

**Mississippi State Department of Health
Division of Health Planning and Resource Development
November 2008**

**CON Review FSF-NIS-0808-024
Advanced Medical Imaging of Greenville, LLC
Establishment and Provision of MRI Services in
Washington County
Capital Expenditure: \$0
Location: Greenville, Washington County, Mississippi**

STAFF ANALYSIS

I. PROJECT SUMMARY

A. Applicant Information

Advanced Medical Imaging of Greenville, Inc. is a Mississippi Limited Liability Company whose registered agent is David S. Roundsavali. The entity, domiciled in Greenville, Mississippi, has two managing members – A. Harvey Tackett, CFO, and John L. Herzog, President.

B. Project Description

Advanced Medical Imaging (Advanced) requests Certificate of Need (CON) authority to establish fixed base MRI services at a full-service, free-standing diagnostic imaging center to be located in Greenville, Mississippi. The center will be located in space to be leased in a yet to be constructed building. The MRI services will be provided six days a week, on a 1-5T unit, during normal business hours and after hours as needed. According to the applicant, no construction, renovation, or capital expenditure will be needed to institute the provision of these services. The equipment will be procured through a reputable vendor and will be financed through a lease agreement.

The applicant's final objectives for the proposed project are to increase the availability, accessibility, and continuity of healthcare services in Washington County, Mississippi, through the offering of MRI services, along with a full complement of diagnostic imaging modalities. The applicant believes that the provision of these services in Greenville will enable more Mississippians to receive a full continuum of care without leaving the state or the service area and will reduce wait times, inconvenience, and expense of travel that is often required for Washington County residents in need of MRI services.

Advanced asserts that the equipment is proposed to be installed within six to nine months after approval of CON. The application contained a proposed agreement with Toshiba which the applicant states is contingent upon receiving final approval of the requested CON. Should circumstances change significantly during the pendency of the lease, Advance states it will consider other, similarly situated vendors in order to secure the best piece of equipment at the lowest possible cost.

The applicant projects 1.1 FTE personnel will be required for the services as an annual cost of 66,189 the first year.

The MSDH Division of Health Facilities Licensure and Certification has approved the site for the services.

II. TYPE OF REVIEW REQUIRED

Projects which propose the establishment of MRI services are reviewed in accordance with Section 41-7-191, subparagraph (1)(d)(xii) 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 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 4, 2008.

In addition, this project is reviewed under the FY 2007 State Health Plan in effect on August 8, 2008, when this application was received. The 2009 State Health Plan has an effective date of August 11, 2008.

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

A. State Health Plan (SHP)

The *FY 2007 State Health Plan* contains criteria and standards which an applicant is required to meet before receiving Certificate of Need (CON) authority for the acquisition or otherwise control of MRI equipment and for the offering of MRI services. This application is in substantial compliance with applicable criteria and standards.

Criteria and Standards for the Acquisition or Otherwise Control of MRI Equipment

SHP Criterion 1- Need

The entity desiring to acquire or otherwise control MRI equipment must document that the equipment shall perform a minimum of 1,700 procedures per year using the procedures estimation methodology presented in the 2007 Plan. The 2007 Plan provides, however, that: "Applicants for non-hospital based MRI facilities may submit affidavits from referring physicians in lieu of the estimation methodology required for hospital-based facilities. MRI procedures projected in affidavits shall be based on actual MRI procedures referred during the year."

The applicant asserts that there are at least four separate bases of need supporting this application:

1. There is an objective need for additional service in the service area, as evidenced by local physicians' assessments.
2. There is a definite need for non-hospital based service in Greenville, Washington County, and General Hospital Service Area (GHSA) 2 (the only MRI services at present in Washington, Leflore, Bolivar, Coahoma, Quitman, Sunflower counties are exclusively in hospital settings. The ONLY freestanding MRI services available in all of GHSA 2 are in Southaven and Olive Branch, in DeSoto County, well outside the reasonable travel distance for residents of Washington County).
3. Mississippi residents are currently being forced to wait for service in a hospital setting or to leave the state (in favor of Arkansas) to receive service.
4. Area physicians' practices are growing, as is the level of need for MRI service in the area.

The application contained 24 affidavits signed by physicians indicating that they will collectively refer 4,000 MRI procedures per year. The applicant submits that these affidavits contain commitments from physicians in a variety of specialty practice areas (including family medicine, cardiology, general practice, internal medicine, urology, nephrology, and general surgery), totaling at least 2,875 procedures in each of the first three years of operation. According to the applicant, these procedures, which more than satisfy the need requirement set forth in the *2007 State Health Plan*, are based on the supporting physicians' historical referral patterns and the growth those physicians anticipate in their practices over the coming three years.

Advanced plans to install a 1.5 Tesla open-bore fixed based MRI unit, which applicant states will provide higher power than many of the units in the Service Area and will make available additional types of scans and reports on all body types due to the open construction of the unit. According to Advanced, it will be able to provide a complete continuum of imaging services to patients.

SHP Criterion 2 – Assurances

Advanced certified that the Toshiba 1.5 Tesla open-bore MRI unit is FDA approved; that only qualified personnel will be allowed to operate the equipment; and that if the equipment is to be rented, leased, or otherwise used by other qualified providers on a contractual basis, no fixed/minimum volume contracts will be permitted.

In addition, the application contained a proposed contract for the lease of the equipment with Toshiba.

SHP Criterion 3 – Information Recording/Maintenance

Advanced provided written assurance that, if the CON is granted, it will record and maintain all information required in parts a through d of this criterion. In addition, Advanced certified that it will comply with and respond to all requirements imposed by the department regarding provision of information and will do so within 15 business days of request.

SHP Criterion 4 – Authorized Entity

The applicant provided documentation that Advanced Medical Imaging, Inc. is authorized to do business with the state of Mississippi.

SHP Criterion 5 – Authorization to Provide MRI

The applicant seeks authorization to provide MRI equipment and services by this application.

CON Criteria and Standards for the Offering of MRI Services

SHP Criterion 1 – Need

As stated above, the applicant submitted affidavits signed by physicians attesting that they will collectively refer over 4,000 MRI procedures by the third year of operation.

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

Projected MRI Procedures		
Year 1	Year 2	Year 3
1,512	1,764	2,016

*According to the applicant, increased utilization and expansion of the medical staff will result in an increase of MRI referrals in the second and third years.

According to the FY 2007 *State Health Plan*, there were 10 MRI service sites in GHSA 2 in FY 2005, operating 9.8 FTE MRI units. Updated information indicates that there were 13 MRI service sites in FY 2007, operating 11.45 FTE MRI units. These units performed 22,382 MRI procedures in FY 2007 for an average of 1,955 procedures per FTE MRI unit. Attachment 1 shows the MRI sites in GHSA 2, both fixed and mobile, and full time equivalents (FTEs).

SHP Criterion 2 - Documentation of Diagnostic Imaging Modalities

Advanced certified that a full range of diagnostic imaging modalities for verification and complementary studies will be available at the time MRI services begin, including, but not limited to, computed tomography (CT), ultrasound, and conventional radiology.

SHP Criterion 3 - Accessibility

Advanced certified that neither the facility nor medical personnel affiliated with Advanced will have policies or procedures which would exclude patients because of race, color, age, sex, ethnicity, or ability to pay.

SHP Criterion 4 - Staffing

The applicant affirmed that it will employ a director who is a full-time, board eligible radiologist or nuclear medicine imaging physician, or other board eligible licensed physician whose primary responsibility during the prior three years has been in the acquisition and interpretation of clinical images. According to the applicant, the director will have knowledge of MRI through training, experience, or documented post-graduate education and will document at least one week of full-time training with a functional MRI facility.

Advanced further certified that it will employ a full-time MRI technologist-radiographer or a person who has had equivalent education, training, and experience, who shall be on-site at all times during operating hours. This individual will be required to be experienced in computed tomography or other cross-sectional imaging methods, or have the equivalent training in MRI spectroscopy.

SHP Criterion 5 - Research Staffing

The applicant affirmed that Advanced will not use MRI equipment for experimental procedures but that it will comply with this criterion should that intent change in the future.

SHP Criterion 6- Data Requirement

The applicant affirmed that it 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 MRI equipment. Also, the applicant states they will record source of payment for procedures and the total amounts charged during the fiscal year.

SHP Criterion-7- CON Approval

Advanced is seeking CON approval for both the acquisition of MRI equipment and the provision of MRI services.

B. General Review (GR) Criteria

Chapter 8 of the *Mississippi Certificate of Need Review Manual, 2008 revision*, 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

The application was reviewed for compliance with the FY 2007 State Health Plan as discussed above.

GR Criterion 2 - Long Range Plan

According to the applicant, Advanced's long range plan is to provide high quality, accessible, affordable, state of the art imaging and diagnostic services to residents of Greenville, Washington County, and neighboring communities.

GR Criterion 3- Availability of Alternatives

The applicant states that it considered two alternatives to the project - simply not pursuing the project and applying for inclusion on a mobile MRI route two or three days per week.

Advanced did not choose either of these options as neither was in the best interest of patients. The applicant states that once Advanced began to seek physician involvement in the project, it became apparent that the need for service in Greenville and Washington County is greater than would adequately be served by a mobile service one, two, or three days per week.

The applicant states that by electing to provide MRI services through a fixed base unit, Advanced will be able to make MRI services available up to seven days a week, if needed. In addition, the scan times and quality of reads are superior in a fixed based unit to almost any mobile unit, and it is Advanced's intent to provide the highest possible quality of service to the patients who will utilize the MRI. According to the applicant, the access to high quality MRI services in Greenville will allow Mississippians who are currently traveling to Arkansas and otherwise out of the service area, or who are waiting in order to receive basic diagnostic services in a hospital setting to receive those services closer to home and in a setting that is more accessible and will have no wait times to receive needed tests.

GR Criterion 4 - Economic Viability

Based on the applicant's three year projected operating statement, this project will be economically viable. The three-year projected operating statement contained in the application indicates net income of \$278,601 the first year, \$234,701 the second year, and \$385,218 the third year of operation.

The applicant states that the cost for an MRI scan will be \$360 per scan and the charge to patients will be \$1,030 per scan the first year. The applicant's proposed costs and charges are reasonable, compared to similar providers.

The applicant's projected level of utilization is in line with similar facilities in the service area. The applicant's projected volume of utilization for the MRI for the first year is 1,512 procedures, 1,764 the second year, and 2,016 the third year of operation.

GR Criterion 5 - Need for the Project

According to the applicant, there is a need for additional MRI service in Washington County and GHSA 2. The applicant believes that this CON will enable residents of GHSA 2 to receive needed imaging services in their proximate geographic area without the waits imposed in the hospital setting.

The application contains approximately 26 letters and affidavits from physicians, community leaders and agencies, local businesses, and consumers.

GR Criterion 6- Access to the Facility

The applicant affirms that all residents of the health planning service area, hospital service area, and patient service area, 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.

GR Criterion 7- Information Requirement

Advanced states that it will record and maintain the information stated in this criterion regarding charity care, care to the medically indigent, and Medicaid populations 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

Advanced is located in General Hospital Service Area 2 (GHSA 2). According to updated information, GHSA 2 had a total of 13 MRI sites (mobile and fixed) in FY

2007, utilizing approximately 11.45 FTE units. These sites and units performed a total of 22,382 MRI procedures in 2007.

The applicant submits that MRI services are currently provided via fixed based unit at Delta Regional Medical Center, also located in Greenville, Mississippi. Advanced proposes to offer similar services 24 hours a day, 7 days a week, on a 1.5 T open-bore fixed based unit. Advanced services will be offered in a freestanding building so that patients will be able to park, walk in, get their scan, and leave. The applicant believes that this will enable the hospital to focus on its inpatients without being forced to juggle schedules to fit in outpatient procedures throughout the day every day.

The applicant does not expect this project to have an adverse impact on other providers of MRI services as there are no other freestanding MRI providers anywhere in GHSA 2 except DeSoto County.

GR Criterion 9 - Availability of Resources

The applicant states that it already has a medical director. Other personnel will be recruited in a manner that will not adversely impact existing area service providers, according to the applicant.

Advanced believes that the proposed project will enhance the availability of ancillary services in the specified geographic area, as there currently is a shortage of imaging services and complete lack of availability of freestanding outpatient services for MRI or any diagnostic imaging needs in Greenville, Washington County, and all of GHSA 2 except the northernmost region (DeSoto County).

GR Criterion 11- Health Professional Training Programs

Advanced states that it will offer the proposed services for health professional training programs.

GR Criterion 16 - Quality of Care

Advanced submits that the project will be serviced by highly skilled and qualified radiologists, specially trained to provide MRI services. The applicant states that it intends to assure increased access to the highest quality of MRI services for all residents of Greenville, Washington County, and the service area.

IV. FINANCIAL FEASIBILITY

A. Capital Expenditure Summary

There is no capital expenditure associated with this project. The applicant proposes to acquire the MRI equipment through an operating lease.

B. Method of Financing

This project does not require financing since there is no capital expenditure.

C. Effect on Operating Costs

Advanced's three-year projected operating statement is provided in Attachment 2.

D. Cost to Medicaid/Medicare

The applicant's projection to third party payors is as follows:

Payor	Utilization Percentage	First Year Revenue
Medicaid	30%	\$ 467,217
Medicare	30%	467,217
Other	40%	<u>622,956</u>
Total	100%	\$1,557,390

V. RECOMMENDATION OF OTHER AFFECTED AGENCIES

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

VI. CONCLUSION AND RECOMMENDATION

This project is in substantial compliance with the criteria and standards for the acquisition or otherwise control of MRI equipment and offering of MRI services as contained in the *FY 2007 Mississippi State Health Plan*, Chapter 8 of the *Mississippi Certificate of Need Review Manual, 2008 revision*; 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 Advanced Medical Imaging of Greenville, LLC.

Attachment 1
 General Hospital Service Area 2
 Location and Number of MRI Procedures

Facility	Location	Type/No. of Equip.	Number of Procedures FY 2005	Number of Procedures FY 2006	*Number of Procedures 2007	Days Operated 2007	FTE Unit 2007
Baptist Memorial-DeSoto	Southaven	F(3)	5,268	6,144	7,128	M-Sun (336 Hrs)	3.00
Bolivar Medical Center	Cleveland	F(1), M(1)	1,719	968	339	M-F(40 hrs)	2.00
Carvel Imaging Center.	Olive Branch	F	3,326	3,392	1,039	M-F (72.5 Hrs)	1.00
Carvel Imaging Center	Southaven	F	CON	402	2,395	M-F(52.5 Hrs)	1.00
Delta Regional Medical Center	Greenville	F	2,576	3,121	2,599	M-F(40hrs)	1.00
DeSoto Imaging Specialists	Southaven	M	CON	0	1,012	TWF(28.5 Hrs)	.71
Greenwood Leflore Hospital	Greenwood	F	3,555	3,872	4,345	M-F(40 Hrs)	1.00
Northwest MS Regional Medical Ctr.	Clarksdale	M	1,781	1,986	1,938	M-F(40 hrs)	1.00
P&LC-N. Sunflower Medical Ctr	Ruleville	M	-	CON	113	Tu. (3 Hrs)	.08
P&LC-Quitman County Hospital	Marks	M	-	CON	29	Th. (3 Hrs)	.08
S. Sunflower County Hospital	Indianola	M	367	452	610	W (9 Hrs)	.23
Tyler Holmes Memorial Hospital	Winona	M	54	260	326	W (4 Hrs)	.10
University Hospital & Clinics	Lexington	M	340	538	509	M (10 Hrs)	.25
Totals			17,825	21,135	22,382		11.45

Source: FY 2007 State Health Plan, Applications for Renewal of Hospital License for Calendar Years 2005 and 2006, and Fiscal Years 2005 and 2006 Annual Hospital Reports MRI survey conducted for calendar years 2006 and 2007.

F – Fixed Unit
 M -Mobile MRI unit
 FTE – Full Time Equivalent Units

Note: FTEs are calculated for mobile units only. If a unit is at one site for 5 days or more or 40 hours or more it is counted at 1 FTE unit. All fixed units are counted as one unit regardless of the number of hours in operation.

ATTACHMENT 2

**Advanced Medical Imaging of Greenville, LLC
 Three-Year Operating Statement**

	Year 1	Year 2	Year 3
Revenue			
Inpatient Care Revenue			
Outpatient Care Revenue	\$1,557,300	\$1,880,549	\$2,224,400
Gross Patient Care Revenue	\$1,557,300	\$1,880,549	\$2,224,400
Charity	\$ 155,739	\$ 188,055	\$ 222,422
Deductions from Revenue	579,350	699,564	827,484
Net Patient Care Revenue	\$ 822,221	\$ 992,930	\$1,174,494
Total Operating Revenue	\$ 822,221	\$ 992,930	\$1,174,494
Operating Expenses			
Salaries	\$ 52,000	\$ 107,640	\$ 111,407
Benefits	10,920	22,604	23,396
Supplies	45,360	54,772	64,788
Services	84,804	84,949	95,412
Lease Expense	323,400	455,400	455,400
Depreciation			
Interest			
Other	27,216	32,863	38,873
Total Operating Expense	\$ 543,700	\$ 758,228	\$ 789,276
Net Operating Income	\$ 278,511	\$ 234,702	\$ 385,218
Assumptions			
Number of Scans	1,512	1,764	2,016
Charge per Scan	\$ 1,030	\$ 1,066	\$ 1,103
Cost per Scan	\$ 360	\$ 430	\$ 392