# STATE OF GEORGIA

# SPECIALIZED CARDIOVASCULAR SERVICES COMPONENT PLAN

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**AND**
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**Proposed by the Cardiovascular Services Technical Advisory Committee on May 3, 2001**
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## 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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# INTRODUCTION

## A. STATEMENT OF PUBLIC POLICY FROM THE DEPARTMENT OF COMMUNITY HEALTH

The Department of Community Health was created in 1999 by the Georgia General Assembly in response to a growing concern about fragmentation of health care delivery at the state level. The legislation outlined several purposes for the Department including the development of a state health care infrastructure that would be more responsive to the consumers it serves while improving access to services and healthcare coverage and promoting wellness. The Department has embarked on this charge with great enthusiasm and fervor. Since the formation of the Department of Community Health, several components of the State Health Plan have been revised to reflect the new regulatory focus and policy integration.

The Department is responsible for managing the state's health planning program which establishes standards and criteria for awarding Certficates-of-Need to health care facilities and certain specialized diagnostic or treatment services. The Department works to contain health care costs by avoiding unnecessary duplication of services, equipment and facilities and helps to enforce quality-of-care standards. The Department is committed to ensuring that providers assume a share of the responsibility for the health care needs of low-income citizens and underserved or at-risk members of their local community. Financial access, clinical proficiency and community outreach are cornerstones of the Department's mission.

The Department of Community Health has chosen to update the Specialized Cardiovascular Services Plan and Rules to describe the current regulatory framework within which providers will be required to operate and to ensure the protection of the public and payor systems. Additionally, changes in cardiovascular technology, coupled with rapid statewide expansion of these services and the Department's new policy directions provided the major emphasis for revisiting Georgia's Specialized Cardiovascular Services Plan and rules at this time.

To offer adult or pediatric cardiac catheterization services or open heart surgical services, a provider must obtain certificate-of-need approval from the Department. It is the Department's hope that this revised plan will more adequately:

- Emphasize the Department's commitment to promoting access to cardiovascular health care services by fostering an environment that encourages delivery of services to all persons;

- Incorporate clinical and other advances occurring in cardiovascular health which specifically affect cardiac catheterization and open heart surgical services;

- Establish a more objective need formula which examines cardiovascular disease rates in local communities;

- Reflect the Department's emphasis on access to primary and preventive care services;

- Emphasize the role of healthcare providers and their responsibility to positively impact the community's health status; and

- Advocate the Department's commitment to continuity of care, quality improvement standards and data reporting systems in healthcare facilities in the state.

The Department is committed to fostering the development of a preeminent healthcare system for Georgia. In

addition to improving the health status and health outcomes of Georgians, the state's healthcare initiatives will also serve as a model for the nation. Healthcare facilities that are beneficiaries of public funds in Georgia will be held accountable for the healthcare of members of their local communities. Such facilities will be expected to fulfill commitments made during the Certificate of Need application process including adhering to those standards (i.e., volume, community services, quality, cost, financial access, etc.), and other commitments outlined in the CON application process.

## B. PLANNING PROCESS

The Health Strategies Council, a 27-member board appointed by the Governor, is responsible for developing Georgia's State Health Plan and addressing policy issues concerning access to health care services through a public process. Georgia's original Adult Cardiovascular Services Plan and Rules were issued in 1983. In 1984, the Health Strategies Council adopted a plan and rules for Adult Open Heart Surgery Services. In 1986, the Adult Cardiovascular Services Component Plan was updated. Included in this update was a methodology to assess the state's need for Pediatric Open Heart Surgery Services and Cardiac Catheterizations Services. In 1989, a new, comprehensive Cardiovascular Services Plan was issued. In 1995, the Adult Cardiac Catheterization section of the plan was updated.

In December 2000, the executive committee of the Health Strategies Council voted to convene a Technical Advisory Committee (TAC) to develop a new Specialized Cardiovascular Services Plan and related rules. Council members concurred that changes in cardiovascular technology, the rapid statewide expansion of cardiovascular services and the need to incorporate the Department of Community Health's new strategic direction into all of the Department's planning documents provided the catalyst for revisiting Georgia's Specialized Cardiovascular Services Plan and regulatory guidelines at this time.

Membership of the TAC included clinical experts, advocates, payers, providers, and experts in the field of cardiovascular health and other interested parties. A listing of TAC members is provided in the appendices. The TAC held an initial meeting in January 2001 with subsequent meetings in February and March. Staff provided research materials and draft materials for review and revision between meetings. A final meeting was held in May 2001. The committee's recommendations were informed by the newly revised guidelines of the American College of Cardiology/American Heart Association, that were released in late April.

At the initial meeting of the Technical Advisory Committee, Department of Community Health Commissioner Russ Toal charged the committee with making policy recommendations about cardiovascular services in the state, including making recommendations for a methodology that will be used in the state's Certificate of Need process. He encouraged the TAC to submit a methodology that would determine the need for services, not solely on the basis of a numerical need, but would also address community health status, access to primary and preventive services and technological enhancements. Committee members were also asked to address such issues as peer review, access and availability of services, regulatory compliance, continuity of care standards, quality of care, and community education, including prevention and intervention services for cardiovascular services. The Commissioner encouraged the TAC to develop clear expectations for compliance by both existing and future service providers.
This component plan encapsulates the Department's new policy directions for cardiovascular services. The Department has set forth the following initiatives:

- Ensure statewide access to quality cardiovascular services using national research and guidelines;
- Repeal authorization for new mobile cardiac catheterization labs;

- Require greater commitment of providers to offer health promotion, disease prevention programs and community education programs and linkages;

- Ensure that providers commit to serving patients regardless of ability to pay and/or payor source including a written commitment to provide indigent and charity care;

- Ensure participation in any State Health Benefit, Medicaid, PeachCare, and Medicare programs and to encourage providers to accept all clinically appropriate patients regardless of payer source;

- Ensure continuity of care, outcome monitoring and quality improvement systems, including participation in data reporting, and peer review processes;

- Utilize appropriate mechanisms to enforce commitments made by providers during the application process.

Information presented in this plan is the result of research of current literature, including the guidelines of the American College of Cardiology, the American Heart Association, and the American Academy of Pediatrics and investigation of the cardiovascular services plans from other states. While information was collected from all states with CON programs, the committee concentrated its efforts on plans from the states of Illinois, Massachusetts and New York. These state plans were selected because TAC members felt that they represented comprehensive planning documents which effectively utilized volume thresholds, incorporated performance standards, demonstrated health education and community education guidelines, and assured financial and geographic access as integral parts of the planning processes for quality cardiovascular services. Members also examined data elements taken from the Society of Thoracic Surgery, research from the Northern New England group, JCAHO ORYX indicators for acute myocardial infarction along with Georgia data from the most recent DCH services survey, hospital discharge data and research conducted by the Division of Public Health, Department of Human Resources.

During their deliberations the Technical Advisory Committee members asserted the following principles:

**Volume**:

The TAC strongly advocated that applicant facilities as well as the cardiologists and surgeons directing these programs be required to perform some minimum number of cardiac catheterization and open heart procedures. These minimum guidelines should be in keeping with the recommendations of the American College of Cardiology (ACC) and the American Academy of Pediatrics. TAC members asserted that minimum physician and facility volumes are critical in the determination of patient outcomes and program quality. They agreed that providers should be required to document and demonstrate in the application process that these minimum volumes are being met or, in the case of a new applicant, would be met. Research continues to underscore the clear benefits in facilities that perform at or above the recommended volume of procedures versus low volume facilities.

The TAC spent a considerable amount of time discussing electrophysiological (EP) studies and distinguishing these studies from cardiac catheterization procedures. EP refers to a procedure that involves the recording of intracardiac electrical signals and programmed electrical stimulation. The EP study either may be performed for diagnostic purposes only or may be part of a combined diagnostic and therapeutic procedure. In the vast majority of situations, EP is performed on an elective basis. EP requires the placement of electrode catheters for pacing and recording in multiple cardiac chambers.

EP studies are useful to determine the mechanisms and physiological characteristics and drug responses of supraventricular tachycardias and to determine whether arrhythmias are suitable for drug, device or ablation therapy. They can also be used to assess the effects of pharmacological therapy and to select patients for nonpharmacological treatment. EP has also been used to assess the future risk of serious antiarrhythmic events and to provide data on which prophylactic therapy may be based.

Because EP studies usually take much longer than a routine catheterization procedure, the committee suggested that EP studies should have a procedural weighting of double that of a catheterization and that performance volume thresholds should be in line with those established by the North American Society of Pacing and Electrophysiologists and the ACC. In calculating need for catheterization labs, the Committee recommended that each EP study should represent 2.0 procedure equivalents for those studies performed in a traditional catheterization lab. The Committee also incorporated an exemption to allow consideration for dedicated EP laboratories under the exception provisions.

Although recognized as an emerging field, few programs have provided EP services in the past. The most recent data indicates that during 1999, 630 EP studies were reported in the State of Georgia. The hospitals with the highest volumes reported 214 and 122 studies respectively while the hospitals with the lowest volumes reported 31 and 7 respectively.

**Adverse Impact**

TAC members recognized that service expansion or initiation of a new service has the potential to negatively impact existing cardiovascular services. They felt this adverse impact consideration to be particularly important for Open Heart programs. As such, for cardiac surgical programs the TAC recommended that no service be impacted such that its volume thresholds would drop below established minimum standards (200 procedures) or greater than ten percent (10%) of the annual average service volume from the two proceeding years. For approved programs that are not yet operational, market share volume should be incorporated from the approved CON application. Emphasizing the important link between volume and quality, they reinforced provisions from prior rules that exclude adverse impact data from any provider not operating at minimum capacity.

For catheterization services, the TAC felt strongly that existing capacity should be used before new programs or laboratories are established. Further, the group felt strongly that volume was important to ensuring quality. The group considered impact to be adverse if it would cause an existing or approved program to perform at less than 80% optimal capacity. In the situation where a program is already operating below 80% of capacity, the Department uses an operating standard to gauge adverse impact by a 10% or greater drop in volume.

## Community Outreach

TAC members agreed that all facilities, existing or new, that offer specialized cardiovascular services should be required to engage and support community health education outreach efforts including establishing community linkages, spearheading patient outcome monitoring, and conducting health promotion activities. They acknowledged that open heart programs do not ordinarily serve as entry points for patients into the healthcare system but felt strongly that such providers should be involved in a comprehensive planning process, with other local service providers to promote planning for a continuum of cardiac-related services within the service area. Heart disease prevention programs could be provided by the applicant hospital or through formal referral agreements. Members agreed that the establishment and maintenance of systems to assist in tracking and follow-up to determine attendance at referred services and status of risk management should be considered critical components of the applicant's outreach efforts.

The community outreach components were important standards emphasized by Commissioner Toal and the TAC took this charge very seriously. They also found considerable supporting documentation for requiring community outreach from other states with similar CON statutes. Ensuring that existing facilities are in or come into compliance with the community outreach standards is a major goal of the TAC's fashioning of expansion requirements in the rules.

## Quality

Members asserted at the onset of their deliberations that all providers offering cardiac catheterization services must have appropriate transfer agreements or onsite backup open-heart surgical services. For freestanding catheterization programs, the TAC felt that applicants should document a formal transfer agreement and continuity of care procedures with at least one existing cardiac surgery program. For catheterization programs providing angioplasty, the group felt that Open Heart backup should be required on site.

Additionally, they felt strongly that peer review processes should occur beyond the confines of the applicant facility to include benchmarking outcomes, based on national norms. These types of systems are readily available through ACC and STS, and the Georgia Hospital Association is developing these types of programs to support Georgia clinical sites. The TAC proposed that applicants must document a system of outcome monitoring and quality improvement where clinical results can be monitored for performance on a regular basis. They encouraged the Department to enhance their regulatory compliance capabilities as it relates to post approval monitoring. They expressed strong support for using the Department's enforcement mechanisms in the event providers fail to comply with related program standards, commitments and minimum thresholds stipulated during the application process.

The TAC felt that quality was so important that a new applicant could seek an exemption from the need standard based on the failure of existing providers to exhibit outcomes in keeping with national rates. The quality aspect of services was one of the few stipulated in the rules as meriting an exemption from both the need and adverse impact standards. These exemptions simply allow an applicant to be considered; the burden of proof for compelling the exemption resides with the applicant.

## Access

Financial access was a key value of the Department and the TAC in this planning process. The failure to promote meaningful financial access on the part of some current providers of both catheterization and open-heart surgical services was a major reason for the development of a new, comprehensive plan. Unquestionably, applicants seeking to provide new services should be required to commit to future performance expectations in the area of financial access and should be judged in the application process on past behavior of the facility and the parent company. Further, the past performance of any applicant and its parent organization should be considered in the decision process. The Department's operating standard is to review the three most recent prior years in terms of compliance with indigent and charity commitments and service to representative segments of the community. Failure to fulfill a service commitment or to serve representative populations may constitute grounds for denying an application and/or taking corrective action.

The TAC supported the Department's initiatives to foster an environment that assures access to care for individuals unable to pay, regardless of race, age, sex, creed, religion or disability or the patient's ability to pay. Further, TAC members supported the requirements that applicants for new or expanded specialized cardiovascular services should be required to submit a written commitment that assures that services for indigent and charity patients be offered at standards which meet or exceeds three percent of annual, adjusted gross revenues and the requirement to participate in the Medicaid and Medicare programs or to accept any Medicaid or Medicare eligible patient for services unless the patient is clinically inappropriate. They agreed with the Department that applicant hospitals should participate in the State Health Benefits Insurance programs or other publicly funded programs for which the service is eligible.

TAC members strongly asserted that current providers, who may be in technical compliance with prior guidelines, should be held to a standard of financial access in keeping with the spirit and purpose of the regulatory statute. As such, any significant expenditure, sizeable increase in service volume or the addition of a new laboratory should be considered a basis for undergoing the review process. The TAC did not wish to create a paperwork bottleneck for service expansion, so they suggested that a program should be allowed to expand their specialized cardiovascular services through the submission of documentation that demonstrates the applicant's compliance with the key community outreach, quality and financial access provisions of the rules.

The TAC felt that access to care, both financial and geographic, was of great importance. The provisions that allow a new applicant to seek an exemption from the need standard stipulate criteria that, among others, include "cost, financial access or geographic accessibility." These grounds for exemption deal with the access standards. The TAC concurred with the Department's philosophy that one of the core components of the Certificate-of-Need program is to ensure access for all populations. The Health Strategies Council reinforced the TAC's values by ensuring that an applicant for open heart surgery services seeking an exemption to address an atypical barrier due to geographic accessibility would not be required to comply with any distance limitations. These exemptions simply allow an applicant to be considered; the burden of proof for compelling the exemption resides with the applicant.

## C. American College of Cardiology & American Heart Association Guidelines

Since 1980, the American College of Cardiology (ACC) and the American Heart Association (AHA) have jointly produced guidelines to address the full range of standards and criteria recommended by experts for the provision of quality care. The ACC/AHA Guidelines for Coronary Artery Bypass Graft (CABG) Surgery, for Cardiac Catheterization, and for Percutaneous Coronary Interventions (PCI) are the guideposts for clinical care in specialized cardiovascular services. These documents outline specific strategies for cardiovascular disease management and procedures; they are intended to assist physicians in clinical decision making by describing a range of generally acceptable approaches for the diagnosis, management and prevention of specific diseases or conditions.

These guidelines are broad-based and attempt to define practices that meet the needs of most patients in most circumstances. They formed the basis of the decision-making process throughout the technical advisory committee's planning process. The CABG guidelines provide a framework for patient outcomes. They delineate the core variables that were found to be predictive of mortality after CABG which include such risk factors as urgency of operation, age, prior heart surgery, sex, LVEF, percent stenosis of the left main coronary artery, and the number of major coronary arteries with greater than 70% stenosis.

The technical advisory committee addressed the area of volume thresholds and referenced the CABG guidelines for guidance in making this recommendation. The number of procedures has been correlated with patient outcomes. These guidelines suggest that after reviewing several national databases, that a bright line cut-off at approximately 200 cases defined high and low-volume institutions. After reviewing the data from several studies, AHA/ACC pointedly conclude that survival after CABG is negatively affected when carried out in institutions that perform fewer than the minimum threshold number (200) of cases annually. Similar conclusions have been drawn regarding individual surgeon volumes. Because of the clear distinction with program results, the guidelines recommend outcome tracking and close monitoring of institutions or individuals that perform less than 100 cases annually.

While much of the volume standards have been questioned because of the inability to adequately distinguish preoperative co-morbidity data from post-procedure complications data. Research that was conducted in 1986 in New York State (Hannan et al), noted that after adjusting for case mix, high volume institutions that performed greater than 223 cases annually experienced significantly lower mortality than did institutions performing fewer than 223 cases annually. The same relationship was true for individual surgeon volumes performing fewer than 116 CABG procedures annually. Between 1987 and 1992, hospitals in the Department of Veterans Affairs reported on patients that were operated on during this time. They noticed higher variations in mortality rates between low-volume hospitals. A review of the Society of Thoracic Surgery (STS) examined the data of 124,793 patients that were operated on by greater than 1,200 surgeons in greater than 600 institutions. They found that in institutions that performed less than 100 cases annually the observed mortality rate of 5.0% was significantly higher than the expected rate of 3.0%.

**Angioplasty Guidelines**: The ACC and the Society for Cardiac Angiography and Intervention (SCA&I) issued new guidelines for PCI (angioplasty) procedures in 2001, nearly 10 years following the last guidelines publication for these procedures. The guidelines focus much of their discussion on the practice strategies for individual clinicians. With respect to facility services, the guidelines highlight the following:

> **Volume Standards**: Recent data suggest a lower mortality rate among patients undergoing primary angioplasty in higher-volume centers. The greatest advances in treatment are occurring in this area. Rapid change coupled with sophisticated techniques make it particularly important that both facilities and clinicians perform large numbers of procedures to master proficiency and decrease the chance for

negative outcomes.

**Surgical Back-up:** The guidelines do not endorse the performance of elective percutaneous coronary interventions (PCIs) in a facility without cardiac surgery capability. They stressed the importance of ensuring that a mechanism for backup and bailout are in place to provide assistance should patients become unstable in a freestanding laboratory. Further, interventional procedures of any kind should not be performed in a freestanding facility.

However, the new guidelines do recognize the difficult balance between emergent care in hospital-based settings without surgical back-up. All things being equal, the ACC/AHA committee would recommend that patients receive PCI in a setting that has the clinical capability to respond to any possible challenge. Nonetheless, the group recognizes the difficulty born by geographic access for those patients who do not respond to preferred stabilizing interventions and who are significant distances from surgical centers. In rare instances, it may be appropriate to acknowledge the value of well-trained, hospital-based cardiologists who have significant experience in this field to perform emergent PCIs without surgical backup. Several members and the TAC as a whole acknowledged this delicate balance between geographic access and proven volume/proficiency based quality. The group was clear that this was not a discretionary power that should be granted to any catheterization program and certainly not to any freestanding program. TAC members asked the Department to consider strategies to allow research into possible benefits of specialized emergent services in a very controlled environment that assured patient safety.

**Quality Assurance:** Quality assurance focuses on individual physicians and treatment teams and then extends to the performance of the laboratory as a whole. A continuous quality–improvement program should be included in the laboratory's overall design. As an example, one measure of outcome is the number of "normal diagnostic cardiac catheterizations performed." "Normal" refers to no disease or insignificant (< 50% diameter narrowing) coronary stenoses in patients studied primarily for the identification of coronary artery lesions. In some laboratories "normal" coronary arteries may be especially prevalent and this may skew outcomes benchmarking. It is important therefore to promote peer review and outcome monitoring that accounts for case mix and clinical anomalies. The TAC worked to incorporate the quality, peer review standards while guarding against any regulatory guidelines that would encourage providers to "cherry-pick" so as to present results at or above those of peers.

The ACC/AHA guidelines provide a sophisticated road map for planners. In the area of specialized cardiovascular services, perhaps more so than any other regulated health service, there are clear threshold criteria. It is important to note that these criteria are "minimums" and, in many cases, Georgia planners and professionals have embraced standards in excess of the minimum for service recipients. In the field of specialized cardiovascular services, the national standards based on significant research and numerous clinical trials, are strong guiding forces in the development of regulatory criteria.

## II. OVERVIEW

### A. Overview of Coronary Heart Disease

According to the American Heart Association, cardiovascular disease is a leading cause of disability in the nation. Data from the National Heart, Lung, and Blood Institute indicates that over 7 million Americans suffer from coronary heart disease, the most common form of heart disease. Scientists believe that many of these incidents could be prevented because coronary heart disease is related to certain aspects of lifestyle. Risk factors include high blood pressure, high blood cholesterol, smoking, obesity and a sedentary lifestyle. Although medical treatments for heart disease have improved tremendously over the years, controlling risk factors remains the key to preventing illness and death from coronary heart disease.

Coronary heart disease (CHD) is the number one killer of both men and women in the United States. Data from the National Heart, Lung and Blood Institute indicate that each year, more than 500,000 Americans die of heart attacks caused by coronary heart disease. CHD is caused by a thickening of the inside walls of the coronary arteries. This thickening, called atherosclerosis, narrows that space through which the blood can flow, decreasing and severely cutting off oxygen and other needed nutrients to the heart. Shortness of breath may be the earliest sign of CHD. Victims may also feel tightness, pain, burning pressure or a squeezing sensation behind the breastbone. Pain could also occur in the arms, neck or jaws. There is a wide range and severity of CHD. Some people have no symptoms at all, while others experience mild intermittent chest pain. Others may have more pronounced and steady pain. Because CHD varies so much from one person to another, the way a doctor diagnoses and treats CHD varies tremendously. Examinations for CHD may include such tests as electrocardiogram, stress test, nuclear scanning or coronary angiography. While the majority of patients with cardiovascular disease (CVD) can be treated using lifestyle changes and medications, others with more serious forms of the disease can be stabilized with medications such as nitroglycerin, beta or calcium channel blockers, and/or high blood pressure medications. Some patients may require more aggressive interventions such as therapeutic cardiac catheterization or surgery.

Cardiac catheterization and open-heart surgery are specialized cardiovascular services. Cardiac catheterization is a medical, diagnostic or therapeutic procedure during which a physician inserts a catheter into a vein or artery of a patient. With the aid of x-rays and an electronic image intensifier, the physician then manipulates the free end of the catheter to travel along the course of the blood vessel into the chambers of the heart. For diagnostic purposes cardiac catheterizations are performed to detect and identify defects in the great arteries of the heart or abnormalities in the heart structure, whether congenital or acquired. Findings from cardiac catheterizations are important in determining whether therapeutic interventions are needed and, if so, the type of intervention up to the need for open-heart surgery.

Increasingly, the most common treatment using catheterization is percutaneous transluminal coronary (PCI) angioplasty, more commonly known as balloon angioplasty, a procedure where a catheter, positioned in a narrowed coronary artery with a tiny balloon at its tip, is inflated and deflated to stretch or break open the narrowing and improve the passage for blood flow. If angioplasty does not widen the artery or if complications occur, bypass surgery may be needed. During coronary artery bypass operation, a blood vessel, usually taken from the leg or chest, is grafted onto the blocked artery, bypassing the blocked area. The blood can then go around the obstruction to supply the heart with enough blood to relieve chest pain.

Open-heart surgery is a surgical procedure performed directly on the heart or its associated veins or arteries, during which a heart/lung bypass machine (extracorporeal pump) is utilized to perform the work of the heart and lungs. Coronary artery bypass graft surgery (CABG), also known as coronary revascularization, is the most

commonly performed adult open-heart procedure. Though emergency procedures are common, this surgery is usually done on an elective rather than an emergent basis with the most common reason being to alleviate chest pain (angina pectoris) that results from the heart being deprived of an adequate supply of oxygenated blood. The flow of blood is restricted due to blockage in the coronary arteries. The blocked area of one or more arteries is circumvented by grafting vessels taken from the patient's legs or chest to the aorta and to the affected coronary arteries below the occlusion. Blood with its necessary supply of oxygen then can flow to the heart through the grafted vessels.

## B. Incidence of Cardiovascular Disease in Georgia

Cardiovascular disease is the leading cause of death in Georgia. A recent article appearing in Georgia Trend Magazine, indicates that Georgia death rates for cardiovascular disease are 10% higher than the national rate and in Atlanta, 10,000 people will suffer a stroke during t2001. In some rural Georgia counties, more than half the deaths are due to stroke, heart attack and other cardiovascular diseases. For a large number of Georgians, historical traditions of eating rich diets of fried foods and foods smothered with creamed sauces likely plays a significant role in influencing dietary habits and placing Georgians at increased risks.

Current information from the American Heart Association and the Department of Human Resources, Division of Public Health indicates that cardiovascular death rates have declined in both Georgia and the United States over the past 18 years. This decrease has been linked to changes in technology and overall lifestyle changes. Although the Georgia CVD death rate continues to decline, the rate of decline is slowing. Data from the *1999 Georgia State of the Heart Report* indicates that from 1980-1992, the CVD death rate declined by an average of 2.5 % per year. In contrast, from 1992-1997, the rate of decline had slowed to only 0.7% per year.

Race and gender disparities are strikingly obvious. In Georgia, men have higher rates than women, and blacks have higher rates than whites. In 1997, the risk of CVD was 25% higher for black males than white males and 32% higher for black females than white females. Black men have approximately 60% more premature death from CVD than white men; and black women have over twice the burden of premature deaths as white women. While some of these differences have been linked to cultural, educational and social barriers, decreased access to health care likely presents the largest barrier.

According to a recent study in the Annals of Thoracic Surgery, "despite the reductions in mortality caused by heart disease as well as in mortality overall, during the past 50 years, the racial gap between African-Americans and whites in the leading causes of death, including heart disease, is actually wider today than it was in 1950". This article further cites research that suggests that even at the highest socioeconomic–status strata, where racial differences in access to care and in attitudes should be at a minimum, marked racial differences exist in heart disease risk and outcome. The author suggests that other factors such as stress, residual socioeconomic-status differences, or biological differences may be responsible. After adjusting for differences in several major risk factors and for divergent socioeconomic levels, researchers have not been able to account for a major portion of the observed disparities.

While males have higher rates of CVD than females, there are actually more CVD deaths among females than males. A recent article in *Georgia Trend Magazine* indicates that women die from heart attacks at higher rates than men, and more women have a second heart attack than men. Women also have a higher rate than men of re-hospitalization within six months of a heart attack. Among the reasons that clinicians have cited for this disparity is the acknowledgement that the symptoms for heart attacks in women do not necessarily mirror the symptoms in men. Some of the classic symptoms including intense chest pain, shooting pain through the shoulders and down the arm, and sweating may not always occur in women. Chest pains may be interpreted

by women as palpations. Further complicating the issue is the fact that these palpations may not be recognized as a serious condition and medical care is often delayed. Clinicians also cited a women's age as a major reason why women exhibit different symptoms and recover more slowly. The article noted, that on average, women lag ten years behind men in risk for heart disease. While men experience higher risk beginning as early as the 40's and 50's, the risk for women generally does not manifest until after menopause.

The disparities in deaths between males and females in Georgia are evident. Data from the *1999 Georgia State of the Heart Report* indicates that in 1997, there were 10,868 deaths among males, but 12,591 deaths among females. Late onset, longevity and delayed diagnosis of females likely accounts for this disparity. In Georgia, death rates from CVD are about 30 percent higher for blacks than whites. This difference occurs in both males and females. Further, there are more premature deaths from CVD among blacks, particularly among black men. The reasons for these differences are not well understood, but may be a result of a higher percentage of blacks with high blood pressure, or with factors related to poverty, such as poor diet or decreased access to health care.

The Department's commitment to addressing disparities in the health status of Georgia's growing population is evident through the establishment of several offices including the Office of Minority Health, the Office of Rural Health Services and the Office of Women's Health. These offices were established to define concrete ways to close the disparities in health and to increase access to care for underserved populations in the state. The Office of Minority Health concentrates its efforts on identifying the health issues of African American, Asian and Hispanic/Latino communities and finding effective ways to reach populations at risk. The Office of Rural Health Services focuses on building rural health system networks, supporting rural hospitals and identifying ways to make health care available to rural Georgians. The Office of Women's Health raises awareness of women's nonreproductive health issues including serving as a clearinghouse for women's health information for purposes of planning and coordination. During 2000, the Office of Women's Health has focused on cardiovascular heath.

Despite statewide initiatives to address Georgia's cardiovascular health, the two most common forms of CVD, heart attacks and strokes together accounted for more deaths in every Georgia county than any other cause of death. CVD is a major cause of costly hospitalization and disability. Data from the *1999 Georgia State of the Heart Report*, indicates that in 1997, more than 23,000 deaths or nearly 40% of all deaths in the state were related to cardiovascular events. During 1997, there were 133,000 hospitalizations, representing over 666,000 days in the hospital due to CVD. Charges for these services have totaled $1.8 billion. During this same period, CVD accounted for twenty-two (22%) of all hospital charges. The average charge for a hospital stay was $13,350.00.

Other state data include the following:

- Among Georgians 85 years and older, CVD is increasing;
- In 1997, a Georgian was hospitalized with CVD every four minutes while every 22 minutes, a Georgian died from CVD;
- One in five Georgians who died from CVD in 1997 was younger than 65;
- CVD death rates in Georgia are 10% higher than the national rate;
- More than half of all Georgia adults are overweight; and

- More than half of all Georgia adults have two or more CVD risk factors that can be changed.

Providers and other health care partners are being encouraged, and in some cases are showing great initiative, in developing patient and community education programs that address some of the disparities in health status and impact patients' overall quality of life. Preventive approaches are given credit for reductions in morbidity and mortality rates. Among the efforts to reduce risks are the development of community education programs that focus on smoking, diet, hypertension, and exercise.

In addition to its well-known association with cancer, smoking is a major cardiovascular disease risk factor. According to a 2000 report of the GHA Partnership for Health & Accountability, tobacco use is the most preventable cause of death, is a major cause of heart disease (threefold increase in risk of heart attack), and is responsible for more than 430,000 deaths nationally and 10,000 deaths in Georgia. According to the World Health Organization (WHO) one year after quitting smoking, the risk of coronary heart disease (CHD) decreases by 50% and within 15 years, the relative risk of dying from CHD for an ex-smoker approaches that of a long-time non-smoker. While annually $146 million is spent on tobacco advertising in Georgia, the state spends more than $250 million for the treatment of smoking related illnesses. The outcome of tobacco-related research, which recommends the adoption of healthy lifestyle changes, including smoking cessation programs, to reduce a person's risk of lung cancer, heart attack, stroke, or respiratory illness further supports the Department's emphasis on the development of community education programs.

## C. SUMMARY OF CARDIOVASCULAR SERVICES IN GEORGIA

The State of Georgia has an ample supply of resources to address the state's cardiovascular service needs. While there is a disproportionate concentration of resources in the metro-Atlanta area, there appears to be adequate statewide distribution of providers. Recent data from the Department of Community Health/Division of Health Planning indicates that there are ninety-three (93) cardiac catheterization laboratories in the State of Georgia, five (5) of which serve pediatric patients and sixteen (16) existing Open Heart Surgical Services providers, two (2) providing services to pediatric patients. Graph 1 displays the location of existing and approved facilities that provide cardiac catheterization and open heart surgery services in the state.

During 1999, 10,449 open-heart surgeries were performed (both adult and pediatric), while 83,439 cardiac catheterizations were performed, inclusive of pediatric cases. The hospital with the lowest annual volume of open-heart surgeries reported 90 procedures, while the highest annual volume was 1,677 procedures. Four (4) facilities reported volumes below 300 procedures. Eighty-five percent (85%) of the pediatric open-heart procedures were performed at Children's Healthcare of Atlanta; fifteen percent (15%) were performed at Medical College of Georgia. During 1999, the hospital with the highest volume of angioplasties reported 2,919 procedures, whereas the hospital with the lowest volume reported 50 procedures. Both of these hospitals are located in metro-Atlanta.

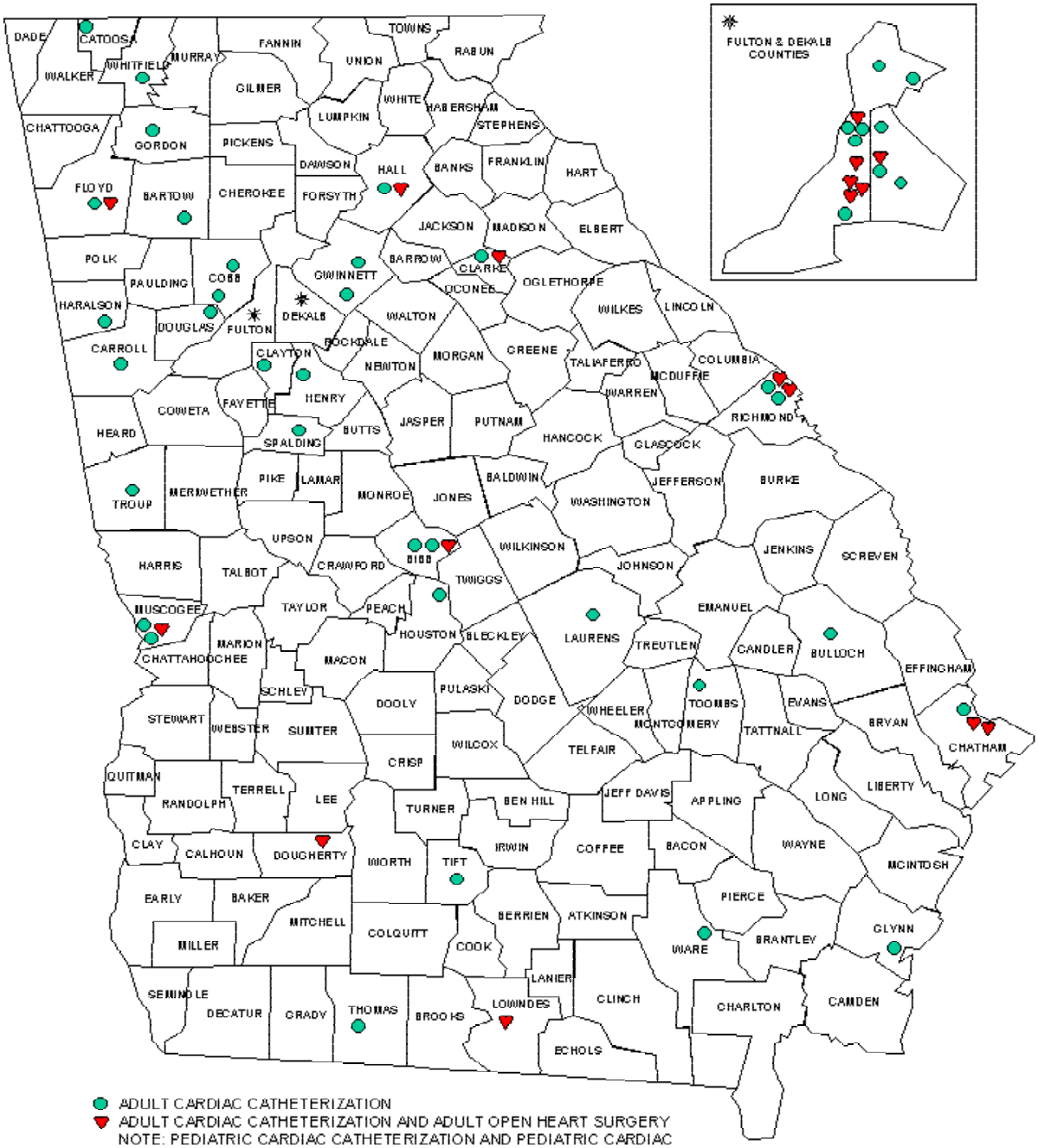
An overview of the use of specialized cardiovascular services in Georgia reveals significant growth in cardiac catheterization. Facilities with open-heart services have catheterization laboratories that are authorized to perform both therapeutic and diagnostic cardiac catheterization procedures. Generally, those without open-heart services may perform only diagnostic procedures. Data from the 1999 Annual Cardiac Catheterization Services Survey indicate that approximately 77% of all cardiac catheterization procedures were diagnostic, while 23% were therapeutic in nature. From 1992-1999, diagnostic cardiac catheterization procedures increased approximately 29%, increasing from 45,985 procedures in 1992 to 64,553 procedures in 1999. Therapeutic catheterization procedures, on the other hand, increased over 40%, moving from 11,320 procedures in 1992 to 18,886 procedures in 1999. The increase in catheterization procedures across the board

reflects the emerging patterns of care. Diagnostic cardiac catheterizations are performed to detect and identify defects in the great arteries of the heart or abnormalities in the heart structure, and may also serve to reduce or delay the need for open-heart surgery. Therapeutic cardiac catheterizations are emerging intervention strategies, being used to clear coronary arteries through balloon techniques or to open arteries with stents. The growth in angioplasty is mirrored by a flat trend in open-heart surgery.

## Graph 1

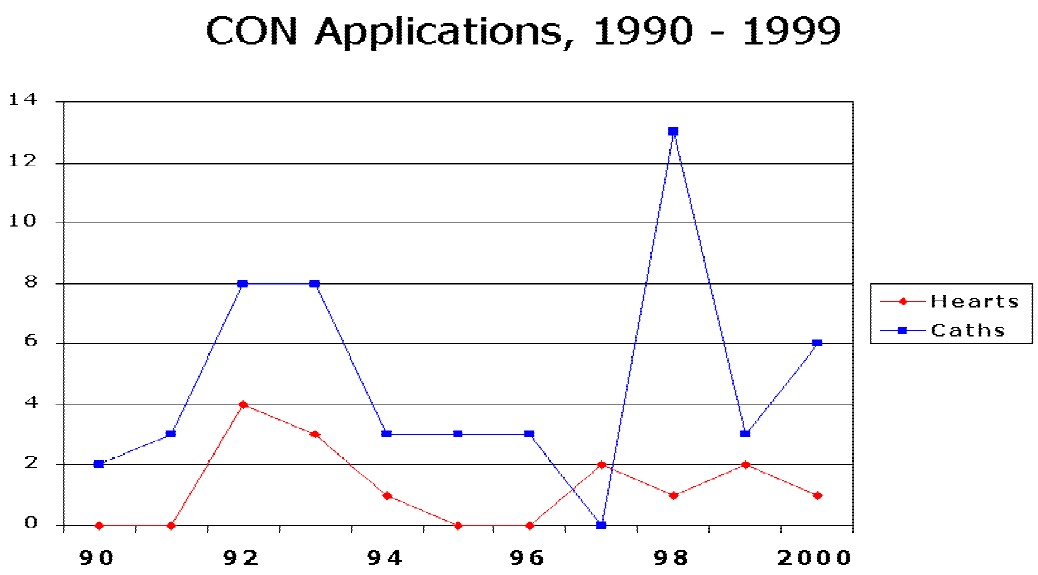
# GEORGIA

### Existing and Approved Adult Cardiac Catheterization and Open Heart Surgery Services

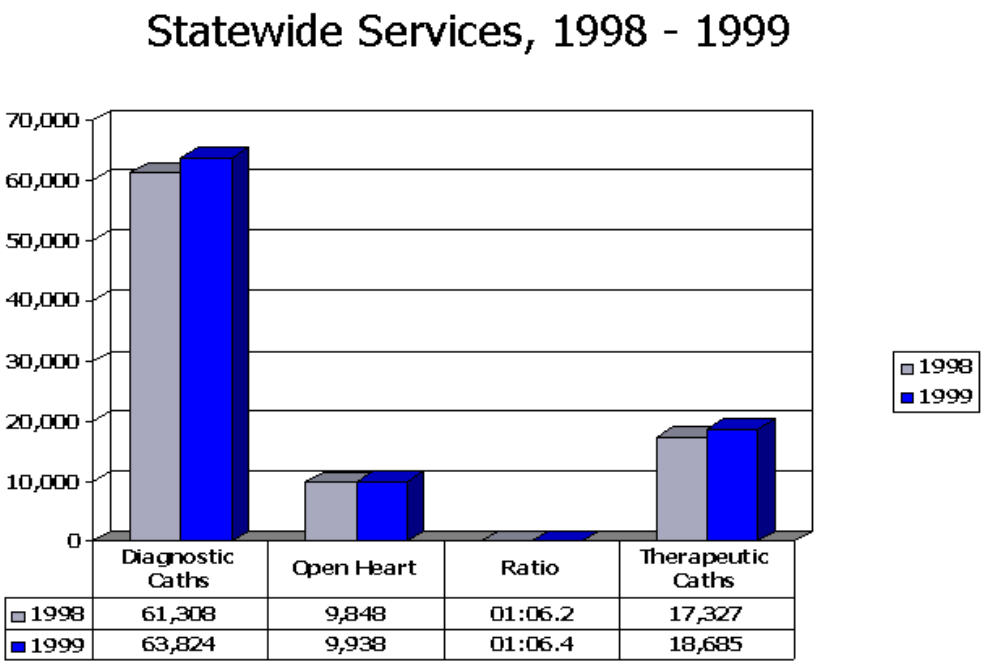


The number of applications from providers seeking to perform open-heart surgery has remained somewhat stable over the last several years. While two sites have recently been approved, between 1992-2000, fourteen (14) applications were submitted and nine (9) applications were denied. The Health Planning Review Board, (HPRB) has reversed two (2) decisions. The HPRB is appointed by the Governor for administrative and judicial review of the CON decisions. In recent years, the number applications to establish cardiac catheterization laboratories have continued to increase. During 1998, thirteen (13) applications were submitted, of those ten (10) were approved. During 1999, while there was a decrease in the number of applications, all of the completed applications were approved. During 2000, of six (6) submitted applications, five (5) were approved. (See Graph 2.)

**Graph 2: CON Applications**



**Graph 3: Statewide Services**




| | Diagnostic Caths | Open Heart | Ratio | Therapeutic Caths |
|---|---|---|---|---|
| 1998 | 61,308 | 9,848 | 01:06.2 | 17,327 |
| 1999 | 63,824 | 9,938 | 01:06.4 | 18,685 |

Closer examination of Graph #3 indicates that during 1998, over 61,300 adult diagnostic catheterizations, 17,327 therapeutic cardiac catheterizations and 9,848 open-heart procedures were performed. The resulting ratio of adult open-heart surgeries to adult diagnostic cardiac catheterizations is (1) adult open-heart surgery to 6.2 adult diagnostic cardiac catheterizations (1:6.2.) This implies 16.1% of adult diagnostic cardiac catheterizations resulted in open-heart surgery. Likewise during 1999, there were over 63,800 diagnostic cardiac catheterization procedures and 18,685 therapeutic cardiac catheterizations and 9,938 open heart procedures. The resulting ratio of adult open-heart surgeries to adult diagnostic cardiac catheterizations is one (1) adult open-heart surgery to 6.4 adult diagnostic cardiac catheterizations (1:6.4); this implies that 15.6% of adult diagnostic cardiac catheterizations resulted in open-heart surgery.

Technological advances have continued to impact the delivery of cardiac catheterization services for both adult and pediatric patients. A review of adult and pediatric cardiovascular services data from 1995-1999 indicates that there have been an increasing number of adult cardiac catheterization procedures each year during this time period. On average, both diagnostic and therapeutic procedures have increased by some 3,300 procedures in each of the past five years. In 1995, there were a total of 65,623 procedures; by 1999, programs reported in excess of 82,500 catheterization procedures. During this time both the number of diagnostic and therapeutic cardiac catheterization procedures have increased, with the total number of diagnostic catheterizations far outpacing the number of therapeutic catheterizations. The availability of technology to perform these procedures in an expedient and efficient manner likely plays a role in the increasing number of cardiac catheterization procedures. The total number of pediatric catheterizations has hovered near 1,000 procedures annually.

Between 1995-1999, there has been very little variation between the adult and pediatric open heart surgical services. During this time there has been a total of 50,527 adult open-heart procedures, an average of 10,105

procedures annually. Annual numbers have ranged from 9,800 to 10,500, reflecting little variation in the number of procedures each year. Likewise, during this same five year time period, there have been a total of 2,176 pediatric open heart procedures or approximately 435 procedures per year. Annual procedures have ranged from 408 to 511. The growth in angioplasty likely plays a role in this flat trend in the annual number of adult and pediatric open heart surgical procedures.

## III. GUIDELINES

The rules proposed by the TAC for Adult Cardiac Catheterization Services, Adult Open Heart Surgical Services and Pediatric Cardiac Catheterization and Open Heart Surgery are included as Appendix A to this plan. Following is an outline of the applicability, definitions and need methodologies for each set of rules, and a summary of the core components common to all of the rules. The rationale for each of the distinct need methodologies and for the common core standards are included in this section of the plan. As appropriate, cross-references to the applicable sections of the rules are provided.

**Applicability, Definitions and Need Methodology by Service**

### ADULT CARDIAC CATHETERIZATION

**(a) Applicability**

1. For Certificate of Need (CON) purposes, Adult Cardiac Catheterization Services is classified as a specialized service and is defined as a new institutional health service which must be delivered in a permanently fixed location in either an acute care hospital or in a diagnostic, treatment, or rehabilitation center (DTRC). A certificate of need will be required prior to the establishment of a new or expanded adult cardiac catheterization service.
2. If the services will be provided within a licensed acute care hospital, the hospital shall be the applicant.
3. If cardiac catheterization services will be provided in a DTRC , the organizational entity which develops the service shall be the applicant.

**Rationale:** The applicability standards require a CON for any new or expanded service. They allow for hospital-based and free-standing facilities. New mobile facilities are no longer allowed under these rules.

**(b) Definitions.**

1. "Adjacent acute care hospital" means an acute care hospital which is physically connected to another acute care hospital in a manner that emergency transport of a patient by a stretcher or gurney can be achieved rapidly, conveniently, and effectively without the use of motorized vehicles.
2. "Adult" means a person 15 years of age and over.
3. "Authorized service" means an adult cardiac catheterization service which is either existing or approved. An existing service is an authorized service which has become operational, and an approved service is an authorized service which has not yet become operational.
4. "Capacity" means 1300 adult cardiac catheterization procedure equivalents per dedicated and multipurpose room per year. In the computation of the use rate (percent of capacity) of authorized adult cardiac catheterization rooms, each adult diagnostic cardiac catheterization and other cardiac catheterizations of similar complexity shall equal a 1.0 procedure equivalent, each coronary angioplasty procedure shall equal 1.5 procedure equivalents, and each electrophysiological (EP) study shall equal 2.0 procedure equivalents. If pediatric catheterizations are performed in room in which adult cardiac catheterizations are performed, each pediatric procedure shall equal 2.0 procedure equivalents.
5. "Cardiac catheterization" means a medical diagnostic or therapeutic procedure during which a catheter is inserted into a vein or artery in the patient; subsequently, the free end of the catheter is manipulated by the physician to travel along the course of the blood vessel into the chambers or vessels of the heart. X-rays and an electronic image intensifier are used as aids in placing the catheter tip in the desired position. When the catheter is in place, the physician is able to perform various diagnostic studies and/or therapeutic procedures on the heart or its vessels.
6. "Cardiac catheterization service" means an organized program which serves inpatients and/or outpatients of an acute care hospital or diagnostic, treatment and rehabilitation center (DTRC) with a room or a suite of

rooms, with equipment to perform angiographic, physiologic, and as appropriate, therapeutic cardiac catheterization procedures. An authorized adult cardiac catheterization service is prohibited from performing coronary angioplasty procedures unless the acute care hospital where the service is located meets the requirements identified in 272-2-.09(7)(c)(6).
7. "Coronary angioplasty" means a cardiac catheterization procedure to treat coronary artery disease by utilizing a catheter with a balloon, laser, laser-assisted device, rotational device, stent placement or other mechanical means to unblock an occluded coronary artery.
8. "Diagnostic cardiac catheterization" means 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. Post-operative evaluation of the effectiveness of prostheses (e.g. heart valves or vein grafts) also can be accomplished through use of diagnostic cardiac catheterization.
9."Diagnostic, treatment, or rehabilitation center (DTRC)" means 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 part of a hospital.
10. “Expanded Service” or “Expansion” means an adult cardiac catheterization service that undertakes any capital renovation or construction project in and to the physical space within the hospital where the cardiac catheterization services are or will be offered, the cost of which exceeds the capital expenditure threshold at that time; or acquires a piece of diagnostic or therapeutic equipment with a value above the equipment expenditure threshold at that time which is to be utilized in the provision of cardiac catheterization services; or seeks the addition of a new catheterization laboratory or room regardless of cost. Replacement or repair of existing diagnostic or therapeutic equipment utilized in the provision of such services is not an expansion for purposes of these rules.
11. “Horizon year” means the last year of a five year projection period for need determinations for any adult cardiac catheterization services.
12. "Official inventory" means the Department’s inventory of all authorized hospital-based and diagnostic, treatment, or rehabilitation center (DTRC) adult cardiac catheterization laboratories or any other authorized laboratory approved for operation at the time of adoption of these rules.
13. "Official state component plan" means the document related to specialized cardiovascular services developed by the Department adopted by the Health Strategies Council and approved by the Board of Community Health.
14. "Procedure" means a cardiac catheterization study or treatment or combination of studies and/or treatments performed in a single session on a single patient who appears for cardiac catheterization.
15. "Planning area" means each of the planning areas designated in the official State Component Plan.
16. "Therapeutic cardiac catheterization" means the performance of cardiac catheterization for the purpose of ameliorating certain conditions which have been determined to exist in the heart or great arteries or veins of the heart.

**(c) Need Standard or Methodology**

1. The need for new or expanded adult cardiac catheterization services shall be determined through application of a numerical need method and an analysis of service demand based on an assessment of the aggregate utilization rate of existing services;

(i) the numerical need for new or expanded adult cardiac catheterization services shall be determined by a population-based formula which includes current usage patterns and projected population as follows:

(I) calculate the state adult cardiac catheterization rate for the most recent year of reported survey or hospital and outpatient discharge data by dividing the total number of adult cardiac catheterizations performed on Georgia residents by the total state adult CNI population;

(II) determine the projected adult cardiac catheterization procedures for the horizon year by multiplying the state rate by the adult CNI population for the planning area for the horizon year;

(III) adjust the projected adult cardiac catheterization procedures for the planning area by adding the out-of-state hospital-based catheterizations for the most recent year based on the percentage of total procedures performed on out-of-state patients by hospitals in each planning area;

(IV) convert projected adult cardiac catheterization procedures to procedure equivalents by multiplying the projected procedures by the statewide rate of equivalents per catheterization; and

(V) determine the projected net surplus or deficit for adult cardiac catheterization capacity, expressed in terms of rooms/laboratories, in the planning area by subtracting the rooms/laboratories needed for the total projected procedure equivalents calculated in steps (I) through (IV) from the total capacity (1300 procedure equivalents per room/laboratory) based on the official inventory.

(ii) before a new or expanded adult cardiac catheterization service will be approved in any planning area, the aggregate utilization rate of all adult cardiac catheterization services in that planning area shall be 85 percent or more during the most recent year;

**Rationale for Need Standard**: The need standard for adult cardiac catheterization is based on objective supply calculation and a market responsive demand factor. The supply calculation is based on the assumption, carried forth from previous rules, that each cath lab has an optimal volume or capacity of 1300 procedures. The current rate of service to Georgia residents is calculated by dividing the number of procedures by total adult CNI population. This rate is then multiplied by the horizon year adult population to determine future Georgia resident need. Out of state utilization is factored into the projection at a level commensurate to current use. These calculations are used to achieve a procedure equivalent. The total numbers are then divided by 1300 to arrive at projected labs by planning area. Surplus or deficit calculations are made by subtracting current lab availability from projected lab need. This objective standard must also be measured against actual demand such that new services or laboratories may only be approved in a planning area if the aggregation utilization within the area is 85% or more of existing service capacity. This provision protects against building new programs when current infrastructure is underutilized.

**ADULT OPEN HEART SURGICAL SERVICES**

**(a) Applicability**

A Certificate of Need will be required prior to the establishment of a new or, subject to certain stipulations, expanded adult open heart surgical service.

**(b) Definitions**

1. "Adult" means persons 15 years of age and over.
2. "Authorized service" means an adult open heart surgery service which is either existing or approved. An existing service is an authorized service which has become operational, and an approved service is an authorized service which has not become operational.
3. “Coronary Angioplasty” means a cardiac catheterization procedure to treat coronary heart disease by utilizing a catheter with a balloon, laser, laser-assisted device, rotational device, stent placement or other mechanical means to unblock an occluded coronary artery.
4. “Expanded Service” or “Expansion” means an adult open heart surgery service that undertakes any capital renovation or construction project in and to the physical space within the hospital where the adult open heart surgery service is or will be offered, the costs of which exceed the capital expenditure threshold at that time; or acquires a piece of diagnostic or therapeutic equipment with a value above the equipment expenditure threshold at that time which is to be utilized in the provision of open heart surgery services; or, for any service a full four (4) years or more following implementation of an approved Certificate of Need, any increase in adult

open heart surgery volume resulting in a 25% or more increase in procedures being performed by the service over the higher annual number of procedures having been performed during the most recent prior two calendar years. Replacement or repair of existing diagnostic or therapeutic equipment utilized in the provision of such service is not an expansion for purposes of these rules.

5. "Official State Component Plan" means the document related to specialized cardiovascular services developed by the Department established by the Health Strategies Council and adopted by the Board of Community Health.

6. "Open heart surgery" means surgery performed directly on the heart or its associated veins or arteries during which a heart and lung by-pass machine (extracorporeal pump) may be used to perform the work of the heart and lungs.

7. "Open heart surgery service" means an organized surgical program which serves inpatients of a hospital which has a suitable operating room or suite of operating rooms, equipment, staff, intensive care unit, and all support services required to perform adult open heart surgery. The adult open heart surgery service shall be located in an acute care hospital which has an authorized adult cardiac catheterization service.

8. "Procedure" means an adult open heart surgery operation or combination of operations performed in a single session on a single patient who appears for open heart.

**(c) Need Standard or Methodology**

1. (i) An application for new adult open heart surgery services shall be considered by the Department only if each and all of the following conditions are met:

(I) an applicant must have operated an existing adult cardiac catheterization service which is located in an acute care hospital setting for at least three (3) years prior to the date of application; and

(II) an applicant shall document, based on actual service data of the applicant, survey data provided to the Department and other supporting research and documentation, that the hospital's existing adult cardiac catheterization service generated a minimum of 250 or more adult open heart surgery procedures in each of the two (2) calendar years immediately prior to submittal of the application; and

(III) an applicant shall project and, if approved, shall document that the proposed adult open heart surgery service will be performing a minimum of 300 adult open heart surgery procedures per year within three years of initiation of the service. Such projections, at a minimum, shall include consideration of patient origin data for open heart and catheterization services, the use rate of existing services, and referral data and market patterns for existing hospital services, and cardiovascular disease incidence rates and related health indicators; and

(IV) an applicant shall document that existing and approved adult open heart surgery services in the state are not predicted to be adversely impacted as a result of the establishment of the new service. Impact on an existing or approved service shall be determined to be adverse if, based on the number of cases projected to be performed by the applicant, any of the existing or approved services would have either a decrease in volume equal to or greater than ten percent (10%) of the average annual service volume in the proceeding two calendar years or a decrease of less than ten percent (10%) of the annual service volume in the proceeding two calendar years but which would result in such service falling below a minimum of 200 open heart surgical procedures annually. In the case of an approved service, service volume should be projected in accordance with the volume projections in the approved application. An existing service which has been operational for four or more years and has not performed a minimum of 200 open heart surgical procedures in at least one of the past four years shall be excluded from a determination of adverse impact.

(V) if multiple applications are joined or comparatively reviewed, the Department shall

determine whether the individual impact of the establishment of each proposed service or the cumulative impact of the establishment of two or more proposed services would adversely impact an existing or approved service or any of the proposed services if established.

**Rationale for Need Standard**: Open Heart Surgical Services and the host of ancillary services necessary to support these programs require specialty qualifications; these are not services that can or should be available in every community. The planning area for these services is the entire state. The challenge for regulatory officials is to balance necessary access against the quality and cost-containment goals of guidelines. There are currently 16 open heart programs in the state, located in the various regions. New program development should be based on a clear need for services and a determination that new development will not have an adverse impact on existing services.

The need and quality aspects are addressed by requiring an applicant to have operated a catheterization lab for at least 3 years and to have generated from their hospital at least 250 open heart surgical cases in the past two years. The applicant then has to document using defensible data sources an ability to perform at least 300 surgery procedures per year within 3 years of service initiation. For open heart programs, volume is a proven key to avoiding adverse outcomes. Understaffed, low skill and low volume programs have been shown to result in low quality and adverse outcomes.

The adverse impact guidelines protect the human and financial investment already made by the state. Starting a new program to the detriment of current, quality programs is not a goal of health planning. In the instance that current programs are not meeting the needs of their patients or potential patients, other guidelines address those situations. A loss of 10% of average annual service volume for any provider or less than 10% if the loss would cause the service to fall below 200 annual procedures would be considered to be adverse impact. Programs already operating below 200 after 4 or more years of operation are excluded from adverse impact calculations. Calculations of adverse impact should review the actual patient origin data from current providers in comparison to the projected service volume of the applicant once the new program would achieve full operation (3 years out). In the rare instance of multiple applications being reviewed at one time, the adverse impact review would focus on what the individual and collective impact might be as well as the impact that each such applicant might have on each other.

## PEDIATRIC CARDIAC CATHETERIZATION AND OPEN HEART SURGERY

### (a) Definitions

1. "Authorized service" means a pediatric cardiac catheterization service or pediatric cardiac surgery service which is either existing or approved. An existing service is an authorized service which has become operational, and an approved service is an authorized service which has not become operational.
2. "Capacity" means:
    (i) for a pediatric catheterization service:
        (I) in considering applications for a new pediatric cardiac catheterization service, 750 procedures per year per authorized service regardless of the number of rooms used; or
        (II) in considering applications for expansion of an existing service, 750 pediatric cardiac catheterization procedures per dedicated room per year in the existing service (3 per day per room, 5 days per week, 50 weeks per year) and for each multipurpose room in the existing service, 750 procedures (special procedures and pediatric cardiac catheterization procedures) per year. If adult and pediatric cardiac catheterization are performed in the same room in a service seeking to expand, the capacity of the room shall be equivalent to 750 pediatric procedures with adult procedures performed in the room weighted in proportion to pediatric procedures as being 0.50 for each adult cardiac catheterization or special procedure, except

for each adult coronary angioplasty, which shall be 0.75, in order to determine the service's use rate; or

(ii) for a pediatric cardiac surgery service, the number of pediatric cardiac surgery procedures which could be performed annually as reported by each hospital with an authorized service and based on survey and other reported data. In determining capacity, a hospital must consider factors such as available operating rooms which can be used for pediatric cardiac surgery, cardiac surgical intensive care beds and other pediatric intensive care beds available for pediatric patients, general bed capacity, and any other factors which impact the determination.

3. "Cardiac catheterization" means a medical diagnostic or therapeutic procedure during which a catheter is inserted into a vein or artery in the patient; subsequently, the free end of the catheter is manipulated by the physician to travel along the course of the blood vessel into the chambers or vessels of the heart. X-rays and an electronic image intensifier are used as aids in placing the catheter tip in the desired position. When the catheter is in place, the physician is able to perform various diagnostic studies and/or therapeutic procedures on the heart or its vessels.

4. "Closed heart surgery" means an operation performed directly on the heart or its associated veins or arteries which does not require use of a heart and lung bypass machine (extracorporeal pump) to perform the work of the heart and lungs. Such operations often require the bypass machine to be available on standby for use if the surgery needs to be changed to open heart with the machine then performing the work of the heart and lungs.

5. . "Official State Component Plan" means the document related to specialized cardiovascular services developed by the Department, established by the Health Strategies Council, and adopted by the Board of Community Health.

6. "Open heart surgery" means surgery performed directly on the heart or its associated veins or arteries during which a heart and lung bypass machine (extracorporeal pump) is used to perform the work of the heart and lungs.

7. "Pediatric" refers to children 14 years of age and under.

8. "Pediatric cardiac catheterization service" means an organized program which serves pediatric patients of a hospital which has a room or suite of rooms with the equipment, staff, and all support services required to perform angiographic, physiologic, and, as appropriate, therapeutic cardiac catheterization procedures. The pediatric cardiac catheterization service shall be located in a pediatric tertiary hospital. Procedures may be performed in a room dedicated to cardiac catheterization and/or in a special procedures or multipurpose room not exclusively used for cardiac catheterization.

9. "Pediatric cardiac surgery" means an operation performed directly on a pediatric patient's heart or its associated veins or arteries, including open heart and closed heart surgery procedures but excluding surgical procedures for the closure of neonatal patent ductus arteriosus.

10. "Pediatric cardiac surgery service" means an organized surgical program which serves pediatric inpatients of a hospital which has a suitable operating room or suite of operating rooms, equipment, staff, and all support services required to perform closed heart and open heart operations for pediatric patients. The pediatric cardiac surgery service shall be located in a pediatric tertiary hospital.

11. "Pediatric tertiary hospital" means a teaching center, specialty medical or large community hospital characterized by serving pediatric patients from a large region or the entire state with sophisticated technology and support services to provide highly specialized medical and surgical care for unusual and complex medical problems of pediatric patients.

12. "Procedure" means a cardiac catheterization study or treatment or combination of studies and/or treatments performed in a single session on a single patient who appears for cardiac catheterization or a pediatric open or closed heart operation or combination of operations performed in a single session on a single patient who appears for pediatric cardiac surgery.

13. "Service area," for pediatric cardiac catheterization and pediatric cardiac surgery means the State of Georgia.

**(b) Need Standard or Methodology**

1. An applicant for new pediatric cardiac catheterization and pediatric cardiac surgery services must be a pediatric tertiary hospital. Due to the highly specialized nature of pediatric cardiac catheterization and pediatric cardiac surgery services, applicants for these services must propose to provide both pediatric cardiac catheterization and pediatric cardiac surgery. Only those projects which meet all applicable standards for both services will be approved.

2. New pediatric cardiac catheterization services shall be approved in the state only if each and all of the following conditions are met:

(i) the combined use rate for all existing and approved pediatric cardiac catheterization services in the state has been at or above 80 percent of capacity for the past two years as documented through surveys submitted to the Department;

(ii) an applicant must project that the proposed service will be operating at a minimum of 150 procedures per year within three years of initiation of the service in order to maintain and strengthen skills. Such projection at a minimum shall include consideration of patient origin data and the use rate of existing services; and

(iii) an applicant must show that authorized pediatric cardiac catheterization services which would be impacted by the establishment of the new service are not predicted to perform less than the minimum quality level of 150 procedures annually as a result of the establishment of the new service.

3. (*provisions relate to expansion)*

4. New pediatric cardiac surgery services shall be approved in the state only if each and all of the following conditions are met:

(i) the combined use rate of all authorized pediatric cardiac surgery services in the state has been at or above 80 percent of capacity for the past two years as documented through surveys submitted to the Department;

(ii) an applicant must project that the proposed service will be operating at a minimum of 100 pediatric cardiac surgery procedures per year, of which at least 50 are open heart operations, within three years of initiation of the service in order to maintain and strengthen skills. Such projections at a minimum shall include consideration of patient origin data and the use rate of existing services; and

(iii) an applicant must show that authorized pediatric cardiac surgery services which would be impacted by the establishment of the new services are not predicted to perform less than the minimum quality level of 100 procedures annually, of which at least 50 are open heart operations, as a result of the establishment of the new service.

**Rationale for Need Standard:** Pediatric services are so specialized in nature that the need standards are understandably quite rigid. First, only a pediatric tertiary hospital proposing to provide both catheterization and surgical services may even apply. Secondly, the capacity criteria is quite high: 750 procedures for catheterizations and a self-established limit for surgical services based on a hospital's assessment of critical and support capacity. Before any new service can be considered, utilization for existing cath and surgery services must be at or above 80% of capacity. Further, any new applicant must be able to project that the new program could perform at least 150 caths and 100 surgical procedures within 3 years of operation. Finally, the new applicant could not impact any current providers such that volume would fall below 150 cath procedures or 100 surgical procedures. The planning area for these services is the entire state.

**Core Components Common to All Rules**

**EXCEPTION TO NEED**

**Rationale for Exception to Need Standards: Adult Cardiac Catheterization [272-02-09(7)(c)(2)(i)]; Adult Open Heart Surgical Services [272-02-09(13)(c)(1)(ii)]; and there are no exceptions to need standards for pediatric services.**

The Department may allow an exception to the need standard to remedy an atypical barrier to specialized cardiovascular services based on cost, quality, financial access, or geographic accessibility. 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 specialized diagnostic, or treatment services. The Department uses rigorous need methodologies to contain health care costs to avoid the unnecessary duplication of services, equipment and facilities which also supports quality-of-care standards.

In rare 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 the case of Open Heart services, the exception also exempts the applicant from complying with the adverse impact requirements. In any submission to seek consideration under the exception provisions, the burden of proof is placed on the applicant to demonstrate that these accessibility problems exist. The rules provide some examples of delivery system problems which might merit consideration as a ground for an exception.

COST: An atypical barrier to services based on cost may include the failure of existing providers of surgical services to provide services at reasonable cost, as evidenced by the provider's charges and or reimbursement being significantly higher than the charges and or reimbursement of other providers in the planning area and/or the state. Significantly higher would be defined as one or more standard deviations from the mean of charges among similar types of providers. The TAC noted that charges do not equate to reimbursement particularly in the case of government and third party payers; therefore, they felt it would be important to consider charges as well as reimbursement in any such review.

QUALITY: The TAC spent a considerable amount of time discussing the issue of quality of care and its importance in the initiation and maintenance of good specialized cardiovascular services. They stressed the importance of benchmarking of outcomes against national database standards. The TAC examined several bodies of research, which reinforced the importance of peer review. They cited the ACC/AHA Guidelines, which reiterated the importance of organized, quality improvement programs to include participation in national data registries, such as the ACC, National Cardiovascular Data Registry (NCDR). Because quality is such an

important component of the regulatory guidelines for specialized cardiovascular services, the rules reflect that an atypical barrier based on quality may include the failure of existing providers to provide services with outcomes generally in keeping with accepted clinical guidelines of the American College of Cardiology, peer review programs and comparable state rates for similar populations.

INDIGENT/CHARITY CARE & MEDICAID: One of the core goals of the Department of Community Health is to develop and sustain a health care infrastructure that is more responsive to the consumers while improving access and coverage. This includes planning for coverage of uninsured and underinsured Georgians, currently estimated at 1.3 million people. As the state Medicaid agency, the Department also must ensure that citizens using this health care plan receive equitable access to coverage. The TAC felt strongly that providers should assume some of the responsibility for providing care to its local residents, particularly those that may have limited financial resources.

Research from recent literature suggests that the uninsured do not receive needed health care services. This is a particularly dire situation for uninsured patients with heart disease or hypertension. This report suggests that people with heart disease and no health insurance are 2.5 times more likely than the insured not to have a regular source of care and four times more likely to not receive care because they cannot afford it. In addition, the study found, one quarter of uninsured people with heart disease and hypertension did not receive care or prescribed medication because the money to pay for it was needed for food, clothing, or housing costs.

The Department is committed to ensuring that providers take responsibility for the health care of their local areas by serving as a conduit for the provision of local health care services regardless of the patients' ability to pay. For these reasons, the rules acknowledge that an atypical barrier to services based on financial access may include the repeated failure, as exhibited by a documented pattern over two or more years prior to the submission of the application, of existing providers within the community to provide services to indigent, charity and Medicaid patients. For adult cardiac catheterization services, the comparison should be done among providers within the applicable planning area, hence the term "providers" is used in the proposed rules. In the case of open heart services, the comparison must be done at a defined sub-state community/health care market area since the planning area is the entire state. The terms "provider or providers" are proposed in the rules to clarify that in a defined community/health care market the analysis is conducted so as to include the provider(s) in that area, whether it be one or many. In a metropolitan area with multiple providers, any case for lack of financial access would, by necessity, have to include an evaluation of all providers within that metropolitan area.

GEOGRAPHIC ACCESSIBILITY: Specialized cardiovascular services should be accessible without diluting quality or increasing cost. Due to the necessity of having highly skilled clinical and support staff, infrastructure and other resources, regionalized planning has been the necessary approach for service planning for catheterization and adult open heart surgery services. While the need methodologies should provide for geographic access, the TAC and the Department felt it important to safeguard the rural areas of Georgia by allowing an applicant to present evidence that lack of geographic accessibility presented a barrier to care. For catheterization services, one example of an atypical barrier to services based on geographic accessibility might be the failure of citizens to receive equitable care as reflected through a significantly lower rate of services as compared to a significantly higher rate of CVD than the state as a whole.

LABORATORY UTILIZATION AND EP STUDIES: In the case of adult cardiac catheterization, two additional exception provisions are in the rules. Any laboratory having actual utilization exceeding 90% of capacity (1170 of 1300) over the past two years may seek an exception to need. The TAC also authorized a new exception for any program seeking to establish a lab solely for the purpose of conducting EP studies. The group was clear that such focused services could be considered under the exception to need provisions. However, any successful applicant should be restricted to providing only EP studies and should have exhibited full compliance with ACC guidelines for these specialized services.

**EXPANSION**

**Rationale for Regulatory Requirements Related to Expansion: Adult Cardiac Catheterization [272-02-09(7)(c)(2)(ii)]; Adult Open Heart Surgical Services [272-02-09 (13)(c)(2)]; and Pediatric Cardiac Catheterization and Open Heart Surgical Services [272-02-.09(16)(b)(3) and (5)]**

Capital renovation, construction projects or new equipment acquisitions in excess of the capital/equipment expenditure thresholds at the time are considered expansions for existing providers of specialized adult cardiovascular services. Any provider seeking expansion for these purposes should be required to comply with the guidelines that address quality, continuity of care, health promotion and disease prevention initiatives, community outreach, and non-discriminatory access to care. However, these expansion efforts should not be subject to the need and adverse impact requirements. For pediatric services, because of their very specialized nature, the rules have required and continue to require that expansion as a result of capital/equipment expenditures should meet a test of minimum volume/service increases.

In the case of adult cardiac catheterization services, the regulatory guidelines have and continued to adhere to an established capacity volume for laboratories. Any program seeking to increase volume would need to add an additional laboratory. The addition of a laboratory, except as it relates to those programs operating at or above 90% capacity for two years or those seeking to provide solely EP services, is considered an expansion that is subject to both the need and adverse impact criteria.

For open heart surgical services, significant growth (25% or more) in the number of procedures performed by fully operational programs over the past two calendar years would be defined as an expansion. The growth percentage is determined by comparing projected/current year procedures to the higher number of procedures performed in the most recent past two years. The TAC and the Department recognize the value of high volume, high quality services so they have attempted to streamline the application process for this type of expansion so that it doesn't cause undue financial burden or become administratively arduous. An existing service seeking this type of expansion would first be authorized to seek a determination that the service is in compliance with the specific provisions outlined in 272-02-.09(13)(c)(3),(4),(5),(7),(8), & (10) (community outreach, quality of care and financial accessibility). Should the Department determine that the facility is in compliance with all of these guidelines, the service would not be required to secure a certificate of need. The TAC and legal staff have equated this to what is known as a "letter of non-reviewability." In the event the facility is not in compliance with these key service requirements, then an application would be required to secure compliance. However, the applicant could seek an expedited review under those rules. At the suggestion of the TAC, the Department is proceeding concurrently with an amendment to the expedited review provisions to reflect this understanding.

**FAVORABLE CONSIDERATION**
**Rationale for Guideline: Adult Open Heart Surgical Services [272-02-09 (13)(c)(6)]**

In considering applications joined for review for new adult open heart surgery services, the Department may give favorable consideration to an applicant which historically has provided a higher annual percentage of unreimbursed services to indigent and charity patients and a higher annual percentage of services to Medicare and Medicaid patients. Since provision of financially accessible services to those unable to pay for care is considered to be very important, the Department may give special consideration when considering competing applications to the applicant that has a stronger record of serving this population.

**CLINICAL CAPACITY AND COMPETENCE**
**Rationale for Guidelines Related to Clinical Capacity and Competence: Adult Cardiac Catheterization [272-02-09(7)(c)(5),( 6), and (7)]; Adult Open Heart Surgical Services [272-02-09 (13)(c)(3),(7) and (8)]; and Pediatric Cardiac Catheterization and Open Heart Surgical Services [272-02-09(16)(6),(7),( 8) (11), and (12)]**

Quality control is essential for the consistent high quality level of performance that is required of any medical service. However, given the specialized nature of cardiovascular services, it is paramount that an applicant for new or expanded specialized cardiovascular services demonstrate compliance with or the intent to achieve optimal standards established by the American College of Cardiology, the American College of Surgeons, the Advisory Council for Cardiothoracic Surgery of the American College, and the American Academy of Pediatrics, Guidelines for Pediatric Cardiology Diagnostic and Treatment Centers. These organizations set forth the quality benchmarks and minimum standards against which to evaluate clinical and physical environments, including staffing requirements, support services, physical plant and equipment and represent the state-of- the-art protocols for operations of a high quality open heart surgery program.

Federal and state governments have established standards for the delivery of hospital services, which must be met in order to maintain Medicare/Medicaid certification and state licensure status. In addition, the Joint Commission on Accreditation of Health Care Organizations (JCAHO) evaluates hospitals on a voluntary basis for JCAHO accreditation. An applicant must provide any Medicare/Medicaid certification evaluations performed in the past three years to document to the Department's satisfaction that the facility has not had a history of conditional level deficiencies. The documentation shall include, but not be limited to, any Medicare/Medicaid deficiency reports issued to the facility. The TAC and the Department set forth a requirement that all applicants have proof of JCAHO accreditation, with the exception of new adult catheterization laboratory facilities which would have to be accredited within 18 months of approval.

Clinical guidelines are set forth in all rules that require an applicant to document the ability to provide all of the necessary core and ancillary services to ensure quality care. In the case of adult catheterization programs that do not have onsite open-heart backup, the applicant would have to document a transfer agreement with an appropriate surgical program. Applicants would have to document the availability of cardiologists, surgeons and other clinical personnel as well as a host of procedural competencies and organizational support services. An applicant for open heart surgery services should address how they intend to staff and manage aortic trauma and specialized vascular surgical needs. All applicants must also comply with practice guidelines put forth by national professional organizations such as ACC and STS. Of great importance as well is facility and physician participation in peer review programs and processes that are external to the single facility. There are many options for peer review participation; the key is to ensure that Georgia programs are continually working toward clinical excellence by benchmarking themselves against state and national performance levels. Applicants must also propose a system of outcome monitoring and quality improvement, identifying at least 5 clinical

outcomes that they intend to monitor for performance on a regular basis.

**COMMUNITY OUTREACH**

**Rationale for Guidelines Related to Community Outreach: Adult Cardiac Catheterization [272-02-09(7)(c)(8)]; Adult Open Heart Surgical Services [272-02-09 (13)(c)(4)]; and Pediatric Cardiac Catheterization and Open Heart Surgical Services [272-02-09(16)(b)(9)].**

An applicant for any new or expanded specialized cardiovascular service shall provide a written plan to the Department, which when implemented, will ensure access to a full range of prevention and treatment services for all segments of the population in the documented and proposed service area of the facility and service. The TAC strongly supported the Department's initiative to encourage providers offering specialized cardiovascular services to bear some responsibility for the health status of the local community. The applicant would be responsible for reaching patients not currently served within the service area and who may be at risk of a cardiovascular event. This outreach should involve health education measures that could mitigate against cardiovascular events in the future. Additionally, because the Department and the TAC understand the merits of health education efforts, including the importance of prevention, the applicant would be required to institute a planning process to ensure the continuity of care for cardiovascular services, including prevention. Moreover, providers of specialized cardiovascular services would be required to develop substantive clinical educational programming, at a level that would meet professional continuing education requirements, for community based health professionals.

Prevention of heart disease and cardiac rehabilitation are important, early interventions on the cardiac continuum are necessary components of comprehensive cardiac services. Reaching potential patients prior to an actual cardiovascular event could be of enormous benefit on the community. Preventive approaches to changing lifestyles and dealing with cardiovascular problems can reduce mortality and morbidity, including the medical conditions requiring open-heart surgery. While the applicant would have greater control of the quality of such a program if it were implemented on its campus, the Department and the TAC recognizes that referrals to existing programs within the facility's service area would be a less costly and more efficient process than would the establishment of a new program. Further, community-based organizations may be more effective in reaching patients.

In addition to providing prevention programs for the community-at-large, the applicant would also be responsible for the creation of (or referral to) a heart disease prevention program for cardiac patients that provides information in a very comprehensive manner about risk factors, exercise/diet/drugs, smoking cessation, lifestyle characteristics that may place a patient or relative at risk for an adverse cardiovascular event. In addition to this initiative the applicant would also be required to ensure that appropriate referrals to primary care providers are instituted as part of the education process. A mechanism to track and follow-up the patient to determine attendance at a referred service and other continuity of care measures should also be tightly interwoven into this process.

Clinical intervention for non-cardiac patients who present in an inpatient environment was also important to the TAC and the Department. For these patients, a program that assesses risk factors, provides appropriate counseling and referral for diagnostic evaluation and risk factor modification, referrals and other follow-up are considered to be some minimum interventions. The Department and the TAC concurred that the applicant should bear some of the responsibility for prevention, treatment and rehabilitation. Implicit in all of these activities is an outcomes monitoring and quality improvement program. An applicant for a new or expanded adult open-heart surgery service must document the ongoing provision of or participation in active programs for heart disease prevention and cardiac rehabilitation to serve the hospital's planning area. Heart disease

prevention programs at a minimum should include information on smoking cessation, weight loss, nutrition, dietary education, stress, and hypertension control information. Cardiac rehabilitation programs should include information on exercise, and monitoring programs to reduce reoccurrence of heart attacks and encourage lifestyle changes to decrease heart attack risk factors.

As Commissioner Toal reflected in charging the group, "the need for additional emergent and acute care procedures may be seen as a failure of our health care system to properly intervene." The comprehensive community outreach provisions in all three sets of rules are designed to link high end diagnostic and treatment service providers with health promotion and other interventions to avoid services which bear a heavy personal and financial price tag.

## FINANCIAL ACCESS

### Rationale for Guidelines Related to Financial Access: Adult Cardiac Catheterization [272-02-09(7)(c)(11)]; Adult Open Heart Surgical Services [272-02-09 (13)(c)(5)]; and Pediatric Cardiac Catheterization and Open Heart Surgical Services [ 272-02-09(16)(b)(10)]

An applicant for new or expanded specialized cardiovascular services shall foster an environment, which assures access to care for individuals regardless of ability to pay, payment source or other circumstances. The Department and the TAC strongly endorsed the position that any hospital offering specialized cardiovascular services should be financially accessible to anyone in need. Providers should offer these services to patients regardless of their ability to pay or payment source or circumstances and without discrimination in any fashion. Further, providers should accept all patients who are clinically appropriate. The Department is aware of instances where hospitals refused to accept patients solely because of their inability to pay, forcing the patient to be transferred to another hospital outside of their home community and without appropriate follow-up mechanisms. This type of cherry-picking should not occur in the future.

The TAC recommended that an applicant for any cardiovascular services commit to providing indigent/charity at a level that meets or exceeds three percent of annual, adjusted gross revenues of the specialized cardiovascular service. The TAC agreed that this standard is critical to ensuring access to care for patients who might not otherwise have access to such services. The rules authorize the Department to consider a facility-wide commitment upon request of the applicant. Members were in agreement that a facility-wide commitment would be appropriate if the amount of the commitment is much greater and the commitment would allow access to other services where there is a great need or where services might not have been otherwise available. The applicant would be required to provide this commitment in writing.

Though not stipulated in the rules, the TAC agreed that it would be helpful to patients if applicants posted information about its policies regarding the provision of services regardless of race, age, sex, creed, religion, disability or patient's ability to pay. Several TAC members expressed concern about subcontractors' such as laboratories balance-billing patients. Though not specifically reflected in the rules, they recommended that the Department of Community Health support methods to ensure that all clinical subcontractors have policies in place that would be comparable to the hospital's stated policies.

An applicant for a new or expanded adult open heart surgery service shall provide a written commitment that, subject to good faith negotiations, the applicant will participate in any state health benefits 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 provisions about good faith negotiations were designed to ensure that providers were not totally at the mercy of the Department; the expectation is that providers will participate in the public employees health benefits plans in most cases.

The TAC and the Department further outline that an applicant's or its parent organization's failure to fulfill any previous indigent and charity commitment and/or the failure to provide services to Medicaid and indigent patients at a level commensurate with the community population may be considered sufficient grounds to deny an application. The Department will use data from the three most recent prior years to make these determinations.

## ADDITIONAL STANDARDS

**Rationale for Guidelines Related to Additional Standards: Adult Cardiac Catheterization [272-02-09(7)(c)(12)]; Adult Open Heart Surgical Services [272-02-09(13)(c)(10)]; and Pediatric Cardiac Catheterization an Open Heart [272-02-09(16)(b)(15)]**

The Department and the TAC are committed to providing high quality specialized cardiovascular services to all of the residents of the state. They have established certain minimum standards for care delivery and have defined provider requirements to ensure that there are statewide standards. As a final component to each set of rules, the guidelines require any applicant to agree in writing to certain core conditions. Of paramount importance is the Department's and the TAC strong commitments to ensuring that providers participate in planning and quality improvement sessions with community health providers and advocates. Active participation in data reporting, outcome monitoring and peer review must be documented. Policies and procedures must be in place to ensure that cardiologists and surgeons providing patient care in these specialized programs agree to accept Medicaid, Medicare and PeachCare without discrimination. It does the patient no good to have the hospital accept these payments if the physician is going to refuse such payment sources and require private pay. The applicant must commit to reasonable, comparable charges and submission of all required data and survey information. Finally, the applicant must agree to act in good faith to fulfill the terms and commitments set forth in its application.

## DEPARTMENT'S AUTHORITY TO REVOKE

**Rationale for Guideline Related to Authority to Revoke: Adult Cardiac Catheterization [272-02-09(7)(c)(13)]; Adult Open Heart Surgical Services [272-02-09(13)(c)(11)]; and Pediatric Cardiac Catheterization and Open Heart Surgical Services [272-02-.09(16)(b)(16)]**

The statute authorizes the Department to revoke a Certificate of Need based on the applicant's failure to comply with the defined scope, location, cost, service area, and for the intentional provision of false information during the application process. The Department is committed to exercising its authority to the fullest extent granted by law.

## GOALS, OBJECTIVES AND RECOMMENDED ACTIONS

### A. GOAL

- To ensure that Georgia citizens have access to cost-effective, efficient, and high quality cardiovascular services in appropriate healthcare settings.

### B. OBJECTIVES

- Improve access to cost effective, quality specialized cardiovascular services;
- Encourage providers to take responsibility for the health of their communities;
- Reflect the technological advances and trends in the treatment of cardiovascular disease;
- Encourage continuity of care for specialized cardiovascular services through the development of comprehensive policies and processes;
- Ensure quality and patient safety through peer review, performance monitoring and compliance with appropriate standards and guidelines.
- Improve access to specialized cardiovascular services by mandating the provision of services on a non-discriminatory basis;
- Improve financial access to prevention services and appropriate specialized cardiovascular care 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.
- Analyze the availability, quality and effectiveness of specialized cardiovascular services being provided through collection and analysis of information and statistical data.

### C. RECOMMENDATIONS

The Cardiovascular Services Technical Advisory Committee discussed and recommended the following actions:

- Reconvene this committee within two years to ensure that current technological and clinical advances are implemented in the planning and regulatory review process. Prior to that time, pediatric cardiac service providers should convene to evaluate the state of the service advances and the ability of current standards to address new developments.
- Adopt and implement Certificate of Need (CON) rules for new or expanded specialized cardiovascular services consistent with this Component Plan and approve CON applications accordingly.
- Require applicants for new or expanded cardiac catheterization and open-heart surgical

services to demonstrate plans to provide a full array of cardiovascular services to their local communities (outreach, prevention education, treatment and rehabilitation).

- Require that applicants for new or expanded services demonstrate the intent to achieve optimal clinical and physical environment standards established in the most recent, applicable guidelines of American College of Cardiology, American Heart Association, the Advisory Council for Cardiothoracic Surgery of the American College of Surgeons, the American Academy of Pediatrics, and the North American Society of Pacing and Electrophysiology and other related organizations. Require that existing services seeking to expand meet Joint Commission on Accreditation of Healthcare Organizations (JCAHO) and other standards as outlined in related rules.

- Require applicants for new or expanded cardiac catheterization and open-heart surgical services demonstrate administrative policies showing that they provide services on a non-discriminatory basis and promote financial access for all potential patients.

- Collect data annually, and on an ad hoc basis as needed, to maintain current, accurate information related to availability, quality and effectiveness of services being provided.

- Encourage the Department of Community Health/Division of Health Planning to be more rigorous about sanctioning providers, as authorized by statute.

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# SPECIALIZED CARDIOVASCULAR SERVICES COMPONENT PLAN

## LISTING OF APPENDICES

## LIST OF APPENDICES

# SPECIALIZED CARDIOVASCULAR SERVICES

# COMPONENT PLAN

# APPENDIX A

# Rules as Proposed by the Technical Advisory Committee and the Health Strategies Council

Note: Sections in **boldface** indicate proposed new language and sections with ~~strikethrough~~ indicate language from previous rules recommended for removal.

(7) Adult Cardiac Catheterization Services.

(a) Applicability.

1. For Certificate of Need (CON) purposes, Adult Cardiac Catheterization Services is classified as a specialized service and is defined as a new institutional health service **which must be** delivered in **a permanently fixed location in either** an acute care hospital or in a diagnostic, treatment, or rehabilitation center (DTRC). **A certificate of need will be required prior to the establishment of a new or expanded adult cardiac catheterization service.**

2. If the services will be provided within a licensed acute care hospital, the hospital shall be the applicant. ~~An acute care hospital does not have to apply for a CON to participate in a mobile cardiac catheterization network; however,~~

~~(i) if an acute care hospital wants to change from participation in a mobile cardiac catheterization network to a hospital-based service, the hospital must submit a CON application for hospital-based cardiac catheterization services;~~

~~(ii) if a mobile cardiac catheterization facility serves only one acute care hospital, or if a mobile cardiac catheterization facility is stationed and operated for either more than 30 hours per week or three calendar days per week at one acute care hospital site, the facility will not meet the characteristics of a mobile cardiac catheterization service as defined in these rules; therefore, the hospital at which that mobile facility is stationed will be required to apply for a CON for a hospital-based cardiac catheterization service.~~

3. If cardiac catheterization services will be provided in a **DTRC** ~~permanently fixed site not located in a licensed acute care hospital~~, the organizational entity which develops the service shall be the applicant.

~~4. If cardiac catheterization services will be provided in a mobile cardiac catheterization facility that will provide services for more than one acute care hospital, the mobile vendor shall be the applicant. Mobile cardiac catheterization facilities may provide services only on the campus of a licensed acute care hospital. Approval must be obtained prior to the establishment of a mobile cardiac catheterization network or expansion to additional acute care hospital sites of a mobile cardiac catheterization network except as otherwise provided in these rules. Pursuant to O.C.G.A. 31-6-41(a), a CON is valid only for the defined scope, location, cost, service area and person named and approved in the CON by the Agency;~~

~~(i) the mobile vendor must submit, on the CON application, information about the entire proposed network. This information shall include the capacity to be used at each site and how each hospital network member meets American College of Cardiology/American Heart Association guidelines for quality, personnel, and safety standards;~~

~~(ii) additional CON approval is not necessary for a mobile vendor if:~~

~~(I) an acute care hospital which was part of that vendor's approved network terminates its participation in the network; and/or~~

~~(II) the vendor changes the capacity or number of days it operates at any single location, unless this change results in the mobile facility being operational more than 30 hours per week or three calendar days per week at a single location;~~

~~(iii) the vendor must notify the Agency of any of the above changes in the network within 15 days of the effective date of the change. Failure to comply with this notification requirement may result in revocation of the CON for the mobile vendor.~~

(b) Definitions.

1. "Adjacent acute care hospital" means an acute care hospital which is physically connected to another acute care hospital in a manner that emergency transport of a patient by a stretcher or gurney can be achieved rapidly, conveniently, and effectively without the use of motorized vehicles.

2. "Adult" means a person 15 years of age and over.

3. "Authorized service" means a**n** ~~State Health Planning Agency sanctioned~~ adult cardiac catheterization service which is either existing or approved. An existing service is an authorized service which has become operational, and an approved service is an authorized service which has not yet become operational.

4. "Capacity" means 1300 adult cardiac catheterization procedure equivalents per dedicated and multipurpose room per year. In the ~~Agency's~~ computation of the use rate (percent of capacity) of authorized adult cardiac catheterization ~~dedicated and multipurpose~~ rooms, each adult diagnostic cardiac catheterization and other cardiac catheterizations of similar complexity shall equal a 1.0 procedure equivalent**,** ~~and~~ each coronary angioplasty procedure shall equal 1.5 procedure equivalents**, and each electrophysiological (EP) study shall equal 2.0 procedure equivalents**. If pediatric catheterizations are performed in a ~~dedicated or multipurpose~~ room in which adult cardiac catheterizations are performed, each pediatric procedure shall equal 2.0 procedure equivalents. ~~Pediatric catheterizations shall not be performed in any DTRC.~~

5. "Cardiac catheterization" means a medical diagnostic or therapeutic procedure during which a catheter is inserted into a vein or artery in the patient; subsequently, the free end of the catheter is manipulated by the physician to travel along the course of the blood vessel into the chambers or vessels of the heart. X-rays and an electronic image intensifier are used as aids in placing the catheter tip in the desired position. When the catheter is in place, the physician is able to perform various diagnostic studies and/or therapeutic procedures on the heart or its vessels.

6. "Cardiac catheterization service" means an organized program which serves inpatients and/or outpatients of an acute care hospital or diagnostic, treatment and rehabilitation center (DTRC) with a room or a suite of rooms, with equipment to perform angiographic, physiologic, and as appropriate, therapeutic cardiac catheterization procedures. ~~Procedures may be performed in a room dedicated to cardiac catheterization or in a multipurpose room not used exclusively for cardiac catheterization.~~ An authorized adult cardiac catheterization service ~~shall not be authorized to~~ **is prohibited from** perform**ing** coronary angioplasty procedures ~~as part of the adult cardiac catheterization service~~ unless the acute care hospital where the service is located meets the requirements identified in 272-2-.09(7)(c)6.

7. "Coronary angioplasty" means a cardiac catheterization procedure to treat coronary artery disease by utilizing a catheter with a balloon, laser, laser-assisted device, rotational device, **stent placement** or other mechanical means to unblock an occluded coronary artery.

~~8. "Dedicated room" means a room used only for cardiac catheterization procedures.~~

~~9~~ **8**. "Diagnostic cardiac catheterization" means 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. Post-operative evaluation of the effectiveness of prostheses (e.g. heart valves or vein grafts) also can be accomplished through use of diagnostic cardiac catheterization.

~~10~~ **9**."Diagnostic, treatment, or rehabilitation center (DTRC)" means 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 part of a hospital.

**10. "Expanded Service" or "Expansion" means an adult cardiac catheterization service that undertakes any capital renovation or construction project in and to the physical space within the hospital where the cardiac catheterization services are or will be offered, the cost of which exceeds the capital expenditure threshold at that time; or that acquires a piece of diagnostic or therapeutic equipment with a value above the equipment expenditure threshold at that time which is to be utilized in the provision of cardiac catheterization services; or that seeks the addition of a new catheterization laboratory or room regardless of cost. Replacement or repair of existing diagnostic or therapeutic equipment utilized in the provision of such services is not an expansion for purposes of these rules.**

**11. "Horizon year" means the last year of a five year projection period for need determinations for any adult cardiac catheterization services**.

~~11. "Mobile cardiac catheterization facility" means an entire facility, consisting of one cardiac catheterization room that is transportable by land, sea, or air. It can provide cardiac catheterization services in one location and then can be quickly relocated and set up to provide cardiac catheterization services in another location. A mobile cardiac catheterization facility serves more than one location and is not stationed and operated at any single location for more than 30 hours per week or three calendar days per week. A mobile cardiac catheterization facility cannot be stationed at only one site, regardless of the number of hours or days per week it operates at that site.~~

~~12. "Mobile cardiac catheterization network" means an organizational network comprised of one mobile catheterization facility plus two or more acute care hospitals which offer cardiac catheterization services through that mobile cardiac catheterization facility.~~

~~13. "Mobile vendor" means the owner of a mobile catheterization facility.~~

~~14. "Most recent year" means the most current 12-month period within a month of the date of completion of an application or within a month of the date of completion of the first application when applications are joined. However, if the Agency has conducted a survey for a report period ending within six months of the date of completion of an application or within six months of the date of completion of the first application when applications are joined, the most recent year may be the report period covered by that survey. Example: if the date of completion of an application (or the first application when applications are joined) is any day in June, the most recent year will be the 12 months ending in that month or the preceding month (June or May), at the Agency's discretion. However, if the Agency has conducted a survey for a report period ending any time from December of the preceding year through June of the year the application is complete, that report period may be considered the most recent year.~~

~~15. "Multipurpose room" means a room used for cardiac catheterization and other special procedures.~~

~~16~~ **12**. "Official inventory" means the **Department's** inventory of all authorized hospital-based and diagnostic, treatment, or rehabilitation center (DTRC) adult cardiac catheterization laboratories **or any other authorized laboratory approved for operation at the time of adoption of these rules**. ~~maintained by the Agency based on CON approval and official Agency records. The inventory of mobile facilities shall be based on the capacity available for use at each location as determined by the Agency.~~

~~17~~ **13**. "Official state component plan" means the ~~most recent~~ document related to ~~adult cardiac catheterization~~ **specialized cardiovascular** services developed by the **Department** ~~State Health Planning Agency, established~~ **adopted** by the Health Strategies Council and **approved by the Board of Community Health** ~~signed by the Governor of Georgia~~.

~~18~~ **14**. "Procedure" means a cardiac catheterization study or treatment or combination of studies and/or treatments performed in a single session on a single patient who appears for cardiac catheterization.

~~19~~ **15**. "Planning area" means each of the planning areas designated in the official State ~~Health~~ Component Plan ~~for Adult Cardiac Catheterization Services~~.

~~20~~ **16**. "Therapeutic cardiac catheterization" means the performance of cardiac catheterization for the purpose of ameliorating certain conditions which have been determined to exist in the heart or great arteries or veins of the heart.

(c) Standards.

1. The need for new or expanded adult cardiac catheterization services shall be determined through application of a numerical need method and **an analysis of service demand based on** an assessment of the aggregate utilization rate of existing services;

(i) the numerical need for new or expanded adult cardiac catheterization services shall be determined by a **population-based formula which includes current usage patterns and projected population as follows:** ~~demographic formula which includes the number of patients in a geographic area with generally accepted indications for catheterization study. The following need calculation applies to each planning area. Net need in all appropriate planning areas will be considered for a proposed mobile network;~~

(I) calculate the state adult cardiac catheterization rate for the most recent year of reported **survey or hospital and outpatient discharge** data by dividing the total number of adult cardiac catheterizations performed on Georgia residents by the total state adult CNI population;

(II) determine the projected adult cardiac catheterization procedures for the horizon year by multiplying the state rate by the adult CNI population for the planning area for the horizon year;

(III) adjust the projected adult cardiac catheterization procedures for the planning area by adding the out-of-state hospital-based catheterizations for the most recent year based on the percentage of total procedures performed on out-of-state patients by hospitals in each planning area;

(IV) convert projected adult cardiac catheterization procedures to procedure equivalents by multiplying the projected procedures by the statewide rate of equivalents per catheterization; **and**

~~(V) calculate the projected total procedure equivalents needed at 80 percent utilization in a planning area by dividing the projected procedure equivalents by 80 percent;~~

~~(VI)~~ **(V)** determine the projected net surplus or deficit for adult cardiac catheterization capacity**, expressed in terms of rooms/laboratories,** in the planning area by subtracting the **rooms/laboratories needed for the** total projected procedure equivalents **calculated in steps (I) through (IV)** ~~needed at 80 percent utilization (step 272-2-.09(7)(c)1.(i)(V) above)~~ from the total capacity (1300 procedure equivalents per room/laboratory) **based on the official inventory**. ~~of existing and approved adult cardiac catheterization rooms/laboratories~~;

(ii) before a new or expanded adult cardiac catheterization service will be approved in any planning area, the aggregate utilization rate of all adult cardiac catheterization services in that planning area shall be ~~80~~ **85** percent or more during the most recent year;

~~(iii) the Agency may allow variance from this standard when the Agency determines that unusual circumstances exist which justify such action.~~

2. (i) The ~~Agency~~ **Department** may allow an exception to 272-2-.09(7)(c)1 ~~if~~ **in the following circumstances:**

(I) actual utilization in the applicant's existing service has exceeded 90 percent of capacity over the past two years; ~~or~~

**(II) to remedy an atypical barrier to adult cardiac catheterization services based on cost, quality, financial access, or geographic accessibility. The types of atypical barriers outlined below are intended to be illustrative and not exclusive.**

**A. An atypical barrier to services based on cost may include the failure of existing providers of adult cardiac catheterization services to provide services at reasonable cost, as evidenced by the providers' charges and/or reimbursement being significantly higher (one or more standard deviations from the mean) than the charges and/or reimbursement for other providers in the state and/or planning area.**

**B. An atypical barrier to services based on quality may include the failure of existing providers of adult cardiac catheterization services to provide services with outcomes generally in keeping with accepted clinical guidelines of the American College of Cardiology, peer review programs and comparable state rates for similar populations.**

**C. An atypical barrier to services based on financial access may include the repeated failure, as exhibited by a documented pattern over two or more years prior to the submission of the application, of existing providers of services within the community to provide services to indigent, charity and Medicaid patients.**

**D. An atypical barrier to services based on geographic accessibility may include a planning area which has an adult cardiac catheterization rate significantly less than the state rate (two or more standard deviations from the mean), a cardiovascular disease rate as projected through death and hospital discharge data which is significantly higher than the state rate (two or more standard deviations from the mean), and other demographic risk factors which can be documented through research and clinical studies.**

**E. An applicant seeking approval for a new or expanded adult cardiac catheterization service solely for the purpose of providing cardiac electrophysiological studies may apply for consideration under the terms of an atypical barrier; provided, however, that any such applicant if approved shall be restricted to the provision of electrophysiological studies.**

**(ii) The Department may allow an exception to 272-2-.09(7)(c)1 and (c)3 for any cardiac catheterization service seeking an expansion, other than the addition of another laboratory or room; provided the applicant complies with the general considerations and policies of 272-2.08 and submits an application that demonstrates the applicant's compliance with or documents a plan and agreement to comply with 272-02-.09(7)(c)4, 5, 6, 7, 8, 10, 11 and 12.**

~~(ii) after review of appropriate documentation, the Agency determines that use of other existing capacity within the planning~~

~~area is not a better alternative. Appropriate documentation may include, but is not limited to, information concerning cost, quality and access to care.~~

3. An applicant for a new or expanded adult cardiac catheterization service shall document that authorized cardiac catheterization services which could be adversely impacted by the establishment of the new or expanded service are not predicted to perform less than ~~60~~ **80** percent of capacity as a result of the establishment of the new or expanded service. **In the case of an approved service, service volume should be projected in accordance with the volume projections in the approved application.** ~~The Agency may allow variance from this standard when the Agency determines that unusual circumstances exist which justify such action.~~

4. An applicant for a new or expanded adult catheterization service shall demonstrate a plan whereby the service and its medical staff agree to provide a full array of cardiovascular services to the community, including, but not limited to, education and outreach, prevention and screening, diagnosis and treatment, and rehabilitation.

5. An applicant for a new or expanded adult cardiac catheterization service~~, including mobile vendors and freestanding applicants,~~ shall:

**(i)** demonstrate the ability to meet the optimal clinical and physical environment standards established in the most recent American College of Cardiology/American Heart Association's Guidelines for Cardiac Catheterization and Cardiac Catheterization Laboratories. These standards 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**;**

**(ii) document the availability of, or shall present a plan for recruiting, at least two board-certified cardiologists with training and qualification in cardiac catheterization, and, if applicable with training and qualification in coronary intervention, who will reside within a one hour drive of the service site; and**

**(iii) document a plan for obtaining a sufficient number of clinical, professional and technical staff to safely and effectively operate the service.**

6. An authorized adult cardiac catheterization service shall not perform catheterization procedures requiring open heart surgery backup as part of its service unless the acute care hospital where the service is located:

(i) operates an existing adult open heart surgery service; or

(ii) has ~~an Agency~~ **a Department** approved written agreement for open heart surgery backup with an adjacent acute care hospital as defined by these rules.

7. Catheterization procedures requiring open heart surgery backup include **coronary angioplasty and** the following:

(i) catheter atherectomy;

(ii) catheter endomyocardial biopsy;

(iii) left ventricular puncture;

(iv) percutaneous transluminal coronary angioplasty;

(v) percutaneous catheter balloon valvuloplasty; **and**

~~(vi) transcatheter ablation of arrhythmic foci or conduction pathways; and~~

~~(vii)~~ **(vi)** transeptal catheterization.

8. **An applicant for a new or expanded adult cardiac catheterization service shall:**

**(i) submit a written plan to the Department which, when implemented, will ensure access to cardiac catheterization services for all segments of the population in the documented and proposed service area of the applicant. Such plan shall provide a detailed strategy to reach patients not currently served within the service area, ensure continuity of care for patients transferred between facilities and shall promote planning for a continuum of cardiac services within the service area; and**

**(ii) propose a heart disease prevention and clinical intervention program to be provided by the applicant or through formal referral agreements which, when implemented, shall include:**

**(I) A clinical intervention program for all catheterization patients which shall provide for the following in a comprehensive, systematic way:**

**A. Assessment of risk factors including lipid disorders, hypertension, diabetes, obesity, cigarette smoking, and sedentary lifestyle;**

**B. Assessment of risk factors and referral for appropriate care in first-degree relatives; and**

**C. Assure risk management including modification of lipid disorders by diet/exercise/drugs, modification of blood pressure level by diet/exercise/drugs, control of blood glucose level by diet/exercise/drugs, dietary counseling aimed at reduced caloric and fat intake and appropriate weight management, smoking cessation, and exercise prescription. Patients should be referred to their primary care provider with documentation of treatments provided and actions recommended including preventive therapies.**

**(II) The program, if not operated by a facility with an existing Open Heart Surgical Service, shall submit a written affiliation agreement with at least one Open Heart Surgical Service that provides, at a minimum, for:**

**A. a plan to transport and handle acute cardiac emergencies;**

**B. a plan to facilitate referral of patients for whom surgery or angioplasty may be indicated without unnecessarily repeating diagnostic studies; and**

**C. a plan for ongoing communications between representatives of the Open Heart Surgical Service and the proposed applicant, to allow for review of pre-operative and post-operative processes and specific cases.**

(III) **The program shall provide for annual support and participation in at least three professional education programs targeted to community based health professionals, related to heart disease risk assessment, diagnostic procedures, disease management in clinical settings, and case finding and referral strategies.**

**(IV) Community based heart health promotion:**

**A. The program shall provide for organization of or participation in a consortium of community-based organizations to complete an assessment of heart disease risk factors in the community as well as resources available to provide programs and services. The objective of this consortium is to mobilize and coordinate resources to target at-risk populations in the community; and**

**B. Organization of or participation in at least one major community-based campaign each year related to major heart disease risk factors.**

**(iii) propose a system of outcome monitoring and quality improvement and identify at least five clinical outcomes that the applicant proposes to monitor for performance on a regular basis.**

~~The list contained in 272-2-.09(7)(c)7. will be updated periodically by the Agency based on adopted revisions to the American College of Cardiology/American Heart Association's Guidelines for Cardiac Catheterization and Cardiac Catheterization Laboratories.~~

9. An applicant for a new or expanded adult cardiac catheterization service must project **and, if approved, shall document** that the proposed service will **be performing a minimum of 1040 adult cardiac catheterization procedure equivalents within three years of initiation of the service and annually thereafter within the authorized guidelines for such services**. **Such projections, at a minimum, shall include consideration of patient origin data for catheterization services, the use rate of existing services, referral data and market patterns for existing hospital and DTRC services in the community, and cardiovascular disease incidence rates and related health indicators**. ~~have reached a minimum of 60 percent of capacity by the end of 36 months from initiation of the service and that it will maintain this capacity level annually thereafter.~~ **An applicant seeking approval solely for the purpose of providing electrophysiological (EP) studies shall not be required to document a projected performance minimum but shall be required to document compliance with guidelines for EP studies issued by the American College of Cardiology**

10. An applicant for ~~an~~ **a new or** expanded adult cardiac catheterization service ~~that has been in operation for at least 18 months~~ shall provide documentation that the service is fully accredited by the Joint Commission on Accreditation of Health Care Organizations (JCAHO) ~~or another recognized and appropriate accrediting agency~~ **or, in the case of an applicant proposing a new facility location, shall provide a written commitment to secure full accreditation by JCAHO within eighteen (18) months of initiating operation**.

11. An applicant for a new or expanded adult cardiac catheterization 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 to include disease prevention and intervention services outlined in 272-2-.09(7)(c)8 , that such services shall be provided regardless of race, age, sex, creed, ~~or~~ 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 three percent of annual, adjusted gross revenues for the adult cardiac catheterization service, or the applicant may request that the Department consider allowing the commitment for services to indigent and charity to patients to be applied to the entire facility;**

**(iii) providing a written commitment to accept any patient within the facility's service area, without regard to the patient's ability to pay, unless such patient is clinically inappropriate;**

(iv) **providing a written commitment to participate in the Medicaid, PeachCare and Medicare programs and to accept any Medicaid-, PeachCare- and/or Medicare-eligible patient for services unless such patient is clinically inappropriate;**

**(v) 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**

**(vi) 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.**

~~shall assure access to services to individuals unable to pay and to all individuals regardless of payment source or circumstances by:~~

~~(i) providing evidence of written administrative policies and directives related to the provision of services on a nondiscriminatory basis;~~

~~(ii) providing documentation of the demonstrated performance of the applicant, and any facility in Georgia owned or operated by the applicant's parent organization, of providing services to individuals unable to pay based on the past record of service to Medicare, Medicaid, and indigent and charity patients, including the level of unreimbursed indigent and charity~~

~~care;~~

~~(iii) providing a written commitment that unreimbursed services for indigent and charity patients in the service will be offered at a standard which meets or exceeds three percent of the annual number of adult cardiac catheterization procedures performed by the facility;~~

~~(iv) in a mobile network, the mobile vendor is the entity responsible for making this financial accessibility commitment and is responsible for reporting compliance with this rule. Individual acute care hospitals within a mobile network are responsible for providing documentation of this financial accessibility to the mobile vendor.~~

~~12. An applicant for a new or expanded adult cardiac catheterization service shall demonstrate that charges for the service, when adjusted for inflation, will compare favorably with charges for similar procedures in existing adult cardiac catheterization services located within the same or a similar geographic planning area.~~

~~13. The applicant for a new or expanded adult cardiac catheterization service shall document an agreement to provide Agency requested information and statistical data related to the operation and provision of adult cardiac catheterization services and to report that data to the Agency in the time frame and format requested by the Agency.~~

~~14. The Agency may request information directly from either the vendor or network hospital members of a mobile network.~~

**12. An applicant for a new or expanded adult cardiac catheterization service must agree in writing to the following conditions:**

**(i) establishment and maintenance of a system of continuity of care and coordination of service, as evidenced by regular and ongoing planning and quality improvement sessions with community health providers and advocacy programs;**

**(ii) participation in a data reporting, quality improvement, outcome monitoring, and peer review system within the applicant hospital or DTRC as well as a national, state or multi-program system which benchmarks outcomes based on national norms and which shall be named in the application and which provides for peer review between and among professionals practicing in facilities and programs other than the applicant hospital or DTRC;**

**(iii) development of procedures to ensure that cardiologists and any other physicians providing care in the cardiac catheterization service or related services shall be required to accept Medicaid, PeachCare and Medicare payment for services without discrimination;**

**(iv) commitment that charges for services shall be reasonable and comparable to other providers in the state and the service area;**

**(v) provision of all required data and survey information to the Department as requested; and**

**(vi) commitment to act in good faith to fulfill all provisions and commitments documented in the application for a new or expanded service.**

**13. The department may revoke a Certificate of Need after notice to the holder of the certificate and a fair hearing pursuant to the Georgia Administrative Procedure Act for failure to comply with the defined scope, location, cost, service area, and person named in an application as approved by the Department and for the intentional provision of false information to the Department by an applicant in that applicant's application.**

(13) Adult Open Heart Surgery Services.

**(a) Applicability**

**A Certificate of Need will be required prior to the establishment of a new or, subject to certain stipulations, expanded adult open heart surgical service.**

~~(a)~~ **(b)** Definitions.

1. "Adult" means persons 15 years of age and over.
~~2. "Annual total volume" means the number of adult open heart surgery procedures performed in an existing service in the most recent year.~~
~~3.~~ **2**. "Authorized service" means an ~~Agency sanctioned~~ adult open heart surgery service which is either existing or approved. An existing service is an authorized service which has become operational, and an approved service is an authorized service which has not become operational.
~~4. "Most recent year," for the purposes of surveys conducted by the Agency, means the most current 12-month period within a month of the date of completeness of an application or within a month of the date of completeness of the first application when applications are joined. If the Agency has conducted a survey within six months of the date of completeness of an application or within six months of the date of completeness of the first application when applications are joined, the Agency may consider the most recent year to be the report period covered by the prior survey.~~
**3. "Coronary Angioplasty" means a cardiac catheterization procedure to treat coronary heart disease by utilizing a catheter with a balloon, laser, laser-assisted device, rotational device, stent placement or other mechanical means to unblock an occluded coronary artery.**
**4. "Expanded Service" or "Expansion" means an adult open heart surgery service that undertakes any capital renovation or construction project in and to the physical space within the hospital where the adult open heart surgery service is or will be offered, the costs of which exceed the capital expenditure threshold at that time; or that acquires a piece of diagnostic or therapeutic equipment with a value above the equipment expenditure threshold at that time which is to be utilized in the provision of open heart surgery services; or, for any service a full four (4) years or more following implementation of an approved Certificate of Need, that increases adult open heart surgery volume to a level resulting in a 25% or more increase in procedures being performed by the service over the higher annual number of procedures having been performed during the most recent prior two calendar years. Replacement or repair of existing diagnostic or therapeutic equipment utilized in the provision of such service is not an expansion for purposes of these rules.**
5. "Official State ~~Health~~ Component Plan" means the document related to specialized cardiovascular services developed by the **Department** ~~Agency~~ established by the **Health Strategies Council** ~~Georgia State Health Policy Council~~, and **adopted by the Board of Community Health** ~~signed by the Governor of Georgia~~.
6. "Open heart surgery" means surgery performed directly on the heart or its associated veins or arteries during which a heart and lung by-pass machine (extracorporeal pump) ~~is~~ **may be** used to perform the work of the heart and lungs.
7. "Open heart surgery service" means an organized surgical program which serves inpatients of a hospital which has a suitable operating room or suite of operating rooms, equipment, staff, intensive care unit, and all support services required to perform adult open heart surgery. The adult open heart surgery service shall be located in an acute care hospital which has an authorized adult cardiac catheterization service.
8. "Procedure" means an adult open heart surgery operation or combination of operations performed in a single session on a single patient who appears for open heart.
~~9. "State proportion of adult diagnostic cardiac catheterization relative to adult open heart surgeries" means the rate calculated by dividing the total number of adult open heart surgery procedures as reported annually by all authorized services in the state by the total number of adult diagnostic cardiac catheterization procedures as reported annually by all authorized services in the state. The state population shall be determined by the Agency based on the most recent edited data from the Annual Hospital Questionnaire and Cardiac Catheterization and Open Heart Surgery Specialized Services Addenda.~~

~~(b)~~ **(c)** Standards.

1. (i) **An application for** ~~N n~~**n**ew adult open heart surgery services shall be **considered by the Department** ~~approved~~ only if each and all of the following conditions are met:
   (I) an applicant must **have** operate**d** an existing adult cardiac catheterization service which is located in an acute care hospital setting **for at least three (3) years prior to the date of application**; and
   (II) an applicant shall document, **based on actual service data of the applicant, survey data provided to the Department and other supporting research and documentation,** that the hospital's existing adult cardiac catheterization service generated ~~180~~ **a minimum of 250** or more adult open heart surgery procedures in ~~the 12-month period~~ **each of the two (2) calendar years immediately** prior to submittal of the application ~~based on the~~

~~latest reported state proportion of adult diagnostic cardiac catheterization relative to adult open heart surgeries~~. ~~In highly unusual circumstances, this requirement may be waived if the applicant can document that the actual number of adult diagnostic cardiac catheterization patients who were referred for and underwent open heart surgery in the 12-month period prior to the submittal of the application was 180 or more. Sufficient documentation must be provided and must be deemed acceptable by the Agency to prove the actual number of patients who were referred for and underwent an adult open heart surgery procedure~~; and

(III) an applicant shall project **and, if approved, shall document** that the proposed adult open heart surgery service will be performing a minimum of ~~200~~ **300** adult open heart surgery procedures per year within three years of initiation of the service. Such projections, at a minimum, shall include consideration of patient origin data **for open heart and catheterization services**, the use rate of existing services, and **referral data and market patterns for existing hospital services, and cardiovascular disease incidence rates and related health indicators** ~~, if applicable, documented referrals~~; and

(IV) an applicant shall document that ~~authorized~~ **existing and approved** adult open heart surgery services in the state are not predicted to be adversely impacted as a result of the establishment of the new service. **Impact on an existing or approved service shall be determined to be adverse if, based on the number of cases projected to be performed by the applicant, any of the existing or approved services would have either a decrease in volume equal to or greater than ten percent (10%) of the average annual service volume in the proceeding two calendar years or a decrease of less than ten percent (10%) of the annual service volume in the proceeding two calendar years but which would result in such service falling below a minimum of 200 open heart surgical procedures annually. In the case of an approved service, service volume should be projected in accordance with the volume projections in the approved application.** An existing service which has been operational for four or more years and has not performed a minimum of 200 **open heart surgical** procedures in at least one of the past four years shall be excluded from a determination of adverse impact. ~~Impact on an existing or approved service shall be determined to be adverse under the following conditions:~~

~~(I) an existing service which performed 350 or more procedures in the most recent year, or since service initiation if operational for less than one year, would perform less than 350 procedures annually as a result of the loss of open heart surgery referrals, unless the reduction in the existing service's annual total volume would be 10 percent or less, or the existing service would continue to perform more than 350 procedures annually but would be predicted to have a substantial reduction in annual total volume as a result of the impact of the establishment of any new service within one year of initiation of a previously approved service; or~~

~~(II) an existing service which has performed less than 350 procedures in the most recent year would continue to perform less than 350 procedures annually as a result of the loss of open heart surgery referrals, unless the reduction in the existing service's annual total volume would be 10 percent or less; or~~

~~(III) an approved service or an existing service which has been operational less than one year has performed less than 350 procedures since service initiation would perform less than 350 procedures annually as a result of the impact of one or more commonly shared factors, including the same or overlapping market areas, similar referral patterns, geographic proximity, use of the same cardiac or surgical group(s), or other relevant factors; and/or~~

~~(IV)~~ **(V)** if multiple applications are joined or comparatively reviewed, the ~~Agency~~ **Department** shall determine whether the individual impact of the establishment of each proposed service or the cumulative impact of the establishment of two or more proposed services would adversely impact an existing or approved service or any of the proposed services if established. ~~For purposes of evaluating the potential adverse impact of the establishment of proposed services on existing and approved services, the approaches listed in 272-2-.09(13)(b)1.(iv)(I), 272-2-.09(13)(b)1.(iv)(II), and 272-2-.09(13)(b)1.(iv)(III) shall be used in making the adverse impact determination. For purposes of evaluating the potential adverse impact of the establishment of proposed services on each other, each proposed service shall be treated as if it were an approved service under 272-2-.09(13)(b)1.(iv)(III). The Agency shall approve only the proposed service or combination of proposed services which, if established, would not adversely impact an existing and/or approved service and/or any other proposed service if approved.~~

(ii) **The Department may allow an exception to the need standard and adverse impact requirements in 272-02-09(13)(c)(1)(i) of this paragraph to remedy an atypical barrier to open heart surgery services based on cost, quality, financial access, or geographic accessibility. The types of atypical barriers outlined below are intended to be illustrative and not exclusive.**

**(I) An atypical barrier to services based on cost may include the failure of existing providers of open heart surgical services to provide services at reasonable cost, as evidenced by the providers' charges and/or reimbursement being significantly higher (one or more standard deviations from the mean) than the charges and/or reimbursement for other providers in the state.**

**(II) An atypical barrier to services based on quality may include the failure of existing providers of open heart surgical services to provide services with outcomes generally in keeping with accepted clinical guidelines, peer review programs and comparable state rates for similar populations.**

**(III) An atypical barrier to services based on financial access may include the repeated failure as**

**exhibited by a documented pattern over two or more years prior to the submission of the application, of an existing provider or group of providers of open heart surgical services within the community to provide services to indigent, charity and Medicaid patients.**

2. ~~Expansion of an~~ **(i) An** existing adult open heart surgery service **seeking an expansion or expanded service due to a capital or equipment expenditure** shall be approved ~~only~~ if the applicant complies with the general considerations and policies of 272-2-.08 and **submits an application that demonstrates the applicant's compliance with or documents a plan and agreement to comply with** the provisions of 272-2-.09(13) ~~(b)~~ **(c) 3, 4, 5, 7, 8, and 10.** ~~which relate to the expansion of existing adult open heart surgery services.~~

**(ii) Any existing service seeking an expansion or expanded service based on an increase in procedures pursuant to the definition in 272-02-09(13) (b) (4) may request a determination from the Department that the service is fully in compliance with the provisions of 272-02-.09 (13) (c) 3, 4, 5, 7, 8, and 10. The Department may issue a determination that the service is in compliance. If the Department issues such a determination, the service will not be required to apply for a certificate of need. If the Department determines that the service is not in compliance with the above referenced conditions, the service will be required to submit a Certificate of Need application. Such an application will be eligible for mandatory expedited review pursuant to Rule 272-02-04(2)(m).**

3. An applicant **requesting** ~~for~~ a new or expanded adult open heart surgery service shall:

(i) document that the open heart surgery service shall have the capability to implement circulatory assist devices such as intra-aortic balloon assist and prolonged cardiopulmonary procedures, including at a minimum:

(I) repair ~~or~~ **and** replacement of heart valves; and
(II) cardiac revascularization; and
(III) treatment of cardiac trauma; and
(IV) repair of congenital defects in adults; and
**(V) repair of acute aortic dissection; and**

(ii) document that the applicant has available to the open heart surgery service a full range of hospital-based diagnostic, ancillary, and support services, including the following organizational departments or services:

(I) medicine: cardiology, hematology, nephrology; and
(II) radiology: diagnostic, nuclear medicine; and
(III) surgery: cardiovascular, thoracic; and
(IV) pathology: anatomic, clinical, blood bank, coagulation laboratory; and
(V) anesthesiology: inhalation therapy; **echocardiology in the operating room;** and
(VI) neurology; and
(VII) special laboratories: cardiac catheter/angiographic; and
(VIII) clinical dietary; and
(IX) cardiac surgical intensive care unit; and
(X) **pacemaker therapy; and**
**(XI) cardiac rehabilitation services; and**
**(XII) renal dialysis; and**
~~(X)~~ **(XIII)** social services.

~~4. An applicant for new or expanded adult open heart surgery service shall~~

(iii) document that the service shall be available for elective procedures as needed, at least eight hours per day, five days a week, and shall document the capability to rapidly mobilize surgical and medical support teams for emergency cases 24 hours per day, seven days per week, including a plan for utilizing this capability when needed to perform emergency procedures.

**4. An applicant for a new or expanded adult open heart surgery service shall:**

**(i) submit a written plan to the Department which, when implemented, will ensure access to cardiac surgical services for all segments of the population in the documented and proposed service area of the facility and service. Such plan shall provide a detailed strategy to reach patients not currently served within the service area, ensure continuity of care for patients transferred between facilities and shall promote planning for a continuum of cardiac services within the service area; and**

**(ii) propose a heart disease prevention program to be provided by the applicant or through formal referral agreements which, when implemented, shall include:**

**(I) Clinical intervention for cardiac patients (any inpatient or outpatient with a principal diagnosis of ischemic heart disease). These patients are at high risk for development of adverse cardiovascular events and the program shall provide for the following in a comprehensive, systematic way:**

**A. Assessment of risk factors including lipid disorders, hypertension, diabetes, obesity, cigarette smoking, and sedentary lifestyle;**

**B. Assessment of risk factors and referral for appropriate care in first-degree relatives;**

**C. Assure risk management including modification of lipid disorders by diet/exercise/drugs, modification of blood pressure level by diet/exercise/drugs, control of blood glucose level by diet/exercise/drugs, dietary counseling aimed at reduced caloric and fat intake and appropriate**

**weight management, smoking cessation, and exercise prescription. Patients should be referred to their primary care provider with documentation of treatments provided and actions recommended; and**

**D. Establishment and maintenance of systems to assist in tracking and follow-up to determine attendance at referred services and status of risk management.**

(II) **Clinical intervention for non-cardiac patients (any inpatient or outpatient whose principal diagnosis is not ischemic heart disease). For these patients, the program shall encourage the following:**

**A. Assessment of risk factors including, hypertension, hypercholesterolemia, smoking, obesity, sedentary lifestyle, and history of diabetes;**

**B. Provision of appropriate counseling and referral for diagnostic evaluation, treatment and risk factor modification; and**

**C. Establishment and maintenance of record systems to assist in documenting risk factors identified, referrals made, and other follow-up action taken.**

**(III) The program shall assure access to cardiac rehabilitation services, provided either by the hospital itself or through formal referral agreements**.

**(IV) The program shall provide for annual support and participation in at least three professional education programs targeted to community based health professionals, related to heart disease risk assessment, disease management in clinical settings, and case finding and referral strategies.**

**(V) Community based heart health promotion:**

**A. The program shall provide for organization of or participation in a consortium of community-based organizations to complete an assessment of heart disease risk factors in the community as well as resources available to provide programs and services. The objective of this consortium is to mobilize and coordinate resources for target populations in the community; and**

**B. Organization of or participation in at least one major community-based campaign each year related to major heart disease risk factors.**

**(iii) propose a system of outcome monitoring and quality improvement and identify at least five clinical outcomes that the applicant proposes to monitor for performance on a regular basis.**

5. An applicant for a new or expanded adult open heart surgery service shall ~~provide~~ **foster an environment which assures access to individuals unable to pay, regardless of payment source or circumstances, by the following:**

(i) ~~evidence of~~ **providing** a written policy regarding the provision of **any** services **provided by or on behalf of the applicant to include disease prevention and intervention services outlined in 272-02-.9(13)(c)4, that such services shall be provided** regardless of race, age, sex, creed, ~~or~~ 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 three percent of annual, adjusted gross revenues for the adult open heart surgery service, or the applicant may request that the Department allow the commitment for services to indigent and charity to patients to be applied to the entire facility;**

**(iii) providing a written commitment to accept any patient without regard to the patient's ability to pay, unless such patient is clinically inappropriate;**

~~evidence of a written policy for the provision of adult open heart surgery service regardless of a patient's ability to pay for the service; and~~

(iv) **providing a written commitment to participate in the Medicaid, PeachCare and Medicare programs and to accept any Medicaid-, PeachCare- and/or Medicare-eligible patient for services unless such patient is clinically inappropriate;**

**(v) 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**

(vi) 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.**

~~applicant's demonstrated practice, indicating more than a mere commitment, of providing services, to individuals unable to pay based on the hospital's past record of service to Medicare, Medicaid, and indigent/charity patients, including the hospital's level of unreimbursed indigent/charity care.~~

~~6. An applicant for a new or expanded adult open heart surgery service shall provide sufficient documentation, including a plan for actively meeting this requirement, that unreimbursed care for indigent and charity patients in a new or expanded service shall be offered at a standard which meets or exceeds three percent of the annual number of adult open heart surgery procedures performed by the service.~~

~~7 . If an applicant for a new or expanded adult open heart surgery service, or any facility in Georgia owned or operated by the applicant's parent organization, received a Certificate of Need with the exception that a certain level of unreimbursed indigent/charity~~

~~care would be provided, official Agency Indigent Care Surveys shall indicate that these expectations have been met. An applicant's history, or the history of any facility owned or operated by the applicant's parent organization, of not providing the specific Certificate of Need expectation or unreimbursed indigent and/or charity care at or above the expected level shall constitute sufficient justification to deny an application for a new or expanded adult open heart surgery service. Mandatory denial of an application as a result of not meeting the expected level of indigent/charity care shall apply only to the indigent care performance of the actual applicant entity.~~

~~8~~ **6**. In considering ~~competing~~ applications **joined for review** for new adult open heart surgery services, the ~~Agency~~ **Department** may give favorable consideration to an applicant which historically has provided a higher annual percentage of unreimbursed services to indigent and charity patients and a higher annual percentage of services to Medicare and Medicaid patients.

~~9~~ **7**. An applicant for a new or expanded adult open heart surgery service shall:

(i) demonstrate the intent to achieve the optimal standards established by the ~~Intersociety Commission for Heart Disease Resources and the Subcommittee on Cardiac Surgery Standards of the Cardiovascular Committee of the~~ American College of Surgeons **and the Advisory Council for Cardiothoracic Surgery of the American College** for evaluating the clinical and physical environments of cardiac surgical services and covering professional qualifications and responsibilities, staffing requirements, support services, physical plant, and equipment; and

(ii) document the availability of; or shall present a plan for recruiting, a qualified surgeon certified by the American Board of Thoracic Surgery with special qualifications in cardiac surgery; and

(iii) document a plan for obtaining a sufficient number of professional and technical staff; including cardiac intensive care nurses, for the size of the adult open heart surgery program proposed and document that the operating room team necessary for an adult open heart surgical procedure shall be available, including a cardiovascular surgeon who is board certified by the American Board of Thoracic Surgery; a second physician who is a cardiovascular or thoracic surgeon or surgical resident; a board-certified anesthesiologist trained in open heart surgery; a circulating nurse or scrub nurse (RN); an operating room technician or registered nurse trained in cardiac procedures; and one or two pump technicians, with one being certified and one qualified.

~~10~~ **8**. An applicant for a new or expanded adult open heart surgery service shall provide documentation that the hospital is fully accredited by the Joint Commission on Accreditation of Healthcare Organization (JCAHO)~~, if the hospital has participated in the JCAHO accreditation process,~~ and also shall provide sufficient documentation that the hospital has no history of significant licensure deficiencies and no history of conditional level Medicare and/or Medicaid certification deficiencies in the past three years and has no outstanding licensure and Medicare and/or Medicaid certification deficiencies.

~~11~~ **9**. An applicant for a new ~~or expanded~~ adult open heart surgery service shall demonstrate that charges **and/or reimbursement rates** for the service shall compare favorably with charges **and/or reimbursement rates** in existing adult open heart surgery services in the state when adjusted for annual inflation. When determining the accuracy of an applicant's projected charges for adult open heart surgery procedures, the ~~Agency~~ **Department** may compare the applicant's history of charges **and/or reimbursement rates** for cardiac catheterization procedures and other treatments and/or interventions for disorders of the circulatory system and for open heart procedures, if applicable, with such charges **and/or reimbursement rates** in other similar hospitals.

~~12. In considering competing applications for a new adult open heart surgery service, the Agency may give favorable consideration to the applicant which historically has had lower charges for cardiovascular and other related services provided by the hospitals.~~

~~13~~ **10**. An applicant for a new or expanded adult open heart surgery service must **agree in writing to the following conditions:** ~~provide documentation that the proposal is consistent with the following as specified in the current official State Health Component Plan~~:

(i) **establishment and maintenance of a system of** continuity **of care** ~~:~~ **and** coordination of service, **as evidenced by regular and ongoing planning and quality improvement sessions with community health providers and advocacy programs**; and

(ii) **participation in a data reporting, quality improvement, outcome monitoring, and peer review system within the applicant hospital as well as a national, state or multi-hospital system which benchmarks outcomes based on national norms and which shall be named in the application and which provides for peer review between and among professionals practicing in facilities and programs other than the applicant hospital;** ~~quality: training and patient review, peer review, and utilization review process; and~~

(iii) **development of procedures to ensure that any surgeon authorized to perform open heart surgery for the hospital shall be required to perform at least 100 procedures on annual basis across his or her various practice settings, and shall be required to accept Medicaid or Medicare payment for services without discrimination;** ~~information requirements: data collection systems~~.

**(iv) commitment that charges for services shall be reasonable and comparable to other providers in the state and the service area;**

**(v) provision of all required data and survey information to the Department as requested; and**

**(vi) commitment to act in good faith to fulfill all provisions and commitments documented in the application for a new or expanded service.**

**11. The department may revoke a Certificate of Need after notice to the holder of the certificate and a fair hearing pursuant to the Georgia Administrative Procedure Act for failure to comply with the defined scope, location, cost, service area, and person named in an application as approved by the Department and for the intentional provision of false information to the Department by an applicant in that applicant's application.**

(16) Pediatric Cardiac Catheterization and Open Heart Surgery.

(a) Definitions.

1. "Authorized service" means ~~an Agency sanctioned~~ **a** pediatric cardiac catheterization service or pediatric cardiac surgery service which is either existing or approved. An existing service is an authorized service which has become operational, and an approved service is an authorized service which has not become operational.
2. "Capacity" means:
(i) for a pediatric catheterization service:
(I) in considering applications for a new pediatric cardiac catheterization service, 750 procedures per year per authorized service regardless of the number of rooms used; or
(II) in considering applications for expansion of an existing service, 750 pediatric cardiac catheterization procedures per dedicated room per year in the existing service (3 per day per room, 5 days per week, 50 weeks per year) and for each multipurpose room in the existing service, 750 procedures (special procedures and pediatric cardiac catheterization procedures) per year. If adult and pediatric cardiac catheterization are performed in the same room in a service seeking to expand, the capacity of the room shall be equivalent to 750 pediatric procedures with adult procedures performed in the room weighted in proportion to pediatric procedures as being 0.50 for each adult cardiac catheterization or special procedure, except for each adult coronary angioplasty, which shall be 0.75, in order to determine the service's use rate; or
(ii) for a pediatric cardiac surgery service, the number of pediatric cardiac surgery procedures which could be performed annually as reported by each hospital with an authorized service and based on **survey and other reported** data ~~reported on the most recent official Agency survey~~. In determining capacity, a hospital must consider factors such as available operating rooms which can be used for pediatric cardiac surgery, cardiac surgical intensive care beds and other pediatric intensive care beds available for pediatric patients, general bed capacity, and any other factors which impact the determination. ~~Sufficient data related to pediatric cardiac surgery capacity shall be supplied by authorized services in a format requested by the Agency to support Agency validation of the reported capacity. In compliance with 272-2 .05, hospitals with pediatric cardiac surgery services shall report to the Agency any changes in capacity which occur subsequent to the latest Agency initiated survey of such information.~~
3. "Cardiac catheterization" means a medical diagnostic or therapeutic procedure during which a catheter is inserted into a vein or artery in the patient; subsequently, the free end of the catheter is manipulated by the physician to travel along the course of the blood vessel into the chambers or vessels of the heart. X-rays and an electronic image intensifier are used as aids in placing the catheter tip in the desired position. When the catheter is in place, the physician is able to perform various diagnostic studies and/or therapeutic procedures on the heart **or its vessels**.
4. "Closed heart surgery" means an operation performed directly on the heart or its associated veins or arteries which does not require use of a heart and lung bypass machine (extracorporeal pump) to perform the work of the heart and lungs. Such operations often require the bypass machine to be available on standby for use if the surgery needs to be changed to open heart with the machine then performing the work of the heart and lungs.
~~5. "Dedicated room" means a cardiac catheterization lab or an operating room which is equipped, staffed, scheduled, and used routinely during normal working hours for performance of cardiac catheterization procedures or pediatric cardiac surgery procedures. Other types of procedures may be performed in such a room on an occasional basis.~~
~~6. "Most recent year," for purposes of Agency conducted surveys, means the most current 12-month period within a month of the date of completeness of an application or within a month of the date of completeness of the first application when applications are joined. If the Agency has conducted a survey within six months of the date of completeness of an application or within six months of the date of completeness of the first application when applications are joined, the Agency may consider the most recent year to be the report period covered by the prior survey.~~
~~7. "Multipurpose room" means a cardiac catheterization lab or operating room which is equipped, staffed, scheduled, and routinely used part of the time during normal working hours for the performance of cardiac catheterization procedures for pediatric cardiac surgery procedures and part of the time for other types of radiological procedures or for other surgical procedures.~~
~~8.~~ **5.** . "Official State ~~Health~~ Component Plan" means the document related to specialized cardiovascular services developed by the **Department** ~~State Health Planning Agency~~ ,established by the **Health Strategies Council** ~~Georgia State Health Policy Council~~, and **adopted by the Board of Community Health** ~~signed by the Governor of Georgia~~ .
~~9.~~ **6.** "Open heart surgery" means ~~an operation~~ **surgery** performed directly on the heart or its associated veins or arteries during which a heart and lung bypass machine (extracorporeal pump) is used to perform the work of the heart and lungs.
~~10.~~ 7**.** "Pediatric" refers to children 14 years of age and under.
~~11.~~ **8.** "Pediatric cardiac catheterization service" means an organized program which serves pediatric patients of a hospital which has a room or suite of rooms with the equipment, staff, and all support services required to perform angiographic, physiologic, and, as appropriate, therapeutic cardiac catheterization procedures. The pediatric cardiac catheterization service shall be located in a pediatric tertiary hospital. Procedures may be performed in a room dedicated to cardiac catheterization and/or in a special procedures or

multipurpose room not exclusively used for cardiac catheterization.
~~12.~~ **9.** "Pediatric cardiac surgery" means an operation performed directly on a pediatric patient's heart or its associated veins or arteries, including open heart and closed heart surgery procedures but excluding surgical procedures for the closure of neonatal patent ductus arteriosus.
~~13.~~ **10.** "Pediatric cardiac surgery service" means an organized surgical program which serves **pediatric** inpatients of a hospital which has a suitable operating room or suite of operating rooms, equipment, staff, and all support services required to perform closed heart and open heart operations for pediatric patients. The pediatric cardiac surgery service shall be located in a pediatric tertiary hospital.
~~14.~~ **11.** "Pediatric tertiary hospital" means a teaching center, specialty medical or large community hospital characterized by serving pediatric patients from a large region or the entire state with sophisticated technology and support services to provide highly specialized medical and surgical care for unusual and complex medical problems of pediatric patients.
~~15.~~ **12.** "Procedure" means a cardiac catheterization study or treatment or combination of studies and/or treatments performed in a single session on a single patient who appears for cardiac catheterization or a pediatric open or closed heart operation or combination of operations performed in a single session on a single patient who appears for pediatric cardiac surgery.
~~16.~~ **13.** "Service area," ~~as defined in the most recent official State Health Component Plan for Specialized Cardiovascular Services,~~ **for pediatric cardiac catheterization and pediatric cardiac surgery** means the State of Georgia.

(b) Standards.

1. An applicant for new pediatric cardiac catheterization and pediatric cardiac surgery services must be a pediatric tertiary hospital. Due to the highly specialized nature of pediatric cardiac catheterization and pediatric cardiac surgery services, applicants for these services must propose to provide both pediatric cardiac catheterization and pediatric cardiac surgery. Only those projects which meet all applicable standards for both services will be approved.
2. New pediatric cardiac catheterization services shall be approved in the state only if each and all of the following conditions are met:
   (i) the combined use rate for all existing and approved pediatric cardiac catheterization services in the state ~~was at least~~ **has been at or above** 80 percent of capacity for the **past two years as documented through surveys submitted to the Department** ~~most recent year; and~~
   (ii) an applicant must project that the proposed service will be operating at a minimum of 150 procedures per year within three years of initiation of the service in order to maintain and strengthen skills. Such projection at a minimum shall include consideration of patient origin data and the use rate of existing services; and
   (iii) an applicant must show that authorized pediatric cardiac catheterization services which would be impacted by the establishment of the new service are not predicted to perform less than the minimum quality level of 150 procedures annually as a result of the establishment of the new service.
3. An application for expansion of an existing pediatric cardiac catheterization service which exceeds the capital expenditure threshold shall be approved in the state only if the applicant's existing service has operated at a use rate of at least 80 percent of capacity for each of the past two years and the applicant can project a minimum of 150 additional pediatric procedures per year within three years of initiation of the service expansion **and the applicant demonstrates compliance with or documents a plan and agreement to comply with the applicable provisions of 272-02-.09 (16) (6) through (15)** .
4. New pediatric cardiac surgery services shall be approved in the state only if each and all of the following conditions are met:
   (i) the combined use rate of all authorized pediatric cardiac surgery services in the state ~~was at least~~ **has been at or above** 80 percent of capacity for the **past two years as documented through surveys submitted to the Department** ~~most recent year; and~~
   (ii) an applicant must project that the proposed service will be operating at a minimum of 100 pediatric cardiac surgery procedures per year, of which at least 50 are open heart operations, within three years of initiation of the service in order to maintain and strengthen skills. Such projections at a minimum shall include consideration of patient origin data and the use rate of existing services; and
   (iii) an applicant must show that authorized pediatric cardiac surgery services which would be impacted by the establishment of the new services are not predicted to perform less than the minimum quality level of 100 procedures annually, of which at least 50 are open heart operations, as a result of the establishment of the new service.
5. An application for expansion of an existing pediatric cardiac surgery service which exceeds the capital expenditure threshold shall be approved in the state only if the applicant's existing service has operated at a use rate of at least 80 percent of capacity for each of the past two years and the applicant can project a minimum of 100 additional pediatric cardiac surgery procedures, of which at least 50 are open heart operations, within three years of initiation of the service expansion **and the applicant demonstrates compliance with or documents a plan and agreement to comply with the applicable provisions of 272-02-.09 (16) (6) through (15)** .
6. An applicant for a new or expanded pediatric cardiac catheterization service shall:
   (i) document that the applicant is a pediatric tertiary hospital, which serves pediatric patients from a large region or the entire state, with sophisticated technology and support services to provide highly specialized medical and surgical care for unusual and complex medical problems of pediatric patients; and
   (ii) document that, in addition to the basic requirements described for adult cardiac catheterization services, the hospital

shall have support services and equipment necessary for the diagnosis and treatment of infants and children as specified by the ~~Intersociety Commission for Heart Disease Resources~~ **American College of Cardiology** and the American Academy of Pediatrics.

7. An applicant for a new or expanded pediatric cardiac surgery service shall:

(i) document that the applicant is a **pediatric** tertiary hospital, which serves pediatric patients from a large region or the entire state, with sophisticated technology and support services to provide highly specialized medical and surgical care for unusual and complex medical problems of pediatric patients; and

(ii) document that, in addition to the basic requirements described for adult open heart surgery, the hospital shall have support services and equipment necessary for surgery on infants and children as specified by the ~~Intersociety Commission for Heart Disease Resources~~ **American College of Cardiology** and the American Academy of Pediatrics**, Guidelines for Pediatric Cardiology Diagnostic and Treatment Centers**. This includes a complete pediatric cardiology unit, a neonatal intensive care unit, a pediatric intensive care unit, and a general pediatric unit with pediatric subspecialists in hematology, endocrinology, pulmonary neurology, and radiology.

8. An applicant for a new or expanded pediatric cardiac catheterization service **or for a new or expanded pediatric cardiac surgery service** shall document that the service shall be available for the performance of procedures as needed at least eight hours per day, five days per week, and shall document the capability to rapidly mobilize the ~~study~~ **surgical and medical support** team**s** for emergency procedures 24 hours per day, seven days per week, including a plan for utilizing this capability when needed to perform emergency procedures.

9. ~~An applicant for a new or expanded pediatric cardiac surgery service shall document that the service shall be available for elective procedures as needed at least eight hours per day, five days per week, and shall document capability to rapidly mobilize the surgical and medical support teams for emergency cases 24 hours per day, seven days per week, including a plan for utilizing this capability when needed to perform emergency procedures.~~ **An applicant for a new or expanded pediatric cardiac catheterization service and/or pediatric cardiac surgery service shall:**

**(i) submit a written plan to the Department which, when implemented, will ensure access to services for all segments of the population in the documented and proposed service area of the applicant. Such plan shall provide a detailed strategy to reach patients not currently served within the service area, ensure continuity of care for patients transferred between facilities and shall promote planning for a continuum of cardiac services within the service area; and**

**(ii) propose a heart disease prevention and clinical intervention program to be provided by the applicant or through formal referral agreements which, when implemented, shall include:**

**(I) A clinical intervention program for all patients which shall provide for the following in a comprehensive, systematic way:**

**A. Assessment of risk factors including lipid disorders, hypertension, diabetes, obesity, cigarette smoking, and sedentary lifestyle;**

**B. Assessment of risk factors and referral for appropriate care in first-degree relatives; and**

**C. Assure risk management including modification of lipid disorders by diet/exercise/drugs, modification of blood pressure level by diet/exercise/drugs, control of blood glucose level by diet/exercise/drugs, dietary counseling aimed at reduced caloric and fat intake and appropriate weight management, smoking cessation, and exercise prescription. Patients should be referred to their primary care provider with documentation of treatments provided and actions recommended including preventive therapies.**

(II) **The program shall provide for annual support and participation in at least three professional education programs targeted to community based health professionals, related to heart disease risk assessment, diagnostic procedures, disease management in clinical settings, and case finding and referral strategies.**

**(III) Community based heart health promotion:**

**A. The program shall provide for organization of or participation in a consortium of community-based organizations to complete an assessment of heart disease risk factors in the community as well as resources available to provide programs and services. The objective of this consortium is to mobilize and coordinate resources to target at-risk populations in the community; and**

**B. Organization of or participation in at least one major community-based campaign each year related to major heart disease risk factors.**

**(iii) propose a system of outcome monitoring and quality improvement and identify at least five clinical outcomes that the applicant proposes to monitor for performance on a regular basis.**

10. An applicant for new or expanded pediatric cardiac catheterization and pediatric cardiac surgery services shall ~~provide~~ **foster an environment which assures access to individuals unable to pay, regardless of payment source or circumstances, by the following:**

(i) ~~evidence of~~ **providing** a written policy regarding the provision of **any** services **provided by or on behalf of the applicant** regardless of race, age, sex, creed, ~~or~~ 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 three percent of annual, adjusted gross revenues for the pediatric cardiac catheterization and surgical services, or the applicant may request that the Department consider allowing the commitment for services to indigent and charity to patients to be applied to the entire facility;**

**(iii) providing a written commitment to accept any patient within the facility's service area, without regard to the patient's ability to pay, unless such patient is clinically inappropriate;**

~~evidence of a written policy for the provision of adult open heart surgery service regardless of a patient's ability to pay for the service; and~~

**(iv) providing a written commitment to participate in the Medicaid and PeachCare programs and to accept any Medicaid- and/or PeachCare-eligible patient for services unless such patient is clinically inappropriate;**

**(v) 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**

**(vi) 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.**

~~(iii) documentation of the applicant's demonstrated practice, indicating more than a commitment, of providing services to individuals unable to pay based on the hospital's past record of services to Medicare, Medicaid, and indigent/charity patients, including the hospital's level of unreimbursed indigent/charity care. Consideration will be given to the applicant's compliance with 272-2 .08(2)(e).~~

~~11. If an applicant for new or expanded pediatric cardiac catheterization and pediatric cardiac surgery services, or any facility in Georgia owned or operated by the applicant's parent organization, received a Certificate of Need with the expectation that a certain level of unreimbursed indigent/charity care would be provided, the official Agency Indigent Care Surveys shall indicate that these expectations have been met. An applicant's history, or the history of any facility owned or operated by the applicant's parent organization, of failure to provide the specific Certificate of Need expectation of unreimbursed indigent/charity care at or above the expected level shall constitute sufficient justification to deny an application for pediatric cardiac catheterization and pediatric cardiac surgery services.~~

~~12.~~ **11.** An applicant for a new or expanded pediatric cardiac catheterization service shall:

(i) demonstrate the intent to achieve the optimal standards established by ~~the Intersociety Commission for Heart Disease Resources and t~~he American Academy of Pediatrics**, Guidelines for Pediatric Cardiology Diagnostic and Treatment Centers** ~~Section on Cardiology~~ for evaluating the clinical and physical environments of cardiac catheterization services and covering professional qualifications and responsibilities, staffing requirements, supporting services, physical plant, and equipment; and

(ii) document the availability of; or shall present a plan for recruiting, a qualified service director who is a physician, board-certified in pediatrics, with subspecialty training and board eligibility in pediatric cardiology and who is competent to perform physiologic and angiographic procedures or both; and

(iii) document a plan for obtaining a sufficient number of professional and technical staff for the size of the pediatric cardiac catheterization service proposed, including a pediatric nurse, radiologic technologist, cardiopulmonary technician, and darkroom technician and document that the staff required for most procedures shall be available, including two physicians, one nurse, and two technicians, with the nurse and technicians cross trained to cover technical responsibility of the monitoring and recording technicians.

~~13.~~ **12.** An applicant for a new or expanded pediatric cardiac surgery service shall:

(i) demonstrate the intent to achieve the optimal standards established by ~~the Intersociety Commission for Heart Disease Resources, the Subcommittee on Cardiac Surgery Standards of the Cardiovascular Committee~~ **the Advisory Council for Cardiothoracic Surgery** of the American College of Surgeons, and the American Academy of Pediatrics, **Guidelines for Pediatric Cardiology Diagnostic and Treatment Centers** ~~Section on Cardiology~~ for evaluating the clinical and physical environments of cardiac surgical services and covering professional qualifications and responsibilities, staffing requirements, supporting services, physical plant, and equipment; and

(ii) document the availability of, or shall present a plan for recruiting, a qualified pediatric cardiac surgery director who is a pediatric cardiovascular surgeon, board-certified in thoracic surgery, with special emphasis and experience in surgery for congenital heart disease; and

(iii) document a plan for obtaining a sufficient number of professional and technical staff, including pediatric cardiac intensive care nurses, for the size of the pediatric cardiac surgery service proposed, including at least two board-qualified cardiac surgeons on the staff of the hospital and a cardiovascular surgical team which includes a neonatologist, a pediatric

anesthesiologist, a pediatric radiologist, a pediatric cardiologist, a nurse clinician, and backup of medical social services.
~~14.~~ **13.** An applicant for new or expanded pediatric cardiac catheterization and pediatric cardiac surgery services shall provide documentation that the hospital is fully accredited by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) ~~, if the hospital has participated in the JCAHO accreditation process,~~ and also shall provide sufficient documentation that the hospital has no history of significant licensure deficiencies and no history of conditional level Medicare and Medicaid certification deficiencies in the past three years and has no outstanding licensure and Medicare and Medicaid certification deficiencies.
~~15.~~ **14.** An applicant for new or expanded pediatric cardiac catheterization and pediatric cardiac surgery services shall demonstrate that the applicant's charges **and/or reimbursement** for pediatric cardiac catheterization and pediatric cardiac surgery services shall compare favorably with charges **and/or reimbursement** in existing pediatric cardiac catheterization and pediatric cardiac surgery services in the state, when adjusted for annual inflation.
~~16. In considering competing applications for new pediatric cardiac catheterization and pediatric cardiac surgery services, the Agency may give special consideration to an applicant which historically has lower charges for cardiovascular and other related services provided by the hospitals.~~
~~17~~. **15.** An applicant for new or expanded pediatric cardiac catheterization and**/or** pediatric cardiac surgery services must **agree in writing to the following conditions:** ~~provide documentation that the proposal is consistent with the following as specified in the current official State Health Component Plan~~:

(i) **establishment and maintenance of a system of** continuity **of care** ~~:~~ **and** coordination of service, **as evidenced by regular and ongoing planning and quality improvement sessions with community health providers and advocacy programs**; and

(ii) **participation in a data reporting, quality improvement, outcome monitoring, and peer review system within the applicant hospital as well as a national, state or multi-hospital system which benchmarks outcomes based on national norms and which shall be named in the application and which provides for peer review between and among professionals practicing in facilities and programs other than the applicant hospital;** ~~quality: training and patient review, peer review, and utilization review process; and~~

(iii) **development of procedures to ensure that any surgeon or cardiologists authorized to perform pediatric cardiac services for the hospital shall be required to accept Medicaid and PeachCare payment for services without discrimination;** ~~information requirements: data collection systems~~.

**(iv) commitment that charges for services shall be reasonable and comparable to other providers in the state and the service area;**

**(v) provision of all required data and survey information to the Department as requested; and**

**(vi) commitment to act in good faith to fulfill all provisions and commitments documented in the application for a new or expanded service.**

**16. The department may revoke a Certificate of Need after notice to the holder of the certificate and a fair hearing pursuant to the Georgia Administrative Procedure Act for failure to comply with the defined scope, location, cost, service area, and person named in an application as approved by the Department and for the intentional provision of false information to the Department by an applicant in that applicant's application.**

# SPECIALIZED CARDIOVASCULAR SERVICES COMPONENT PLAN

# APPENDIX B

# Members, Technical Advisory Committee

**Cardiovascular Services Technical Advisory Committee**
**of the Health Strategies Council**
**Department of Community Health, Division of Health Planning**

**Membership List**

**Elizabeth Brock, Committee Chair**
President, Pallets Incorporated, Atlanta
Member, Health Strategies Council

**William W. Calhoun, Esq.**
Attorney at Law
Langley & Lee, Albany

**Neil Gordon, MD, PhD, MPH**
Medical Director
Center for Heart Disease Prevention
Candler/St. Josephs Health System
Savannah

**George Jeter**
Columbus Regional Healthcare System
GHA/AHA Board Member
Retired CFO, AFLAC, Columbus

**Ellis Jones, MD**
Professor, Division of Cardiothoracic Surgery
School of Medicine, Emory University

**Chris Leggett, MD**
Cardiologist
Medical Associates of N. Georgia, Canton
President, Southeastern Chapter, AHA

**Linda Lowe**
Healthcare Consumer Advocate, Atlanta

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**Dorothy (Vi) B. Naylor**
Executive Vice-President
Georgia Hospital Association

**Elizabeth Ofili, MD**
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Morehouse School of Medicine
President, Association of Black Cardiologists

**Bruce Perry, MD**
Medical Director
Kaiser Permanente

**Charles E. Powell**
Executive Director, Community Cardiovascular Council,
Savannah

**Kenneth Powell, MD**
Cardiovascular Health Section
Division of Public Health
Georgia Department of Human Resources

**Daniel W. Rahn, MD**
President, Medical College of Georgia

**William T. Richardson, FACHE**
President and CEO, Tift General Hospital

**Stanley W. Sherman, MD***
ACC Governor
President, Georgia Chapter of ACC
Medical Association of Georgia

**Nanette K. Wenger, MD**
Professor, School of Medicine
Emory University
Chief of Cardiology, Grady Health System

**Eric Wilson, MD**
Family Practice, Athens

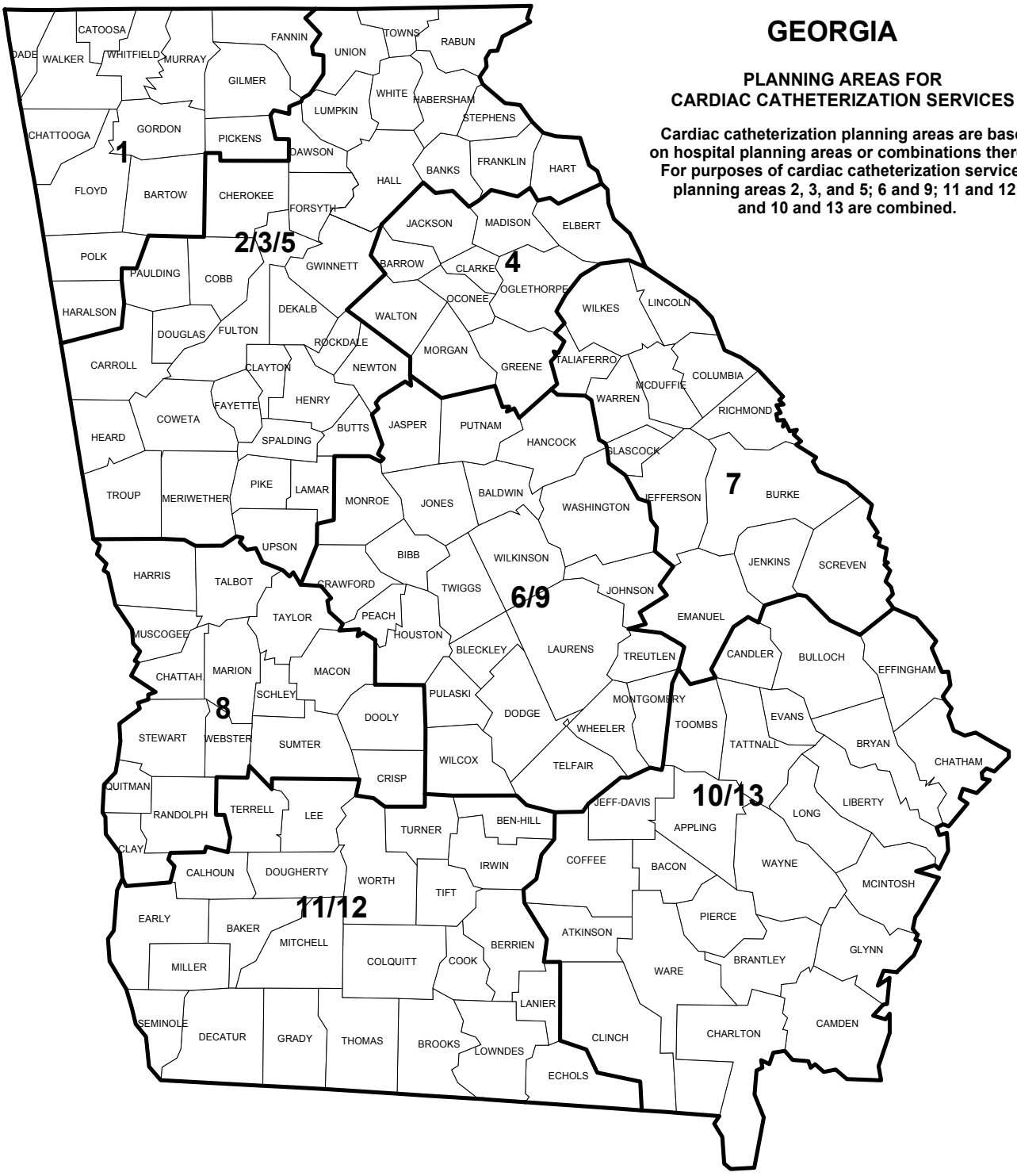
* jointly representing MAG

# SPECIALIZED CARDIOVASCULAR SERVICES

# COMPONENT PLAN

# APPENDIX C

# Planning Areas for
# Adult Cardiac Catheterization Services




Please Note: Adult Open Heart Surgical Serivces and all Pediatric Services use a statewide planning area.

# SPECIALIZED CARDIOVASCULAR SERVICES COMPONENT PLAN

# APPENDIX D

## Cardiovascular Service Rates by County

## RATES PER 100,000 POPULATION
## CVD HOSPITAL DAYS OF CARE, CARDIAC CATHETERIZATION AND OPEN HEART SURGERY
## 1999 Survey and Hospital Discharge Data

| | Cardiovascular Hospital Days of Care<br>Mean = 1843.97<br>Median = 1748.83<br>Std. Deviation = 874.53<br>Range = 1708.03 – 1979.91 | | Cardiac Catheterization<br>Mean= 1211.14<br>Median = 1137.26<br>Std. Deviation = 620.61<br>Range = 1114.67 - 1307.61 | | Open Heart Surgical Procedures<br>Mean = 137.05<br>Median = 127.55<br>Std. Deviation = 82.92<br>Range = 124.17 - 149.93 | |
|---|---|---|---|---|---|---|
| **county name** | | **Significance** | | **Significance** | | **Significance** |
| Appling County, GA | 1361.32 | _ | 1835.08 | _ | 119.94 | _ |
| Atkinson County, GA | 1439.34 | _ | 534.61 | _ | 95.96 | _ |
| Bacon County, GA | 1939.22 | **0** | 849.01 | _ | 19.3 | _ |
| Baker County, GA | 2377.66 | _ | 801.77 | _ | 221.18 | _ |
| Baldwin County, GA | 2190.56 | _ | 1353.69 | _ | 161.21 | _ |
| Banks County, GA | 1306.4 | _ | 941.82 | _ | 136.72 | **0** |
| Barrow County, GA | 1262.8 | _ | 1217.45 | **0** | 159.94 | _ |
| Bartow County, GA | 904.74 | _ | 1301.49 | **0** | 163.52 | _ |
| Ben Hill County, GA | 3462.29 | _ | 1390.64 | _ | 188.85 | _ |
| Berrien County, GA | 1675.84 | _ | 1337.04 | _ | 36.3 | _ |
| Bibb County, GA | 2682.69 | _ | 2021.99 | _ | 234.17 | _ |
| Bleckley County, GA | 1493.72 | _ | 2130.1 | _ | 265.16 | _ |
| Brantley County, GA | 1748.83 | **0** | 1281.04 | **0** | 21.59 | _ |
| Brooks County, GA | 2555.51 | _ | 638.88 | _ | 18.61 | _ |
| Bryan County, GA | 1529.06 | _ | 1262.61 | **0** | 176.27 | _ |
| Bulloch County, GA | 1315.56 | _ | 1195.42 | **0** | 122.1 | _ |
| Burke County, GA | 1959.77 | **0** | 702.07 | _ | 137.83 | **0** |
| Butts County, GA | 1420.02 | _ | 2078.35 | _ | 174.1 | _ |
| Calhoun County, GA | 5226.9 | _ | 729.34 | _ | 101.3 | _ |
| Camden County, GA | 410.36 | _ | 104.18 | _ | 6.38 | _ |
| Candler County, GA | 3149.78 | _ | 1139.28 | **0** | 156.37 | _ |
| Carroll County, GA | 1428.66 | _ | 1137.26 | **0** | 135.67 | **0** |
| Catoosa County, GA | 583.49 | _ | 335.89 | _ | 5.76 | _ |
| Charlton County, GA | 1405.62 | _ | 539 | _ | 0 | _ |
| Chatham County, GA | 1908.61 | **0** | 1138.43 | **0** | 152.88 | _ |
| Chattahoochee County, GA | 360.27 | _ | 174.13 | _ | 78.06 | _ |
| Chattooga County, GA | 2589.9 | _ | 2323.04 | _ | 201.24 | _ |
| Cherokee County, GA | 616.86 | _ | 894.94 | _ | 117.87 | _ |
| Clarke County, GA | 1129.77 | _ | 831.88 | _ | 83.85 | _ |
| Clay County, GA | 510.78 | _ | 340.52 | _ | 56.75 | _ |
| Clayton County, GA | 1314.29 | _ | 803.83 | _ | 122.12 | _ |
| Clinch County, GA | 1153.21 | _ | 1093.31 | _ | 0 | _ |

## RATES PER 100,000 POPULATION
## CVD HOSPITAL DAYS OF CARE, CARDIAC CATHETERIZATION AND OPEN HEART SURGERY
## 1999 Survey and Hospital Discharge Data

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|---|---|---|---|---|---|---|
| Cobb County, GA | 575.11 | _ | 808.34 | _ | 114.99 | _ |
| Coffee County, GA | 1733.51 | **0** | 437.67 | _ | 45.77 | _ |
| Colquitt County, GA | 1704.15 | _ | 302.03 | _ | 34.38 | _ |
| Columbia County, GA | 585.13 | _ | 770.53 | _ | 91.09 | _ |
| Cook County, GA | 2375.47 | _ | 361.91 | _ | 52.64 | _ |
| Coweta County, GA | 1157.71 | _ | 661.07 | _ | 125.28 | **0** |
| Crawford County, GA | 864.22 | _ | 1065.87 | _ | 124.83 | **0** |
| Crisp County, GA | 2175.7 | _ | 1332.56 | _ | 145.37 | **0** |
| Dade County, GA | 951.51 | _ | 358.45 | _ | 0 | _ |
| Dawson County, GA | 1724.68 | **0** | 1317.03 | _ | 213.23 | _ |
| Decatur County, GA | 2204.36 | _ | 110.59 | _ | 3.69 | _ |
| DeKalb County, GA | 1034.93 | _ | 606.85 | _ | 96.34 | _ |
| Dodge County, GA | 3053.01 | _ | 2176.79 | _ | 242.48 | _ |
| Dooly County, GA | 3968.18 | _ | 2367.49 | _ | 287.55 | _ |
| Dougherty County, GA | 2363.95 | _ | 977.89 | _ | 127.55 | **0** |
| Douglas County, GA | 879.63 | _ | 1046.34 | _ | 109.68 | _ |
| Early County, GA | 849.34 | _ | 181.41 | _ | 24.74 | _ |
| Echols County, GA | 355.17 | _ | 355.17 | _ | 0 | _ |
| Effingham County, GA | 933.02 | _ | 909.56 | _ | 125.1 | **0** |
| Elbert County, GA | 2623.56 | _ | 1301.45 | **0** | 222.07 | _ |
| Emanuel County, GA | 3222.13 | _ | 1658.59 | _ | 180.59 | _ |
| Evans County, GA | 2963.62 | _ | 1377.74 | _ | 148.68 | **0** |
| Fannin County, GA | 1467.41 | _ | 2042.76 | _ | 205.86 | _ |
| Fayette County, GA | 684.15 | _ | 923.38 | _ | 100.67 | _ |
| Floyd County, GA | 2627.7 | _ | 2155.25 | _ | 237.39 | _ |
| Forsyth County, GA | 901.89 | _ | 689.86 | _ | 97.22 | _ |
| Franklin County, GA | 2729.01 | _ | 1242.81 | **0** | 176.07 | _ |
| Fulton County, GA | 2040.61 | _ | 703.92 | _ | 103.78 | _ |
| Gilmer County, GA | 1355.86 | _ | 1917.43 | _ | 247.9 | _ |
| Glascock County, GA | 4638.36 | _ | 1768.87 | _ | 235.85 | _ |
| Glynn County, GA | 2197.37 | _ | 994.92 | _ | 26.49 | _ |
| Gordon County, GA | 2182.72 | _ | 1503.6 | _ | 171.57 | _ |
| Grady County, GA | 2111.11 | _ | 273.15 | _ | 9.26 | _ |
| Greene County, GA | 1802.19 | **0** | 808.85 | _ | 99.33 | _ |
| Gwinnett County, GA | 638.34 | _ | 680.13 | _ | 100.98 | _ |

## RATES PER 100,000 POPULATION
## CVD HOSPITAL DAYS OF CARE, CARDIAC CATHETERIZATION AND OPEN HEART SURGERY
## 1999 Survey and Hospital Discharge Data

| | Cardiovascular Hospital Days of Care<br>Mean = 1843.97<br>Median = 1748.83<br>Std. Deviation = 874.53<br>Range = 1708.03 – 1979.91 | | Cardiac Catheterization<br>Mean= 1211.14<br>Median = 1137.26<br>Std. Deviation = 620.61<br>Range = 1114.67 - 1307.61 | | Open Heart Surgical Procedures<br>Mean = 137.05<br>Median = 127.55<br>Std. Deviation = 82.92<br>Range = 124.17 - 149.93 | |
|---|---|---|---|---|---|---|
| Habersham County, GA | 1300.34 | _ | 1982.79 | _ | 122.96 | _ |
| Hall County, GA | 1629.49 | _ | 1234.49 | **0** | 141.13 | **0** |
| Hancock County, GA | 2896.31 | _ | 1105.46 | _ | 110.55 | _ |
| Haralson County, GA | 1719.19 | **0** | 1695.25 | _ | 179.5 | _ |
| Harris County, GA | 645.05 | _ | 1232.66 | **0** | 101.62 | _ |
| Hart County, GA | 2029.47 | _ | 881.4 | _ | 194.36 | _ |
| Heard County, GA | 934.22 | _ | 686.37 | _ | 114.39 | _ |
| Henry County, GA | 1507.36 | _ | 795.11 | _ | 192.17 | _ |
| Houston County, GA | 1639.66 | _ | 1651.74 | _ | 177.44 | _ |
| Irwin County, GA | 2200.2 | _ | 914.93 | _ | 65.35 | _ |
| Jackson County, GA | 2286.4 | _ | 1336.51 | _ | 176.66 | _ |
| Jasper County, GA | 1888.75 | **0** | 1152.14 | **0** | 188.88 | _ |
| Jeff Davis County, GA | 2422.53 | _ | 1777.57 | _ | 228.1 | _ |
| Jefferson County, GA | 1881.51 | **0** | 1153.54 | **0** | 139.99 | **0** |
| Jenkins County, GA | 2047.38 | _ | 1095.11 | _ | 285.68 | _ |
| Johnson County, GA | 1326.42 | _ | 1362.59 | _ | 120.58 | _ |
| Jones County, GA | 725.1 | _ | 1214.23 | **0** | 111.55 | _ |
| Lamar County, GA | 1225.85 | _ | 1299.13 | **0** | 186.54 | _ |
| Lanier County, GA | 4397.18 | _ | 905.3 | _ | 28.74 | _ |
| Laurens County, GA | 2030.64 | _ | 1511.6 | _ | 218.54 | _ |
| Lee County, GA | 1203.89 | _ | 651.21 | _ | 81.4 | _ |
| Liberty County, GA | 861.06 | _ | 554.49 | _ | 41.88 | _ |
| Lincoln County, GA | 1726.83 | **0** | 2854.06 | _ | 299.8 | _ |
| Long County, GA | 1515.67 | _ | 562.64 | _ | 80.38 | _ |
| Lowndes County, GA | 1627.39 | _ | 778.57 | _ | 14.05 | _ |
| Lumpkin County, GA | 1274.53 | _ | 1117.74 | **0** | 116.33 | _ |
| McDuffie County, GA | 1838.27 | **0** | 724.31 | _ | 87.1 | _ |
| McIntosh County, GA | 1858.81 | **0** | 4439.39 | _ | 464.7 | _ |
| Macon County, GA | 1805.58 | **0** | 380.92 | _ | 45.71 | _ |
| Madison County, GA | 2177.88 | _ | 1479.69 | _ | 162.65 | _ |
| Marion County, GA | 1563.65 | _ | 1784.92 | _ | 103.26 | _ |
| Meriwether County, GA | 1970.23 | **0** | 837.56 | _ | 112.83 | _ |
| Miller County, GA | 1962.65 | **0** | 427.35 | _ | 15.83 | _ |
| Mitchell County, GA | 2544.89 | _ | 857.72 | _ | 75.4 | _ |
| Monroe County, GA | 753.79 | _ | 1163.14 | **0** | 124.8 | **0** |

## RATES PER 100,000 POPULATION
## CVD HOSPITAL DAYS OF CARE, CARDIAC CATHETERIZATION AND OPEN HEART SURGERY
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|---|---|---|---|---|---|---|
| Montgomery County, GA | 1935.32 | **0** | 1362.36 | _ | 127.32 | **0** |
| Morgan County, GA | 1107.73 | _ | 997.6 | _ | 148.99 | **0** |
| Murray County, GA | 872.59 | _ | 922.71 | _ | 76.65 | _ |
| Muscogee County, GA | 2139.43 | _ | 1134.8 | **0** | 124.69 | **0** |
| Newton County, GA | 1726.56 | **0** | 1091.07 | _ | 146.91 | **0** |
| Oconee County, GA | 1329.2 | _ | 962.24 | _ | 118.24 | _ |
| Oglethorpe County, GA | 933.93 | _ | 2326.18 | _ | 103.77 | _ |
| Paulding County, GA | 436 | _ | 606.88 | _ | 66.59 | _ |
| Peach County, GA | 2120.34 | _ | 2152.34 | _ | 232.04 | _ |
| Pickens County, GA | 1122.53 | _ | 1369.86 | _ | 237.82 | _ |
| Pierce County, GA | 1771.7 | **0** | 1411.04 | _ | 31.64 | _ |
| Pike County, GA | 1648.35 | _ | 1037.85 | _ | 175.52 | _ |
| Polk County, GA | 2266.09 | _ | 2023.1 | _ | 229.34 | _ |
| Pulaski County, GA | 2201.22 | _ | 2787.41 | _ | 191.41 | _ |
| Putnam County, GA | 1093.47 | _ | 1719.87 | _ | 285.73 | _ |
| Quitman County, GA | 245 | _ | 408.33 | _ | 204.16 | _ |
| Rabun County, GA | 2250.31 | _ | 1417.4 | _ | 153.43 | _ |
| Randolph County, GA | 1834.75 | **0** | 811.28 | _ | 124.81 | **0** |
| Richmond County, GA | 1698.28 | _ | 1302.61 | **0** | 158.69 | _ |
| Rockdale County, GA | 991.76 | _ | 1104.86 | _ | 113.1 | _ |
| Schley County, GA | 2456.32 | _ | 860.98 | _ | 101.29 | _ |
| Screven County, GA | 2330.08 | _ | 1375.92 | _ | 255.83 | _ |
| Seminole County, GA | 1305.72 | _ | 193.82 | _ | 0 | _ |
| Spalding County, GA | 1580.63 | _ | 1362.73 | _ | 119.33 | _ |
| Stephens County, GA | 1685.62 | _ | 1886.94 | _ | 181.59 | _ |
| Stewart County, GA | 3628.58 | _ | 1060.66 | _ | 148.86 | **0** |
| Sumter County, GA | 2343.6 | _ | 883.23 | _ | 137.11 | **0** |
| Talbot County, GA | 3443.82 | _ | 1492.32 | _ | 143.49 | **0** |
| Taliaferro County, GA | 3846.15 | _ | 2234.93 | _ | 207.9 | _ |
| Tattnall County, GA | 2456.84 | _ | 1476.19 | _ | 166.92 | _ |
| Taylor County, GA | 2256.55 | _ | 1568.72 | _ | 132.74 | **0** |
| Telfair County, GA | 3691.04 | _ | 2402.24 | _ | 385.76 | _ |
| Terrell County, GA | 2936.19 | _ | 954.93 | _ | 98.17 | _ |
| Thomas County, GA | 2221.65 | _ | 580.47 | _ | 23.31 | _ |
| Tift County, GA | 1649.76 | _ | 881.68 | _ | 73.02 | _ |

## RATES PER 100,000 POPULATION
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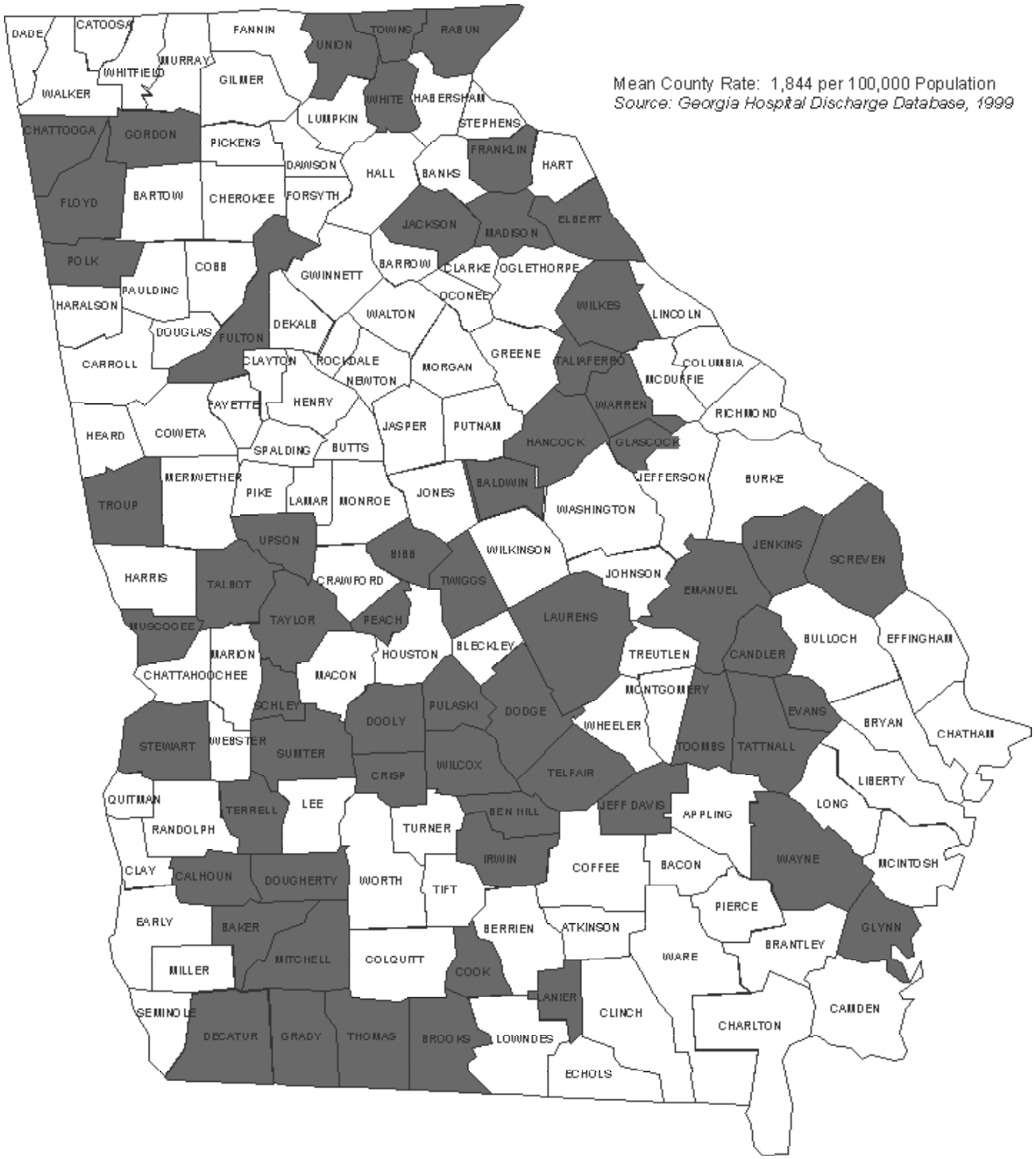
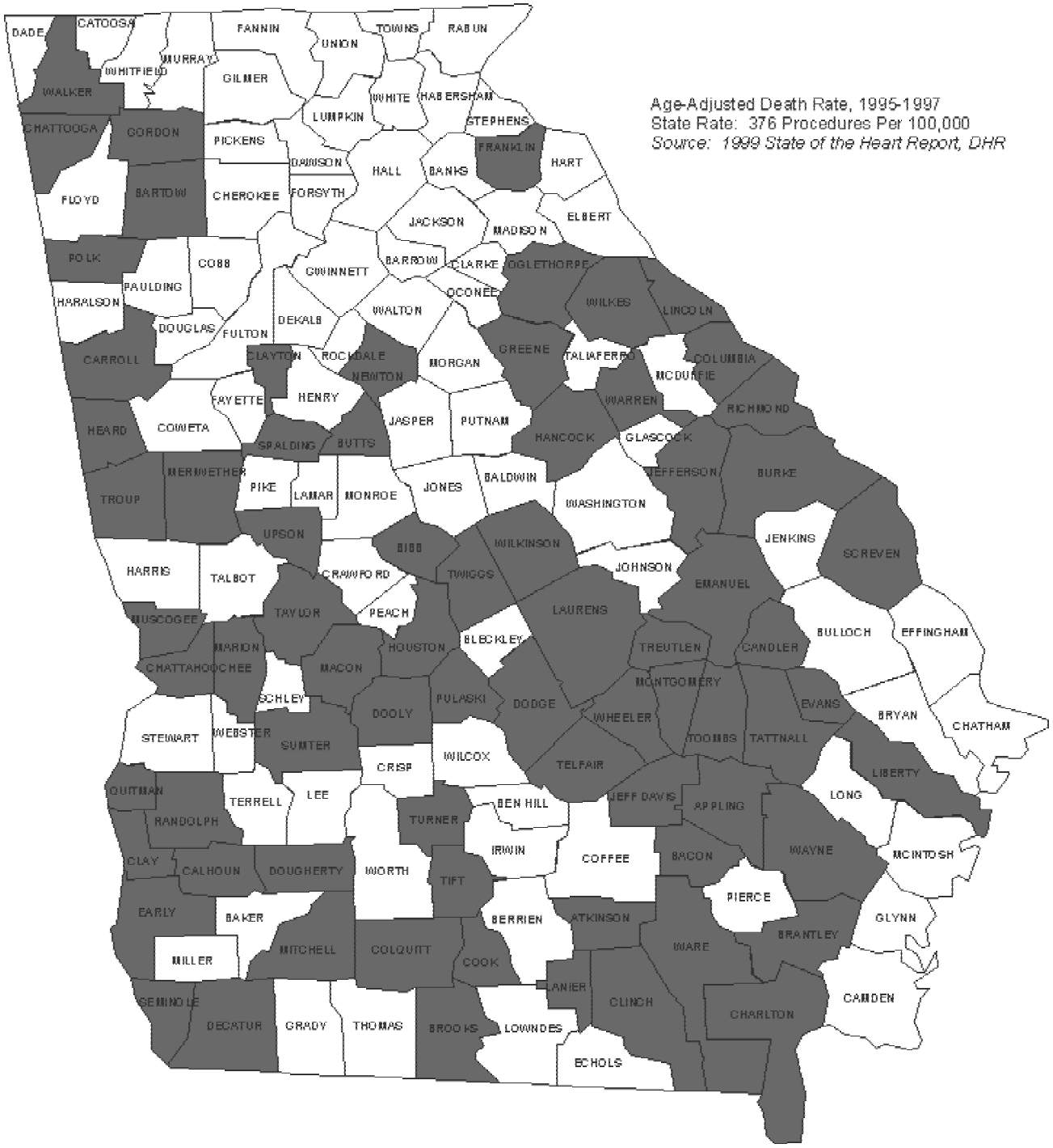
|---|---|---|---|---|---|---|
| Toombs County, GA | 2273.95 | _ | 1523.66 | _ | 180.84 | _ |
| Towns County, GA | 2704.55 | _ | 2352.27 | _ | 340.91 | _ |
| Treutlen County, GA | 1550.65 | _ | 1634.92 | _ | 168.55 | _ |
| Troup County, GA | 2435.33 | _ | 1241.48 | **0** | 74.83 | _ |
| Turner County, GA | 919.02 | _ | 940.64 | _ | 129.74 | **0** |
| Twiggs County, GA | 2637.77 | _ | 1421.85 | _ | 137.28 | **0** |
| Union County, GA | 2094.7 | _ | 1410 | _ | 145.06 | **0** |
| Upson County, GA | 2385.61 | _ | 1887.07 | _ | 240.04 | _ |
| Walker County, GA | 1780.41 | **0** | 648 | _ | 6.35 | _ |
| Walton County, GA | 940.2 | _ | 1095.76 | _ | 145.3 | **0** |
| Ware County, GA | 3116.49 | _ | 1660.42 | _ | 14.19 | _ |
| Warren County, GA | 2617.28 | _ | 1218.11 | **0** | 98.77 | _ |
| Washington County, GA | 1396.18 | _ | 1519.95 | _ | 143.58 | **0** |
| Wayne County, GA | 2491.21 | _ | 1116.75 | **0** | 164 | _ |
| Webster County, GA | 1225.6 | _ | 1089.42 | _ | 90.79 | _ |
| Wheeler County, GA | 1706.41 | _ | 1850.33 | _ | 267.27 | _ |
| White County, GA | 2390.77 | _ | 1533.39 | _ | 192.36 | _ |
| Whitfield County, GA | 1468.4 | _ | 1097.09 | _ | 80.51 | _ |
| Wilcox County, GA | 2399.25 | _ | 1967.92 | _ | 310.01 | _ |
| Wilkes County, GA | 3685.11 | _ | 1951.5 | _ | 265.25 | _ |
| Wilkinson County, GA | 1934.36 | **0** | 2062.71 | _ | 330.03 | _ |
| Worth County, GA | 1974.83 | **0** | 934.04 | _ | 128.99 | **0** |

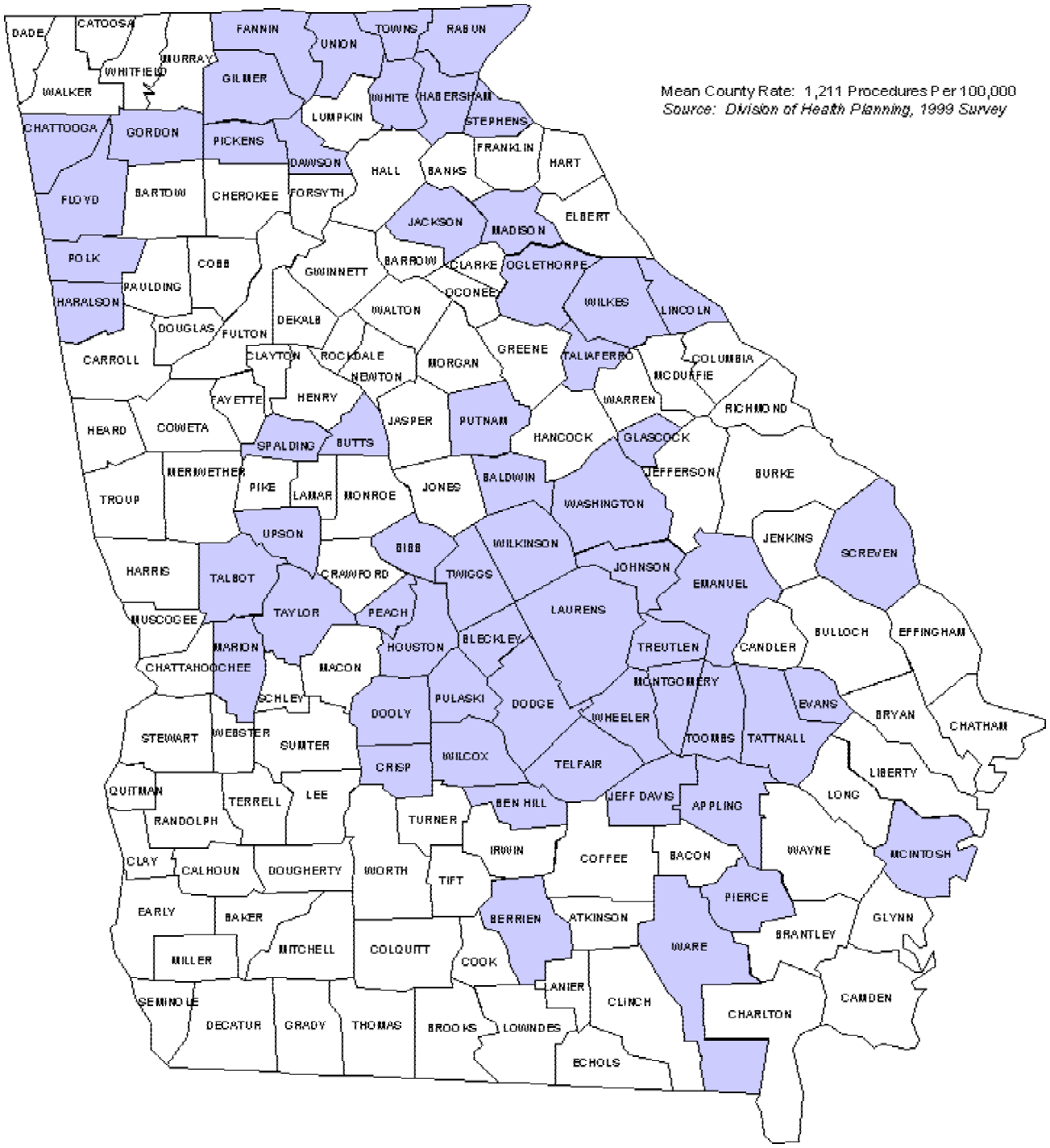
## Hospitalization Days for Heart Disease
## Counties with Rates Significantly Higher than Mean Rate



## Deaths from Cardiovascular Disease
## Counties with Rates Significantly Higher than State Average



## Cardiac Catheterization Procedures
## Counties with Rates Significantly Higher than Mean



# Open Heart Surgical Procedures
## Counties with Rates Significantly Higher than Mean