

**DIVISION OF HEALTH PLANNING AND RESOURCE DEVELOPMENT
NOVEMBER 2005**

CON Review: FS-NIS-0905-039

DeSoto Imaging & Diagnostics, L.L.C.

**Acquisition and Provision of Digital Subtraction Angiography Equipment/Services-
Southaven**

Location: Southaven, DeSoto County, Mississippi

Capital Expenditure: \$ 0

STAFF ANALYSIS

I. PROJECT SUMMARY

A. Applicant Information

DeSoto imaging and Diagnostics, L.L.C. is a limited liability company established for the purpose of providing out-patient diagnostic imaging services. The application contains a copy of its certification of formation and a letter of good standing signed by the Mississippi Secretary of State.

B. Project Description

DeSoto Imaging & Diagnostics, L.L.C. seeks Certificate of Need authority to lease an AXIOM Artis FA digital subtraction angiography (DSA) machine and to offer digital subtraction angiography services. The AXIOM FA is a universal floor-mounted angiographic single-plan C-arm system for digital subtraction acquisition for vascular and non-vascular diagnostics and interventions.

The applicant proposes to offer outpatient DSA services five days a week in Southaven, DeSoto County, Mississippi, through the above described fluoroscopic angiographic equipment. This project will not involve a capital expenditure.

II. TYPE OF REVIEW REQUIRED

The Mississippi Department of Health will review applications for a Certificate of Need for the acquisition or otherwise control of digital subtraction angiography equipment/services and associated cost under applicable statutory requirements of Section 41-7-173, and 41-7-193, Mississippi Code of 1972, as amended. The project is also reviewed under Section 41-7-191, paragraph (1)(d)(vii) Mississippi Code of 1972, annotated as amended.

In accordance with Section 41-7-197 (2) of the Mississippi Code of 1972 Annotated, as amended, any 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, 2005.

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

A. State Health Plan (SHP)

The *FY 2006 State Health Plan* addresses policy statements and specific criteria and standards which an applicant is required to meet before receiving CON authority to provide DSA services. This application is not in substantial compliance with applicable criteria and standards.

SHP Criterion 1 – Need

The *State Health Plan* states that the applicant for DSA services shall demonstrate that proper protocols for screening, consultation, and medical specialty backup are in place before services are rendered by personnel other than those with specialized training. Specifically, the protocols shall include, but are not limited to, having prior arrangements for consultation/backup from:

- 1) a cardiologist/cardiothoracic surgeon for procedures involving the heart;
- 2) a neurologist/neurosurgeon for procedures involving the brain; and
- 3) a vascular surgeon for interventional peripheral vascular procedures.

The applicant states that proper protocols described in the *State Health Plan* will be in place before outpatient DSA services are rendered by personnel other than those with specialized training and offered two letters from physicians agreeing to provide consultation and back-up services as evidence. However, these letters did not include the specialty or area of expertise of the physicians offering backup consultation. They only offered “consultation/backup for procedures involving heart/brain.” Prior arrangement for a vascular surgeon for interventional peripheral vascular procedures is lacking.

The applicant further states that DSA services will be provided only to outpatients who have been screened for problems which would increase the chance of needing the help of these consultants. Procedures will only be performed on those patients where risk of adverse effects is relatively low. A list of procedures which the applicant proposes to perform and protocols the applicant will follow are contained in the application.

SHP Criterion 2 – Certificate of Need Approval of Equipment

The applicant is requesting Certificate of Need authority to lease an AXIOM Artis FA digital subtraction angiography machine through this application.

B. General Review (GR) Criteria

Chapter 8 of the *Mississippi Certificate of Need Review Manual, May 13, 2000*, (as amended) addresses general criteria by which all CON applications are reviewed. The applicable criteria are as follows:

GR Criterion 1 – Consistency with the State Health Plan

The *FY 2006 State Health Plan* requires an applicant for DSA services to demonstrate that prior arrangements for consultation/backup for certain medical specialist will be in place before DSA services are provided. The applicant did not fully demonstrate the support of a vascular surgeon. Therefore, the application is not in substantial compliance with the SHP.

GR Criterion 2 – Long Range Plan

The applicant's long range plan is to provide high quality, accessible, affordable health care to the residents of GHSA 2. The proposed service is consistent with this plan as it will provide increased access to patients in need of quality care and treatment, according to the applicant

GR Criterion 3 – Availability of Alternatives

DeSoto Imaging & Diagnostics, L.L.C. considered not applying for authority to provide DSA services. This option was in conflict with their long-range plan of offering high quality, accessible, and affordable healthcare to the residents in GHSA 2.

GR Criterion 4 – Economic Viability

a. Proposed Charges

DeSoto Imaging and Diagnostics, L.L.C. proposes that during the first year of operation, a cost of \$821 will be incurred. The applicant projects a charge of \$2,238 per DSA procedure. This project is economically viable based upon the applicant's income projection of \$60,718, \$169,547, and \$291,357 during the first, second, and third years of operation, respectively.

b. Projected Level of Utilization

DeSoto Imaging and Diagnostics, L.L.C. estimates that it will perform 813 procedures in the first year, 1,125 procedures in the second year, and 1,313 procedures in the third year. This equates to: 3.25 procedures per day in year one, 4.5 procedures per day in year two, and 5.25 procedures per day in year three. The applicant did not demonstrate the need methodology used to determine the number of patients nor did the applicant demonstrate the origin of these patients.

GR Criterion 5- Need for the Project

The applicant stated that the population growth of DeSoto County continues at a rapid pace with more than seven families moving into the county each day.

Slightly more than half of the population growth in the entire eight-county Memphis metropolitan area between 2000 and 2004 occurred in DeSoto County, according to the U.S. Census Bureau. This continuing growth has made Southaven Mississippi's seventh largest city and Olive Branch the ninth. According to the applicant, experts contend the continuing growth will push Southaven to the fifth largest city in just a few years.

According to the applicant, Baptist Memorial Hospital-DeSoto (BMH-DeSoto), which has only one DSA lab, is in the process of adding an additional 140 beds to its facility. The new bed tower is not scheduled for completion until at least November 2006. BMH-Desoto's current lab is fully used and in many cases the hospital must delay tests for its patients. Inpatients and outpatients are both treated at the hospital. The backlog causes unnecessary delays in patients receiving treatments. In addition, the hospital will not be immediately expanding interventional radiology services. This action will further contribute to additional delays in patient treatment and potentially increase adverse outcome, according to the applicant. The applicant does not anticipate any adverse impact on BMH-De-Soto or any other DSA provider in the service area.

A representative of BMH-DeSoto stated that the DSA service at the hospital is operating at only 62 percent of capacity and the approval of an additional DSA provider in the area would transfer procedures away from the existing provider. Approval of the application would increase duplication in GHSA 2 to performance of this service.

GR Criterion 6 -- Access to the Facility or Service

a. Medically Underserved Populations

The applicant states that it will respond to the needs of the medically underserved.

b. Providing Uncompensated Care

The applicant intends to comply with all federal and state laws including, but not limited to, Section 504 and the Americans with Disabilities Act.

c. Services to Medicare, Medicaid, and Medically Indigent Patients

The applicant states that it will serve Medicare and medically indigent patients. However, due to the Division of Medicaid's current policy not to reimburse independent diagnostic facilities for procedures performed on Medicaid-primary patients, DeSoto Imaging and Diagnostics, L.L.C. will not participate in the Medicaid program.

The applicant contends that their inability to serve Medicaid-primary patients will in essence deny Medicaid patient access to the proposed facility.

d. Range of Means

The applicant does not believe its proposed DSA services will have an adverse impact on other existing providers.

GR Criterion 7 – Information Requirement

The applicant affirms that all information required by this criterion will be recorded, maintained, and reported to the Mississippi Department of Health within 15 business days of request.

GR Criterion 8 – Relationship to Existing Health Care System

According to the applicant, the proposed project will enhance and strengthen the existing health care system by providing DSA services to all citizens seeking such services.

General Hospital Service Area 2 Digital Subtraction Angiography Procedures FY 2004	
Hospital (GHSA 2)	DSA Procedures Reported
Bolivar Medical Center	135
Northwest MS Regional Medical Center.	188
Baptist Memorial Hospital–DeSoto, Inc.	0*
Greenwood Leflore Hospital	2,568
Delta Regional Medical Center	25

Source: Annual Survey of Hospitals and Application for Renewal of License for Calendar Year 2004.

***NOTE:** Even though BMH-DeSoto County has reported the capacity to perform DSA for several years, no DSA procedures have ever been reported by the facility. However, a representative of the hospital stated that DSA services are performed in a Special Procedures Laboratory at BMH-DeSoto. The laboratory can perform 20 DSA procedures per day and during calendar year 2004, a total of 3,275 DSA procedures were performed at the Special Procedures Laboratory.

GR Criterion 9 – Availability of Resources

The application contained letters from several local physicians, two of which offered consultation/backup for procedures involving heart/brain procedures. According to the applicant, other support personnel will be employed locally. The applicant expects an increase of \$195,000 for the annual cost of three additional personnel.

GR Criterion 10 – Relationship to Ancillary Services

The applicant expects that this project will have no adverse effect on ancillary or support services, but that the project will strengthen and complement the availability of existing health care services to residents of the service area.

GR Criterion 12 – Access by Health Professional Schools

The applicant states that it will offer its proposed services for health professional training programs.

GR Criterion 14 – Construction Projects

This project will not involve construction.

GR Criterion 16 – Quality of Care

According to the applicant, the proposed services will be provided by a group of highly skilled and qualified physicians specially trained for these services. The applicant intends to assure that each recipient of DSA services receives the highest quality of care. However, the staff could not determine from the application whether the qualifications and areas of expertise required by *FY 2006 State Health Plan* were available to the applicant for back-up or consultation.

IV. FINANCIAL FEASIBILITY

A. Capital Expenditure Summary

This project does not involve a capital expenditure.

B. Method of Financing

This project does not involve a capital expenditure. Operating funds of DeSoto Imaging and Diagnostics, L.L.C. will be used to lease the DSA equipment.

C. Effect on Operating Cost

The applicant's projections of expenses, utilization, and results from operation for the first three years following completion of the project are included in Attachment 1.

D. Cost to Medicaid/Medicare

A breakdown of the applicant's revenue by payor type is as follows:

DeSoto Imaging & Diagnostics, L.L.C. Offering of Digital Subtraction Angiography Services		
Patient Mix by Payor Type	Utilization Percentage	First Year Cost
Medicare	43	\$ 782,382
Medicaid	0	0
Other Payors	57	\$ 1,037,112
Total	100	\$ 1,819,494

V. RECOMMENDATIONS OF OTHER AFFECTED AGENCIES

The Division of Medicaid was provided a copy of this application for review and comments. The Division takes no position on this project.

VI. CONCLUSIONS AND RECOMMENDATION

This project is not in substantial compliance with the criteria and standards for the establishment of DSA services as contained in the *FY 2006 State Health Plan*; the *Certificate of Need Review Manual*, revised 2000; as amended, and all adopted rules, procedures, and plans of the Mississippi Department of Health.

The application does not comply with State Health Plan and General Criteria for the acquisition and otherwise control of DSA equipment and services. Specifically, the applicant did not provide evidence of having prior arrangements for consultation/backup from:

- a. a cardiologist/cardiothoracic surgeon for procedures involving the heart;
- b. a neurologist/neurosurgeon for procedures involving the brain; and
- c. a vascular surgeon for interventional peripheral vascular procedures.

Also, the existing providers of DSA services will likely be adversely impacted due to low utilization of existing equipment and services.

The Division of Health Planning and Resource Development recommends disapproval of the application submitted by DeSoto Imaging & Diagnostics, L.L.C. for the lease of an AXIOM Artis FA, a universal floor-mounted angiographic single-plan C-arm system for digital subtraction acquisition for vascular and non-vascular diagnostics and interventions, and the offering of digital subtraction angiography services in Southaven, DeSoto County, Mississippi.

Attachment I

**DeSoto Imaging & Diagnostics, L.L.C.
Three Year Projected Operating Statement
Offering of Digital Subtraction Angiography Services**

Revenue	First Year	Second Year	Third Year
Gross Patient Revenue	\$ 1,819,494	\$ 2,517,750	\$ 2,938,494
Deduction From Gross Patient Revenues			
Third Party Contractual Adjustments	(1,037,111)	(1,435,117)	(1,674,941)
Provisions for Bad Debts/Charity Care	(54,585)	(75,533)	(88,155)
Total Deductions	<u>\$1,091,696</u>	<u>\$ 1,510,650</u>	<u>\$1,763,096</u>
Net Patient Revenue	\$ 727,798	\$ 1,007,100	\$1,175,398
Expense			
Salaries	\$ 195,000	\$ 265,850	\$ 273,826
Utilities	18,000	18,000	18,000
Procedure Supplies	130,080	185,625	223,210
Equipment Lease	198,000	198,000	198,000
Equipment Maintenance	0	43,178	43,178
Facility Rent	96,000	96,000	96,000
Miscellaneous Supplies	<u>30,000</u>	<u>30,900</u>	<u>31,827</u>
Total Expense	<u>\$ 667,080</u>	<u>\$ 837,553</u>	<u>\$ 884,041</u>
Net Income (Loss)	<u>\$ 60,718</u>	<u>\$ 169,547</u>	<u>\$ 291,357</u>
Assumptions			
Number of Patients	813	1,125	1,313
Treatments (Procedures) Per Patient	1	1	1
Average Number of Treatments (Procedures)	813	1,125	1,313
Cost/Treatment (Procedure)	\$ 821	\$ 745	\$ 673
Charge/Treatment (Procedure)	\$ 2,238	\$ 2,238	\$ 2,238