs should not be initiated solely by inexperienced physicians. This standard is consistent with the recommendations of the ACC Expert Consensus Document on Cardiac Catheterization Laboratory Standards.
17. **Staff and Service Availability:** Respondents to the Questionnaire generally favored including a standard requiring 24/7 emergency coverage for therapeutic cardiac catheterization programs, which is consistent with nationally recognized guidelines. However, upon consideration of a comment on the Draft Standards, the Division has revised this standard to reflect the difficulties of initiating a new service with immediate 24/7 emergency coverage.

24/7 emergency coverage provides a consistent service to a community, giving community residents an accurate expectation of the care available locally to them, and demonstrates committed financial and programmatic investment in providing a very resource-intensive service. However, for the very reason that providing 24/7 emergency coverage is such a resource-intensive endeavor, we recognize that opening a new cardiac catheterization program with immediate 24/7 coverage could prove overly burdensome.

However, allowing expedient transfer during a cardiac catheterization laboratory's non-operating hours provides an opportunity for a larger number of facilities, particularly in suburban and rural areas, that could provide therapeutic cardiac catheterization services. An unintended consequence of allowing too many cardiac catheterization providers in a region could be to adversely affect those providers seeking to maintain 24/7 emergency coverage.

This final standard reflects the above considerations to provide a process that ultimately yields greater access to therapeutic cardiac catheterization services.

- 18. Expansion of Services to Include Therapeutic Cardiac Catheterization:** This standard pertains to the orderly development of the health care system, as successful diagnostic cardiac catheterization programs are more likely to have the resources and patient base to expand the services offered. The Division recognizes that this standard does not address an applicant currently providing no cardiac catheterization services that proposes to provide both diagnostic and therapeutic cardiac catheterization services. The Division particularly welcomes feedback on how best to promote the orderly development of cardiac catheterization services under these circumstances.

### **Specific Standards and Criteria for the Provision of Pediatric Cardiac Catheterization Services**

- 19. Minimum Volume Standard:** This standard is consistent with national guidelines on the provision of pediatric cardiac catheterization services.
- 20. Physician Requirements:** This standard is consistent with the most recent ACC Clinical Expert Consensus Document on Catheterization Laboratory Standards.
- 21. Open Heart Surgery Availability:** This standard is consistent with the most recent ACC Clinical Expert Consensus Document on Catheterization Laboratory Standards.

### **Specific Standards and Criteria for the Offering of Mobile Cardiac Catheterization Services**

- 22. Minimum Volume Standard:** Questionnaire respondents generally agreed with a prorated minimum volume standard for a diagnostic catheterization program offered in a mobile laboratory. Such a standard is consistent with nationally recognized guidelines. For the rural exception, given the requirement that the applicant share staff with a tertiary facility, a proper amount of experience to maintain competency should be maintained. In addition, provided that other procedures may be performed in a cardiac catheterization laboratory, this standard sets a minimum volume only for diagnostic cardiac catheterizations per nationally



recognized guidelines. Finally, this standard addresses a concern raised by a Questionnaire respondent; an applicant should not be able to rely predominantly on projected EP study and peripheral vascular procedures to demonstrate the need for a mobile cardiac catheterization laboratory.

23. **Limitations on Procedure Types in Mobile Facilities:** Several respondents to the Questionnaire indicated that, especially in temporary situations, such as during a physical expansion of a hospital, cardiac catheterization services may need to be moved to a temporary laboratory. This standard allows cardiac catheterization programs to maintain consistency in their scope of services during construction impacting fixed laboratories.
  
24. **Non-Cardiologist Physician and Staff Competence:** In rural settings where the provision of cardiac catheterization services is sought to increase access to health care, it is likely that the attending cardiologist will not reside in close proximity to the mobile laboratory. This standard is intended to assure the competency of the full-time facility staff to manage the cardiac catheterization laboratory and to deal effectively with complications and emergencies. This standard is consistent with the most recent ACC Clinical Expert Consensus Document on Catheterization Laboratory Standards.



STATE OF TENNESSEE

**STATE HEALTH PLAN**  
**POLICY RECOMMENDATIONS FOR IMPROVING THE PROVISION**  
*OF*  
**CARDIAC CATHETERIZATION SERVICES**

The 2009 State Health Plan expresses *Five Principles for Achieving Better Health*. These include:

- 1. The purpose of the State Health Plan is to improve the health of Tennesseans*
- 2. Every citizen should have reasonable access to health care*
- 3. 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*
- 4. Every citizen should have confidence that the quality of health care is continually monitored and standards are adhered to by health care providers*
- 5. The state should support the development, recruitment, and retention of a sufficient and quality health care workforce*

Note that Principles 2-5 are derived from the policy statements contained in TCA § 68-11-1625(b). The State Health Plan Advisory Committee also advised the addition of Principle 1.

In light of these principles, the 2009 State Health Plan sets forth the following policy recommendations specifically relating to the provision of cardiac catheterization services in Tennessee. These recommendations are the result of extensive dialog between the Division of Health Planning, other state departments and agencies, and members of the provider community throughout Tennessee. They are intended to provide direction to all providers of cardiac catheterization services and to the Health Services and Development Agency (HSDA) in considering applications for such services. However, these recommendations extend beyond the current certificate of need (CON) program and are not to be considered standards and criteria by the HSDA in granting CON applications.

In order to implement these recommendations, the Division intends to work with providers of cardiac catheterization, the Tennessee Department of Health, and other health planning stakeholders to pursue necessary information, dialog, and action steps and to identify measurable objectives.

1. **Access to Emergency Services:** Every citizen in Tennessee experiencing the onset of emergency symptoms related to ST-Segment Elevation Myocardial Infarction (STEMI) should be able to receive emergent coronary intervention within 90 minutes of presenting to an emergency department. In addition, every citizen in Tennessee should be within 90 minutes driving time of a hospital offering appropriate services for such a condition.

Rationale: The first part of this recommendation recognizes the importance of prudently administering emergency care for STEMI patients. A “door to balloon time” of 90 minutes is consistent with nationally recognized guidelines. The second part of this recommendation refers to the accessibility of therapeutic cardiac catheterization services. In meetings with providers throughout Tennessee, participants stressed the importance of receiving emergency cardiac care in a timely manner. The Division recommends that the CON program help ensure that citizens in Tennessee have ready access to high quality emergency cardiac catheterization services.

2. **Assuring the Monitoring of Health Care Quality:** In order to assure citizens in Tennessee that health care quality is monitored, all providers of cardiac catheterization services should participate in a systematic quality-monitoring program that allows comparability of quality (outcomes) and performance (efficiency) among providers. The State of Tennessee recognizes the National Cardiovascular Data Registry (NCDR)<sup>1</sup> as the gold standard for such a program. In addition, the State of Tennessee should consider how best to develop a reasonable quality review program that could include the NCDR or another approach deemed more appropriate for Tennessee.

Rationale: Meetings with providers throughout Tennessee revealed widespread interest in a focused effort to improve the quality of cardiac care in our state. Providers pointed to the NCDR as the best system available to monitor and help improve quality. However, participation in the NCDR is data intensive and requires substantial staff time. The Division believes that quality monitoring and improvement efforts are vital to improving our health and health care system; however, the Division is also sensitive to the burdens such efforts can place on providers to the detriment of their patients. In addition, several providers suggested that the State should convene a group of practitioners that could review sensitive quality information and advise the State accordingly. The Division agrees that such a group could contribute to quality improvement efforts, though the Division does not have a position on the makeup of this group or how it would

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<sup>1</sup> View website: <https://www.ncdr.com/>

interact with the State. The Division's preferred first step in this matter is to consult with the Department of Health on the development of a reasonable quality monitoring and improvement system that will collect appropriate data for analysis without overly burdening providers.

- 3. Accommodating a Clarified Definition of Cardiac Catheterization Services:** The Certificate of Need program in Tennessee has lacked clarity on the definition of cardiac catheterization services, including whether electrophysiological (EP) studies specifically qualify as a cardiac catheterization service. Based upon numerous provider interviews and consultation with the Tennessee Hospital Association, the Division of Health Planning has determined that, for the purpose of the Certificate of Need program, EP studies are a cardiac catheterization service. Both procedures involve similar clinical methods, similar sets of expertise, and similar—if not the same—equipment. Given this clarification of the definition of cardiac catheterization services, the State of Tennessee, led by the Division of Health Planning and the Department of Health, should review the ramifications for the licensure system and for existing providers of EP services—particularly those providers who initiated EP services without receiving a CON for cardiac catheterization services. This review may result in a revision of these standards and criteria for cardiac catheterization services to further specify specific standards for EP procedures.

Rationale: Several respondents to the Questionnaire on Cardiac Catheterization Services for the Revision of Certificate of Need Standards and Criteria (Questionnaire) strongly urged the Division to clarify the definition of cardiac catheterization services and decide whether or not to include EP studies in the definition. With assistance from the Tennessee Hospital Association, the Division sought guidance from experts and current providers, the majority of whom agreed that EP studies are a cardiac catheterization service due to the reasons mentioned in the recommendation. Should this clarified definition have any ramifications for any current providers of EP studies, the Division intends to work with all appropriate parties to address any resulting concerns.

- 4. Assuring Health Care Quality Through Maintaining Physician Skill:** Tennesseans should be assured that providers of cardiac catheterization services provide quality care. In order to comply with nationally recognized guidelines intended to maintain physician proficiency, the Division recommends that all providers of adult cardiac catheterization services ensure that each physician participating in its program is performing 75 procedures per year based on a two-year average; all providers of pediatric cardiac catheterization services should ensure that each physician participating in its program is performing 50 pediatric procedures per year based on a two-year average. These cases do not necessarily have to be performed at the same facility. The data needed to verify operator volumes is currently collected by the Department of Health through its Hospital Discharge Data System. The Division sees this effort closely connected with Policy Recommendation 2.

Rationale: The American College of Cardiology recommends that interventional cardiologists perform at least 75 procedures per year and that pediatric cardiologists perform at least 50 procedures per year to maintain proficiency. Respondents to the Questionnaire agreed that maintaining individual physician volume is relevant to providers of all types of cardiac catheterization services. The Division recognizes that many physicians operate at multiple facilities, which is reflected in this recommendation. In addition, the Division suggests that the implementation of this recommendation be included in the future, broader discussion of developing a quality improvement program referenced in Policy Recommendation 2.

5. **Improving Aggregate Utilization Data:** To promote an accurate understanding of the services available in Tennessee and to meet the data needs resulting from these revised standards and criteria, the Certificate of Need program requires more specific cardiac catheterization utilization data than is currently reported in the Joint Annual Report (JAR). Data needed includes summary level information on the number and type of procedures performed (including diagnostic cardiac catheterizations, elective and emergent therapeutic cardiac catheterizations, electrophysiological (EP) studies, percutaneous coronary intervention (PCI), and possibly other procedures); indications of whether the procedure was performed in a laboratory authorized under the CON program or in another setting (such as general operating room); each patient's county of residence; and revenue, ICD-9, and procedure codes.

The Division plans to work with the Department of Health, the HSDA, and stakeholders of the CON program to survey the universe of cardiac catheterization data already available to the State. This survey will include the Hospital Discharge Data System, the Joint Annual Report, and other sources identified as relevant. Based upon this survey, the Division may identify needed modifications or additions to current reporting streams. However, since some of these changes may take some time to implement, after considering currently available data the Division may recommend a temporary approach to more quickly collect data needed by the CON program. For instance, all providers of cardiac catheterization could voluntarily report the above summary level information to the HSDA through its Equipment Registry or to the Department of Health Division of Health Statistics as an addendum to the JAR.

Rationale: Once finalized, these standards and criteria will require additional data to properly consider an application to provide cardiac catheterization services. The Division intends to work with all relevant stakeholders to develop a rational and reasonable data compilation process to serve the CON program. The Division has held initial discussions with the Department of Health in preparation of this effort.

6. **Minimum Volume Standards and Program Quality:** All providers of cardiac catheterization services should strive to meet the appropriate minimum procedure volume standards prescribed by these or subsequent standards and criteria. The Division will work with the Department of Health to assess what steps could be taken should a provider fall below these minimum standards to assure program quality and integrity until the standard is met.

Rationale: Several respondents to the Questionnaire stated that all providers of cardiac catheterization services should be required to meet minimum volume requirements, not just new applicants. The Division agrees that volume standards should apply to all providers and intends to work with all relevant stakeholders to develop a reasonable review process in conjunction with Policy Recommendations 2 and 4.

7. **Developing Economic Efficiencies Through Increasing Efficiency and Accuracy of Information:** Capitalizing on and organizing the wealth of information generated through the health care system is key to increasing economic efficiency. All providers of cardiac catheterization services should strive to support the development of e-prescribing and electronic health records. Understanding that many delicate issues must be resolved before widespread adoption of these technologies may take place, providers should engage in the public process currently addressing these issues and pursue opportunities when feasible and where available.

Rationale: The Division had considered requiring applicants to comment on their current or intended use of e-prescribing and electronic health records. Respondents to the Questionnaire suggested that such comments would only add to the paperwork of filing an application without providing much benefit. The Division acknowledges this concern. However, the Division still encourages all providers to participate (and understands that many already do) in the public processes that are developing these technologies.

8. **Accountability for Existing Freestanding Providers:** The Division advises that it will work with the Department of Health to create a process through which existing freestanding providers of cardiac catheterization services that are not on a hospital campus receive oversight from a proper authority. This oversight should be extended to future freestanding providers of cardiac catheterization services.

Rationale: In revising these standards and criteria, the Division learned of a small number of freestanding providers of cardiac catheterization services that, as a result of legislative inconsistencies, are not required to be licensed by the Department of Health or any other proper authority. The Division believes that, in the interest of assuring the provision of quality care to the public, the Division should consult with the Department Health and the HSDA on how to resolve this matter and welcomes comments from stakeholders on appropriate action.

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# Tennessee State Health Plan

**2009**

## **Section 3**

### **Appendices C – H to the State Health Plan**

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## **APPENDIX C. Health Services and Planning Act Policy Statement**

### **Tennessee Code Annotated Section 68-11-1625(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.



## **Appendix D. State Task Forces and Specific Issue Health Plans**

The following are state planning task forces that have or are developing strategic plans concerning specific health issues. These plans will inform the development of the State Health Plan, and, through discussions with these task forces and relevant stakeholder groups, the Division of Health Planning may incorporate these plans into the State Health Plan.

### **Infections Task Force**

The Department of Health created the Infections Task Force in response to Public Chapter 323 (2005). The Task Force studies healthcare-acquired infections and makes recommendations to the Department of Health. The latest available report from the Task Force may be found here:

<http://health.state.tn.us/Downloads/MRSAreport307.pdf>.

### **Adult Emergency Oral Health Task Force**

Public Chapter 998 (2008) directed the Department of Health to convene a task force to “develop a statewide strategy for the provisions of adult emergency oral health care, utilizing public and private sector resources.” The task force produced an initial report with short and long-term recommendations in early 2009 and plans to continue meeting. The report may be found here:

<http://health.state.tn.us/Downloads/adultemoralhealth08.pdf>.

### **The Tennessee Alzheimer’s Disease Task Force**

Public Chapter 566 (2007) created the Tennessee Alzheimer’s Disease Task Force, “the public welfare requiring it.” The Task Force was “directed to assess the current and future impact of Alzheimer’s disease on Tennesseans; to examine the existing industries, services, and resources addressing the needs of persons with Alzheimer’s disease, their families, and caregivers; and to develop a strategy to mobilize a state response to this public health crisis.” The Task Force’s Final Report, prepared by the Tennessee Commission on Aging and Disability, is available here:

<http://www.tennessee.gov/comaging/documents/ataskforce.pdf>

### **The Tennessee Cervical Cancer Elimination Task Force**

Public Chapter 921 (2006) created the Tennessee Cervical Cancer Elimination Task Force as a subcommittee of the Tennessee Comprehensive Cancer Control Coalition. The Task Force has established a goal of eliminating cervical cancer by 2040. The group’s report, the Cervical Cancer Prevention Plan, is available here:

<http://health.state.tn.us/Downloads/CervicalCancerPreventionPlan.pdf>.

### **Tennessee Veterans Task Force (TMHDD)**

The Tennessee Veterans task force is a collaboration of the Tennessee Department of Mental Health and Development Disabilities and a number of veterans and mental health groups. The task force focuses on expanding and strengthening the system of care for active duty service members and returning veterans and their families by convening

trainings, compiling resources, and identifying gaps with an emphasis on building long-term system capacity. More information on the task force may be found here: [http://www.tennessee.gov/mental/A&D/A\\_D\\_veterans.html](http://www.tennessee.gov/mental/A&D/A_D_veterans.html).

### **Tennessee Obesity Task Force**

In 2008 the Department of Health convened a work group to develop a strategic plan addressing obesity and related health problems in Tennessee.

### **Tobacco Use Prevention, Control, and Cessation Strategic Plan**

In 2008, the Department of Health Tobacco Use Prevention and Control Program (TUPCP) convened stakeholders from across the state to form a Strategic Planning Work Group to establish a five-year plan for a comprehensive statewide tobacco control initiative for the period 2009-2013. The plan aims to “change social norms to reduce and eliminate the burden of tobacco-related death and illness for all people and communities of Tennessee.” More information on the TUPCP may be found here: <http://health.state.tn.us/healthpromotion/index.html>.

### **Tennessee Office of eHealth Initiatives**

The Tennessee Office of eHealth Initiatives under the Department of Finance and Administration serves as the single coordinating authority for the exchange of eHealth information in Tennessee. It collaborates with private and public sector health care stakeholders through the statewide eHealth Advisory Council, established by Governor Bredesen in 2006. The Advisory Council is currently transitioning into a new body as the State of Tennessee prepares for changes in the eHealth landscape brought by the federal Health Information Technology for Economic and Clinical Health (HITECH) Act of 2009.

**APPENDIX E. CoverRx Co-Pay Sliding Scale Based on Income**

<b>CoverRx Co-Pay Sliding Scale Based on Income</b>			
<b>Persons in Household</b>	<b>At or Below FPL</b>	<b>101% to 150% FPL</b>	<b>151% to 250% FPL</b>
1	\$10,830	\$10,831 - \$16,245	\$16,246 - \$27,075
2	\$14,570	\$14,571 - \$21,855	\$21,856 - \$36,425
3	\$18,310	\$18,311 - \$27,465	\$27,466 - \$45,775
4	\$22,050	\$22,051 - \$33,075	\$33,076 - \$55,125
5	\$25,790	\$25,791 - \$38,685	\$38,686 - \$64,475
6	\$29,530	\$29,531 - \$44,295	\$44,296 - \$73,825
7	\$33,270	\$33,271 - \$49,905	\$49,906 - \$83,175
8	\$37,010	\$37,011 - \$55,515	\$55,516 - \$92,525

**Co-Pay Structure**

Generics: 30 day supply	\$3	\$5	\$8
Generics: 90 day supply*	\$3	\$10	\$16
Brand/Insulin/Diabetic Supplies: 30 day supply or up to covered limit	\$5	\$8	\$12
All Others	Lesser of Discount, MAC or U&C	Lesser of Discount, MAC or U&C	Lesser of Discount, MAC or U&C

\*90 day supplies available only through mail order and select retail pharmacies that have chosen to participate. Check with your local pharmacy to see if 90 day supplies are available at that location.

**APPENDIX F. Comparison of Tennessee Health System Performance with Top-Performing Systems in Other States**

<b>Indicator</b>	<b>If Tennessee's performance improved to the level of the best-performing state for this indicator, then:</b>	
Insured Adults	279,990	more adults (ages 18-64) would be covered by health insurance (public or private), and therefore would be more likely to receive health care when needed.
Insured Children	61,304	more children (ages 0-17) would be covered by health insurance (public or private), and therefore would be more likely to receive health care when needed.
Adult Preventive Care	184,252	more adults (ages 50 and older) would receive recommended preventive care, such as colon cancer screenings, mammograms, pap smears, and flu shots at appropriate ages.
Diabetes Care	75,699	more adults (ages 18 and older) with diabetes would receive three recommended services (eye exam, foot exam, and hemoglobin A1c test) to help prevent or delay disease complications.
Childhood Vaccinations	12,220	more children (ages 19-35 months) would be up-to-date on all recommended doses of five key vaccines.
Adults with a Usual Source of Care	299,823	more adults (ages 18 and older) would have a usual source of care to help ensure that care is coordinated and accessible when needed.
Children with a Medical Home	157,360	more children (ages 0-17) would have a medical home to help ensure that care is coordinated and accessible when needed.
Preventable Hospital Admissions	34,929	fewer preventable hospitalizations for ambulatory care sensitive conditions would occur among Medicare beneficiaries (age 65 and older) and
	\$153,503,000	dollars would be saved from the reduction in hospitalizations.
Hospital Readmissions	5,156	fewer hospital readmissions would occur among Medicare beneficiaries (age 65 and older) and
	\$49,769,000	dollars would be saved from the reduction in readmissions.
Hospitalization of Nursing Home Residents	3,363	fewer long-stay nursing home residents would be hospitalized and
	\$28,361,000	dollars would be saved from the reduction in hospitalizations.

Indicator	If Tennessee's performance improved to the level of the best-performing state for this indicator, then:	
Mortality Amenable to Health Care	3,276	fewer premature deaths (before age 75) might occur from causes that are potentially treatable or preventable with timely and appropriate health care.

**Source:** "Tennessee: Estimated Impact of Improving State Performance," Commonwealth Fund, Accessed on 1/7/09 at:  
[http://www.commonwealthfund.org/improvement/Tennessee Code Annotated/lcs/improvement/Tennessee Code Annotated/lcs\\_show.htm?doc\\_id=501809](http://www.commonwealthfund.org/improvement/Tennessee%20Code%20Annotated/lcs/improvement/Tennessee%20Code%20Annotated/lcs_show.htm?doc_id=501809)

## **APPENDIX G. State Health Plan Advisory Committee Members**

### *State Government Members:*

- Chair of the Senate General Welfare, Health, and Human Resources Committee – Senator Rusty Crowe
- Chair of the House Health and Human Resources Committee – Representative Joe Armstrong
- Comptroller of the Treasury – Justin P. Wilson
- Commissioner of Finance and Administration – Dave Goetz
- Commissioner of Health – Susan R. Cooper, MSN, RN
- Commissioner of Mental Health and Developmental Disabilities – Virginia Trotter Betts
- Deputy Commissioner of Finance and Administration and Director of the Bureau of TennCare – Darin J. Gordon
- Executive Director, Health Services and Development Agency – Melanie Hill

### *Non-State Government Members:*

- American Health Planning Association – Arthur Maples, president; Baptist Memorial Hospital (Memphis)
- Long term care – Bruce Duncan, Assistant Vice President, National HealthCare Corp. (Murfreesboro)
- Health Insurance – David Locke, BlueCross BlueShield of Tennessee (Chattanooga)
- Tennessee Hospital Association – Mary Layne Van Cleve, COO (Nashville)
- Tennessee Medical Association – Albert J. Grobmyer, III, MD (Memphis)
- Public Policy – Rita Geier, Senior Fellow for Public Health, the Howard H. Baker Center for Public Policy, UT-Knoxville (Knoxville)
- Business – Cristie Travis, Memphis Business Coalition on Health (Memphis)

## Appendix H. Tennessee Environment Scan of Uninsured, FQHC, CAH, and Rural Health Clinics

*Information prepared by the Vanderbilt Center for Better Health*

### Summary

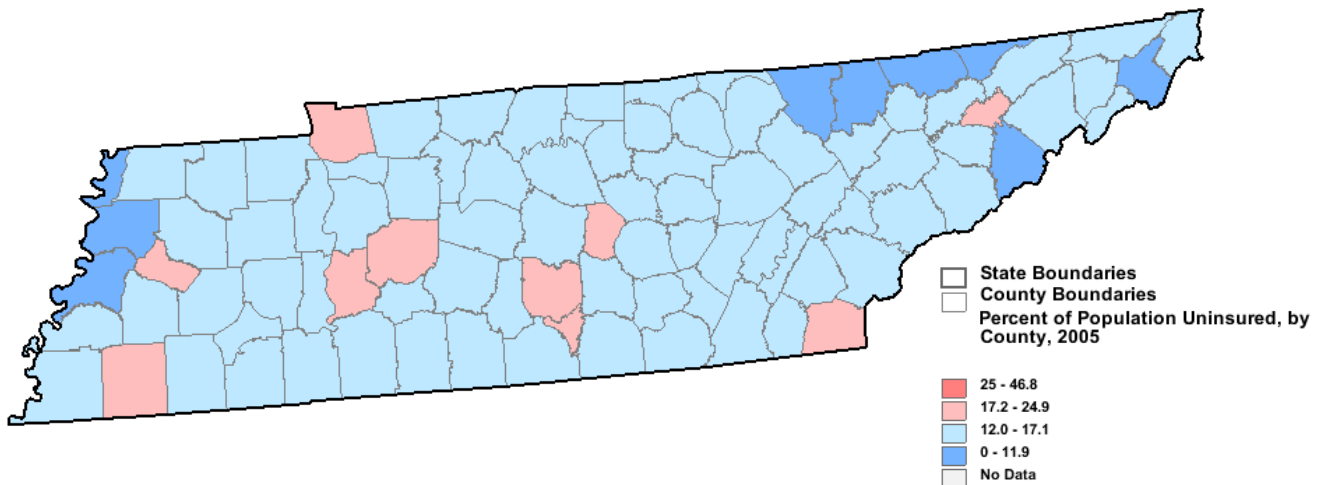
In Tennessee there are:

- 774,563 uninsured people
- 108 Federally Qualified Health Centers
- 15 Critical Access Hospitals
- 60 Rural Health Clinics

### Uninsured and Underinsured

*Data source: U.S. Census Bureau, Annual Social and Economic Supplement, 2004*

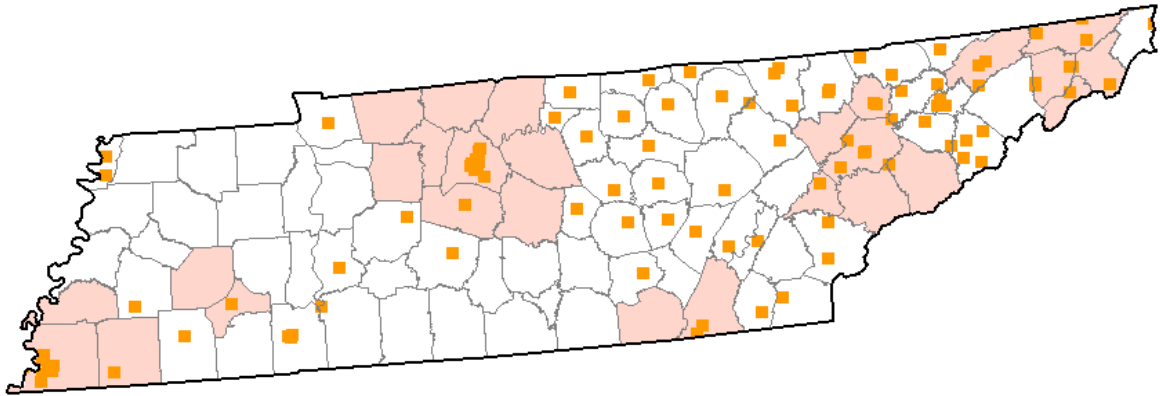
For reporting purposes, the Census Bureau broadly classifies health insurance coverage as private coverage or government coverage. Private health insurance is a plan provided through an employer or a union or purchased by an individual from a private company. Government health insurance includes the federal programs Medicare, Medicaid, and military health care; the Children’s Health Insurance Program (CHIP); and individual state health plans. People were considered “insured” if they were covered by any type of health insurance for part or all of the previous calendar year. They were considered “uninsured” if they were not covered by any type of health insurance at any time in that year.



## Federally Qualified Health Centers (FQHC)

*Data source: Centers for Medicare and Medicaid Services (CMS), Quarter 4, 2008*

Federally qualified health centers (FQHCs) include all organizations receiving grants under section 330 of the Public Health Service Act, certain tribal organizations, and FQHC Look-Alikes. FQHCs qualify for enhanced reimbursement from Medicare and Medicaid, as well as other benefits. FQHCs must serve an underserved area or population, offer a sliding fee scale, provide comprehensive services, have an ongoing quality assurance program, and have a governing board of directors.



*Metropolitan counties are shaded. Rural counties are non-shaded.*

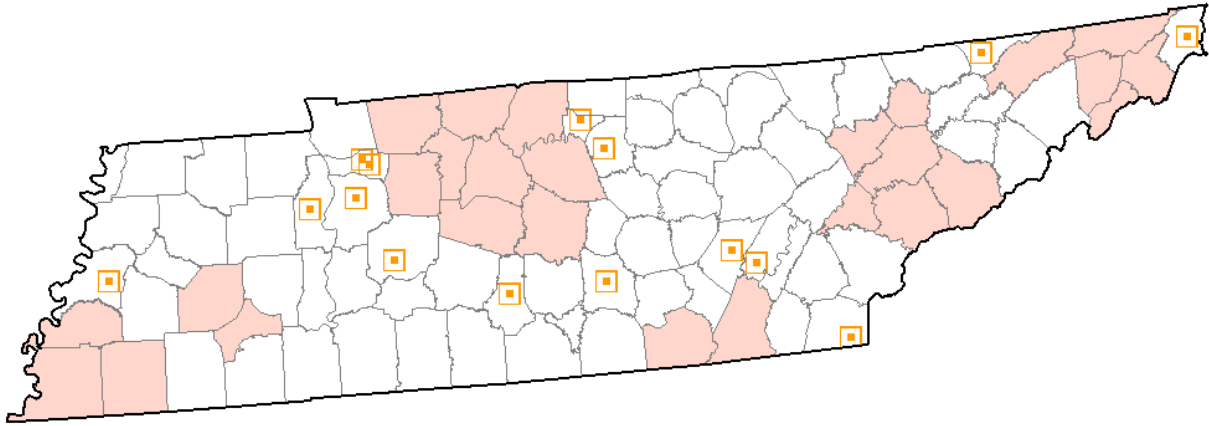


## Critical Access Hospitals

*Data source: Centers for Medicare and Medicaid Services (CMS), Quarter 4, 2008*

The Critical Access Hospitals (CAH) program was designed to improve rural health care access and reduce hospital closures. Critical Access Hospitals provide essential services to a community and are reimbursed by Medicare on a "reasonable cost basis" for services provided to Medicare patients.

A Critical Access Hospital (CAH) is a hospital that is certified to receive cost-based reimbursement from Medicare. The reimbursement that CAHs receive is intended to improve their financial performance and thereby reduce hospital closures. Each hospital must review its own situation to determine if CAH status would be advantageous. CAHs are certified under a different set of Medicare Conditions of Participation (CoP) that are more flexible than the acute care hospital CoPs.



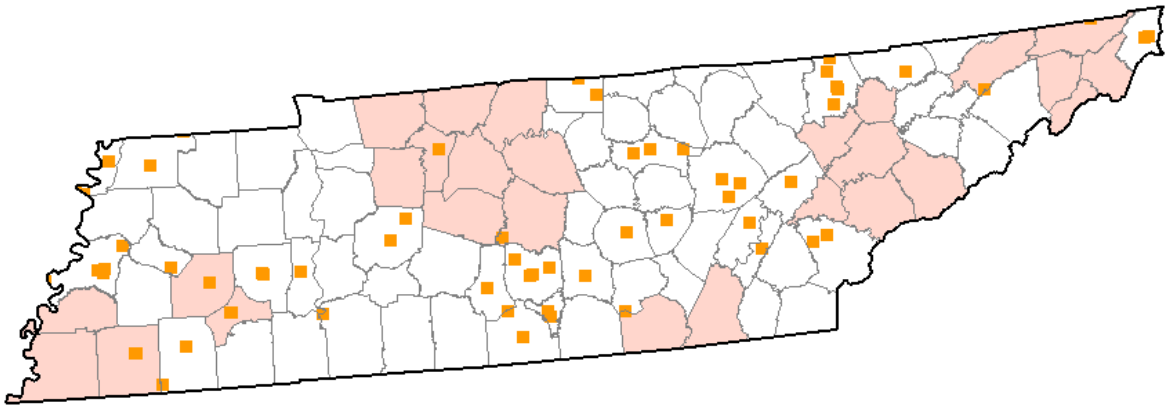
*Metropolitan counties are shaded. Rural counties are non-shaded.*

## Rural Health Clinics

*Data source: Centers for Medicare and Medicaid Services (CMS), Quarter 4, 2008*

See Appendix X for a definition of “rural.” The Rural Health Clinics (RHCs) program is intended to increase primary care services for Medicaid and Medicare patients in rural communities. RHCs can be public, private, or non-profit. The main advantage of RHC status is enhanced reimbursement rates for providing Medicaid and Medicare services in rural areas. RHCs must be located in rural, underserved areas and must use midlevel practitioners.

A Rural Health Clinic is a clinic certified to receive special Medicare and Medicaid reimbursement. The purpose of the RHC program is improving access to primary care in underserved rural areas. RHCs are required to use a team approach of physicians and midlevel practitioners such as nurse practitioners, physician assistants, and certified nurse midwives to provide services. The clinic must be staffed at least 50% of the time with a midlevel practitioner.

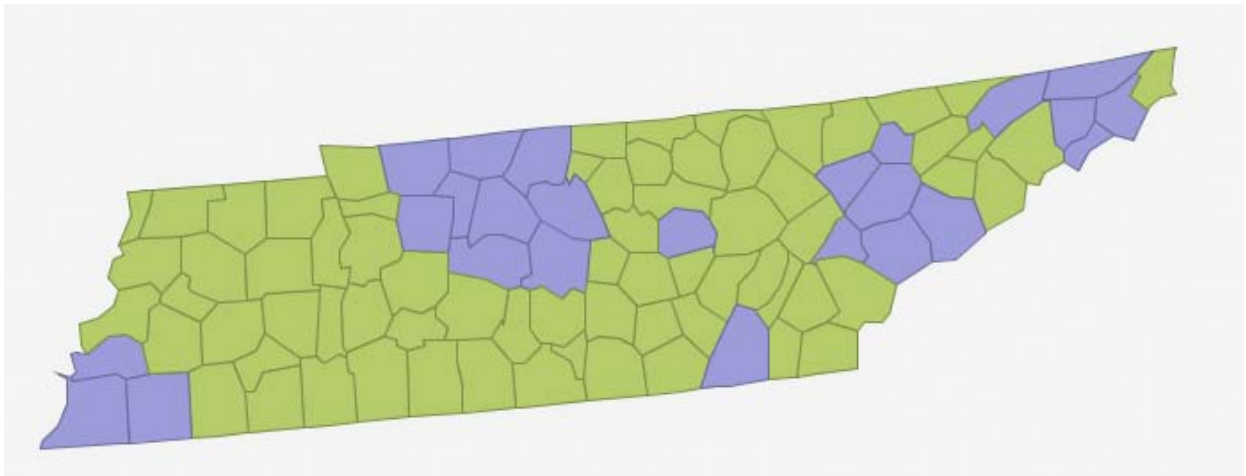


*Metropolitan counties are shaded. Rural counties are non-shaded.*

## Defining Rural

The United States Census Bureau has taken the lead in creating a working definition of rural by defining what is urban or metropolitan, then defining rural by exclusion. The Bureau defines an urbanized area (UA) as consisting of adjacent, densely settled census block groups (BGs) and census blocks that meet minimum population density requirements along with adjacent densely settled census blocks where together they encompass a population of at least 50,000 people. Urban clusters (UC) have a similar definition; however, the overall population can be 2,500 to less than 50,000. These categories are based on definitions adopted by the U.S. Department of Health and Human Services Office of Rural Health Policy (ORHP/HHS). Counties are first classified as either rural or urban depending on the MSA in which they are located.

- Rural: Non-metropolitan counties, as designated by the MSA method, shall be considered rural. However, portions of urban metropolitan counties may be classified as rural if their census block or tract number is identified by "Goldsmith Modification" methodology. The "Goldsmith Modification" identified rural "pocket" areas within larger urban metropolitan counties.
- Urban: Metropolitan counties, as measured by the U.S. Office of Management and Budget's MSA method, shall be designated as urban, except for metropolitan counties identified by census block or tract in the "Goldsmith Modification."



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# Tennessee State Health Plan

**2009**

## **Section 4**

### **Certificate of Need Work Papers (Attachments to the State Health Plan)**

Responses to Public Comments Received on the Proposed Certificate of Need Standards and Criteria for Positron Emission Tomography (PET) Services	<b>1</b>
Responses to Public Comments Received on the Proposed Certificate of Need Standards and Criteria for Cardiac Catheterization Services	<b>4</b>



STATE OF TENNESSEE  
DIVISION OF HEALTH PLANNING

**RESPONSES TO PUBLIC COMMENTS  
RECEIVED ON THE PROPOSED CERTIFICATE OF NEED STANDARDS AND  
CRITERIA**

*FOR*

**POSITRON EMISSION TOMOGRAPHY SERVICES**

July 29, 2009

The following are summarized comments received by the Division of Health Planning on the Proposed Certificate of Need Standards and Criteria for Position Emission Tomography (PET) Services. Our response follows each comment and indicates whether the comment led to changes appearing in the Final Certificate of Need Standards and Criteria for PET Services.

1. We received several comments regarding combined PET/CT scanners. Several commenters correctly indicated that the majority of new PET scanners now being installed also have CT scanning capabilities. The commenters asked that the standards and criteria specifically address the counting of PET and CT towards the unit's minimum number of procedures standard.

Response: We agree that more definition is needed regarding the counting of PET and CT scans towards a unit's minimum number of procedures standard. In these final standards and criteria, we indicate that only scans involving the PET component of a combined PET/CT machine count toward this standard.

2. Two commenters questioned how realistic the proposed minimum number of procedures standard will be. They were concerned that the proposed minimum is excessive when compared with other states and that two years is too short a time to meet this standard.

Response: We do not agree that the proposed minimum number of procedures standard is excessive. Minimum thresholds across the U.S. range from 750 to

2100 scans per year. We feel that a minimum standard of 1600 scans per year is appropriate given the information currently available to us. However, in light of these concerns and the new information made available after the implementation of these standards and criteria, it is our intention to closely monitor utilization and to adjust the minimum standard in the future if it appears necessary.

3. Several commenters noted the heavy burden of reporting data to three separate state agencies as required by proposed Standard 7. The commenters suggested one state agency should collect the data and share it with the others as needed.

Response: We agree with the commenters that the proposed reporting requirements are burdensome and unnecessary. In these final standards and criteria, we clarify that the applicant should report data as requested by the Health Services and Development Agency to help maintain the Agency's Equipment Registry.

4. We received numerous comments suggesting that the minimum number of procedures standard for mobile units should be based on the number of days in operation rather than a set standard of three days. The commenters explained that many mobile PET units only operate one day per week and that it would be improper to hold these units to a three-day standard.

Response: We agree that the mobile unit minimum standard should be based on the number of days in operation. The final standard sets the annual minimum capacity at 320 procedures per day of operation per week.

5. Two commenters advised that the exception for underserved areas in proposed Standard 8 is too broad and is susceptible to abuse by applicants. The commenters noted that without more formal guidance the exception may be inappropriately utilized by applicants seeking approval for a service in a saturated market.

Response: We understand and are sympathetic to the position of the commenters that proposed Standard 8 could be utilized inappropriately by some applicants. However, Standard 8 does not allow the HSDA to waive all other standards in considering applicants that claim to meet the criteria of Standard 8. Moreover, we have clarified that Standard 8 is to be considered in light of the criterion of Need as defined by Rule 0720-4-.01 (1).

6. One commenter suggested that Standard 3, which requires the applicant to document the absence of a lower cost alternative, is not necessary because no other service can provide the information yielded by a PET scan.

Response: Given the continual technological developments in health care, we intend to apply this standard to all applicable CON standards and criteria revisions. Consistently maintaining this standard throughout all appropriate CON standards and criteria will help ensure overall vigilance in controlling unnecessary costs. Moreover, we do not feel that complying with this standard is burdensome, as prudent applicants will have necessarily researched any potential less expensive alternatives.

7. We received one comment stating that the Tennessee Board of Pharmacy regulates the handling of medical isotopes and radiopharmaceuticals rather than the federal Nuclear Regulatory Commission, as stated in proposed Standard 6e.

Response: We have removed language from Standard 6e regarding the Nuclear Regulatory Commission. Standard 6e now requires licensure and regulatory oversight from the Tennessee Board of Pharmacy and/or the Tennessee Board of Medical Examiners, whichever is appropriate.

8. One commenter argued that 31 days after the end of the calendar year is not a realistic amount of time within which to prepare the annual report required by Standard 7.

Response: We have revised Standard 7 to provide that an applicant should provide assurances that it will submit data in a timely fashion as requested by the HSDA to maintain the HSDA Equipment Registry.



STATE OF TENNESSEE  
DIVISION OF HEALTH PLANNING

**RESPONSES TO PUBLIC COMMENTS  
RECEIVED ON THE PROPOSED CERTIFICATE OF NEED STANDARDS AND  
CRITERIA**

*FOR*

**CARDIAC CATHETERIZATION SERVICES**

July 29, 2009

The following are comments the Division of Health Planning received on the Proposed Certificate of Need (CON) Standards and Criteria for Cardiac Catheterization Services (Draft Standards). Our response follows each comment and indicates whether the comment led to changes appearing in the Final Certificate of Need Standards and Criteria for Cardiac Catheterization Services (Final Standards).

**General Comments**

1. While I appreciate the need for a new approach to developing CON standards and criteria, I think that the proposal is too complex. The concepts included in the draft go far beyond the decision of whether a project for new cardiac catheterization services is needed, is financially feasible, and contributes to the orderly development of healthcare in the State. It is unclear as to whether parts of the draft will be included in the final version (such as the rationale). If so, an "executive summary" might be in order to summarize clearly and succinctly the main concepts.

Response: We acknowledge that the format of the Draft Standards may be confusing. Therefore, we have created an executive summary for these Final Standards and have separated the more general Policy Recommendations for cardiac catheterization services, which extend beyond the scope of the CON program, into a new document.



2. [We] would like to make a general comment on the proposed cardiac catheterization guidelines being that the proposed guidelines are a huge improvement over the current guidelines. Clearly defining diagnostic and therapeutic procedures and development of standards for hospitals, freestanding laboratories, and mobile laboratories will be very helpful distinctions to have in the review of CON applications for cardiac catheterization services.

Response: We appreciate the positive feedback in this comment.

## **Definition of Cardiac Catheterization**

3. On page 1 under definition of cardiac catheterization, the last sentence should clarify that cardiac catheterization services include diagnostic cardiac catheterizations, therapeutic cardiac catheterizations and electrophysiology (EP) studies, both diagnostic and therapeutic.

Response: We agree with this comment and have made changes in these Final Standards accordingly.

4. There are separate definitions for diagnostic cardiac catheterization, therapeutic cardiac catheterization, and EP study; however there is not a separate definition for peripheral vascular catheterization.

Peripheral vascular catheterization and EP studies have definitions but there are no standards that address these procedures. Are these procedures not to be considered in a CON application?

Regarding the definition for Diagnostic-Equivalent Procedures and Weight-This table is included in the definitions but does not appear to be utilized with any of the volume standards in the criteria and standards, unless the definition of a case is equal to one diagnostic equivalent procedure. If that is the case, then that should be more clearly stated. Additionally in the column of "Procedures Included" for Therapeutic EP studies the word "alations" should most likely be "ablations".

Response: In these Final Standards, we have included a definition of each type of service listed in the "weighted cases" procedures list, including peripheral vascular catheterizations. In addition, we have clarified that only cardiac catheterization procedures count towards the minimum volume standard but that all procedures listed may count towards measuring laboratory capacity. We have also corrected the spelling error.

5. Defining cardiac catheterization, cardiac catheterization laboratory, diagnostic cardiac catheterization, therapeutic cardiac catheterization, and Electrophysiological (EP) Study are appropriate. It would be helpful to define electrophysiological (EP) procedure, peripheral vascular (PV) study and peripheral vascular (PV) procedure as well, since it is common practice within Tennessee tertiary referral hospitals with cardiovascular centers of excellence to perform these procedures in cardiac catheterization laboratories as well.

Examples of EP studies and procedures and peripheral vascular (PV) studies and procedures should also be provided following the definitions. HSDA's Assistant Executive Director's comments address the fact that although the draft document recognizes PV and EP studies and interventional procedures are being performed in cardiac catheterization laboratories, there are no standards that address these studies and interventional procedures. Minimally, these procedures should be considered in their consumption of time as part of the utilization of an existing cardiac catheterization laboratory as well as in consideration of new Certificate of Need (CON) applications.

Response: As noted above, we have included a definition of each type of service listed in the “weighted cases” procedures list, including peripheral vascular catheterizations. In addition, we have clarified that only cardiac catheterization procedures count towards the minimum volume standard but that all procedures listed may count towards measuring laboratory capacity.

### **Definition of Mobile Cardiac Cath Laboratory**

6. While it is mentioned later in the document, to be consistent with the definition of freestanding facility, the definition of mobile cardiac catheterization laboratory should include that mobile cardiac catheterization laboratories shall perform diagnostic procedures only unless they are permanently fixed on a hospital's campus.

Response: We agree with this comment, though we have clarified that facilities approved to perform therapeutic cardiac catheterizations without on-site open heart surgery backup may temporarily perform these procedures in a mobile laboratory on the facility's campus during construction impacting the fixed laboratories.

### **Age for Pediatrics**

7. [We] recommend defining pediatrics as “any cardiac catheterization procedure performed on a person less than 15 years of age” for purposes of measuring capacity and defining a pediatric cardiac catheterization laboratory. Children ages 16 & 17 can have more mature anatomy (hearts) and should not be limited to only

receiving treatment at a pediatric laboratory. Defining pediatrics as “less than 18” could create an access issue for these 16 & 17 year olds. This definition should not prevent a person under 20 years old with congenital heart defects from going to a pediatric cardiac catheterization laboratory for services.

Response: We agree with this comment and have made changes in these Final Standards accordingly.

## **Definition of Need for New Services**

8. By providing that "[a] need shall be determined to exist" if existing providers are at a certain utilization volume appears to make this a mandatory requirement, removing the Agency's discretion to make a case by case determination of need.

Response: We agree with this comment and have modified the definition of need for new services to read, “a need likely exists if...”

## **Existing CON Holders Versus New Applicants**

9. An overarching introductory paragraph should explain that existing CON holders and pending applicants are not retroactively affected by the new standards and criteria for cardiac catheterization. Specifically it should be noted that an existing provider offering diagnostic cardiac cath services does not have to obtain a CON to start offering therapeutic cardiac cath services. If the provider’s original CON was limited on its face to diagnostic cardiac cath services, the provider would be required to comply with the appropriate rules for removal of a condition on their CON.

Response: We agree with this comment and have made changes in these Final Standards accordingly.

## **Rules and Definitions for “Weighted Case” and “Procedure”**

10. [We] propose the following rules:

- To determine laboratory capacity, count weighted cases. To count weighted cases, only count the weight of the highest weighted procedure during a case.
- To determine operator/physician volume competency, count procedures. When counting procedures, count separately each of the diagnostic studies or therapeutic procedures done during the same case following the catheterization.

- The 2005 ACC/AHA/SCAI Practice Guideline Update for Percutaneous Coronary Intervention counts procedures to determine operator/physician competency.

Response: We agree with this comment and have made changes in these Final Standards accordingly.

11. [We] suggest the following definitions:

- Cardiac Catheterization Weighted Case: For purposes of these standards and criteria and for measuring laboratory capacity, “weighted case” shall mean one visit to a cardiac catheterization laboratory or another procedure room by one patient. If multiple procedures are performed between admission and discharge to the laboratory or procedure room, a weighted case is equal to the highest weighted diagnostic –equivalent procedure in a case.
- Cardiac Catheterization Procedure: a medical diagnostic or therapeutic intervention during which a catheter is manipulated by a physician to travel along the course of a blood vessel into the chambers or vessels of the heart. When the catheter is in place, the physician is able to perform various diagnostic studies and/or therapeutic procedures in the heart. Each procedure should be counted separately when measuring minimum standards for competency.
- On page 3, the meaning is clear around using the terms procedure or case. However, since the implication is really that "cases" are to be counted, the term "case" should be used consistently in the rest of the document.

Response: We agree with this comment and have made changes in these Final Standards accordingly.

## **Procedure Weighting System**

12. On page 2, the categories diagnostic peripheral vascular catheterization and therapeutic peripheral vascular catheterization are not addressed in the definitions - they first appear in this weight section. I question the basis of the weight system and the need to include vascular procedures - since this standard should be the basis for initiation of cardiac catheterization services. Adding these procedures to room utilization could potentially mask a very small volume cardiac catheterization service that is using the room for other purposes - which is OK from an efficiency perspective - but may not paint a clear picture as to the utilization, accessibility, or need for additional cardiac catheterization services. Also, there is no reference for the basis of the weight system.

Response: In order for an applicant to be successful, it must demonstrate that it can perform the stated minimum volume of cardiac catheterization procedures independent of EP studies or peripheral vascular catheterizations (see Standards 12 and 14 regarding minimum volume standards). Thus, including these additional procedures in the measurement of laboratory utilization helps demonstrate the utilization and efficiency of the laboratories; the separate volume consideration of cardiac catheterizations helps ensure that a need for cardiac catheterization will be met.

We have added a rationale statement for the weighting system to the Final Standards.

13. Regarding the definition for Diagnostic-Equivalent Procedures and Weight-This table is included in the definitions but does not appear to be utilized with any of the volume standards in the criteria and standards, unless the definition of a case is equal to one diagnostic equivalent procedure. If that is the case, then that should be more clearly stated. Additionally in the column of "Procedures Included" for Therapeutic EP studies the word "alations" should most likely be "ablations".

Response: We agree with this comment and have made changes in these Final Standards accordingly.

14. Diagnostic-Equivalent Procedures and Weight: This table is included in the definitions but does not appear to be utilized with any of the volume standards in the criteria and standards, unless the definition of a case is equal to one diagnostic equivalent procedure.

In our discussions with several hospital representatives and Health Services and Development Agency (HSDA) review staff, recognition of the diversification of procedures being performed in cardiac catheterization laboratories is a huge step forward in updating the current criteria and standards. However, the use of the weighting system has several major disadvantages in developing a measurement system for utilization of cath lab capacity:

- 1) It has several limitations which will create a lot of additional unnecessary work when it needs updating.
- 2) It creates an additional level of work for providers in submission of utilization data on an annual basis as well as for CONs.
- 3) Grouping information by six general categories distorts the true picture of utilization by laboratory.

4) In discussing the generalized weighting system with hospital representatives and also reviewing numerous cardiac cath laboratory CON applications over the past five and one-half years with the HSDA, it is apparent that each individual laboratory within each individual provider mix has a different mix of procedures. While the six generalized weighting categories moves closer to recognizing this new procedure diversification trend, it distorts the true nature of understanding the utilizations trends within cardiac cath labs and the differences between provider programs. It will present cumbersome issues for modifications in the future as diversification continues.

5) Excerpted pages (provided in the attached materials) from a multi institutional survey and study performed by the Cardiology Preeminence Roundtable of The Advisory Board, a nationally recognized hospital consultative and advisory group, displays the variability in times for the various new procedures which are now being performed in cardiac catheterization laboratories.

Response: While it is true that procedure times between different programs may vary, we believe that, on average, the weighted case system will provide the HSDA a basic sense of laboratory utilization that will inform its decision-making process. We agree that a study measuring average procedure times in Tennessee would be helpful, but, unfortunately, at this time the state does not have the time or resources to conduct this kind of study. Additionally, once the weighting system is implemented, it can be modified over time to reflect changes in hospital and clinical operations.

## **Cardiac Catheterization Laboratory Capacity**

15. Cardiac Catheterization Laboratory Capacity (draft page 3) and the definition of need for new services (draft page 12) should be consistent with the weighted procedures measurements. The increase in the number of cases that is recommended below would result from the clarification that the requirement is to count the highest weighted procedure for each case.

Cardiac Catheterization Laboratory Capacity: the capacity of dedicated and multipurpose cardiac catheterization laboratories is equal to 2000 weighted cases per year. This number is based on 50 weeks of 40 hours each, assuming an average case time, including room turnover and setup, of 60 minutes.

Under the definition of need for new services, the utilization threshold should be equal to or greater than 70% of capacity (i.e. 70% of 2000 cases).

Response: We agree with this comment and have made changes in these Final Standards accordingly.

16. The Cath Lab industry has long recognized that 800 cases a year constitutes a fully utilized laboratory, given the down time, maintenance and repair of equipment and preservation and restocking of appropriate consumables. Indeed, 800 cases a year is generally used the country over in large corporations and small ones to justify the need for a second cardiac catheterization laboratory. A laboratory can perform 1300 cases a year for a very short period of time before problems develop as a result of an excessive caseload. A caseload of more than 1000 per year for a laboratory is clearly excessive.

Response: By weighting cases based upon average complexity, we believe that these Final Standards allow for a comparable measurement across facilities that realistically reflects cardiac catheterization laboratory utilization.

### **Age Group-Specific Utilization Rate**

17. Page 4 details a way to calculate historical state utilization rates by age group. Who will be the keeper/calculator of this data? Who will verify this calculation against available data sources? Although worthy, this approach seems too complex since the applicant can comment on the demographics of the service area and why the projected utilization may vary from the average.

Response: The Department of Health Division of Health Statistics already maintains the data and will perform all necessary calculations.

18. There is a typo in the last bullet point where single is misspelled in single-year.

Response: This typographical error has been corrected.

19. Age Group-Specific Historical State Utilization Rate-Would it also make sense to take the age cohorts and break those down by gender as well, e.g., Is the difference between the use rate for females and males Age 65-69 statistically significant?

Response: The Department of Health Division of Health Statistics will report to the Division of Health Planning whether the gender use rate for cardiac catheterization services is statistically significant. If it is, we will consult with the Division of Health Statistics on how the age group-specific historical state utilization rate formula should be altered.

20. Phone calls to several CON recipients who have terminated their freestanding cardiac catheterization laboratories have revealed Medicare reimbursement to freestanding cardiac cath labs has been reduced to the point where they are paying 30% less than hospital reimbursement for the same cath procedure performed by the same doctor on the same piece of equipment. Thus, the freestanding centers are getting out of the cardiac cath business and selling their equipment to the local hospitals. Only two outpatient cardiac catheterization laboratory remain operating today - one in Memphis and one in Nashville. The freestanding cardiac cath labs' historical volumes have been significant and their utilization should not be ignored in the determination of the Age Group-Specific Historical State Utilization Rate.

Response: We will work with the Department of Health to ensure that data from freestanding facilities are collected and included in analyses.

### **Emergency Transfer Plan**

21. The transfer should be to a nearby, not nearest, open heart surgical facility (within 60 minutes) that is reviewed/tested on a regular (quarterly basis).

Response: We agree with this comment and have made changes in these Final Standards accordingly.

### **Open Heart Surgery Availability**

22. [Our] suggestion to clarify first sentence: Acute care facilities proposing to offer adult therapeutic cardiac catheterization services shall not be required to maintain an on-site open heart surgery program; however those that do not maintain an on-site open heart surgery program should follow the most recent ACC/AHA/SCAI Practice Guideline Update for Percutaneous Coronary Intervention.

Response: We agree with this comment and have made changes in these Final Standards accordingly.

23. "#2. Open Heart Surgery Availability" needs to be revised. If a therapeutic catheterization lab without on-site open heart surgery needs to replace their permanent equipment, a viable temporary solution may be to have a mobile unit on site while the equipment is being replaced. The language currently included does not appear to permit this temporary solution.

Response: We agree with this comment and have made changes in these Final Standards accordingly.



24. Page 5: Under 1. Access to Emergency Services/Rationale - the 4th line down has a typo – needs “of” inserted between accessibility and therapeutic so that it reads accessibility of therapeutic.

Response: This typographical error has been corrected.

## **Access**

25. In the final analysis, what happens in the emergency room at small hospitals throughout the state is that people die and become horribly disabled from cardiovascular conditions which could have been treated successfully and promptly in a nearby local facility by use of catheterization and cardiovascular interventional services. We think it would be to the benefit of the citizens of the state of Tennessee if the planning process and the planning agencies assisted with the development and regulation of services distributed more broadly than is now planned.

Response: The Final Standards allow the HSDA to lower the volume standard when access is deemed limited for a rural area. In addition, one of the five Principles for Achieving Better Health contained in the State Health Plan is that “Every citizen should have reasonable access to health care.” Thus, the health planning process will continue to consider the accessibility of all services to Tennesseans, and future standards and criteria for cardiac catheterization services will reflect identified needs and trends.

26. "#11. Access" should be revised to state that emergent cardiac services should be provided regardless of ability to pay. The current language could be interpreted to mean elective procedures, which would be inappropriate.

Response: We agree with this comment, though we have altered Standard 11 to give the HSDA broader guidance on access to health care.

27. Page 13 Section 11 speaks to access - which should be addressed (and is currently addressed) in the overall criteria and not specific to cardiac catheterization services.

Response: That “Every citizen should have reasonable access to health care” is one of Five Principles for Achieving Better Health contained in the State Health Plan. We agree that the overall criterion of need does include access to health care. Specifically, as stated by Rule 0720-4-.01 (1) (e), the HSDA is to consider “The special needs of the service area population, including the accessibility to consumers, particularly women, racial and ethnic minorities, and low-income

groups.” After considering further Draft Standard 11, we have decided to modify Standard 11. The new criteria build upon the overarching CON criterion of need to provide the HSDA with clearer guidance on improving access to health care.

## **24/7 Staff Coverage for Emergencies**

28. As I submitted in the second round of comments, I would urge the standards to give some flexibility as it relates to 24/7 interventional coverage, assuming certain requirements are met. The appropriate standard should be that the original receiving facility/ED can get the patient to the appropriate therapeutic catheterization services within 90 minutes of arrival, either in their on-site catheterization lab or at a hospital that they have a transfer relationship with, including clinical and transfer protocols. For example, an ST elevated MI patient arrives at the ED of Hospital A, but an interventionalist is unavailable at hospital A at that time. Hospital A must be able to get the patient to hospital B's catheterization lab within 90 minutes of the patient's original arrival at hospital A's ED. As new programs are ramping up, it takes time to recruit enough interventional cardiologists to effectively support 24/7 coverage. Therefore, if therapeutic services can be offered the majority of the time, patients will benefit from having that service located in their community and on occasion when an interventionalist is not available, they should have transfer protocols in place to deliver care at a nearby facility within the same 90 minute standard. This system approach has proven to be effective in various states across the country.

Response: We recognize inherent positives and negatives in either requiring 24 hour-a-day/7 days-a-week (24/7) emergency coverage or allowing expedient transfer during a laboratory's non-operating hours as described in this comment. 24/7 emergency coverage provides a consistent service to a community, giving community residents an accurate expectation of the care available locally to them, and demonstrates committed financial and programmatic investment in providing a very resource-intensive service. However, for the very reason that providing 24/7 emergency coverage is such a resource-intensive endeavor, we recognize that opening a new cardiac catheterization program with immediate 24/7 coverage could prove overly burdensome.

On the other hand, allowing expedient transfer during a cardiac catheterization laboratory's non-operating hours provides an opportunity for a larger number of facilities, particularly in suburban and rural areas, that could provide therapeutic cardiac catheterization services. An unintended consequence of allowing too many cardiac catheterization providers in a region could be to adversely affect those providers seeking to maintain 24/7 emergency coverage.

Given these considerations, in these Final Standards we have modified the criterion of 24/7 emergency coverage for all facilities proposing to provide therapeutic cardiac catheterization services. In these Final Standards such

applicants should present a plan for reaching 24/7 emergency coverage within three years of initiating the service or present a signed transfer agreement with another facility capable of treating transferred patients in a cardiac catheterization laboratory on a 24/7 basis within 90 minutes of the patient's arrival at the originating emergency department.

## Physician Competency

29. On page 7, Section 4 speaks to physician competency - which is an important component particularly in setting up a new cath lab. However, I'm not sure that the data needed to verify operator volumes is currently available. Would the Department of Health accumulate this data? What would be done with it? Again, it is the responsibility of the applicant to state the necessary data about the physicians being recruited to establish a program.

Response: This comment refers to Policy Recommendation 4. We envision the review of operator volume levels to be part of a larger quality of cardiac care initiative referenced by Policy Recommendation 2, which we have clarified in these Final Standards. Further, while the Department of Health's Hospital Discharge Data System contains the necessary volume data regarding physicians who practice in a hospital settings, additional work is needed—and is in the planning stages—to collect volume data on physicians who perform procedures in freestanding facilities.

30. In General, but also specifically applying to Page 7: Assuring Health Care Quality Through Maintaining Physician Skill: As the trend shifts away from the necessity to perform invasive procedures, it is possible that these standards require too many procedures. There should probably be some qualifying language in the beginning of the document that indicates from where the standards are taken, and that if the standards change, those changes may be taken into consideration. I think we all agree that there should be as much flexibility in this process as possible, even though it is anticipated at this time that standards will be updated on a regular basis. I am also not sure that the last sentence in that section is correct. I believe that the data needed is from the Tennessee Hospital Association (THA) Hospital Discharge Data System rather the Department of Health Discharge Data System (although THA furnishes it to Department of Health.)

Response: This comment also refers to Policy Recommendation 4, which proposes that a new process be developed to review annually operator volume levels. We agree that individual operator volume standards should be tied to nationally accepted guidelines, and we would urge the group that ultimately administers any quality of cardiac care program to follow nationally accepted guidelines.

31. The Division should be made aware that it may inadvertently foster the performance of perhaps less than necessary therapeutic catheterizations if all physicians are held to a 75 case per year per operator standard. This could inadvertently lead to unnecessary procedures and potential harm to patients as well as drive up the cost of health care in Tennessee.

Is the Division aware of the declining trend in the incidence of acute MI which could again inadvertently foster the performance of perhaps less than necessary procedures if using a 75 case minimum? This trend could also trigger an unnecessary review of successful therapeutic catheterization programs.

Has the division taken into account currently successful community-based therapeutic catheterization programs which do not meet and will likely never meet the proposed 75 case minimum guideline?

Should the surrogate for quality be a number below which has not been studied and that has not been verified to be an accurate correlate for quality?

Response: Physician competency is an important factor in providing high quality of care, and competency requires regular performance. Therefore, following the recommendations of the American College of Cardiology, we believe that a suggested minimum operator volume guideline tied to a nationally accepted guideline is in the best interests of Tennesseans. In the future, we envision that operators who fail to meet this guideline could be reviewed by peers and experts on a case-by-case basis. We agree that any ongoing review of operator volume levels, much less of overall program quality, will require further thinking, planning, and collaboration before implementation.

## **Diagnostic-Only Laboratories**

32. The document proposes that catheterization laboratories be prevented from treating patients who are discovered to be at high risk for catastrophe soon. This is a particularly objectionable provision for several reasons. The first is that it imposes a situation where a fully equipped hospital with well-trained personnel is allowed to diagnose but not treat people who are critically ill.

To deny a patient, who has come to an emergency room with unstable coronary symptoms, the right to diagnosis and treatment in that facility is the wrong thing to do. Statistics from the ACC have shown that mortality is about 1.5% with an acute myocardial infarction if you are taken to the Cath Lab and the lesion is opened within 90 minutes. Mortality rate is 6% if you cannot. The inability to provide interventional services at most community hospitals has also led to a disproportionate concentration of cardiologists in large cities where they are allowed to work, often on people who simply got there too late because they had

to travel from a facility that was denied the capacity to treat its service area by a provision like this. I genuinely believe that talented, experienced cardiologists would move to smaller communities where they are able to use their enormous skill to the benefit of patients there.

We respectfully request that the notion that interventional services require separate approval be abandoned. We currently have among the worst cardiovascular morbidity and mortality statistics in the entire country in western Tennessee partly because of restraints against diagnosis and therapy in our communities and we ought to stop doing that. The upshot of coronary intervention too late, should the patient survive, is an individual with severe ischemic cardiomyopathy. These patients are among the most unfortunate of our citizens and their care is horrendously expensive.

Response: We are sensitive to incidences of myocardial infarction and recognize that extending access to therapeutic cardiac catheterization services may in some instances save lives. Modifying the requirement of 24/7 emergency coverage to provide therapeutic cardiac catheterization services could make providing such services more feasible for rural community hospitals. However, if a local therapeutic cardiac catheterization laboratory is not available on a 24/7 basis, access to therapeutic services is still an issue for patients served by that facility during non-operating hours. If the cardiac catheterization laboratory is available on a 24/7 basis, maintaining an adequate patient volume per cardiologist remains a key concern, as operator volume is an important factor in maintaining that operator's competency, thus the quality of care received by patients. We believe maintaining operator competency should be a high priority as therapeutic cardiac catheterization services are extended into previously un-served and underserved areas. Therefore, we maintain a distinction in these Final Standards between those cardiac catheterization laboratories that offer only diagnostic services and those that offer both diagnostic and therapeutic services.

33. General Comment and specifically High Risk/Unstable Patients: clarify that these guidelines apply only to those projects to initiate cardiac catheterization services that are filed after their adoption. In particular, any applicant who currently provides cardiac catheterization services does not need additional approval to provide therapeutic cardiac catheterization services if they previously received approval for the initiation of cardiac catheterization services.

If a CON was approved with a specific condition, i.e. specifically limited to diagnostic services only, as evidenced by the placement of a condition on the face of the certificate itself, an additional CON for the initiation of therapeutic services is still not necessary, but the applicant would need to follow the appropriate procedure to have the condition on its CON lifted.

Response: We agree with this comment. Also, in these Final Standards we have clarified that removing the condition placed on the CON would be the process for moving from a diagnostic-only to a therapeutic program.

34. Currently a certificate of need is required for the initiation of cardiac catheterization services. To limit an applicant to diagnostic services only, the HSDA members would have to approve an application with conditions limiting the applicant to diagnostic services.

Response: We will work with HSDA staff to ensure that HSDA members fully understand the procedure for limiting a proposed cardiac catheterization program to diagnostic procedures only.

## Quality

35. There is a lot of attention to “quality” in the proposed criteria. I think that it is important for the CON decision to ensure that the appropriate resources are included in any application - and that certainly impacts quality. However, as currently configured within the statutes, the Health Services and Development Agency (HSDA) does not have any authority to monitor health care quality other than insuring that certain standards are proposed to be in place and appropriate resources have been allocated to implement them.

On page 6, Section 2 talks about assuring the monitoring of health care quality. HSDA is not set up as a Board to provide quality oversight - just the decision around implementation of a project. The applicant needs to plan for adequate resources to provide a quality program - but there is no basis for monitoring quality in the current CON laws. It would make more sense to include those parameters that need to be included in planning for the service.

Response: This comment references Policy Recommendation 2, which recommends the establishment of a systematic quality-monitoring program that allows comparability of quality (outcomes) and performance (efficiency) among providers. We agree that the HSDA does not currently have either the authority or the resources to monitor provider quality on an ongoing basis, nor are we certain that it is the appropriate entity to conduct such work. Through Policy Recommendation 2 we recommend the initiation of a dialog among stakeholders on the proper approach to establish a systematic quality-monitoring program.

36. My concern is that State agencies are not yet staffed or organized to perform in-depth quality of care regulation as effectively as patients and providers deserve. If the Cath (and other) proposed CON standards require such an expansion of State control, then some other part of the State Health Plan needs to identify and

request the levels of funding, expertise, and process that will be required to do that job with great competence. This is not something that should be tacked onto existing Agencies at their current levels of resources.

For example, the Licensure Board has had industry-wide regulatory power; and it has a process for competently enforcing certain design and quality standards-but those relate primarily to basic health and safety. The Licensing Board has a staff with inspection authority, technical expertise in what they are inspecting, and significant Board expertise in the issues they regulate. They have a well-defined inspection and hearing process to ensure that they can ascertain facts, make informed judgments, and enforce those standards with fairness and consistency across the entire industry. But they have never been asked to control the entire design, staffing, and operation of acute care services to the extent that professional associations have made recommendations on design, staffing, and operation.

The HSDA is even more limited in its scope of authority and its staffing. If the Guidelines want the HSDA to impose more sophisticated quality of care standards on Tennessee providers, then the Plan should recommend that the General Assembly give to the HSDA—

- a. new authority to gather quality of care data and enforce quality of care standards on all providers, not just the tiny minority of new 01' expanding providers that happen to need a CON;
- b. more expertise in the clinical aspects of quality of care standards; and
- c. a system for enforcing compliance with quality standards, that is separated from the "need" determination process that is now available. The current CON process is characterized by competitor debates and questions and answers between the Board and applicants. A better process for enforcing compliance with quality standards would be a non-adversarial process for demonstrating compliance after the hearing that grants CON approval. It is a waste of everyone's time to make every applicant provide great details on operational aspects of a proposal before it is even approved. That is why the current scheme provides for a CON to be issued before the proposal's design is fleshed out further in the Licensure process.

Response: “Every citizen should have confidence that the quality of health care is continually monitored and standards are adhered to by health care providers” is one of the Five Principles for Achieving Better Health as part of the State Health Plan. Since the CON program is informed by the State Health Plan, CON standards and criteria must reflect the principles of the State Health Plan. We agree that the HSDA does not currently have either the authority or the resources to monitor provider quality on an ongoing basis, nor are we certain that it is the appropriate entity to conduct such work. Through Policy Recommendation 2 we

recommend the initiation of a dialog among stakeholders on the proper approach to establish a systematic quality-monitoring program.

Furthermore, while the HSDA does not have the authority to monitor provider quality on an ongoing basis, determining whether an applicant plans to monitor the quality of its services fits directly under the HSDA's role of assessing an applicant's contribution to the orderly development of the health care system. Moreover, a standard that initial quality controls should be in place when initiating a new service is entirely consistent with the CON criterion of orderly development of the health care system. Notably, several standards contained in the Guidelines for Growth, 2000 Edition (e.g., for Magnetic Resonance Imaging, Extra-Corporeal Shock Wave Lithotripsy, among others.) contain such requirements.

37. These standards and criteria appear to have transformed the CON Board from an approval body to an on-going performance monitoring organization. While the impetus for that transformation seems to be the overarching State Health Plan revision that is in progress, it is concerning that we are developing standards for a particular service when it is not clear what the broader State Health Plan landscape will look like. In particular, on-going performance management can be resource intensive and our state is currently facing significant budget challenges. If on-going performance monitoring is going to be performed, I suggest that the focus be on quality with a limited, well-defined, and nationally accepted set of quality indicators. If based on these indicators there are outliers, these outlier catheterization service providers should be allowed the opportunity to present a plan for improvement.

Response: See response to Comment 36.

38. Some proposed Guidelines pertain to "need", and some define levels of "efficient utilization". Those types of Guidelines are very important for the HSDA to update. I offer no comments on those. Other proposed Guidelines extend CON review aggressively into the area of *quality of service*, which differs from "need" and "efficient utilization" standards, both conceptually and legally. "Quality" guidelines define how one should design, staff, and operate a service if approved to offer the service. For simplicity I call them "quality" standards, since they are usually developed by private professional associations to optimize patient care outcomes-not to ensure optimal utilization of capital investment.

Response: See response to Comment 36.

39. It may be difficult to have ongoing compliance and enforcement.



Response: We agree with this comment. However, ongoing compliance and enforcement will yield benefits to Tennessee's health care system and its patients. Properly developing a systematic quality-monitoring program will take time and involvement from many stakeholders.

40. Has the Division reviewed current standards of performance in Middle Tennessee area medium sized community hospitals that currently perform therapeutic catheterization?

Response: Yes, we have.

### **Accountability to Standards**

41. There are also references to "accountability" but the issues are not clear - accountability for what and accountability to whom. Insuring that certain standards are met on an ongoing basis or after implementation is not within the purview of the HSDA. There are several sections on pages 9-11 that speak to accountability and oversight of existing programs. HSDA is an approving body, not an oversight body.

On page 6, Section 3, it is unclear about the consequences for any providers who may have implemented EP services without a CON.

Response: We have heard from many stakeholders that improving the accountability of providers to the CON standards and criteria will better serve the CON process. However, we acknowledge that the framework for greater accountability – who should be the enforcer, how and to what extent should standards be enforced, etc. – is not yet in place. We have subsequently clarified this position in these Final Standards. The Division of Health Planning presented information to the Board for Licensing Health Care Facilities at its May, 2009 meeting on the need for greater accountability in the CON program. We look forward to continuing this emerging conversation with the Board and all other CON stakeholders. Among many topics, this conversation will include a discussion on providers who have implemented EP services without a CON.

42. The language that providers "should be held accountable for the promises made in an application" could be troubling, perhaps depending on what is considered a "promise." Most assertions made in an application are necessarily projections - not statements of fact. For example, a projection that a certain volume will be achieved is a projection that is justifiably scrutinized first by the staff and subsequently by the Agency. Financial projections are also made, but economy and other factors beyond the applicant's control can change, and those financial projections may not be realized. A provider should not be "held accountable" for

failing to reach good faith projections in the absence of a showing of intentional misrepresentation or deceit. And again, if being "held accountable" means having a CON revoked or restricted after its issuance, then due process safeguards are required.

Response: See response to Comment 41.

43. It was recognized during the public meeting that many of the standards and criteria in the document are based on nationally accepted "guidelines." I encourage you to use language consistent with standard #6 on page 11 in that states, "Where providers are not in compliance, they shall maintain appropriate documentation stating the reasons for noncompliance and the steps the provider is taking to ensure quality." This type of language is consistent with a guideline as opposed to a requirement.

Response: We agree with this comment. As noted in our response to Comment 41, the specifics of increased accountability for providers offering CON-regulated services should be developed through a public process that includes all interested stakeholders.

## **Data Reporting**

44. Page 8, Section 5 speaks to submitting data needed by the CON program. This process needs to be coordinated with the collection of data for the Joint Annual Reports - although, as currently configured, the required data would be very complex since the types of procedures proposed in the weighting scheme can be performed in a cardiac cath lab, an EP lab, medical imaging room (vascular procedures), or other kinds of procedure rooms. Again, I think the proposal is too complex for determining whether a new cardiac cath service is needed.

Response: The Department of Health Division of Health Statistics has informed us that it is willing to revise the Joint Annual Report of Hospitals (JAR) to accommodate the new criteria and data requirements. We will work with the Division of Health Statistics, the Tennessee Hospital Association, the Hospital Alliance of Tennessee, and other interested stakeholders to ensure that appropriate data are available for analysis of cardiac catheterization services CON applications. We believe it is important to establish what data are needed in the JARs by first revising the standards and criteria.

45. The Section proposes an ongoing age group specific historical state utilization rate to be maintained by the Department of Health. The map accompanying the Proposed 2009 Standards and Criteria for Cardiac Catheterization Services displays the distribution of Tennessee hospitals performing cardiac

catheterizations for 2007. The map information's source is the 2007 Joint Annual Report of Hospitals. The HSDA staff identified seven freestanding cardiac catheterization laboratories which have not reported ongoing utilization to the Tennessee Department of Health's Joint Annual Report (because they are not hospitals, ASTC's or ODC's) or the HSDA Medical Equipment Registry (because cardiac catheterization laboratories were not defined under the HSDA Medical Equipment Registry's enabling legislation as required to report). With the HSDA staffs experience in equipment registration, it is requested that you consider the HSDA Medical Equipment Registry for the State Health Plan's repository for collection of cardiac cath lab utilization information. HSDA Medical Equipment Registry personnel could then coordinate with the Department of Health's Division of Health Statistics population and epidemiological staff to develop the Age Group-Specific Historical State Utilization Rates. (Listing of "non-listed" cath labs is included in original comments).

Response: We urge the group of stakeholders that will study changes to the JAR, as recommended by Policy Recommendation 5, to address how to gather data from cardiac catheterization providers that do not currently report any information to the Department of Health.

## **E-Health**

46. Page 8, Section 7 speaks to e-prescribing and electronic health records. These systems are not under the purview of the HSDA and it is inappropriate to include them in the criteria.

Response: This section encourages applicants to participate in the public process that will lead to the widespread adoption of e-health technologies, which is a component of the State Health Plan. We believe that such participation contributes to the orderly development of the state's health care system and thus falls directly under the purview of the HSDA.

## **Volume Standards**

47. If a long standing community-based therapeutic catheterization program has a demonstrated record (8 years) of mortality rates lower than large tertiary centers despite lower case loads per operator (than the proposed number) is it fair or wise to choose a case load number higher to judge quality?

Response: As the state works to develop a systematic quality monitoring process, the advisory group to this process could identify alternative approaches to measuring and ensuring quality. This group then could advise the state on programs failing to meet the volume requirements. We acknowledge that this process will be a new one for providers in Tennessee; we are committed to

working with providers and the Department of Health to develop an effective and reasonable program for improving the quality of cardiac care in Tennessee.

## **Policy Recommendations**

48. The policy statements are laudable as goals and objectives, but are not appropriately placed under the purview of the HSDA. I defer to the Agency as to what its resources will allow it to do in terms of enforcement and oversight, but I would point out that it is a part-time, essentially volunteer board with a relatively small staff. Just getting through the CON applications during the one day per month meetings is a challenge. Adding to that, for example, a "periodic review process" of all providers to assure that "minimum volume requirements" are met, (Policy Recommendation 6) has the potential of bogging down the CON process. Adding to the staff or otherwise putting additional resources into the Agency to enable it to carry out these additional duties would no doubt result in additional filing fees for applicants.

Requiring a provider to meet minimum volume requirements, and presumably jeopardizing its authorization to provide the service for its inability to do so, is a substantive revision that should at a minimum require formal rule-making if not a statutory amendment, and due process protections.

A significant concern is that these proposals have the potential of abrogating the Agency's discretion in making decisions on CON applications. Changing the nomenclature from "Guidelines" to "Standards and Criteria" appears to be more than mere semantics. The prefatory language states: "Applicants proposing to provide any type of cardiac catheterization services must meet the following minimum standards."

The shortcoming of the current Guidelines is they are outdated and often do not reflect the current market and/or clinical realities of a particular service. But I believe extreme caution should be taken not to promulgate a set of "standards and criteria" which could be interpreted as being mandatory, thereby unduly tying the hands of the Agency and undermining its expertise.

Response: We agree that the HSDA's statutory charge does not extend to enforcement and oversight. We also agree that the HSDA should maintain its flexibility and independent judgment in its decision-making. Accordingly, throughout these Final Standards we have substituted precatory language for directive language. We note, however, that item 5 in the cardiac catheterization standards and criteria contained in the Guidelines for Growth, 2000 Edition reads: "A CON proposal to provide expanded cardiac catheterization services shall not be approved unless existing services within the proponent's facility are demonstrated to be currently utilized at 80% of service capacity." Similarly strong language can be found Guidelines for Growth, 2000 Edition standards and

criteria. Given this precedent, we believe this new language and nomenclature makes no change in the HSDA's decision-making authority. As we continue to revise the CON standards and criteria under the State Health Plan, we will work to ensure that the HSDA is given appropriate flexibility based on well researched and up-to-date standards and criteria.

49. It would be helpful to list the actual criteria and standards separately from any policy statements or rationale for purposes of user-friendliness as applicants use them in the completion of a CON application.

Response: We agree with this comment and have made changes in these Final Standards accordingly.

50. It is apparent from the proposed format of the draft that the Division of Health Planning staff recognizes that the current draft of the Proposed 2009 Standards and Criteria for Cardiac Catheterization Services is a "work in progress" and has some additional refining to be done before finalization. The current draft intertwines the criteria and standards with the additional work program tasks which need to be performed among state agencies and provider members of the health care industry. It would be helpful for applicants and agency reviewers to list the actual criteria and standards separately from any policy statements, rationale for purposes of user-friendliness, or future work program tasks. It would enhance brevity and add clarity to footnote such statements and remove them to appendices separately entitled Rationale, Future Work Program Tasks for updating the criteria and standards, and Future Health Planning Policy Statements.

In addition, consideration should be given to recommending development of regional heart care networks structured much along the same concepts as the Department of Health's Guidelines for the Regionalization of Perinatal Services. The state health plan would encourage partnerships between the major tertiary care heart centers and rural hospitals. The major centers would support through education, training, and technical and clinical backup for the rural providers. Communication linkages would promote the rural hospitals as part of the access points to heart specialized care both for emergency and preventive care. Educational programming from the heart centers would raise the knowledge level for rural providers in providing emergency heart and stabilization services. Telemedicine technology could provide cardiac specialist knowledge and skills to a broader base of Tennessee's rural population. Through such partnerships the level of heart disease prevention and care would be raised through all provider participation. More details on development of heart network partnerships are available if desired.

Response: We are interested in the possibility of developing regional heart care networks, and we look forward to further discussion on this topic. We agree that

the policy recommendations should be listed separately from the standards and criteria and have made that change.

## **Facility Accreditation**

51. This standard holds a facility which applies for a CON to a different and higher standard than a facility that does not apply for a CON. The legislature has determined that all facilities must meet the applicable licensing standards, and the appropriate regulatory body is responsible for setting those standards. If the goal is for every facility in the state to be accredited, the licensing authority should promulgate that requirement, thereby assuring even handed treatment of all facilities.

Response: As a condition of licensure, hospitals must be inspected by a Department of Health surveyor. While accreditation is not a condition of hospital licensure in Tennessee, freestanding cardiac catheterization laboratories in Tennessee are not required to be licensed and, subsequently, are not surveyed by a quality review panel. In order to promote a safe environment for a high-risk procedure such as cardiac catheterization, we believe that all facilities providing cardiac catheterization services should be surveyed by a proper authority, such as the Department of Health or a nationally recognized accrediting body such as the Joint Commission. We agree that Draft Standard 2 would have held licensed facilities applying for a CON to provide cardiac catheterization to a higher standard than other licensed facilities. Therefore, we have clarified in these Final Standards that the HSDA should only consider an applicant's intent to seek accreditation if that applicant is not required by law to be licensed by the Department of Health.

## **Laboratory Environment and Staffing Standards**

52. The current guidelines are void of mentioning personnel qualifications as other Guidelines for Growth criteria and standards do (e.g., MRI). The proposed guidelines refer the applicant to The American College of Cardiology (ACC) guidelines for reference. It would be helpful for the new CON applicant to know what the ACC's internet website address is and how to access the ACC/SCA&I Expert Consensus Document. There appears to be no easily identifiable direct linkage to the document so the researching person must perform a search of the website for "cardiac catheterization laboratory standards." For future reviewers, however, the ACC guidelines is a large 45 page document and there may be confusion regarding which criteria are essential for the applicant to specifically address in filing the CON application. Therefore, several key areas could be addressed directly in the updated guidelines. In considering initiating a cardiac catheterization program, it would be helpful for the applicant and reviewer to know what standards need to be addressed for description of a quality Cardiac

Catheterization program, including the facilities, equipment, personnel qualifications, support facilities, supportive clinical expertise, operating policies and procedures for emergencies and connectivity with other cardiac programs through prearranged communications and transfer agreements. For example:

- 1) Facilities should not only include designed and constructed in compliance with 2006 AIA Guidelines for Design and Construction of Healthcare of Healthcare Facilities, but also should consider close proximity, if not immediate adjacency of a pre-op and recovery area with cardiac monitoring capabilities for each bed along with central monitoring at a central nursing station. Reference is directed to Table 13 of the ACC/SCA&I Expert Consensus Document.
- 2) Equipment: Cardiac catheterization laboratory radiographic and monitoring equipment should be approved for its intended use by the FDA.
- 3) Personnel: The ACC document notes a cardiac cath laboratory should have
  - a) A medical director with minimal credentials of board certification in interventional cardiology who is responsible for the clinical leadership of the cath lab.
  - b) all medical staff members performing procedures in the diagnostic cardiac catheterization laboratory should at a minimum be board certified or board eligible in diagnostic cardiology
  - c) all medical staff members performing procedures in the interventional cardiac catheterization laboratory should at a minimum be board certified or board eligible in interventional cardiology
  - d) all medical staff members performing EP procedures in the cardiac catheterization laboratory should be at a minimum board certified or board eligible in electrophysiology
  - e) a registered nurse nursing supervisor with critical care nursing experience and be in charge of all nursing personnel in the laboratory, as well as the pre-procedure and post-procedure holding area(s).
  - f) nursing staff members, staffing both the cath lab and the recovery area should be registered nurses with at least one year's experience in critical care nursing and preferably be certified in critical care nursing (CCRN)

g) radiological technologists should have completed appropriate certification credentials, qualifying experience and demonstrated knowledge of radiographic and angiographic imaging principles and techniques, radiation safety and physiological monitoring techniques

h) Laboratory physiological technologists should be skilled in managing blood samples, and performing blood gas measurements and calculations. They should be qualified to monitor and record electrocardiographic and hemodynamic data and have enough skill and experience in interpreting these data to report significant changes immediately to the physician responsible for the patient.

Response: We agree that the staffing and laboratory environment guidelines contained in the ACC/SCA&I Expert Consensus Document (ACC Guidelines) are extensive and very detailed. While highlighting key provisions—particularly concerning staffing and staff credentials—may in theory make this standard more measurable, the question remains whether the HSDA should consider such operational details before a service is initiated. Initiating a new cardiac catheterization services is a complex process, and the administrators of this process should perform their due diligence by consulting and taking direction from nationally derived guidelines. Standard 6 under Standards and Criteria Regarding Certificate of Need Applications for All Cardiac Catheterization Services allows the HSDA to assess whether an applicant intends to perform this due diligence and maintain ongoing consideration of the ACC Guidelines without requiring an applicant to demonstrate operational realities prior to the cardiac catheterization program’s authorization.

We agree that the ACC Guidelines should be more accessible from the standards and criteria and have made that change.

53. It may be helpful to be more specific with regards to staffing because as written it would be hard to measure. Maybe a listing of minimum requirements for nursing and other Cardiac Catheterization laboratory personnel would make this a more measurable standard.

Response: See response to Comment 52.





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