GEORGIA STATE HEALTH PLAN
COMPONENT PLAN

POSITRON EMISSION TOMOGRAPHY

Proposed by the High-End Diagnostic Equipment (PET) Technical Advisory Committee
on January 30, 2002.
Adopted by the HEALTH STRATEGIES COUNCIL on February 15, 2002

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TABLE OF CONTENTS

PREFACE....3

INTRODUCTION….4

A. PLANNING PROCESS… 4

B. OVERVIEW 5

Background….5
Uses of PET Technology… 7
Reimbursement….8
Cost Effectiveness of PET….10
Efficiencies of PET/CT… 10
Statewide Distribution and Access… 11

C GUIDELINES… 13

A. Use of Guidelines… 13
B. Definitions for Guidelines… 13
C. Standards for Guidelines… 14

D. GOALS, OBJECTIVES AND RECOMMENDED ACTIONS… 22

E. REFERENCES 23

Appendix A: Members of High-End Diagnostic Equipment (PET) Technical Advisory Committee
Appendix B: Map, Health Planning Areas

PREFACE

This Component Plan is a product of the Health Strategies Council and the Georgia Department of Community Health/Division of Health Planning, pursuant to the provisions of O.C.G.A. 31-5A-1 et seq. and 31-6-1, et seq. The purpose of the Plan is to identify and address health issues and recommend goals, objectives and system changes to achieve official state health policies.

This Plan has been produced through an open, public participatory process developed and monitored by Health Strategies Council, appointed by the Governor. The Plan is effective upon approval by the Council and the Board of Community Health and supersedes all related sections of previous editions of the State Health Plan and any existing related Component Plan.

For purposes of the administration and implementation of the Georgia Certificate of Need (CON) Program, criteria and standards for review (as stated in the Rules, Chapter 272-1, 272-2 and 272-3) are derived from this Component Plan. The Rules, which are published separately from the Plan and which undergo a separate public review process, are an official interpretation of any official Component Plan which the review function has the legal authority to implement. The Rules are reviewed by the Health Strategies Council, prior to their adoption by the Board of Community Health, for their consistency with the Plan. The Rules, as a legal document, represent the final authority for all Certificate of Need review decisions.

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I. INTRODUCTION

A. Planning Process

Prior to now, the State of Georgia has not developed a component plan and corresponding rules that specifically addressed the need for positron emission tomography (PET) or PET/Computed tomography (CT) diagnostic equipment. While, due to the cost of the equipment, Certificate of Need (CON) approval has been required to initiate or expand this service, applications seeking to offer this service have been evaluated as a new institutional health service using the Division of Health Planning's General Consideration Guidelines.

Effective July 2001, the Centers for Medicare and Medicaid Services (CMS), formerly the Health Care Financing Administration, the federal agency charged with reimbursement for health services for patients qualifying for Medicare entitlements, expanded coverage for PET scan procedures. Enhanced reimbursement made these services more attractive and the Division of Health Planning began receiving CON applications requesting to initiate or to expand PET services.

In the past, the development of these services has not been done in a very comprehensive manner. The Department envisions the acquisition of PET equipment to be more in line with the need for such services. Furthermore, the Department would like to ensure that providers participate in the state's cancer programs and assure that these services are a part of a comprehensive array of imaging and other companion services that are financially and geographically accessible.

On August 30, 2001, the Department of Community Health proposed rules to address the need for High-End Diagnostic and Therapeutic Equipment, which included both PET, PET/CT and Gamma Knife equipment in an attempt to manage the increased CON applications for these types of equipment. Concern was raised about the process and content of those proposed rules. Following consultation with interested parties, the Division and the Health Strategies Council felt it most appropriate to bring together a technical advisory committee (TAC) to review the issues and to develop any needed guidelines. Because the Gamma Knife is used solely as a therapeutic regimen and because there has been less of an interest in this technology, the Department removed it from consideration at this time, opting to examine high-end diagnostic equipment only, namely PET and

PET/CT. The Health Strategies Council formally acted on November 16, 2001 to convene a TAC. The committee has been charged with producing at least one, and possibly two, work products:

- ♣ A recommended set of guidelines and, if appropriate as determined by the scope and depth of the guidelines, a component plan to address the acquisition and use of high-end diagnostic equipment – both for consideration by the Health Strategies Council.

- ♣ If warranted by the guidelines, a set of proposed rules for consideration by the Council and the Board of Community Health.

Membership on the TAC (See Appendix A) included clinical experts, payors, providers and other interested parties. The TAC held its initial meeting in December 2001 with two subsequent meetings in the month of January. Division staff and TAC members were provided with recent literature, listened to expert presentations, reviewed the CON guidelines of other states, and studied other relevant data and materials to inform the group's deliberations.

Members considered the best ways to balance cost containment with access considerations (both geographic and financial). The group also considered issues related to quality and continuity of care as well as the importance of integrating high-end diagnostic services with necessary research, referral and treatment services. The primary goals of the Department of Community Health, Division of Health Planning and the Health Strategies Council have been to ensure that services are appropriately planned, geographically accessible, and linked to the necessary clinical, research and therapeutic services – while protecting government and private purchasers from unnecessary and duplicative costs. The TAC presented its proposal for consideration at the Health Strategies Council's February 2002 meeting. This component plan encapsulates the Department's policy directions for PET services.

B. OVERVIEW

Background

PET is a nuclear medicine technology that uses radioisotopes to allow the noninvasive diagnostic imaging of metabolic processes in living organisms. PET has been in use for over 20 years. During the bulk of this period it has been used primarily for research purposes. The available isotopes used for this system in

earlier years had very short half-lives, ranging from 2 – 20 minutes. As such, PET imaging was restricted largely to sites with their own cyclotrons. This limitation curtailed the spread of the modality. (17)

Acceptance of the technology in the medical community was thwarted by the cost of a PET scanner ($1.5 million to $2. million), the limited availability of F-18 FDG due to too few cyclotrons, lack of reimbursement for Medicare patients, and limited reimbursement by third-party payers.(1) However, changes in reimbursement, advances in research and enhanced technology have moved PET into a clinical setting, and have caused providers to see new potential in PET services.

The Food and Drug Administration approved F-18 FDG as a safe and effective drug for evaluation of metastatic disease in patients already diagnosed with cancer and rubidium-82 for detection of myocardial perfusion abnormalities in patients with known or suspected coronary disease; CMS approved Medicare reimbursement for certain PET procedures. Many researchers believed that the FDA's approval of FDG coupled with CMS's decision to reimburse for select PET indications prompted a number of companies to begin manufacturing and distributing FDG nationally. As a result, the price of FDG has dropped dramatically. These and other reasons have caused heightened interest in this technology.

Like other nuclear medicine technologies, PET defines disease in terms of quantifiably abnormal regional chemistry. However, unlike other imaging technologies such as CT and Magnetic Resonance Imaging, which primarily provide information about anatomical structure, PET can image and quantify biochemical and/or physiological function. PET depicts circulation, function, or metabolism, not just simple anatomy. PET is considered a complementary imaging modality to MRI or CT. PET pinpoints the source of many of the most common cancers, heart and neurological diseases, eliminating the need for redundant tests and diagnostic surgical procedures and displaying information unobtainable through any other means.

PET is the only technology available to provide a three-dimensional metabolic and functional analysis of organs. The use of FDG in cancer imaging is based on the observation of enhanced glycolysis in tumor cells. The standard uptake variable (SUV) is a quantitative measurement used to determine glycolytic activity in tumor cells. A decrease in base line activity is indicative of successful treatment; in contrast if the SUV remains constant or increases a clinician can predict the treatment outcome and decide on an alternative therapy plan for the patient. (2,5)

There is an indication that PET assessment may play a role in reducing patient morbidity due to unnecessary surgery or radiation therapy In some cases, FDG uptake may be reduced after one or two cycles of radiation therapy before conventional imaging modalities recognize a decrease in mass. The changes in FDG uptake are used to predict outcome of treatment and can help clinicians in early determination of therapeutic resistance. Also, PET is useful for follow-up therapy of cancers submitted to chemotherapy or radiotherapy and can be used to compare the nuclear medicine image with the patient's baseline scan to assess treatment response.(2) The use of PET in conjunction with other diagnostic techniques may contribute to down staging or upstaging disease. (3,4,5) Studies showed that PET scans are an excellent tool for preoperative staging of some cancers, especially lung carcinoma. PET imaging reportedly altered patient management in 25-35% of cases studied. (5,8)

A PET scan is painless, except for a mild, skin prick if the tracer is injected. During a PET scan, a positron-producing radioisotope, called a tracer is either injected in the patient's vein or inhaled as a gas. Once the tracer enters the body, it travels through the bloodstream to a specific target organ. The PET scan must be performed immediately following the tracer because the tracer usually decays very quickly. A typical PET scan usually takes between 45 minutes to an hour and requires the patient to lie completely still. The patient lies on the imaging table while the scanner detects the concentration of the isotope within the organ targeted for examination and generates a color image by use of a computer.

Uses of PET Technology

The major applications of PET are in oncology, cardiology and neurology. In oncology, PET is the only technology that can reliably diagnose tumors from post-surgical changes or radiation necrosis, distinguish benign from malignant lesions, identify the optimal site for biopsy, staging of cancers and monitoring the response of tumors to therapy. In cardiology, PET provides highly accurate determinations of coronary artery disease, which would largely eliminate most of the normal coronary angiograms. In addition, PET is the only technology that can accurately determine myocardial viability (considered to be the gold standard), which would lead to ventricular function. PET scan images can also be used to determine how much heart muscle is alive. If the heart muscle is still living, bypass surgery could solve the problems that were thought to require a heart transplant. This can lead to significant improvement in morbidity and mortality for severely ill patients as well as

cost savings. In neurology, PET has proven value in diagnosing Alzheimer's disease, Huntington's disease or multi-infarct dementia, in the determination of seizure focus for surgical resection, and in the evaluation of strokes.

Currently, the vast majority of clinical PET examinations (over 80%) are performed in oncology, for staging of malignant tumors, detection of tumor recurrences and monitoring response to therapy. PET is used in cardiology to assess patients with coronary artery disease and assist with the optimal selection of candidates for appropriate surgery. The most accepted of PET's roles in neurology include typing brain tumors, pre-surgical evaluation of epilepsy, and diagnosis of dementia. PET scanners have shown promise in the early detection of patients with Alzheimer's disease and identifying the causes of childhood seizures. (10,11)

Reimbursement

The rise in popularity of PET scanners coincides closely with a decision by the federal government to pay for PET scans on certain procedures, particularly cancer. Beginning in 1995, Medicare reimbursement was approved for six PET procedures, mostly for cancer. Additional interest in PET scanners surfaced when CMS issued an expanded list of conditions that would be covered. In 1998, prior to the institution of this reimbursement mechanism, approximately 50 scanners existed in the nation. Data provided by Paul Kountz, MD, PhD during his presentation to the TAC indicated that by 1998, providers were performing approximately 65,000 scans per year. In July 1999, CMS announced that three additional diagnoses would be covered. The number of PET scans continued to increase; rising to over 100,000 scans per year. By the year 2000, there were approximately 350 PET instruments in the nation, producing close to 160,000 scans annually. (15)

Recent documents from CMS indicate that as of July 2001, CMS has expanded areas of coverage for PET to include:

- Head and neck cancers
- Pre-surgical evaluation for patients with refractory seizures;
- Diagnosis, initial staging, and restaging of esophageal cancer;
- Diagnosis, initial staging, and restaging of non-small cell lung cancer;
- Diagnosis, staging, and restaging of colorectal cancer;
- Initial staging, and restaging of both Hodgkin's and non-Hodgkin's disease

- Diagnosis, initial staging, and restaging of melanoma. (14)

Medicare coverage has been approved for use of PET scans with FDG for the purpose of development of appropriate treatment plans for patients. CMS is expected to evaluate both the data produced by claims for these services, and data obtained from other sources, to determine whether, and to what extent, this coverage policy may need additional modification in order to assure that the services covered are medically effective for the treatment of Medicare beneficiaries.

Documents dated April 2001 from CMS indicate that Medicare covers PET scans only in clinical situations in which PET results may assist in avoiding an invasive diagnostic procedure or in which the PET results may assist in determining the optimal anatomical location to perform an invasive diagnostic procedure. PET is not covered for screening purposes but is covered in clinical situations in which the stage of the cancer remains in doubt after completion of a standard diagnostic workup or if it could potentially replace one or more conventional imaging studies when it is expected that conventional study information is insufficient for the clinical management of the patient and the clinical management of the patient would differ depending on the stage of the cancer identified. PET is also covered for restaging after the completion of treatment for the purpose of detecting residual disease,detecting suspected recurrence or determining the extent of a known recurrence.

Private sector reimbursement for PET scans varies around the country. In some regions, most private insurance carriers routinely cover PET scans for commonly held clinical applications including the oncology indications listed for Medicare coverage and cardiac perfusion and viability, as well as brain tumors and epilepsy. In other regions, private sector reimbursement is more limited. Georgia Medicaid does not reimburse for PET services; however the Public Employees Health Benefit programs do reimburse for these services.

One could easily surmise that utilization of PET scans will continue to increase as technological enhancements occur and changes in financing and regulatory processes occur. Review of current information from the CMS indicates that PET imaging must be performed on either FDA-approved full-or partial-ring scanners, or coincidence systems that have specific physical features. It is this definition that the division would examine for guidance regarding this technology. Any provider who operates outside of these guidelines would be subject to enforcement action.

Cost Effectiveness of PET

Many reports demonstrate that the cost effectiveness of PET stem from it's high sensitivity and ability to distinguish malignant tumors from benign tumors, thus providing clinicians with information to make improved analytical decisions based on the patient's current metabolic functions.

Expanded use of this technology will allow for extensive research and broader clinical indications. Research is inconclusive on the relationship between PET imaging and clinical decisions that alter patient's treatment, however some studies have shown that there is some clinical benefit, especially in lung carcinoma. (3,4,6) Efficacy in health outcomes is associated with PET use in determining treatment response because of its ability to determine therapeutic response earlier than most conventional imaging modalities thereby allowing costly or invasive treatment to be reduced. The Whole Body PET imaging modality can also prevent excessive testing to derive at a clinical diagnosis because of its ability to examine the whole body at one time. Clinical applications for PET equipment will continue to evolve.

Efficiencies of PET/CT

According to a November 2001 report, a PET/CT combines premier technology from two imaging modalities, making it possible to reveal detailed anatomy and biological processes at the molecular level of internal organs and tissues from one single noninvasive procedure. The PET/CT works by combining PET technology, in which the scanner reads cellular metabolism of glucose, and CT, which builds a clear-cross section of tissue structures using x-rays.

Research indicates that the combined PET/CT scanner is the most powerful imaging tool available for localizing, evaluating and monitoring of head and neck cancer and may be equally useful for other cancers that are difficult to pinpoint. Separately, CT and PET do not provide images with the necessary combination of clear structural definition and metabolic activity that is achieved with the PET/CT. The PET/CT tells the exact size, shape and location of the cancer and provides a specific target for surgery, radiation therapy, or other treatment. The PET/CT can also be used to help develop the best course of treatment for an individual, and then monitor the individual's progress during treatment. Images from the combined PET/CT scanner are particularly useful in

allowing a radiologist to see cancerous activity at a metabolic level and pinpoint its exact location in the tissue so that a biopsy can be performed and appropriate treatment begun (18).

Research indicates that, based on the types of diseases that have been and are expected to be reimbursed by Medicare, the potential patient pool in the United States is approximately 4-million procedures/per year. However only 400,000 procedures are being performed in the United States annually(18). The benefit of this technology is to provide exact localization of disease found on the metabolic PET scan by superimposing that information onto an anatomical map like a CT scan. This provides physicians with valuable information regarding appropriate treatment alternatives. Further, researchers seem to agree that since nearly all PET patients have a CT during some point in their care, most PET candidates could benefit from a PET/CT scan.

The PET/CT would allow physicians to see the exact location and type of growth within the patient's body. Because of this unique ability, researchers have concluded that this equipment should save countless lives, prolong others and make many exploratory operations unnecessary. Physicians would be able to obtain precise information about patients and could make better informed decisions. The PET/CT units are expensive and finetuning remains to be done. Standalone PET equipment will continue to be utilized while this combination technology is refined.

Statewide Distribution and Access

Recent data from the Division of Health Planning indicates that the State of Georgia presently had ten (10) fixed-based PET units (existing and approved) and four (4) mobile units in 2001. Of the fixed units five (5) were approved in 2001; one (1) in 2000 and four (4) between 1987 and 1991. Three (3) of the 4 mobile units were approved in 2000 and one (1) in 2001. Three of the four mobile units, at this time, are not yet in operation. Of the ten existing and approved applications for fixed based PET scan services, six (6) are hospital-based while four (4) are freestanding. There are four (4) existing and approved mobile PET units.. Most of the geographic coverage is evident in the state's urban centers.

Recent applications approved by the Department have required an indigent and charity care commitment. Georgia has history to reference on the performance of established providers. The state intends to draw on this knowledge in order to plan PET development in a meaningful way. While currently the PET

technology is principally used in the areas of oncology and cardiology, the area of neurology is predicted to be the area of greatest growth. PET technology will likely continue to expand particularly in the area of Alzheimer's disease and other dementias. The TAC sought to craft a set of guidelines that would be appropriately progressive without being unduly burdensome.

C. GUIDELINES

A. USE OF GUIDELINES

The following criteria and standards outline the guidelines for the development and delivery of Positron Emission Tomography Services in the State of Georgia as recommended by the TAC for approval by the Health Strategies Council and the Board of Community Health

B. DEFINITIONS

1. "Health Planning Area" or "planning area" means the 13 geographic regions in Georgia as defined in the official State Health Component Plan for use in planning for PET Scan services.

2. "Horizon Year" means the last year of a five-year projection period for need determinations.

3. "Expansion" or "expanded service" means the addition of a fixed unit to an existing service or, in the case of a mobile unit, the addition of a new site not previously served by such mobile unit. The addition of a component or components, such as computer tomography (CT) imaging, to an existing fixed or mobile unit or the upgrade of an existing fixed or mobile unit shall not be considered an expansion and shall not be subject to the need standards; provided, however, that if any such addition or upgrade is subject to review due to the equipment expenditure threshold at that time, the applicant shall demonstrate compliance with or document a plan and agreement to comply with 272-2-.09(22) (c) 4, 5, 6, and 7.

4. "Fixed Unit" means a unit that is stationary within one approved facility.

5. "Mobile Unit" means a unit that is shared by two or more health care facilities and which has a data acquisition system and a computer. In order to meet the definition of mobile unit, the applicant must provide proof of the following:

a. The unit must be on site at each Facility identified in the application at least three (3) days per month.
b. The unit must not be on site at any Facility more than three (3) consecutive operating days per week or twelve (12) total days per month.
c. The facilities involved with the mobile unit are fully informed and participating in the service as evidenced by written agreements or correspondence provided in the application.
d. The applicant, if successful, is limited to providing service only for those facilities approved in the application. Additional facilities may be added to the service list only through an approved application for expansion. The applicant, if successful, may eliminate sites approved in the application; provided that all standards and criteria will still be met and the mobile unit provider and the site being eliminated jointly notify the department in writing of their intent to eliminate the site.
e. The applicant shall project scans per facility on a pro-rated basis for the first year of operation, and such projections shall be used in any need determinations during that first year of operation. Thereafter, in annual surveys, the applicant, if successful, must document scans by each service facility for use in need determinations.

6. "Optimal Utilization" refers to scans per year and shall be defined as 1,500 PET scans per year regardless of whether the diagnostic equipment is a standalone PET scanner or includes another component such as CT. A PET Scan or Study means the gathering of data during a single patient visit from which one or more images may be constructed.

7. "PET Scan Service" or "Service" means a facility that owns one or more units and provides diagnostic imaging through positron emission tomography exclusively or as a dedicated PET/CT unit.

8. "Positron Emission Tomography" or "PET" means a noninvasive diagnostic technology, which enables the body's physiological and biological processes to be observed through the use of positron emitting radiopharmaceuticals.

9. "Unit" means a single piece of equipment that performs PET scans.

C. STANDARDS FOR GUIDELINES

APPLICABILITY

A certificate of need will be required for a new or expanded positron emission tomography (PET) unit

STANDARD 1: NEED

The need for a new or expanded unit shall be determined through the application of a Numerical Need method and an assessment of the aggregate utilization rate of existing and approved units.

(i) The numerical need for a new unit in a planning area shall be determined through the application of a demand-based forecasting model. The model is outlined in the steps listed below, and all data elements relate to each planning area:

A. Calculate the projected incidence of cancer for each county by multiplying the most recent Cancer Incidence Rate, as published by the State Cancer Registry, for each county by the horizon year population for the county;
B. Multiply the projected incidence of cancer by 50% to determine the projected number of patients diagnosed with cancer who might benefit from a scan.
C. Add the number of cancer cases that might benefit from a scan for each county within a Health Planning Area to determine the estimated need for services within a Health Planning Area for persons diagnosed with cancer.
D. Multiply the number of cancer cases for each Health Planning Area from subsection (C) by 1.5 to accommodate for non-oncology patients and for followup scans for oncology patients in the projected need for services.
E. Calculate the number of needed units by dividing the number of individuals who might receive scanning services as determined from subsection (D) by 1,500, which represents the optimal utilization of a unit. Following the determination of whole numbers representing units, if the balance net numerical need in any Health Planning Area is at or above 75% of a unit (1125 individuals needing scans), the needed units shall be rounded up by one unit.

F. Determine the net numerical unmet need for PET scan unit(s) by subtracting the total number of units currently existing or approved for use from the number of needed units.

(ii) Prior to the approval of a new or expanded unit in a planning area, the aggregate utilization rate for all existing and approved units in that planning area shall equal or exceed 90% of optimal utilization for the most recent survey year.

Rationale for Standard 1:

This numeric need methodology was fashioned after that of the State of Illinois. TAC members agreed that a formula which incorporated three factors: population, incidence of cancer that would benefit from PET and an additional weight to account for emerging need in the aging population and cardiovascular disease incidence rates would provide the best indicator of need for PET services. Members agreed that data used to estimate cancer incidence rates should be derived from the Georgia Comprehensive Cancer Registry (GCCR). The GCCR collects statewide data on new cases of cancer and these data are used to estimate cancer incidence rates within Georgia, monitor cancer trends, evaluate possible clusters of cancer, respond to inquiries about cancer from the public, and conduct research.

The major applications for PET technology are in the areas of oncology, cardiology and neurology; however at this time it is principally used in the area of oncology. Increased utilization in the area of dementia is likely in the future. To accommodate for the use of this equipment to provide care to non-oncology patients and followup scans for oncology patients a factor of 1.5 has been used as a multiplier into the need methodology.

A nationwide review of the CON guidelines for PET services, indicate that minimum thresholds range from 750 to 2100 scans per year and the utilization threshold for expansion of services range from 900-5,000 scans per year. Recent applications in the State of Georgia for PET and PET/CT units project the utilization range to be between 1,700 and 2,100 scans per year. The committee felt that an optimal utilization standard of 1,500 scans per year would be appropriate for the State of Georgia regardless of whether the diagnostic equipment is a standalone PET scanner or includes a CT component. No extra time or resources are needed to perform a PET/CT scan versus a solo PET scan.

Due to the high cost and limited utilization of this equipment, the committee recommended that the aggregate utilization for all existing and approved units in the planning area should equal or exceed 90% of optimal utilization before an application for new or expanded services would be approved. This would ensure that these services are being appropriately utilized before providers outlay large capital expenditures.

STANDARD 2: EXPANSION OF SERVICES

(i) An applicant seeking an expansion or expanded service for a fixed unit may be approved only if all provisions of the need standards in 272-2-.09 (22) (c)(1) and all other standards in the rules are met.

(ii) An applicant seeking an expansion or expanded service for a mobile unit may be approved, without meeting the need standards of 272-2-.09(22) (c)(i); provided that the planning area in which the applicant is seeking the expansion or expanded service shows a net numerical unmet need of more than 25% of a unit (375 individuals needing scans) but less than 75% of a unit (1125 individuals needing scans) and provided that all other standards are met and that the affiliation, transfer, or referral agreements provided pursuant to 272-2-.09(22)(c)(6)(i) are executed with a hospital or hospitals within the planning area in which the mobile unit seeks to expand.

Rationale for Standard 2:

TAC members wanted to ensure that patients would be have adequate access to this evolving imaging modality. Members placed great emphasis on geographic access by instituting mechanisms that would ensure that statewide availability, among other considerations would be paramount in the CON evaluation process. Members agreed that no special considerations would be granted to current providers and that all applicants would be required to meet the need methodology standards and all other standards in the rules.

Because of the emphasis on geographic accessibility, members encouraged the planful development of mobile providers. Health Strategies Council members wanted to ensure that the rules would not be unduly burdensome on hospitals that operate mobile units. Members recommended that the definition of a mobile unit include the words "three consecutive operating days per week". This definition recognizes hospitals' need in some instances to park the mobile units on their grounds over the weekend particularly when no weekend use is planned. Mobile providers would be limited to providing services to those sites approved in the their CON application. Additional sites may be approved for mobile providers, if in the planning area in which the mobile applicant is seeking to expand, existing providers are operating at or above 90% of optimal utilization and there exist a net numerical unmet need of between 25%-75% of a unit and provided that all other standards are met, including affiliation, transfer and referral agreements with hospital/s within the planning area in which the mobile unit seeks to expand. This mechanism would ensure that additional patients could be served without requiring providers to outlay large capital expenditures to acquire additional equipment. Where a net numerical need of greater than 75% exist, a new unit would be justified in that area. An applicant seeking to address this unmet need would be required to address the numerical need and all other standards of the PET guidelines.

The mobile applicant may eliminate sites approved in the CON application provided that all standards and criteria will still be met. The mobile unit provider and the site being eliminated jointly must notify the department in writing of their intent to eliminate the site. This notification process will ensure that the Division is made aware of any potential areas of unmet need in a timely manner and will ensure the participation of all parties in the planning of local services. TAC members agreed that this guideline would ensure that mobile providers would not abandon a site without input from a local community provider and that both the mobile provider and the hospital would be actively engaged in the process to plan and develop PET services locally. Additionally, this guideline would ensure that mobile providers limit their services to those sites that were approved in their CON and to ensure that there is continual communication between the mobile provider and the hospital in the event that either wishes to dissolve their relationship.

Members agreed that while the upgrade of a PET unit to incorporate a CT component will likely trigger the CON equipment threshold, the applicant would not be required to address the need standard in order to add a CT component. Members agreed that this upgrade would allow the provider to better serve the patient and would enhance system efficiencies. Additionally, they noted that this combination diagnostic tool is predicted to be the state-of-the-art technology in the imaging field and its acquisition should be encouraged. Members agreed that such an upgrade would be viewed under the General Consideration guidelines. Additional information relating to an upgrade of the PET equipment to include a CT is addressed in the definitions section of this document, under "expansion".

TAC members spent a considerable amount of time discussing SPECT technology and providers' ability to upgrade a Single Photon Emission Computed Tomography unit (SPECT) to provide PET services without complying with these rules. Members emphatically agreed that the upgrade or replacement of SPECT

equipment would be considered a new PET and would trigger these rules. Any provider who operates outside of these guidelines would be subject to enforcement action. Review of current information from the CMS indicates that PET imaging must be performed on either FDA-approved full-or partial-ring scanners, or coincidence systems that have specific physical features. It is this definition that the division would examine for guidance regarding this technology

STANDARD 3: EXCEPTION TO NEED

Exceptions to the need standards and requirements in (c) (1) may be granted by the Department for an applicant meeting one or both of the following criteria:

(i) the applicant has been designated by the Georgia Cancer Coalition as a research, treatment and regional service center, as evidenced by a written recommendation from the Georgia Cancer Coalition, and the applicant has no PET unit and none of the applicant's designated coalition partners in the Health Planning Area has a PET unit.

(ii) the applicant is seeking to remedy an atypical barrier to services based on cost, quality, financial access, or geographic accessibility.

Rationale for Standard 3:

This standard was designed to encourage providers to collaborate, to establish community partnerships and to support the work of the Georgia Cancer Coalition (GCC). The GCC was established by Governor Roy Barnes to build and coordinate a statewide network of cancer care. It requires non-profit organizations, civic groups and private businesses to participate in prevention programs and clinical research to be spearheaded by public and private institutions. The GCC plans to designate three or four centers of excellence and another dozen or so regional centers to provide core services, treatment and research. The TAC and the state wish to ensure that these regional centers, which are likely to serve as the pre-eminent point of treatment for Georgians, will have access to PET technology. Current PET providers are encouraged to partner with GCC and an appropriate regional service system. The strong message, however, is to ensure that GCC designated centers will be given every opportunity to obtain access to PET services. TAC members were emphatic about the need for applicants to submit a written recommendation from the Georgia Cancer Coalition, which establishes the applicant's designation as a research, treatment and regional service center. This written recommendation must substantiate the applicant's active partnership with the Georgia Cancer Coalition. The final decision under this exception standard will be made by the Department.

The Department may allow an exception to the need standard to remedy an atypical barrier to PET services based on cost, quality, and financial or geographic access. The Department of Community Health is responsible for managing the state's health planning program, which establishes standards and criteria for awarding Certificates-of-Need to health care facilities and certain high-end diagnostic equipment. The Department uses need methodologies to avoid the unnecessary duplication of services, equipment and facilities. In some instances, the objective need methodology may not detect underlying or subtle problems in service delivery. For this reason, regulatory guidelines frequently establish mechanisms to seek alternative ways to address these gaps in service delivery. The TAC sanctioned the concept of creating an exception to the need standard for applicants who seek to address atypical barriers to care based on any one of four value-based criteria: cost, quality, financial access, or geographic accessibility. In any CON submission seeking consideration under the exception provisions, the burden of proof is placed on the applicant to demonstrate that these accessibility problems exist.

STANDARD 4: FAVORABLE CONSIDERATION

An applicant for a new or expanded service shall receive favorable consideration if the applicant is a designated participant in the Georgia Cancer Coalition, as evidenced by a written recommendation from the Georgia Cancer Coalition.

Rationale for Standard 4:

An applicant for a new or expanded PET service shall receive favorable consideration if the applicant is a designated participant in the Georgia Cancer Coalition. The intent of this provision is to ensure that designated participants in the Georgia Cancer Coalition are afforded every possible consideration in the certificate of need review process, authorizing the Division to approve any Coalition-designated application submitted in accordance with either the need or exception to need provisions. In the case of competing but equal applications, a designated participant in the Coalition would be awarded the approval. TAC members were emphatic about the need for applicants to submit a written recommendation from the Georgia Cancer Coalition which establishes the applicant's participation in efforts to support the coalition's mission. The Department will make the final decision in the evaluation of favorable consideration.

STANDARD 5: APPLICATIONS JOINED FOR CON REVIEW

(i) In considering applications joined for CON review, the Department may give favorable consideration to an applicant seeking approval for a service with a unit that includes both PET and CT scan capabilities.

(ii) In considering applications joined for review, the Department may give favorable consideration to an applicant that has historically provided a higher annual percentage of unreimbursed services to indigent and charity patients.

Rationale for Standard 5:

TAC members agreed that PET is a viable solo service, however PET/CT equipment offers the value–added diagnostic option of concurrent physiologic and anatomic imaging. This hybrid imaging modality uses a common bed to image patients and allows providers the opportunity to obtain precise information about their patients. The PET/CT would allow physicians to see the exact location and type of growth within the patient's body. Researchers have concluded that this equipment should save countless lives, prolong others and make many exploratory operations unnecessary. Recent literature suggests that the combination of both studies is superior to either one alone and that this fused image will become the standard in nuclear medicine, within the next several years. Due to the efficiency of the PET/CT equipment, TAC members agreed that providers should be given additional consideration and credit for the attainment of this state-of-the-art technology.

One of the core goals of the Department of Community Health is to develop and sustain a health care infrastructure that is responsive to consumers while improving access. The TAC felt strongly that providers should assume some of the responsibility for providing care to community residents, particularly those that may have limited financial resources. Members unanimously agreed that, in applications that are joined for CON review, the applicant that has a stronger record of serving this population should be given favorable consideration.

STANDARD 6: FINANCIAL ACCESS & NON-DISCRIMINATION

An applicant for a new or expanded PET scan service shall foster an environment, which assures access to individuals unable to pay, regardless of payment source or circumstances, by the following:

(i) providing a written policy regarding the provision of any services provided by or on behalf of the applicant that stipulates that any such services shall be provided regardless of race, age, sex, creed, religion, disability, or patient's ability to pay, and documentation or evidence that the applicant has a service history reflecting the principles of such a policy; and

(ii) providing a written commitment that services for indigent and charity patients will be offered at a standard which meets or exceeds five (5) percent of annual, adjusted gross revenues of the PET scan service, or, in the case of an applicant providing other health services, the applicant may request that the Department allow the commitment for services to indigent and charity patients to be applied to the entire facility;

(iii) providing a written commitment to participate in Medicaid, PeachCare and Medicare programs, to the extent such programs reimburse for PET scan services, and to accept any Medicaid-, PeachCare- and/or Medicare-eligible patient for services;

(iv) providing a written commitment that the applicant, subject to good faith negotiations, will participate in any state health benefits insurance programs for which the service is deemed eligible; and

(v) providing documentation of the past record of performance of the applicant, and any facility in Georgia owned or operated by the applicant's parent organization, of providing services to Medicare, Medicaid, and indigent and charity patients. The applicant's or its parent organization's failure to provide services at an acceptable level to Medicare, Medicaid and indigent and charity patients, and/or the failure to fulfill any previously made commitment to indigent and charity care may constitute sufficient justification to deny the application.

Rationale for Standard 6:

Providing full access, free from financial or any other discrimination, is central to Georgia's health care purchasing and regulatory mission. Providers should be expected to adhere to these standards as a criterion for receiving any business or operational approval from the state. The TAC has endorsed the Department's mission of improving health outcomes for all Georgians by continuing to require providers to minimize barriers to the accessibility of health care services. TAC members unanimously recommended the inclusion of accessibility as a standard.

Applicants for new or expanded services would be required to provide evidence of written administrative policies and directives related to the provision of services on a nondiscriminatory basis, including providing services to individuals regardless of race, age, creed, religion, disability, or sex and documentation or evidence that the applicant has a service history reflecting the principles of such a policy. The TAC recommended that an applicant for PET services commit to providing indigent/charity at a level that meets or exceeds five (5%) percent of annual, adjusted gross revenues of PET services. At this time, Medicaid does not reimburse for the cost of

PET scans. In light of this consideration, TAC members have agreed that the establishment of a requirement where providers offer a higher percentage of indigent/charity care would offset the state's customary service-specific rule that require the provision of care to all patients regardless of their ability to pay. The applicant would be required to provide this commitment in writing. Furthermore, applicants are required, subject to good faith negotiations, to participate in any state sponsored or operated health insurance programs for which the service is deemed eligible. The Department of Community Health and the TAC are committed to providing access to care to participants in the state's publicly funded programs. The fact that the Medicaid program does not presently reimburse for PET services was the basis for not requiring providers to serve any patient regardless of ability to pay.

The TAC and the Department further outlined that the Division should consider the past record of the applicant and any facility in Georgia owned or operated by the applicant's parent organization. Failure to meet an existing or previous indigent care commitment and/or failure to serve Medicare, Medicaid and indigent and charity patients at an acceptable level may constitute grounds for denial of an application.

STANDARD 7: QUALITY OF CARE STANDARDS

An applicant for a new or expanded service shall provide evidence of the ability to meet the following quality of care standards:

(i) Document certification or a plan for securing certification for operation of a unit from the Georgia Department of Natural Resources.
(ii) Document that the unit proposed for purchase is approved for use by the U.S. Food and Drug Administration and for reimbursement by the Center for Medicare and Medicaid Services.
(iii) Document that the service will function as a component of a comprehensive diagnostic service and that appropriate referral to treatment and follow-up will be provided. The applicant must have accessible the following modalities and capabilities on site or through contractual agreements, as evidenced by documentation provided at the time of application: computed tomography, magnetic resonance imaging, nuclear medicine, and conventional radiography.
(iv) Document that the PET service shall be under the direction of a physician who is board certified in nuclear medicine or diagnostic radiology or has successfully completed a 6-month training program in nuclear medicine that has been approved by the Accreditation Council for Graduate Medical Education and that included classroom and laboratory training, work experience, and supervised clinical experience; and is licensed as an authorized user of radioactive materials in accordance with the rules of the Georgia Department of Natural Resources.
(v) Document the training and experience in PET scan services of the physician, nuclear medicine technologist, radiology technologist, and operational personnel.
(vi) Document fully the safe and timely access to radiopharmaceuticals.

Rationale for Standard 7:

Quality control is essential for the consistent high quality level of performance that is required of any medical service. Federal and state governments have established standards for the delivery of services, which must be met in order to receive Medicare reimbursement and state licensure status. TAC members spent a considerable amount of time discussing the importance of quality of care standards noting that in the interest of good quality patient care and in order to maximize the potential for good health outcomes all providers should

ensure that PET equipment is being maintained consistent with the provisions of the Department of Natural Resources and the U.S. Food and Drug Administration. They also noted that an array of appropriate companion services, namely, computed tomography, magnetic resonance imaging, nuclear medicine, and conventional radiography should be available to patients. These services could be onsite or provided through contractual arrangements or affiliations.

In addition to the quality of the equipment, members said that the quality of personnel is also critical to the delivery of care. Members have made specific educational training recommendations for personnel involved in the delivery of care. This educational process is important to ensure that patients receive the most accurate diagnosis and appropriate therapy.

Members noted that a provider of PET imaging services must have access not only to a PET scanner but also to radiopharmaceuticals, the tracer that is injected into the patient to facilitate the interpretation of the patient's physiology. Because radiopharmaceuticals have short half-lives, it is important that any provider offering this service assure the timely access to radiopharmaceuticals.

STANDARD 8: CONTINUITY OF CARE

An applicant for a new or expanded service shall provide evidence of the ability to meet the following continuity of care standards:

(i) Document that the applicant provides, or has signed affiliation, transfer, or referral agreements with one or more hospital(s) and health care organizations that provide, the following: comprehensive cancer services, including radiation oncology, medical oncology, and surgical oncology; open heart surgery; medical education; and services for persons with Alzheimer's or other dementias.
(ii) Document a referral system that includes a feedback mechanism for communicating scan results and any other pertinent patient information to the referring physician.
(iii) Document that the applicant will maintain current listings of appropriate clinical indications for PET procedures and will provide such listings to referring physicians and patients.
(iv) Document how medical emergencies will be managed in conformity with accepted medical practice.

Rationale for Standard 8:

The TAC recommended that an applicant document commitment to providing or linking with a continuum of care services, including a mechanism to transfer and refer patients to appropriate services. Additionally, they recommended the inclusion of a feedback mechanism to track and follow-up patients to determine attendance at a referred service. Members agreed that the applicant should be required to maintain current listings of appropriate PET procedures and should make such listings available to referring physicians and patients. Members agreed that the education of referring physicians is very important. They stated that all physicians involved in the care of patients should have a clear understanding of the capabilities and applications of PET imaging and should recognize the value of PET imaging as a staging procedure. This safeguard is necessary to avoid patients from receiving inappropriate and costly therapies when there is a low probability of positive outcomes. Members emphasized the importance of continuity of care and endorsed the recommendation that pertinent patient information should be sent to the patient's referring physician. Further, because of the evolution of the PET imaging technology members felt that this sharing of information would be another mechanism for physicians to keep abreast of changes in the field.

An applicant for PET services should address how they intend to staff and manage medical emergencies and must comply with practice guidelines set forth by nationally recognized or professional organizations. All applicants must institute mechanisms to handle medical emergencies in accordance with accepted medical practice. In the absence of these appropriate companion services onsite, signed agreements with providers who offer an array of services for the PET patient, including oncology, cardiovascular services and aging services should be implemented.

The medical education component of these guidelines refers to appropriate clinical competence to support a training and research environment. It may also include continuing medical education and medical residency training programs.

STANDARD 9: DATA AND INFORMATION REQUIREMENTS

An applicant for a new or expanded PET scan service shall agree to provide the department with all requested information and statistical data related to the operation and provision of services and to report that data to the department in the time and format requested by the department.

Rationale for Standard 9:

The TAC unanimously recommended the inclusion of Data and Information Requirements criterion into the PET guidelines. The proposed need methodology will require provider data for certain components. Further, uniform data is essential to assess changing patterns and to project service needs relevant to the provision of services. As additional emphasis is placed on quality, patient outcomes, cost and other efficiency indicators, collection of data will allow more precise assessment of these factors as well as others which are important to health planning. Applicants will be required to provide data related to the operation and provision of services to the Division of Health Planning by the requested time.

D. GOALS, OBJECTIVES AND RECOMMENDED ACTIONS

GOAL

- To support the Department of Community Health/Division of Health Planning in its efforts to produce a Positron Emission Tomography Services plan which addresses regulatory mandates, changing treatment patterns and the state's vision for access to high-end diagnostic equipment and services.

OBJECTIVES

- To reflect the rapid technological advances in the diagnosis and treatment of cancer, Alzheimer's and other dementias and cardiovascular diseases;

- To ensure access to high-end diagnostic equipment and services by promoting geographic planning and mandating the provision of services on a non-discriminatory basis;

- To support the Georgia Cancer Coalition;

- To encourage continuity of care through the development of comprehensive policies and processes;

- To improve financial access to high-end diagnostic equipment by encouraging the provision of services to indigent and low-income patients and by ensuring provider participation in Medicare, Medicaid, PeachCare, State Health Benefits Plan, and other public reimbursement programs, as appropriate; and

- To analyze the availability of high-end diagnostic services being provided through ongoing collection and analysis of information and statistical data.

RECOMMENDED ACTIONS

- Implement Certificate of Need (CON) rules for Positron Emission Tomography (PET and PET/CT) consistent with this Component Plan and approve CON applications accordingly;

- Reconvene the TAC immediately should PET or PET/CT become the standard for diagnosing brain disorders; otherwise, reconvene in 2 years to update the plan and need considerations. Members specifically recommended that several items be delineated for consideration when this committee reconvenes:
    - Adverse Impact (should such a statement be incorporated in the rules)
    - Optimal Utilization (should the # of scans be raised or lowered)
    - Impact of mobile providers on the system
    - Impact of the Georgia Cancer Coalition on the system

- Encourage the Department of Community Health/Division of Medical Assistance to reimburse providers for PET and PET/CT services.

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GEORGIA STATE HEALTH PLAN
COMPONENT PLAN

APPENDIX A

MEMBERS
HIGH END DIAGNOSTIC EQUIPMENT (PET)
TECHNICAL ADVISORY COMMITTEE

HIGH END DIAGNOSTIC EQUIPMENT (PET) TECHNICAL ADVISORY COMMITTEE
MEMBERSHIP LIST

KURT STUENKEL, FACHE, COMMITTEE CHAIR
President & CEO, Floyd Medical Center
Member, Health Strategies Council

FRANCIS J. TEDESCO, MD, COMMITTEE VICE-CHAIR
President-Emeritus, Medical College of Georgia
Chairman, Health Strategies Council

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CATHY SLADE
President & CEO, Slade & Associates
Member, Health Strategies Council

MICHAEL V. SMITH, MD
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ROBERT W. TRIMM
President & CEO
Satilla Regional Medical Center
Georgia Hospital Association

HAYDN T. WILLIAMS, MD, FACNP
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Georgia Radiological Association

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Atlanta Regional Office

JEROME C. LANDRY, MD
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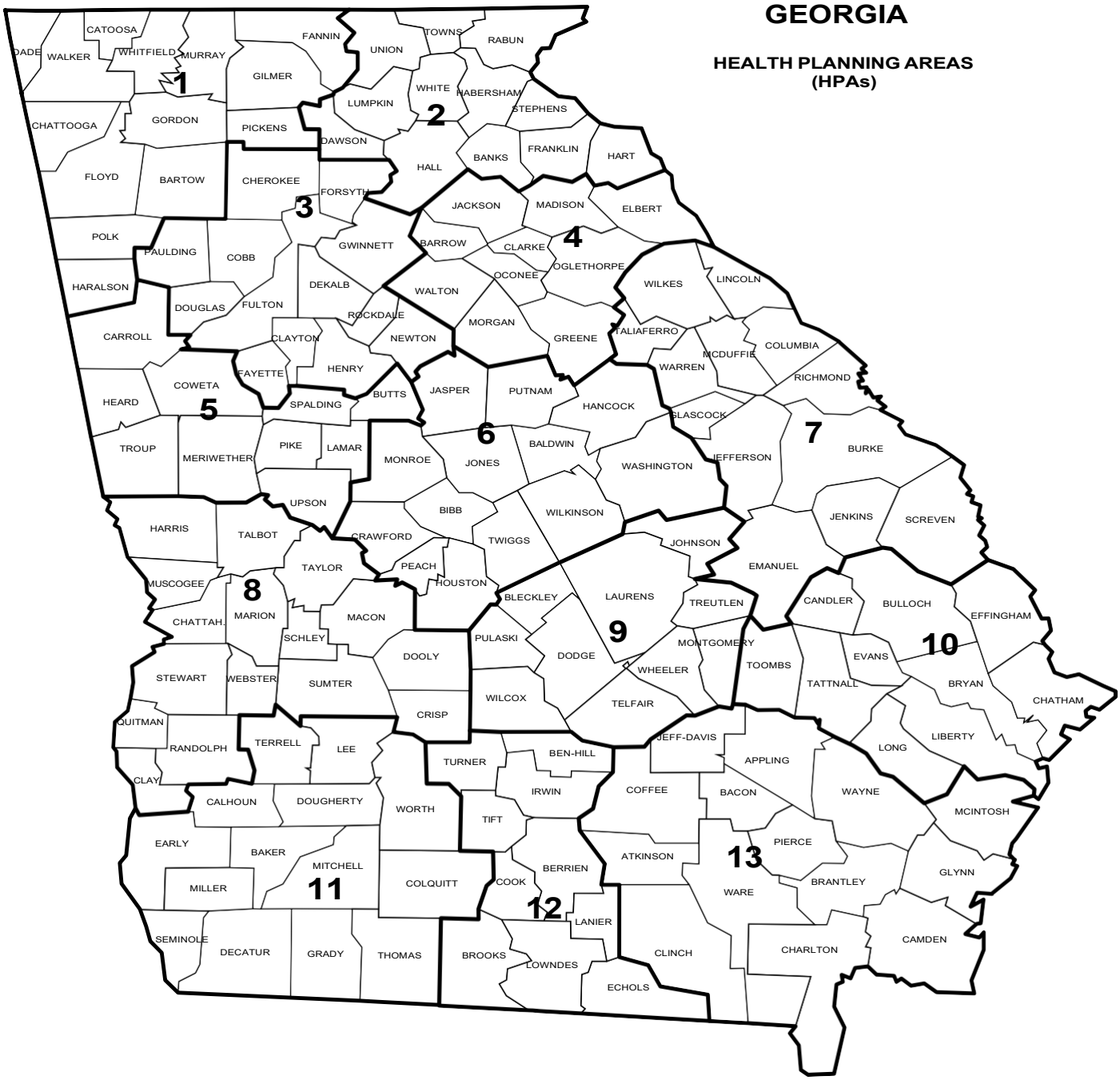
Georgia Cancer Coalition

GEORGIA STATE HEALTH PLAN
COMPONENT PLAN

APPENDIX B

MAP
HEALTH PLANNING AREA


GEORGIA
HEALTH PLANNING AREAS
(HPAs)
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CATOOSA
WALKER
WHITFIELD
MURRAY
GILMER
FANNIN
UNION
TOWNS
RABUN
WHITE
LUMPKIN
NABERSHAM
STEPHENS
GORDON
PICKENS
DAWSON
HALL
BANKS
FRANKLIN
HART
CHATTOOGA
FLOYD
BARTOW
CHEROKEE
FORSYTH
JACKSON
MADISON
ELBERT
POLK
PAULDING
COBB
GWINNETT
BARROW
CLARKE
OGLETHORPE
HARALSON
DOUGLAS
FULTON
DEKALB
WALTON
OCONEE
WILKES
LINCOLN
CARROLL
CLAYTON
ROCKDALE
NEWTON
MORGAN
GREENE
TALIAFERRO
COLUMBIA
MCDUFFIE
WARREN
RICHMOND
COWETA
FAYETTE
HENRY
BUTTS
JASPER
PUTNAM
HANCOCK
GLASCOCK
HEARD
SPALDING
TROUP
MERIWETHER
PIKE
LAMAR
MONROE
JONES
BALDWIN
WASHINGTON
JEFFERSON
BURKE
UPSON
BIBB
WILKINSON
JENKINS
SCREVEN
HARRIS
TALBOT
CRAWFORD
TWIGGS
JOHNSON
EMANUEL
TAYLOR
PEACH
HOUSTON
MUSCOGEE
MARION
MACON
BLECKLEY
LAURENS
TREUTLEN
CANDLER
BULLOCH
EFFINGHAM
CHATTAH.
SCHLEY
PULASKI
DODGE
MONTGOMERY
EVANS
STEWART
WEBSTER
SUMTER
DOOLY
WHEELER
TOOMBS
TATTNALL
BRYAN
CHATHAM
WILCOX
TELFAIR
QUITMAN
RANDOLPH
TERRELL
LEE
CRISP
JEFF-DAVIS
LIBERTY
LONG
APPLING
TURNER
BEN-HILL
CLAY
IRWIN
COFFEE
BACON
WAYNE
CALHOUN
DOUGHERTY
WORTH
TIFT
MCINTOSH
EARLY
BAKER
MITCHELL
ATKINSON
PIERCE
BERRIEN
COLQUITT
COOK
WARE
BRANTLEY
GLYNN
MILLER
SEMINOLE
DECATUR
GRADY
THOMAS
BROOKS
LOWNDES
LANIER
CLINCH
CHARLTON
CAMDEN
ECHOLS