

**MISSISSIPPI STATE DEPARTMENT OF HEALTH
DIVISION OF HEALTH PLANNING AND RESOURCE DEVELOPMENT
MAY 2010**

**CON REVIEW: C-MME-0310-011
CARDIOLOGY ASSOCIATES OF NORTH MISSISSIPPI
ACQUISITION OR OTHERWISE CONTROL OF A PET SCANNER
AND RELATED EQUIPMENT AND PROVIDE PET SERVICES
CAPITAL EXPENDITURE: \$76,000
LOCATION: TUPELO (LEE COUNTY), MISSISSIPPI**

STAFF ANALYSIS

I. PROJECT SUMMARY

A. Applicant Information

Cardiology Associates of North Mississippi, P. A. ("CANM") is a professional corporation located in Tupelo, Lee County, Mississippi. CANM is a physician-owned medical clinic organization which operates four cardiology clinics (Tupelo, Oxford, Columbus, and Starkville). CANM is listed in good standing with the Office of the Secretary of State.

B. Project Description

Cardiology Associates of North Mississippi, P.A. requests Certificate of Need (CON) authority for the acquisition or otherwise control of a Positron Emission Tomography (PET) Scanner and Related Equipment. CANM intends to commence offering cardiac PET services at its Tupelo, Mississippi Clinic on a full-time basis to its cardiac patients.

The applicant proposed to acquire control of a G.E. Discovery ST PET scanner, unit 27 through an operating lease from Alliance Healthcare Service, Inc. ("Alliance"), a CON approved mobile PET equipment provider, for the provision of cardiac PET perfusion diagnostic imaging services at CANM Tupelo five days a week on an out-patient basis.

The applicant states that cardiac PET is a type of procedure performed on a PET scanner; however it does require modification of some of the equipment and/or software utilized by the PET unit. The applicant further states that the specialized equipment and/or software to modify the proposed PET scanner for cardiac use have a cost of approximately \$60,000, which is proposed to be incurred by Alliance.

According to the applicant, the capital expenditure for the proposed project is \$76,000 and will be funded through its accumulated cash reserves. A breakdown of the capital expenditure is as follows: \$49,000 for the construction of a mobile pad and electrical connection to accommodate the coach which houses the PET equipment, \$26,000 for professional and CON filing fees, and \$1,000 for contingency to cover any unanticipated overrun of the estimates.

According to the applicant, CANM will not be sharing the PET unit with other PET service providers and only one additional FTE is required for this project. The applicant projects the following number of procedures:

**Cardiology Associates of North Mississippi, P.A. Tupelo
Projected PET Procedures**

1 Year	Year 2	Year 3
1764	2016	2016

According to the MSDH Division of Health Facilities Licensure and Certification, the proposed project's site is not hospital affiliated and considered Business Occupancy; therefore, is not under the Fire Safety and Construction Division jurisdiction. A site approval is not required.

On March 22, 2010 B.J. Smith, Director of the Division of Radiological Health indicated that its division has been informed of the proposed project and will inspect and provide licenses for the PET if all requirements are met once the CON has been issued.

II. TYPE OF REVIEW REQUIRED

Projects which propose the provision of positron emission tomography (PET) services are reviewed in accordance with Section 41-7-191, subparagraphs (1) (d) (xv) Mississippi Code of 1972, Annotated, as amended, and duly adopted rules, procedures, plans, criteria and standards of the Mississippi State Department of Health.

In accordance with Section 41-7-197(2), of the Mississippi Code 1972, Annotated, as amended, any affected person may request a public hearing on this project within 20 days of publication of the staff analysis. The opportunity to request a hearing expires on June 7, 2010.

III. CONFORMANCE WITH THE STATE HEALTH PLAN AND OTHER ADOPTED CRITERIA AND STANDARDS

A. State Health Plan (SHP)

The *FY2010 State Health Plan* addresses policy statements and service specific criteria and standards which an applicant is required to meet before receiving CON authority to acquire or otherwise control PET equipment and provide PET services. This application is not in substantial compliance with applicable criteria and standards for the acquisition or otherwise control of a PET scanner and related equipment. The Plan does not address criteria and standards for cardiac PET services.

SHP Policy Statement (PS) Regarding PET

PS-2 Indigent/Charity Care: The applicant states that it will provide a reasonable amount of indigent/charity care.

PS 4 – Equipment to Population Ratio: The need for a PET scanner is estimated to be one scanner per 300,000 population. The 2010 population for Mississippi is estimated to be 2,975,550; therefore, there can only be 9.9 or 10 units approved for the state. Currently, there are approximately 13 units (excluding one operated by University of Mississippi Medical Center) operating in the state either through CON approval or Determination Rulings. Alliance alone has three operating units.

The applicant argues that this Policy Statement is not applicable since the equipment to population ratio was met by Alliance in the 2001 CON application. However, the equipment that is the subject of this project was exempted from CON in December 2009 by Determination Ruling as a mobile PET scanner. Mobile PET scanners serve at least two facilities on a mobile approved route. By the applicant's admission, the PET scanner that is the subject of this project will not serve other facilities but will be fixed at the Cardiology Associates office five days a week; thus creating a fixed based unit.

PS-5 Access to Supplies: According to the applicant it will have access to appropriate radio-pharmaceuticals.

PS-6 Services and Medical Specialties Required: The applicant states that the proposed project will function as a component of a comprehensive outpatient diagnostic imaging service through referral relationships with North Mississippi Medical Center and The Imaging Center at Gloster Creek Village which have all of the required diagnostic imaging modalities and capabilities available in close proximity to CANM Tupelo.

The applicant further states that CANM Tupelo has a transfer agreement with North Mississippi Medical Center enabling it access to emergency services.

PS-7 Hours of Operation: The applicant contends that it will have adequate scheduled hours to avoid an excessive backlog of cases and flexibility to add additional periods of operation if scan volumes increase. The applicant proposes the projected hours of operation to be Monday through Friday from 8:00 a.m. to 5:00 p.m.

PS-8 CON Approval Preference: The MSDH may approve applicants proposing to enter joint ventures utilizing mobile and/or shared equipment. The applicant proposes to enter into a contractual agreement with Alliance Imaging to control one of its approved units. However, the applicant does not propose to utilize shared equipment. Although mobile capable, the equipment will be parked at the applicant's facility on a full-time basis.

Certificate of Need Criteria and Standards for the Acquisition or Otherwise Control of a Positron Emission tomography (PET) Scanner and Related Equipment

SHP Criterion 1a - Need

According to the Certificate of Need criteria and standards, an entity desiring to acquire or to otherwise control the PET scanner must project a minimum of 1,000 clinical procedures per year and must show the methodology used for the projection.

According to the applicant, CANM Tupelo and Alliance Imaging, Inc. projects 1,764 procedures to be performed the first year of operation, 2,016 procedures the second and third year.

The application contains an affidavit from a physician at CANM attesting to the number of projected procedures to be referred by CANM for the PET myocardial perfusion imaging procedure.

The applicant states that the methodology utilized to project utilization statistics for the first, second, and third years of operation for the proposed service was to examine the patient charts and statistical data maintained by CANM related to its existing patients' need for perfusion diagnostic imaging scans.

SHP Criterion 1b - Need

The 2010 State Health Plan indicates that the state as a whole shall serve as a single service area in determining the need for a PET scanner. In addition, the Plan states that the need for a PET scanner is estimated to be one scanner per 300,000 population. Based on the 2010 population projection stated in the 2010 State Health Plan, the 2010 projected population for the state has been determined to be 2,975,550. Based on this projected population, only 9.9 or 10 units are needed for the entire state. Currently, through CON approvals and Determination Rulings for equipment costing less than \$1,500,000, the state has approximately 13 units in operation. Alliance alone operates three mobile PET units. Alliance received authorization on January 4, 2010, to operate a fourth mobile unit in the state, which unit is the subject of this application. However, the applicant proposed to utilize the unit on a full-time basis, thus converting it from a mobile PET unit to a fixed based unit.

The applicant is not in compliance with this need criterion 1b.

SHP Criterion 2 – Registered Entity

Cardiology Associates of North Mississippi requests approval to provide fixed PET services at its facility through utilization of a PET scanner unit, which they will obtain control of through an operation lease with Alliance Imaging. The applicant proposed that the PET scanner be located at its facility on a full-time basis.

Both the applicant and Alliance Imaging, Inc. are registered to conduct business in the state of Mississippi.

SHP Criterion 3 – Impact on Existing Providers

The Plan states that the department will approve additional PET units in a service area with existing equipment only when the existing PET scanners in that service area is performing an average of 1,500 procedures per PET unit per year.

The applicant contends that the existing PET equipment serving North Mississippi Medical Center in Tupelo, located in General Hospital Service Area 2, is performing an average of more than 2000 clinical procedures per unit per year.

The applicant believes that its projection of utilization will be higher than those experienced by some other facilities providing PET services within GHSA 2. This is considered because of the fact that The Imaging Center at Gloster Creek Village has suspended its PET services and Magnolia Medical Center's service serves a smaller patient base. According to the applicant, North Mississippi Medical Center's PET service has the highest historical volume in

the state but it only serves oncological and/or neurological patients, and does not have cardiac PET capability.

Staff contends that the existing PET equipment in GHSA 2 is performing an average of 854 clinical procedures per PET unit per year. According to the *FY 2010 State Health Plan* there are three facilities in GHSA 2 providing PET services: Magnolia Regional Health Center performed 488 procedures, North Mississippi Medical Center performed 2,051 procedures, and TIC at Gloster Creek Village performed 24 procedures. In addition, the state as a whole is the PET scanner planning area. According to the 2010 Plan there were 11,234 scans statewide utilizing 12 units for an average of 936 scans per unit. As a result, staff believes that the proposed project could cause an adverse effect on existing providers. Therefore, the applicant is not in compliance with this criterion.

SHP Criterion 4 – Approval from Radiological Health

The applicant affirms that it currently has a Division of Radiological Health permit for handling nuclear and radio-pharmaceutical materials and shall apply for and receive approval from the Division of Radiological Health for the proposed site, plans, and equipment in advance of commencement of PET services at CANM Tupelo.

The applicant assures that the proposed PET service will be offered in a physical environment that conforms to the federal standards, manufacturer's specifications and licensing agencies' requirement as required by this criterion.

SHP Criterion 7 – CON Approval

The applicant is requesting CON approval. Alliance Imaging, Inc. has CON authority to manage the mobile PET scanner equipment under certificate of need #R-0503 for the acquisition and establishment of PET scanner equipment and services and determinations of non-reviewability.

Certificate of Need Criteria and Standards for the Offering of Fixed or Mobile Positron Emission Tomography (PET) Services

SHP Criterion 1 - Need

As previously stated, CANM Tupelo and Alliance Imaging, Inc. projects 1,764 procedures to be performed the first year of operation, 2,016 procedures the second year, and more than 2,016 procedures the third year.

The applicant submits that the assessment of the presence or absence of myocardial ischemia (impaired blood flow to the heart muscle) has been shown to add incremental prognostic information to the assessment of the patient with suspected or known coronary artery disease. The applicant contends that this information is additive to the anatomic information obtained from a cardiac catheterization or cardiac CT angiogram. Thus the measurement of myocardial blood flow, or myocardial perfusion, plays a vital role in determining the most appropriate treatment modality (medication, coronary stenting or surgery (coronary artery bypass grafting)) for a given patient. The applicant lists as an example, the current American College of Cardiology guidelines which recommended that coronary stenting be performed in an obstructed coronary artery only in the presence of an abnormal myocardial perfusion imaging study. Thus, a myocardial perfusion imaging study is

the gatekeeper to additional interventional procedures and these studies play a vital role in the treatment of patients with known or suspected coronary heart disease.

According to the applicant, there are two modalities of performing myocardial perfusion imaging available: SPECT nuclear and PET perfusion studies.

The applicant states that historically, myocardial perfusion studies have been performed virtually exclusively with a SPECT nuclear gamma camera. This technology has a solid clinical track record and is well established in the field of noninvasive cardiac imaging. CANM contends that in its clinics they perform more than 6,200 of these studies per year. All of the studies are performed utilizing a technetium based nuclear agent such as sestamibi or tetrafosmin. The applicant further states while the technology and application of cardiac SPECT is well established, there are several limitations. Some of the limitations include:

- ✓ The availability of the technetium based agents has been problematic this past year and this is expected to dramatically worsen in the next few years. Shortages occurred on an intermittent basis in 2009 and forced CANM to cancel studies and have an inefficient backlog. CANM was also supplied lower doses of the nuclear agent during those times, which resulted in suboptimal studies, with reduced accuracy. Alternative testing with another agent; thallium, was recommended but thallium has lower energy and results in decreased accuracy, especially in females and obese patients. Additionally, thallium studies expose the patient to a much higher dose of radiation.
- ✓ There is considerable soft tissue attenuation (shadows on the cardiac images) in obese and female patients. This results in less accurate studies.
- ✓ The technetium based agents accumulate in the liver and gut in addition to the heart and can confound the image reconstruction.
- ✓ There is fairly low sensitivity (ability to detect significant coronary artery disease) of 82% of patients and specificity (an abnormality truly represents significant coronary artery disease) of 82% of patients with SPECT imaging. The former results in missed diagnoses while the latter results in more cardiac catheterizations, with resultant increased risk to the patient and adverse economic impact to the healthcare system.
- ✓ The imaging protocols are inefficient requiring 3-4 hours per study, which reduces laboratory throughput and requires purchase of additional cameras and staff to accommodate the demand.
- ✓ The radiation dose to the patient is fairly high -15 mSv with a technetium based agent and 25-30 mSv with thallium. This compares to 5 mSv for a cardiac catheterization. The concern here is the increased risk of development of cancer after exposure to radiation.
- ✓ The declining reimbursement for SPECT studies precludes purchasing the newest technology in SPECT cameras. The newest generation SPECT cameras cost 2-3 times that of the current generation SPECT cameras and are in the price range of current non-hybrid cardiac only PET scanners.

CANM states the more recently, myocardial perfusion studies utilizing PET technology have been shown to have several advantages over SPECT nuclear perfusion imaging. The applicant further states that recent advancements in PET technology as well as nuclear agents have led to more clinical studies and more widespread acceptance of this technique. The applicant submits that there are several advantage of PET myocardial perfusion imaging over SPECT myocardial imaging. They are as follows:

- ✓ The higher energy of the PET nuclear agents provides for improved image quality and thus improved diagnostic accuracy over the SPECT nuclear agents. This results in fewer missed diagnoses and also fewer false positive studies, which results in fewer downstream studies, i.e., cardiac catheterizations.
- ✓ The higher energy of the PET nuclear agents results in less attenuation of the photons by soft tissue and thus results in improved and more accurate image in both obese patients and women (breast tissue). Imaging of the obese patient is a major challenge in CANM's patient population and is a major problem in SPECT imaging in CANMs' practice. Mississippi is the most obese state in the nation and CANM foresee imaging problems in this realm to only worsen. For this reason the applicant feels PET is required not only in its practice, but in major cardiology programs throughout Mississippi.
- ✓ The short half-life of Rb-82 (75 seconds) results in much less radiation exposure to the patient (about 1/5 – 1/3) as much as a technetium based cardiac scan), thus reducing the patient's long term cancer risk.
- ✓ The very short life (75 seconds) results in PET imaging protocols in the 45 minute range, resulting in more efficient utilization of the equipment and improved patient satisfaction.
- ✓ Rb-82 is readily available from a Sr-82 generator and is not affected by the factors which are affecting the shortage of the technetium based agents.

According to the applicant, as a result of the foregoing, CANM is essentially compelled to acquire the capability to provide cardiac PET perfusion imaging to its patients and the community of GHSA2.

SHP Criterion 3 – Assurance

The applicant asserts that its proposed PET service will be offered in a physical environment that conforms to the federal standards, manufacturer's specifications and licensing agencies' requirements as stated. The applicant states that all of the considerations have been examined and planned for by CANM or Alliance in the plan for the positioning and installation of the PET scanner and the associated instrumentation, including the appropriate safe storage of radio-pharmaceutical agents. The applicant further states that in the installation environment and in the PET system itself, radiation protection and shielding and control of radioactive emissions into the environment have been designed in to the coach used to transport the PET unit.

In addition, the applicant states that the radio-pharmaceutical providers contractually assure quality control of their products and timely supply of required radio-pharmaceuticals.

SHP Criterion 5 – Availability of Equipment

The applicant states that Alliance Imaging will contract with Bracco of Memphis, Tennessee to provide CANM Tupelo with on-site rubidium generators monthly.

SHP Criterion 6 – Staffing Availability

The applicant documented that qualified staff will be available to accommodate the staffing requirements for the proposed project.

SHP Criterion 7 – Medical Emergencies

The applicant submits that in the event that a medical emergency arise, emergency services will be called and the patient will be stabilized and transported by EMS personnel to the North Mississippi Medical Center emergency room pursuant to an existing transfer/referral agreement. The applicant states that CANM has transfer agreements with North Mississippi Medical Center, Baptist Memorial Hospital-Golden Triangle, Clay County Medical Center, and Baptist Memorial Hospital-Union County. respectively.

SHP Criterion 8 – Referral System

The applicant affirms that CANM will accept appropriate referrals for PET procedures from other local providers and that the patient will be accommodated to the extent possible by extending hours of service, as appropriate, and by prioritizing patients according to standards of need and appropriateness rather than source of referral.

SHP Criterion 9 – Established Protocols

The applicant affirms that protocols will be established to assure that all clinical PET procedures performed are medically necessary and not more appropriately performed by other, less expensive, established modalities.

SHP Criterion 10 – Maintenance of PET Procedures

The applicant affirms that they will maintain a current listing of appropriate PET procedures for use by referring physicians.

SHP Criterion 11 – Maintenance of Required Data

The applicant affirms that CANM shall maintain the data required by this criterion and shall make the same available to the Mississippi State Department of Health upon request.

SHP Criterion 12 – CON Exemption/Approval

Cardiology Associates of North Mississippi is requesting CON authority through the Mississippi State Department of Health to offer full-time PET scanner services utilizing a mobile unit docked at its facility on a full-time basis. CANM will obtain control of the PET equipment through an operating lease of a mobile PET scanner from Alliance Imaging, Inc.

Alliance Imaging, Inc. has CON authority to manage the mobile PET scanner equipment under certificate of need #R-0503 for the acquisition and establishment of PET scanner equipment and services and determinations of reviewability.

B. General Review (GR) Criteria

Chapter 8 of the *Mississippi Certificate of Need Review Manual*; revised December, 2009; addresses general criteria by which all CON applications are reviewed. This application is in substantial compliance with general review criteria.

GR Criterion 2 - Long Range Plan

According to the applicant, CANM's long range plans include ultimately delivering a full line of cardiac treatment services and modalities, together with necessary ancillary diagnostic imaging and monitoring services, to enable its patients to receive all of their cardiology treatment and follow-up short of surgery at CANM.

GR Criterion 3 - Availability of Alternatives

The applicant considered the following two alternatives:

1. Take no action – This alternative was rejected because it was determined to be detrimental to CANM's patients in light of the technetium shortage and other factors.
2. Purchasing a PET scanner to install at CANM Tupelo. This alternative was rejected because the *2010 State Health Plan* does not support the acquisition or control of new PET equipment. In addition, the capital expenditure required to obtain the PET scanner would be substantial.

Finally, the applicant considered obtaining cardiac scanning enabled PET equipment by way of an operating lease with an equipment provider which would reduce the financial risk and would substantially reduce the capital expenditure necessary to provide that service locally to CANM's patients. The applicant states that such service arrangements will provide flexibility in scheduling the time and volume of PET services to match its patients' PET requirements.

GR Criterion 4 - Economic Viability

According to the applicant's three-year projections, the proposed project will sustain a net loss of \$49,076 the first year of operation; yet result a net gain of \$404,776 for the second and third years of operation, respectively.

- a. **Proposed Charge:** The applicant projects charges of \$408 for the first year of operation and \$608 per PET procedure for the second and third years of operation for the proposed project. The applicant projects costs of \$683 for the first year and \$598 for the second and third years of operation.
- b. **Projected Levels of Utilization:** CANM anticipates the following number of PET procedures will be performed during the first, second, and third years of operation: 1,764; 2,016; 2,016 scans, respectively. The application contains an affidavit from the director of Non-Invasive Cardiac Imaging of CANM attesting to the number of SPECT procedures performed in 2008 and 2009 that had limitations. The director also projected the number of procedures that would be referred by CANM physicians for PET scans.
- c. **Project's Financial Feasibility Study:** The application contains a statement from CANM's Chief Financial Officer asserting that the clinic is capable of undertaking the financial obligation of the proposed project.

GR Criterion 5 - Need for the Project

- a. **Access by Population Served:** The applicant states that CANM is accessible to all residents of the service area, including low income persons, racial and ethnic minorities, women, handicapped persons and other underserved groups, and the elderly. The applicant further contends that the population currently served by CANM will have access to the proposed PET services.
- b. **Relocation of Services:** This application seeks to establish positron emission tomography services. The proposed cardiac PET services will be implemented through an operating lease agreement with Alliance Imaging, Inc., an existing provider of mobile PET services.
- c. **Probable Effect on Existing Facilities in the Area:** The applicant states that there will be no adverse impact to the existing health care system in General Hospital Service Area 2 as a result of the proposed project.

The applicant further states that CANM will be providing cardiac PET serves to its existing patient population and neither of the other facilities in GHSA 2 currently provides cardiac PET services.

- d. **Community Reaction:** The application contains two (2) letters of support for the proposed project.

GR Criterion 6 - Access to the Facility or Service

According to the applicant, all residents of GHSA 2, including Medicaid recipients, charity/medically indigent patients, racial and ethnic minorities, women, handicapped persons, and the elderly, will have access to the services of the facility.

The following table shows the projected gross patient revenue percentage and actual dollar amount of health care provided to medically indigent patients for the first two years upon completion of the proposed project:

Projected Year	Gross Patient Revenue (%)	Gross Patient Revenue (\$)
1	2.16%	\$1,569,921
2	2.16%	\$1,569,921

GR Criterion 7 - Information Requirement

The applicant affirms that it will record and maintain the requested information required by this criterion and make it available to the Mississippi State Department of Health within 15 days of request.

GR Criterion 8 - Relationship to Existing Health Care System

Cardiology Associates of North Mississippi is located in General Hospital Service Area 2. According to the *FY 2010 State Health Plan*, in FY 2008, GHSA 2 had two mobile PET providers and one fixed who performed a total of 2,563 PET procedures.

The applicant states that the active PET providers of GHSA 2 are North Mississippi Medical Center in Tupelo, Mississippi which is 1 mile away from the CANM Tupelo and Magnolia Medical Center in Corinth, Mississippi which is approximately 49 miles from CANM Tupelo. The applicant further states that neither North Mississippi Medical Center nor Magnolia Medical Center, or any other facility in Mississippi currently provides cardiac PET services.

The applicant believes that the proposed PET service at CANM is aimed at a particular population which is comprised of CANM's patients who need cardiac PET services and cannot currently obtain the cardiac PET evaluation necessary in Mississippi. As a result, CANM do not believe there will be an adverse impact on other providers of PET services in Mississippi.

Staff contends that this project should not have an adverse affect on existing providers in GHSA 2.

GR Criterion 9 - Availability of Resources

The applicant states that no new PET technicians will be required to staff the proposed PET service, but one additional nurse will be hired to assist the PET technician operating the PET unit. However, the required maintenance personnel will be provided by Alliance and other required personnel such as: nursing, housekeeping, nuclear medicine technicians, physicists, billing, accounting and managerial are already employed by CANM.

GR Criterion 16 - Quality of Care

The applicant contends that CANM has a substantial history of quality cardiovascular care and is committed to continuing that same level of care to its patients. The applicant further contends that the entire reason for this proposed new cardiac PET service at CANM is to improve the quality of care being delivered to the existing patient base of CANM by enabling CANM's patients to receive convenient, careful and considerate care in the provision of the PET scans.

IV. FINANCIAL FEASIBILITY

A. Capital Expenditure Summary

The total estimated capital expenditure is allocated as follows:

Cost Item	Projected Cost	% of Total
Construction Cost - New		0.00%
Construction Cost - Renovation	\$49,000	64.47%
Capital Improvements		0.00%
Total Fixed Equipment Cost		0.00%
Total Non-Fixed Equipment Cost		0.00%
Land Cost		0.00%
Site Prep Cost		0.00%
Fees - architectural, engineering, etc.	7,000	9.21%
Fees - legal and accounting	18,000	23.68%
Contingency Reserve	1,000	1.32%
Capitalized Interest		%
Other Cost	1,000	1.32%
Total Proposed Capital Expenditures	<u>\$76,000</u>	<u>100%</u>

The above capital expenditure is proposed for the construction renovation cost of a mobile pad and electrical connections to accommodate the coach, which will house the PET scanner. The proposed project involves approximately 600 square feet of space at an estimated cost of \$13.33 per square foot. The Means Construction Cost Data, 2009, does not compare costs of renovation projects.

B. Method of Financing

The applicant proposes to finance this project through CANM's cash reserves.

C. Effect on Operating Cost

Cardiology Associates of North Mississippi projects the following expenses, revenues, and utilization for the first three years of operation for the PET service:

Three-Year Projected Operating Statement (Project Only)

	Year 1	Year 2	Year 3
Revenue			
Patient Revenue:			
Inpatient			
Outpatient	719,712	1,225,728	1,225,728
Total Gross Patient Revenue	<u>\$ 719,712</u>	<u>\$ 1,225,728</u>	<u>\$ 1,225,728</u>
Charity Care			
Deductions	(\$436,212)	(\$384,048)	(\$384,048)
Total Deductions	<u>(\$436,212)</u>	<u>(\$384,048)</u>	<u>(\$384,048)</u>
Net Patient Revenue	\$1,155,924	\$1,609,776	\$1,609,776
Other Operating Revenue			
Total Operating Revenue	<u>\$1,155,924</u>	<u>\$1,609,776</u>	<u>\$1,609,776</u>
Expenses			
Salaries	\$60,000	\$60,000	\$60,000
Benefits	12,000	12,000	12,000
Supplies			
Services			
Lease	1,128,000	1,128,000	1,128,000
Depreciation	5,000	5,000	5,000
Interest			
Other			
Total Expenses	<u>\$1,205,000</u>	<u>\$1,205,000</u>	<u>\$1,205,000</u>
Net Income (Loss)	<u>\$(49,076)</u>	<u>\$404,776</u>	<u>\$404,776</u>
Utilization			
Inpatient Day			
Outpatient Day			
Procedures	1,764	2,016	2,016
Charge Per Procedure	\$408	\$608	\$608
Cost Per Procedure	\$683	\$598	\$598

D. Cost to Medicaid/Medicare

Patient Mix by Type Payer	Utilization Percentage	First Year Expenses Revenue
Medicaid		
Medicare	72%	\$516,080
Commercial	28%	\$203,632
Self Pay		
Commercial		
Total	<u>100%</u>	<u>\$719,712</u>

V. RECOMMENDATIONS OF OTHER AFFECTED AGENCIES

The Division of Medicaid was provided a copy of this application for review and comment; however, no comments were received as of this staff analysis.

VI. CONCLUSION AND RECOMMENDATION

This project is not in substantial compliance with the criteria and standards for the acquisition or otherwise control of a Positron Emission Tomography Scanner and Related Equipment and Provision of Positron Emission Tomography Services as contained in the FY 2010 State Health Plan; the Mississippi Certificate of Need Review Manual, Revised December, 2009; and duly adopted rules, procedures, and plans of the Mississippi State Department of Health. Specifically, the project does not comply with the following:

- **PS 4 – Equipment to Population Ratio:** The applicant contend that this Policy Statement is not applicable since the equipment to population ratio was met by Alliance in the 2001 CON application. However, staff maintains that this Policy Statement is applicable. The need for a PET scanner is projected to be one scanner per 300,000 population and the department would consider out-of-state population if sufficient documentation is submitted. Since Mississippi’s population is estimated to be 2,975,500, which justifies for only 9.9 or 10 units approved for the state and currently there are approximately 13 units, proposed project does not meet the equipment to population ratio.
- **SHP Criterion 1b – Need:** The Plan indicates that the state as a whole shall serve as a single service area, which has been determined to be 2,975,550 population. In addition, the need criterion states that a minimum population of 300,000 per PET scanner which equates to approximately 9.9 or 10 units. Currently, the state has 13 units in operation. On January 4, 2010, the department granted Alliance approval for an additional mobile PET scanner, costing less than \$1,500,000, which is the subject of this application. Alliance has the authority to operate a total of four mobile units in the state. On the other hand, the applicant requests CON authority to utilize the mobile PET scanner at CANM on a full-time basis and does not intend to share the unit with other providers. Therefore, converting the mobile PET to a fixed unit. As a result, the proposed project does not meet the need requirements as specified in the Plan.

SHP Criterion 3 - Impact on Existing Providers: The applicant failed to address the service area as a whole. Instead, the applicant only referenced North Mississippi Medical Center which performed 2,051 procedures. According to the FY 2010 State Health Plan the three existing PET equipment in GHSA 2 (Magnolia Regional Health Center, North Mississippi Medical Center, and TIC at Gloster Creek Village) performed an average of 854 clinical procedures per PET unit per year. As a result, the applicant does not meet the 1,500 procedures per PET units in GHSA 2. Also, the state as a whole is considered as a PET scanner planning area. The 2010 State Health Plan indicates that there were 11,234 scans performed statewide utilizing 12 PET scanners for an average of 936 scans per unit. Consequently, staff believes that the project could cause an adverse effect on existing providers in GHSA 2; thus, the applicant is not in compliance with this criterion.

Therefore, the Division of Health Planning and Resource Development recommends disapproval of the application submitted by Cardiology Associates of North Mississippi for the proposed project.