

**DIVISION OF HEALTH PLANNING AND RESOURCE DEVELOPMENT (THURMAN)
AUGUST 2004**

CON Review: HG-NIS-0604-019
The Imaging Center at Gloster Creek Village
Establish Mobile PET Services
Capital Expenditure: \$ -0-
Location: Tupelo, Mississippi

STAFF ANALYSIS

I. PROJECT SUMMARY

A. Applicant Information

The Imaging Center at Gloster Creek Village, PLLC, (TIC), is a for-profit member-managed limited liability company authorized to do business in the State of Mississippi. TIC is a closely held, member-managed company having one member at the time of this application, Michael Currie, M.D. Therefore, there is no governing board. TIC will provide PET services to all members of the community, including the poor, handicapped, members of racial or ethnic minorities, women, and the elderly.

TIC does not have existing obligations to provide uncompensated care or community service. Nevertheless, TIC states that it will provide PET services at reduced fees or at no charge for persons who are unable to pay. TIC will participate in the Medicaid and Medicare programs to the extent allowed by those programs. Currently, TIC is a Medicare provider.

B. Project Description

TIC is requesting Certificate of Need (CON) authority to establish mobile Positron Emission Tomography (PET) services at its facility two days per month for ten (10) hours each day. TIC will contract with Insight Health Corporation (Insight) to provide mobile PET services. This contract has not been finalized as it is contingent upon the granting of a Certificate of Need for this application. The trailer will park in the parking lot adjacent to TIC's location at Gloster Creek Village. The PET services will complement the diagnostic imaging services currently being offered at TIC.

TIC currently provides full-time MRI, CT, Ultrasound, Mammography, Nuclear Medicine and Routine X-Ray services to the members of the Tupelo community and surrounding areas. The addition of mobile PET services will allow TIC to complement its service to the community at little additional expense.

Because the services will be provided through a mobile provider, there will be no capital expenditure and minimal start-up expense. Construction will include leveling an existing concrete pad on which the trailer will sit, along with the associated electrical and telephone service for the trailer. The expense for preparing the site will be borne by the lessor of TIC's space at Gloster Creek Village. The site has been approved for the provision of PET services.

TIC was granted a Certificate of Need for the Acquisition of MRI Equipment and Provision of MRI services in 2002. TIC has been in operation since July, 2003. The applicant anticipates the obligation of the capital expenditure on this project within 60 to 90 days of CON approval. Services will begin as soon as the site for the mobile trailer is completed. TIC will provide mobile PET services at its facility two days per month for ten (10) hours each day. This schedule may be adjusted depending on the demand for service.

II. TYPE OF REVIEW REQUESTED

The Mississippi State Department of Health reviews applications for establishment of PET services in accordance with Section 41-7-191, subparagraph (1) (d)(xv) Mississippi Code 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 of 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 September 7, 2004.

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

A. State Health Plan (SHP)

The ***FY 2004 State Health Plan*** addresses policy statements, criteria and standards which an applicant is required to meet before receiving CON authority to provide PET Scanning services. The application submitted by TIC Regional Health Center is in substantial compliance with applicable policy statements and criteria and standards contained in the ***FY 2004 State Health Plan***.

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-5 Access to Supplies: Applicant states that it has access to all necessary radio-pharmaceuticals.

PS-6 Services and Medical Specialties Required: The applicant states that all the required services and specialties are available at TIC or will be provided.

PS-8 CON Approval: The applicant proposes to provide mobile PET services through the utilization of a mobile PET scanner unit. This equipment will provide services to a route that will also include other hospitals. TIC seeks approval to join an existing mobile route.

PS-13 Certification: TIC will utilize a mobile PET vendor for the provision of PET services. TIC is applying for a CON through the Mississippi State Department of Health to offer mobile PET scanner services. Insight has not designated which of its two machines will service the TIC location. However, both units are CON-approved under CONs #R-0494 and #R-0495.

SHP Criterion 1- Need

The Certificate of Need criteria and standards for the acquisition or otherwise control of a Positron Emission Tomography (PET) scanner and related equipment outlined in the ***FY 2004 Mississippi State Health Plan*** states that an entity desiring to acquire or to otherwise control the PET scanner must project a minimum of 750 clinical procedures per year, and must document a minimum population base of 300,000 per PET scanner unit.

TIC offers a wide range of diagnostic imaging services which would be complemented by the availability of a PET scanner. TIC is increasingly being asked by patients and their referring physicians to provide complete work-up and re-evaluation of patients with cancer. Addition of the mobile PET services will allow those patients already utilizing the services of TIC the convenience and cost efficiency of remaining at the same facility for all exams.

Currently, North Mississippi Medical Center is the only facility authorized for PET in the applicant's service area. TIC intends to join a mobile route operated by Insight which is already providing PET services in Mississippi. TIC states that there is a backlog for PET services at the only provider in the area.

Insight has two machines operating in Mississippi. The first unit goes to the Hattiesburg Clinic, Jeff Anderson Memorial Regional Medical Center (Meridian), Memorial Hospital at Gulfport, Singing River Hospital (Pascagoula), North Mississippi Medical Center (Tupelo), Thomas Hospital (Fairhope, Alabama), and Williamson Medical Center (Franklin, Tennessee). This unit performed 1,312 procedures from June 1, 2003, to May 31, 2004.

The second unit goes to Eliza Coffee Rehab (Florence, Alabama), Shoals Hospital (Shoals, Alabama), Gateway Health System (Clarksville, Tennessee), Williamson Medical Center (Franklin, Tennessee), Spartanburg General Hospital (Spartanburg, South Carolina), North Mississippi Medical Center (Tupelo), Memorial Hospital at Gulfport, Jeff Anderson Outpatient Services (Meridian), Hattiesburg Clinic, Greenwood-Leflore Medical Center, and South Central Regional medical Center (Laurel). This unit performed 1,015 procedures from June 1, 2003, to May 31, 2004.

SHP Criterion 2 - Registered Entity

TIC request approval to provide PET services at its facility through the utilization of a mobile PET scanner unit, which will be owned and operated by a mobile PET vendor. TIC affirms that Insight is a registered entity authorized to do business in the State of Mississippi.

SHP Criterion 4 - Assurances

The applicant affirms that PET services will be offered in a physical environment that conforms to federal standards, manufacturer's specifications, and licensing agencies' requirements.

SHP Criterion 5- Approval from Radiological Health

The applicant affirms that it will seek and receive the required approval before services begins.

SHP Criterion 6 - Availability of Equipment

TIC will have access to all necessary cyclotron-produced radio-pharmaceuticals from an off-site medical cyclotron and a radio-pharmaceutical production facility within a two hour air transport radius.

SHP Criterion 7- FDA Approval

TIC will utilize a mobile PET vendor for the provision of mobile PET scanning equipment. The vendor will utilize equipment certified for clinical use by the U. S. Food and Drug Administration.

SHP Criterion 8- Staffing Availability

TIC affirms that all nuclear medicine imaging physicians associated with TIC are licensed by the State for the handling of medical radio nuclides. TIC also states that C. Michael Currie, MD, is a board certified neuroradiologist qualified to supervise performance of and interpretation of PET scans. He, or a qualified associate, will be available during performance of PET exams performed at TIC. Dr. Currie has previously been involved in the design and construction of PET scanners. Dr. Currie's Curriculum Vitae is included in the application.

SHP Criterion 9- Medical Emergencies

The applicant states that it has on-site the necessary equipment to handle a medical emergency in the PET scanner. These include a crash cart with appropriate life saving medications and equipments as well as a Life-Pak 12 resuscitation system. These are available within a few moments notice. During performance of a PET scan, if a medical emergency arises, the technologist will immediately notify the nurse and supervising physician at TIC. If further medical care is needed, North Mississippi Medical Center is available through the use of their ambulance service less than 5 minutes away.

SHP Criterion 10- Referral System

The applicant affirms that referrals from local providers will be accepted and will be accommodated to the extent possible.

SHP Criterion 11- Established Protocols

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

SHP Criterion 12- Maintenance of PET Procedures

The applicant affirms that TIC will maintain current listings of appropriate PET procedures for use by referring physicians.

SHP Criterion 13 - Maintenance of Required Data

TIC affirms that the facility will record and maintain the information required by this criterion and shall make the data available to the Mississippi State Department of Health regarding the operation of the PET equipment. Also, the facility states it will record source of payment for procedures and the total amounts charged during the fiscal year.

SHP Criterion 14 - Contracts

The applicant included a copy of the contract in the application.

SHP Criterion 15- CON Exemption/Approval

TIC is applying for a CON through the Mississippi State Department of Health to offer mobile PET scanner services. Insight has not designated which of its two machines will service the TIC location. However, both units are CON-approved under CONs #R-0494 and #R-0495.

B. General Review (GR) Criteria

Chapter 8 of the *Mississippi Certificate of Need Review Manual 2000*, 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

TIC plans to be a full service diagnostic imaging facility. The applicant believes that the ability to offer PET services will further TIC's goal. TIC has patients who have to go elsewhere to have these services, or go without. TIC has seen increasing requests from its patients and referring physicians for PET services.

GR Criterion 3- Availability of Alternatives

TIC considered purchasing a PET scanner unit, however, this alternative was rejected. Leasing the services of a PET scanner already operating in Mississippi was considered to be a much more efficient use of available resources.

GR Criterion 4 - Economic Viability

Three year operating projections reflect a first year net income of \$45,553, a second year net income of \$100,353, and a third year net income of \$165,043.

GR Criterion 5 - Need for the Project

The applicant submits that TIC will provide service to and will not discriminate against those patients having low incomes, racial and ethnic minorities, women, handicapped persons and other under-served groups, and the elderly.

TIC offers a wide range of diagnostic imaging services which would be complemented by the availability of a PET scanner. TIC is increasingly being asked by patients and their referring physicians to provide complete work-up and re-evaluation of patients with cancer. Addition of the mobile PET services will allow those patients already utilizing the services of TIC the convenience and cost efficiency of remaining at the same facility for all exams.

Currently, North Mississippi Medical Center is the only facility authorized for PET in the applicant's service area. TIC intends to join a mobile route operated by Insight which is already providing PET services in Mississippi. Therefore, the need criterion is already met. TIC states that there is a backlog for PET services at the only provider in the area.

Insight has two machines operating in Mississippi. The first unit goes to the Hattiesburg Clinic, Jeff Anderson Memorial Regional Medical Center (Meridian), Memorial Hospital at Gulfport, Singing River Hospital (Pascagoula), North Mississippi Medical Center (Tupelo), Thomas Hospital (Fairhope, Alabama), and Williamson Medical Center (Franklin, Tennessee). This unit performed 1,312 procedures from June 1, 2003, to May 31, 2004.

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GR Criterion 6- Accessibility

The applicant submits that TIC will be accessible by Medicare, Medicaid and medically indigent patients, to the extent possible. TIC does not discriminate against and will provide access to the poor, physically handicapped, women, elderly, or members of racial and ethnic minorities.

GR Criterion 7- Information Requirement

TIC affirms that they will record and maintain the information required by this criterion and shall make the data available to the Mississippi State Department of Health within fifteen (15) business days of request.

GR Criterion 8 - Relationship to Existing Health Care System

This project should not have significant impact on the health care systems in General Hospital Service Area 1.

GR Criterion 9 - Availability of Resources

TIC affirms that it will provide the necessary radiologists to interpret the scans. All necessary radiology technicians will be provided under contract from Insight Health Corp. C. Michael Currie, MD, is a board certified neuroradiologist qualified to supervise performance of and interpretation of PET scans. Dr. Currie has previously been involved in the design and construction of PET scanners.

GR Criterion 10- Relationship to Ancillary or Support Services

The applicant anticipates that there will be no adverse effect on ancillary or support services.

GR Criterion 15 - Quality of Care

TIC provides high quality radiology services to the citizens of Tupelo and Lee County. The staff at TIC provides personal attention to each patient at TIC. The goal of TIC is to maintain radiology centered on the patient. TIC is licensed by the Mississippi State Department of Health and is certified to participate in the Medicare program.

IV. FINANCIAL FEASIBILITY

A. Capital Expenditure Summary

There will be no capital expenditure incurred as a result of this project.

B. Method of Financing

No debt is incurred as a result of this projected.

C. Effect on Operating Cost

The applicant projects total gross patient revenues of \$225,000, \$450,000, and \$675,000 the first, second, and third year of operation, respectively; expenses of \$84,947, \$160,647, and \$226,457 in year one, two, and three of operation, respectively; and a net income of \$45,553, the first year, \$100,353 the second year, and \$165,043 the third year.

The applicant provided the following operation statement for the first three years:

	YEAR 1	YEAR 2	YEAR 3
GROSS REVENUE	\$ 225,000.00	\$ 450,000.00	\$ 675,000.00
Charity/Indigent Care	\$ (4,500.00)	\$ (9,000.00)	\$ (13,500.00)
Contractual	\$ (83,250.00)	\$ (166,500.00)	\$ (249,750.00)
Bad Debt	\$ (6,750.00)	\$ (13,500.00)	\$ (20,250.00)
NET REVENUE	<u>\$ 130,500.00</u>	<u>\$ 261,000.00</u>	<u>\$ 391,500.00</u>
EXPENSES			
Salaries & Benefits	\$ 2,000.00	\$ 4,400.00	\$ 6,660.00
Supplies	\$ 24,750.00	\$ 49,500.00	\$ 74,250.00
Utilities (Admin. &	\$ 1,750.00	\$ 1,550.00	\$ 1,600.00
Incremental Increase	\$ 197.00	\$ 197.00	\$ 197.00
Lease Cost (Scanner)	\$ 56,250.00	\$ 105,000.00	\$ 143,750.00
TOTAL EXPENSES	<u>\$ 84,947.00</u>	<u>\$ 160,647.00</u>	<u>\$ 226,457.00</u>
NET INCOME	<u>\$ 45,553.00</u>	<u>\$ 100,353.00</u>	<u>\$ 165,043.00</u>
Number of Patients	75	150	225
Number of Procedures	75	150	225
Avg. # Procedures	1	1	1
Cost of Treatment	\$ 1,132.63	\$ 1,070.98	\$ 1,006.48
Charge for Treatment	\$ 3,000.00	\$ 3,000.00	\$ 3,000.00

D. Cost to Medicaid/Medicare

Based on the gross patient revenue projected in this project, the impact of the project on third party payers is as follows for the first year:

Cost to Medicaid/Medicare & Other Payers		
Payor Mix	Utilization Percentage	First Year Cost
Medicaid	8.0%	\$ 6,795.76
Medicare	28.0%	\$ 23,785.16
Blue Cross	16.0%	\$ 13,591.52
Other Payers	40.0%	\$ 33,978.80
Self Pay	8.0%	\$ 6,795.76
Total	100.0%	\$ 84,947.00

TIC projects the amount of bad debt (3%), medically indigent (1%), and charity care (1%) to be approximately 5% of the gross patient revenues.

V. RECOMMENDATION OF OTHER AFFECTED AGENCIES

The Division of Medicaid was provided a copy of this application for comment. The Division of Medicaid do not anticipate any increased cost to Medicaid for inpatient hospital services and that outpatient services will be paid as outlined in the State Plan. The Division of Medicaid does not oppose this application.

VI. CONCLUSION AND RECOMMENDATION

This project is in substantial compliance with the criteria and standards for the acquisition or otherwise control of a Positron Emission Tomography (PET) scanner and related equipment as contained in the *FY 2004 Mississippi State Health Plan*; Chapter 8 of the *Mississippi Certificate of Need Review Manual, 2000*; and all adopted rules, procedures, and plans of the Mississippi State Department of Health.

The Division of Health Planning and Resource Development recommends approval of this application submitted by The Imaging Center.