

**MISSISSIPPI STATE DEPARTMENT OF HEALTH
DIVISION OF HEALTH PLANNING AND RESOURCE DEVELOPMENT
NOVEMBER 2007**

**CON REVIEW: FSF-NIS-0807-018
DESOTO IMAGING & DIAGNOSTICS, LLC
ESTABLISHMENT AND PROVISION OF MOBILE POSITRON
EMISSION TOMOGRAPHY (PET) SERVICES
CAPITAL EXPENDITURE: \$-0-
LOCATION: SOUTHAVEN, DESOTO COUNTY, MISSISSIPPI**

STAFF ANALYSIS

I. PROJECT SUMMARY

A. Applicant Information

DeSoto Imaging and Diagnostics, LLC is a limited liability company established June 20, 2005. The application contains a copy of its certification of formation and a letter of good standing signed by the Mississippi Secretary of State.

DeSoto Imaging and Diagnostics, LLC currently offers digital subtraction angiography, magnetic resonance imaging (MRI), nuclear medicine, ultrasound, x-ray and fluoroscopy services.

DeSoto Imaging and Diagnostic, LLC's officers are Kevin Blackwell and Jason Morris, M.D.

B. Project Description

DeSoto Imaging and Diagnostics, LLC requests Certificate of Need (CON) authority to establish positron emission tomography (PET) services at its facility. DeSoto Imaging and Diagnostics, LLC will contract with Alliance Imaging, Incorporated, Alabaster, Alabama, to provide mobile PET services. DeSoto Imaging and Diagnostics plans to lease, from Alliance Imaging, a General Electric Discover ST PET/CT with 8 slice CT one day a week. The application contains a copy of the proposed services agreement between DeSoto Imaging and Diagnostics and Alliance Imaging for the proposed project.

According to the applicant, no construction will be involved because Alliance Imaging's mobile unit will utilize DeSoto Imaging's existing pad, electrical and telephone services that it currently uses for its mobile MRI services.

DeSoto Imaging indicates that no capital expenditure is associated with this project.

The MSDH Division of Health Facilities Licensure and Certification found the site acceptable for the stated use.

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 December 5, 2007.

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

A. State Health Plan (SHP)

The *FY 2007 State Health Plan* addresses policy statements and service specific criteria and standards which an applicant is required to meet before receiving CON authority to provide PET services. This application is in substantial compliance with applicable criteria and standards. This proposal is for the offering of mobile positron emission tomography 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-5 Access to Supplies: DeSoto Imaging, LLC states that it has established contracts with Cardinal Health and GE Amersham for necessary and appropriate radiopharmaceuticals.

PS-6 Services and Medical Specialties Required: DeSoto Imaging has the following medical specialties services:

- CT services with a 64-slice CT machine on site
- MRI services with a 1.5 tesla MRI unit on site
- Nuclear medicine services with a dual head nuclear medicine camera on site
- Conventional radiography services with a dual purpose x-ray/fluoroscopic radiography unit on site.

The applicant states that all the required services and specialties will be available

during operational hours through contractual services for the proposed project.

PS-8 CON Approval: The applicant proposes to provide mobile PET services through the utilization of a mobile PET scanner unit provided by Alliance Imaging, Inc. This equipment vendor is CON approved for PET equipment/services (CON #R-0503).

SHP Criterion 1a - 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 2007 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.

According to the *FY 2007 State Health Plan*, there are four (4) facilities authorized for positron emission tomography (PET) in the applicant's service area (General Hospital Service Area 2). As reported in the *Plan*, the four locations performed a total of 298 procedures in 2005. There currently exists only one provider in DeSoto County, Baptist Memorial Hospital-DeSoto. The facility offers PET services one day a week through a mobile provider.

The proposed mobile PET services will be shared between DeSoto Imaging and other health care providers on Alliance Imaging's mobile PET services route. The PET system is owned and operated by Alliance Imaging, Incorporated. The applicant proposes to lease, from Alliance Imaging, a General Electric Discover ST PET/CT with 8-slice CT mobile unit at its facility.

The applicant states that the proposed route that DeSoto Imaging will join consists of five facilities: Wesley Medical Center, Hattiesburg; Memorial Hospital at Gulfport; Ocean Springs Hospital, Ocean Springs; Natchez Regional Medical Center, Natchez; and Baptist Memorial Hospital-DeSoto. The referenced facilities performed 1,061 procedures from January-July 2007 by Alliance Imaging. According to the applicant, annualized the route will perform 1,812 procedures excluding the procedures proposed by the DeSoto Imaging Diagnostics, LLC.

The applicant makes the following projections of PET procedures to be performed during the first three years of operation:

Projected PET Procedures

Year 1	Year 2	Year 3
234	312	390

SHP Criterion 1b – Minimum Population of 300,000 Per PET Unit: The minimum population base of 300,000 has been met, because the PET vendor, Alliance Imaging, Incorporated, is approved for mobile PET services in Mississippi CON (#R-0503).

SHP Criterion 2 – Registered Entity

DeSoto Imaging & Diagnostics, LLC requests approval to provide PET services at its facility through the utilization of a mobile PET scanner unit, which will be owned and operated by Alliance Imaging, Inc. DeSoto Imaging affirms that the referenced vendor is a registered vendor authorized to do business in the state of Mississippi.

SHP Criterion 4 - Assurance

DeSoto Imaging asserts that it will comply with this criterion through the establishment of quality control policies and procedures, obtaining appropriate radiation protection and shielding and monitoring of radioactive emissions to the environment.

SHP Criterion 5 – Approval from Radiological Health

DeSoto Imaging & Diagnostics, LLC affirms that it will obtain all necessary approvals from the Division of Radiological Health for the proposed site, plans, and equipment before service begins.

SHP Criterion 6 – Availability of Equipment

The applicant asserts that DeSoto Imaging and/or Alliance Imaging will have access to all necessary cyclotron-produced radiopharmaceuticals from an off-site medical cyclotron and a radiopharmaceutical production facility within a two-hour air transport radius.

SHP Criterion 7 - FDA Approval

DeSoto Imaging & Diagnostics, LLC is proposing to join a mobile PET route operated by Alliance Imaging, which is already providing approved PET services in Mississippi, and is approved by the U.S. Food and Drug Administration.

SHP Criterion 8 – Staffing Availability

DeSoto Imaging & Diagnostics, LLC affirms that all nuclear medicine imaging physicians associated with DeSoto Imaging are licensed by the State for the handling of medical radionuclides. DeSoto Imaging states that Jason Morris, MD, is a board certified radiologist qualified to supervise performance of and interpretation of PET examinations performed at DeSoto Imaging & Diagnostics, LLC. According

to the applicant, Jason Morris, MD, will be available during performance of PET procedures performed at DeSoto Imaging. Dr. Morris has an extensive history of overseeing and interpreting PET examinations. He owns an imaging center in Lake Village, Arkansas, and has performed and interpreted thousands of PET exams over the last four years. Dr. Jason Morris's Curriculum Vitae is included in the application.

SHP Criterion 9 – Medical Emergencies

According to the applicant, DeSoto Imaging has on-site the necessary equipment to handle a medical emergency. The PET unit includes a crash-cart with the appropriate medications and equipment as well as a defibrillator. Dr. Morris is ACLS certified as are the registered nurses, with all the technologists CPR certified. In the unlikely event a medical emergency arises, the PET technologist will immediately notify DeSoto Imaging personnel and the supervising physician who will then oversee the emergency. If further medical care is needed, DeSoto Imaging will call 911 to have the patient transported to the nearest hospital (Baptist Memorial Hospital-DeSoto).

SHP Criterion 10 – Referral System

DeSoto Imaging & Diagnostics, LLC asserts that it will accept appropriate referrals from local providers and will accommodate these referred patients to every extent possible by extending the hours of service and by prioritizing patients according to standards of need and appropriateness rather than source of referral.

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 states they will maintain current listings of appropriate PET procedures for use by referring physicians.

SHP Criterion 13 – Maintenance of Required Data

DeSoto Imaging & Diagnostics, LLC affirms that it will record and maintain all of 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.

SHP Criterion 14 – Contracts

DeSoto Imaging & Diagnostics, LLC provided a copy of the contractual service agreement for the proposed project.

SHP Criterion 15 – CON Exemption/Approval

DeSoto Imaging & Diagnostics, LLC is requesting CON authority through the Mississippi State Department of Health to offer mobile PET scanner services. DeSoto Imaging proposes to contract with Alliance Imaging, Incorporated for PET service. Alliance Imaging has CON approval to control mobile PET scanner equipment. The CON number is R-0503 (acquisition and establishment of PET scanner equipment/services).

B. General Review (GR) Criteria

Chapter 8 of the *Mississippi Certificate of Need Review Manual*, revised November 2006, addresses general criteria by which all CON applications are reviewed. This application is in substantial compliance with general review criteria.

GR Criterion 1 – State Health Plan

This application is in substantial compliance with all the criteria and standards for the establishment and provision of positron emission tomography, as contained in the *Plan*.

GR Criterion 2 - Long Range Plan

According to the applicant, the long-range plan of DeSoto Imaging is to provide a full continuum of high quality, convenient, accessible, and affordable radiological health services to the residents within the community. The proposed service is consistent within this plan, as it will provide increased access to patients in need of quality care and treatment for PET procedures.

GR Criterion 3 - Availability of Alternatives

According to the applicant, DeSoto Imaging considered only two alternatives: to apply for authority to provide PET services, or not to apply for CON authority. DeSoto Imaging considered not applying for authority to provide PET services. However, this option was in conflict with DeSoto Imaging's mission statement and long-range plan of offering a full continuum of high quality, convenient, accessible, and affordable radiological health services to the residents within its service area.

GR Criterion 4 - Economic Viability

Based on the applicant's three-year projections, this project will realize a net income of \$15,909; \$73,386; and \$130,864 for the first, second, and third year of operation, respectively.

- a. **Proposed Charge:** The applicant projects charges of \$3,160 per PET procedure for the first three years of operation for the proposed project. The applicant projects costs of \$1,019 per PET procedure for the first year; \$852 for the second year; and \$751 for the third year of operation.
- b. **Projected Levels of Utilization:** DeSoto Imaging & Diagnostics, LLC makes the following projections of PET procedures to be performed during the first three years of operation: 234, 312, and 390, respectively.
- c. **Project's Financial Feasibility Study:** There is no capital expenditure for this project; therefore, a feasibility study is not required since the capital expenditure does not exceed \$2,000,000.

GR Criterion 5 - Need for the Project

- a. **Access by Population Served:** The applicant asserts that the growth in DeSoto County continues at a rapid pace, and the proposed offering of PET services in the area will allow the community to have an additional choice as to where they receive healthcare services and serve Mississippi patients that currently seek care in Tennessee.
- b. **Relocation of Services:** This application is for the establishment and provision of mobile positron emission tomography services through a contractual agreement with Alliance Imaging, Incorporated, of Alabaster, Alabama an existing provider of PET services.
- c. **Probable Effect on Existing Facilities in the Area:** The applicant asserts that DeSoto Imaging does not anticipate any adverse impact on BMH-DeSoto or to any other PET provider in the service area. DeSoto believes that the proposed project will allow the community to have an additional choice as to where they receive their healthcare services and provide Mississippi patients an alternative to seeking care in Tennessee.
- d. **Community Reaction:** The application contains seven (7) affidavits from area physicians, which shows the number of PET referrals (53) per month, and numerous letters of support from the City of Southaven, businesses, and area residents.

The Department received a letter of opposition from Baptist Memorial Hospital-DeSoto, Inc., Southaven concerning the proposed project.

GR Criterion 6 - Access to the Facility or Service

According to the applicant, all residents of General Hospital Service Area 2 and the state 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 estimated gross patient revenues of health care provided to charity/medically indigent patients for years one and two for the proposed project:

Projected Year	Total Dollar Amount of Gross Patient Revenue
1	\$22,183 (3%)
2	\$29,578 (3%)

According to the applicant, DeSoto Imaging is a new health care provider having been open for eight (8) months as of the application. DeSoto Imaging & Diagnostics, LLC provided 3.4 percent of gross patient revenue to charity/medically indigent patients from January through August 2007.

GR Criterion 7 - Information Requirement

The applicant states 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

DeSoto Imaging, LCC is located in General Hospital Service Area 2. According to the **FY 2007 State Health Plan**, in 2005, GHSA 2 had a total of four mobile PET provider locations, with a total 298 PET procedures. The applicant believes that the project will not have an adverse effect on the existing health care system.

As previously mentioned, the Department received a letter of opposition from Baptist Memorial Hospital-DeSoto, Inc., Southaven concerning the proposed project.

Staff concludes that this project should have no adverse affect on existing providers in GHSA 2.

GR Criterion 9 - Availability of Resources

The applicant states that Alliance Imaging will provide the appropriate trained PET technologists. With Dr. Morris's experience in PET services and DeSoto Imaging's consultation and medical specialty backup services, DeSoto Imaging has appropriate medical staff to provide PET services. In the event an additional radiologist is needed DeSoto Imaging would do a nationwide search for an appropriately credentialed physician.

GR Criterion 16 - Quality of Care

DeSoto Imaging & Diagnostics, LLC is an established vendor of diagnostic services and will be a new provider of PET services. The applicant asserts that DeSoto Imaging & Diagnostics, LLC offers its patients convenience, a comfortable “warm” environment, and affordable quality care. All the equipment at DeSoto Imaging is “state-of-the-art”. Although less than a year old, DeSoto Imaging & Diagnostics, LLC has started its application process to be accredited by the American College of Radiology (ACR).

IV. FINANCIAL FEASIBILITY

A. Capital Expenditure Summary

The applicant indicates that no capital expenditure is associated with this project.

B. Method of Financing

This project requires no financing.

C. Effect on Operating Cost

DeSoto Imaging & Diagnostics, LLC projects the following expenses, revenues, and utilization for the first three years of operation:

DeSoto Imaging & Diagnostics, LLC Three-Year Operating Statement			
	Year 1	Year 2	Year 3
Revenue			
Patient Revenue:			
Inpatient	-0-	-0-	-0-
Outpatient	739,439	985,920	1,232,400
Total Gross Patient Revenue	<u>\$739,439</u>	<u>\$ 985,920</u>	<u>\$ 1,232,400</u>
Charity Care	(\$22,183)	(\$29,578)	(\$36,972)
Deductions	(462,927)	(617,236)	(771,544)
Total Deductions	<u>(\$485,110)</u>	<u>(\$646,814)</u>	<u>(\$808,516)</u>
Net Patient Revenue	<u>\$254,329</u>	<u>\$339,106</u>	<u>\$423,884</u>
Other Operating Revenue	-0-	-0-	-0-
Total Operating Revenue	<u>\$254,329</u>	<u>\$339,106</u>	<u>\$423,884</u>
Expenses			
Salaries	7,800	7,800	7,800
Supplies	81,900	109,200	136,500
Lease	145,600	145,600	145,600
Other	3,120	3,120	3,120
Total Expenses	<u>\$238,420</u>	<u>\$265,720</u>	<u>293,020</u>
Net Income (Loss)	<u>\$15,909</u>	<u>\$73,386</u>	<u>\$130,864</u>
Utilization			
Inpatient Day	-0-	-0-	-0-
Outpatient Day	-0-	-0-	-0-
Procedures	234	312	390
Charge Per Procedure	\$3,160	\$3,160	\$3,160
Cost Per Procedure	\$1,019	\$852	\$751
Charge Per Outpatient Day	-0-	-0-	-0-
Charge Per Inpatient Day	-0-	-0-	-0-
Cost Per Outpatient Day	-0-	-0-	-0-
Cost Per Inpatient Day	-0-	-0-	-0-

D. Cost to Medicaid/Medicare

Patient Mix by Type Payer	Utilization Percentage	First Year Expenses
Medicaid	-0-	\$ -0-
Medicare	32	76,294
Other	68	<u>162,126</u>

Total	<u>100</u>	<u>\$ 238,420</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 writing.

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 2007 State Health Plan**; the **Certificate of Need Review Manual**, revised November 2006; 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 the application submitted by DeSoto Imaging & Diagnostics, LLC for the establishment and provision of mobile positron emission tomography services.