

**MISSISSIPPI STATE DEPARTMENT OF HEALTH  
DIVISION OF HEALTH PLANNING AND RESOURCE DEVELOPMENT  
NOVEMBER 2015**

**CON REVIEW C-NIS-0915-018  
JACKSON HEART CLINIC, PROFESSIONAL ASSOCIATION  
ACQUISITION OF CARDIAC-ONLY PET SCANNER AND  
OFFERING OF CARDIAC-ONLY PET SERVICES  
CAPITAL EXPENDITURE: \$257,992  
LOCATION: JACKSON, HINDS COUNTY, MISSISSIPPI**

**STAFF ANALYSIS**

**I. PROJECT SUMMARY**

**A. Applicant Information**

Jackson Heart Clinic, Professional Association, is a business corporation established in 1973 and is one of the largest cardiology groups in Mississippi, consisting of board-certified cardiologists. The entity has three officer/directors. A Certificate dated September 30, 2015, and signed by the Secretary of State indicates that Jackson Heart Clinic is in good standing with the State of Mississippi.

**B. Project Description**

Jackson Heart Clinic requests Certificate of Need ("CON") authority for the acquisition of a cardiac-only PET scanner and the offering of cardiac-only PET services at the Clinic's offices in the Dominican Plaza, located at 970 Lakeland Drive in Jackson. Jackson Heart Clinic proposes to enter into a lease agreement with CDL Nuclear Technologies, Inc. for the provision of a Cardiac PET System and Suite. The applicant states that there will be limited renovation work of approximately 640 square feet needed to install the Cardiac PET System.

The applicant asserts that through the offering of cardiac-only PET services, Jackson Heart Clinic will be able to greatly enhance the cardiology services it currently offers to its patients. The final objective for the project is to provide this beneficial clinical technology to the Clinic's patients in a convenient and cost-effective setting.

The applicant does not expect the project to require additional staffing.

The total proposed capital expenditure is \$257,992 which will be funded by cash reserves. The applicant states that the project will involve only minor renovation work of approximately 640 square feet needed to install the Cardiac PET System in the Clinic's offices on the 6<sup>th</sup> Floor of the Dominical Plaza.

The application contains a plot plan of the Dominic Plaza site, a schematic drawing of the PET Scanner Suite, and a cost estimate signed by Barlow Eddy Jenkins, P.A., architects. In addition, the MSDH Bureau of Health Facilities approved the site for the project on September 8, 2015.

The applicant expects to obligate the capital expenditure by January 4, 2016, and complete the project by March 1, 2016.

## II. TYPE OF REVIEW REQUIRED

This project is reviewed in accordance with Section 41-7-173, 41-7-191 (1)(d)(xv), and 41-7-193 of the 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 December 7, 2015.

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

### A. State Health Plan (SHP)

The *FY 2015 State Health Plan* contains policy statements, criteria and standards which the applicant is required to meet before receiving CON authority for the acquisition or otherwise control of a Positron Emission Tomography (PET) Scanner and related equipment, including Cardiac only PET scanner and the offering of fixed or mobile PET services including Cardiac Only PET services. This application is in substantial compliance with the applicable policy, criteria and standards stated in the *Plan as follows*:

#### **SHP Policy Statement 1 – CON Review Requirements**

Jackson Heart Clinic submits that it will enter into an operating lease for the cardiac PET equipment. Therefore, no capital expenditure is associated with the equipment.

#### **SHP Policy Statement 2 – Indigent/Charity Care**

Jackson Health Clinic affirmed that it will provide a reasonable amount of indigent/charity care.

**SHP Policy Statement 3 – Service Areas**

Jackson Heart Clinic is located in Jackson, Hinds County, which is in General Hospital Service Area (“GHSA”) 5.

**SHP Policy Statement 4 – Equipment to Population Ratio**

Not applicable.

**SHP Policy Statement 5 – Access to Supplies**

Jackson Heart Clinic states that it will have direct access to appropriate radio-pharmaceuticals through a contractual agreement with Bracco Imaging.

**SHP Policy Statement 6 – Services and Medical Specialties Required**

The applicant submits that the proposed project will function as a component of a comprehensive outpatient diagnostic service through a relationship with St. Dominic-Jackson Memorial Hospital, which has all of the required modalities available, in close proximity to Jackson Heart Clinic. The application contains a letter signed by St. Dominic affirming the arrangement.

**SHP Policy Statement 7 – Hours of Operation**

Jackson Heart Clinic’s PET services will be available during the Clinic’s regular office hours of 8:00 a.m. to 4:30 p.m. Monday through Thursday, and 8:00 a.m. to 3:00 p.m. on Friday.

**SHP Policy Statement 8 – CON Approval Preference**

The application does not propose a joint venture utilizing mobile or shared equipment.

**SHP Policy Statement 9 – CON Requirements**

Jackson Heart Clinic proposes a fixed PET scanner.

**SHP Policy Statement 10 – CON Exemption**

Not applicable.

**SHP Policy Statement 11 – Addition of a Health Care Facility**

Not applicable.

## **SHP Policy Statement 12 – Equipment Registration**

Jackson Heart Clinic affirmed that it will provide the Department of Health with the registration/serial number of the CON-approved PET scanner prior to commencing operations.

### ***Criteria and Standards for Acquisition or Otherwise Control of a PET Scanner including Cardiac only PET Scanner***

#### **SHP Criterion 1 - Need**

The 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.

The applicant submits that Jackson Heart Clinic is comprised of 13 cardiologists and 7 nurse practitioners with extensive training and experience in cardiology and the diagnosis and treatment of heart disease. The Clinic employs close to 100 personnel, including nurses, medical technicians and administration. The applicant states that the Clinic currently conducts more than 500 nuclear cardiac imaging tests on its patients each month and many of those patients would benefit from the superior imaging capabilities provided by a cardiac PET Scanner. Based on an in-depth review and analysis of the Clinic's patient base and the historical volume of nuclear cardiac imaging tests conducted, the applicant projects that it will perform 1,200 cardiac PET procedures during the first year of operation, 1,320 in Year 2 and 1,452 in Year 3. In addition, the application contains an affidavit of J. Clay Hays, Jr., M.D. verifying the number and methodology for the projections.

#### **SHP Criterion 2 – Registered Entity**

Jackson Heart Clinic is properly registered with the Mississippi Secretary of State and is in good standing, as evidenced by the Certificate of Good Standing contained in the application.

#### **SHP Criterion 3 – Performance of Existing Equipment**

Jackson Heart Clinic submits that there are currently no cardiac-only PET scanners in GHSA 5, wherein Jackson Heart Clinic is located.

#### **SHP Criterion 4 – Division of Radiological Health Approval**

The applicant affirmed that Jackson Heart Clinic will receive approval from the Division of Radiological Health for the proposed site, plans and equipment before cardiac PET services begin.

### **SHP Criterion 5– Assurances**

Jackson Heart Clinic affirmed that the required data regarding the cardiac PET equipment will be maintained and made available to the Mississippi State Department of Health upon request.

### **SHP Criterion 6 - Fixed/Minimum Volume Requirement**

The application contains a proposed equipment lease agreement. The applicant certified that the lease agreement will not contain a fixed or minimum volume requirement.

### **SHP Criterion 7 – CON Approval**

With this application, Jackson Heart Clinic has requested CON approval for the control of cardiac PET equipment and the offering of cardiac-only PET services.

### ***Criteria and Standards for the Offering of Fixed or Mobile PET Services, including Cardiac-Only PET Scanner***

#### **SHP Criterion 1 – Need**

In evaluating the need for a cardiac-only PET scanner, Jackson Heart Clinic determined that it will perform approximately 1,200 cardiac PET procedures during the first year of operation, 1,320 during the second year and 1,452 during third year.

#### **SHP Criterion 2 – Utilization of Unit by Other Providers**

The applicant requests a fixed cardiac-only PET unit. The unit will not be utilized by other providers.

#### **SHP Criterion 3 – Written Assurances**

Jackson Heart Clinic affirmed that the cardiac PET services will be offered in a physical environment that conforms to federal standards, manufacturer's specifications and licensing agencies' requirements, including the areas specified by this criterion.

#### **SHP Criterion 4 – Approval from Radiological Health**

Jackson Heart Clinic affirmed that it will receive approval from the Division of Radiological Health for the proposed site, plans and equipment before cardiac PET services begin.

### **SHP Criterion 5 – Access to Radionuclide Production/Radiopharmaceuticals**

The applicant certified that it will have access to a supply of cyclotron-produced radiopharmaceuticals within a two-hour air transport radius through an arrangement with Bracco Imaging.

### **SHP Criterion 6 – Qualified Staff**

Jackson Heart Clinic certified that it will have the necessary qualified staff available to operate the proposed cardiac PET scanner and that the staff will include all of the personnel described by this criterion with the required experience and qualifications.

### **SHP Criterion 7 – Management of Medical Emergencies**

The applicant states that Jackson Heart Clinic will maintain a transfer agreement with St. Dominic-Jackson Memorial Hospital for the emergency transfer of patients. The application contains a letter acknowledging such agreement.

### **SHP Criterion 8 – Acceptance of Referrals**

Jackson Heart Clinic affirmed that it will accept appropriate referrals for cardiac-only PET procedures from other local providers and that these patients will be accommodated, to the extent possible, by extending hours of service. Also, patients will be prioritized according to standards of need and appropriateness rather than source of referral.

### **SHP Criterion 9 – Protocols**

Jackson Heart Clinic affirmed that protocols will be established to assure that all clinical PET procedures performed are medically necessary and cannot be performed by other, less expensive, established modalities.

### **SHP Criterion 10 – Appropriate Procedures**

Jackson Heart Clinic affirmed that it will maintain current listings of appropriate PET procedures for use by referring physicians.

### **SHP Criterion 11 – Data Reporting**

The applicant affirmed that the required data regarding the cardiac PET service will be maintained and made available to the Mississippi State Department of Health upon request.

## **SHP Criterion 12 – CON Approval**

Jackson Heart Clinic has requested CON approval for the control of a fixed cardiac PET scanner, in addition to the offering of cardiac-only PET service by the submission of this application.

### **B. General Review (GR) Criteria**

Chapter 8 of the *Mississippi Certificate of Need Review Manual, Revised September 1, 2011*; addresses general criteria by which all CON applications are reviewed. This application is in substantial compliance with general review criteria contained in the manual.

#### **GR Criterion 1- Consistency with the *State Health Plan***

The project is in substantial compliance with applicable policy statements, criteria, and standards contained in the *FY 2015 Mississippi State Health Plan*.

#### **GR Criterion 2 – Long Range Plan**

The applicant states that the cardiologists of Jackson Heart Clinic evaluated the clinical benefits of offering cardiac PET service to its patients. They concluded that this service would enable the Clinic to offer its patients an important diagnostic tool in the detection and treatment of heart-related disease. Jackson Heart Clinic states that its long-range plan is to ensure the provision of state-of-the-art cardiovascular care to patients throughout the State of Mississippi and surrounding regions.

#### **GR Criterion 3 – Availability of Alternatives**

The applicant states that the only alternative to the proposed project is for Jackson Heart Clinic to continue to offer professional cardiology services to its patients without the clinical benefits of this technology.

The applicant states that the project will benefit the health care system by making cardiac-only PET services available for the first time in GHSA 5, in a convenient and accessible setting.

#### **GR Criterion 4 - Economic Viability**

The applicant asserts that its proposed charges for cardiac PET services compare favorably with the charges of other providers in the service area. Jackson Heart Clinic projects that it will perform 1,200 the first year, 1,320 the second year and 4,452 the third year of operation. In addition, it projects net income of \$859,700 the first year, \$968,900 the second year and \$1,088,967 the third year of operation. Therefore, the project appears to be economically viable.

### **GR Criterion 5 - Need for the Project**

a. **Access by Population Served:** The applicant asserts that the approval of this project will make cardiac-dedicated PET services available to the residents of the service area for the first time. These services will be accessible to low income persons, racial and ethnic minorities, and other underserved groups.

b. **Relocation of Services:** Not applicable.

c. **Current and Projected Utilization of Like Facilities**

The *State Health Plan* provides that cardiac-only PET services will be reviewed and considered in relation to other providers of cardiac-only PET services in the General Hospital Service Area of the proposed provider. The applicant submits that since there are no other providers of cardiac-only PET services in GHSA 5, this project will offer the residents of the area a diagnostic technology that is not currently available.

d. **Probable Effect on Existing/Similar Facilities**

It is not anticipated that this project will have an adverse impact on any other provider, including hospitals which currently offer PET services. The applicant states that it is requesting this service in order to provide its patients with a superior diagnostic test for detecting heart-related disease.

e. **Community Reaction:** The application contains 11 letters of support from cardiologists of Jackson Heart Clinic.

### **GR Criterion 6 - Access to the Facility or Service**

Jackson Heart Clinic affirmed that all residents of the health planning service area, hospital service area or patient service area, including Medicaid recipients, charity/medically indigent patients, racial and ethnic minorities, women, handicapped persons and the elderly have access to the services of the existing facility and will continue to have access. The applicant estimates that it provides approximately 2.4% indigent care.

### **GR Criterion 7 - Information Requirement**

Jackson Heart Clinic affirmed that it will record and maintain the information required by this criterion and make it available to the Mississippi State Department of Health within 15 business days of request.



### **GR Criterion 8 - Relationship to Existing Health Care System**

The applicant submits that cardiovascular disease is the leading cause of death in Mississippi, accounting for over a third of all deaths in the State. Jackson Heart Clinic believes that its PET services will complement existing health services in the service area by offering a unique service dedicated to heart patients. It will offer a convenient, alternative setting for heart patients who will benefit from this superior technology.

Jackson Heart Clinic has a transfer agreement with St. Dominic-Jackson Memorial Hospital.

The Department received no letters of opposition concerning the proposed project.

### **GR Criterion 9 - Availability of Resources**

The applicant asserts that the cardiologists, nurse practitioners and other staff of Jackson Heart Clinic are highly trained and skilled in all aspects of cardiology services, and are well-equipped to implement and operate the proposed project. The applicant does not anticipate the need for additional personnel.

### **GR Criterion 10 – Relationship to Ancillary or Support Services**

The applicant states that Jackson Heart Clinic's team includes cardiologists, nurse practitioners, and other clinical and support staff that will implement and operate the proposed project.

### **GR Criterion 14 - Construction Projects**

- a. **Cost Estimate:** The application contains a cost estimate prepared by a professional corporation, licensed to do business in Mississippi.
- b. **Schematic Drawing:** The application contains a schematic drawing of the proposed project.

### **GR Criterion 16 - Quality of Care**

Jackson Heart Clinic submits that it has demonstrated high quality of care since it was established in 1973. The applicant asserts that its cardiologists are among the most respected physicians in the State. Jackson Heart Clinic is certified for participation in the Medicare and Mississippi Medicaid programs.

**IV. FINANCIAL FEASIBILITY**

**A. Capital Expenditure Summary**

The total estimated capital expenditure is allocated as follows:

	Item	Cost (\$)	Percent (%) of Total
a.	Construction Cost -- New	\$0	0
b.	Construction Cost -- Renovation	238,771	*93.00
c.	Capital Improvements	0	0
d.	Total Fixed Equipment Cost	0	0
e.	Total Non-Fixed Equipment Cost	0	0
f.	Land Cost	0	0
g.	Site Preparation Cost	0	0
h.	Fees (Architectural, Consultant, etc.)	19,221	*7.00
i.	Contingency Reserve	0	0
j.	Capitalized Interest	0	0
j.	Legal and accounting fees	0	.0
k.	Other	0	0
	<b>Total Proposed Capital Expenditure</b>	<b>\$257,992</b>	<b>100.00</b>

\*Totals may not compute due to rounding.

The proposed project involves 640 square feet of renovated space at approximately \$403.11 per square foot (\$257,992/640). The *RS Means Building Construction Cost Data, 2015 Edition*, does not compare costs for renovation projects.

**B. Method of Financing**

The applicant proposes to finance the proposed capital expenditure with cash reserves. The application contains a letter from the Chief Executive Officer confirming that Jackson Heart Clinic has sufficient cash reserves to fund the project.

**C. Effect on Operating Cost**

The Hospital's three-year projected operating statement is presented at Attachment 1.

**D. Cost to Medicaid/Medicare**

The applicant projects the cost to third party payors as follows:

<b>Payor Mix</b>	<b>Utilization Percentage (%)</b>	<b>First Year Revenue (\$)</b>
<b>Medicare</b>	52	\$ 1,447,680
<b>Medicaid</b>	3	83,520
<b>Commercial</b>	39	1,085,760
<b>Self Pay</b>	3	83,520
<b>Charity Care</b>	3	83,520
<b>Other</b>	0	0
<b>Total</b>	<b>100</b>	<b>\$ 2,784,000</b>

**V. RECOMMENDATIONS OF OTHER AFFECTED AGENCIES**

The Division of Medicaid was provided a copy of this application for review and comment; however, the Division of Medicaid has not provided a comment on the proposed project as of the date of this staff analysis.

**VI. CONCLUSION AND RECOMMENDATION**

This project is in substantial compliance with the policy statements, criteria and standards for acquisition or otherwise control of cardiac-only PET equipment and provision of cardiac-only PET services contained in the *FY 2015 Mississippi State Health Plan*; the *Mississippi Certificate of Need Review Manual, 2011 Revision*; and duly adopted rules, procedures, and plans of the Mississippi State Department of Health.

The Division of Health Planning and Resource Development recommends approval of the application submitted by Jackson Heat Clinic for the acquisition of a Cardiac-Only PET Scanner and the Offering of Cardiac-Only PET Services.

**Attachment 1**

<b>Jackson Heart Clinic Three-Year Operating Statement (Project Only)</b>			
	Year 1	Year 2	Year 3
<b>Revenue</b>			
Patient Revenue:			
Inpatient	\$ 0	\$ 0	\$ 0
Outpatient	<u>2,784,000</u>	<u>3,062,400</u>	<u>3,368,640</u>
<b>Gross Patient Revenue</b>	<b>\$ 2,784,000</b>	<b>\$ 3,062,400</b>	<b>\$ 3,368,640</b>
Charity Care	83,520	91,872	101,059
Deductions from Revenue	<u>578,980</u>	<u>636,878</u>	<u>700,566</u>
<b>Net Patient Revenue</b>	<b>\$ 2,121,500</b>	<b>\$ 2,333,650</b>	<b>\$ 2,567,015</b>
Other Operating Revenue	0	0	0
<b>Total Operating Revenue</b>	<b>\$ 2,121,500</b>	<b>\$ 2,333,650</b>	<b>\$ 2,567,015</b>
<b>Expenses</b>			
Operating Expenses:			
Salaries	\$ 60,000	\$ 61,800	\$ 63,654
Benefits	15,000	15,450	15,914
Supplies	1,008,000	1,108,800	1,219,680
Services	0	0	0
Lease	178,800	178,800	178,800
Depreciation	0	0	0
Interest	0	0	0
Other	0	0	0
<b>Total Expenses</b>	<b>\$ 1,261,800</b>	<b>\$ 1,364,850</b>	<b>\$ 1,478,048</b>
<b>Net Income (Loss)</b>	<b>\$ 859,700</b>	<b>\$ 968,800</b>	<b>\$ 1,088,967</b>
<b>Assumptions</b>			
Inpatient days*	0	0	0
Outpatient days*	NA	NA	NA
Procedures	1,200	1,320	1,452
Charge/outpatient day	NA	NA	NA
Charge per inpatient day	NA	NA	NA
Charge per procedure	\$ 2,320	\$ 2,320	\$ 2,320
Cost per inpatient day	NA	NA	NA
Cost per outpatient day	NA	NA	NA
Cost per procedure	\$ 1,052	\$ 1,034	\$ 1,018