DIVISION OF HEALTH PLANNING AND RESOURCE DEVELOPMENT NOVEMBER 2005

CON REVIEW: FS-NIS-0505-015

MEDICAL IMAGING, LLC D/B/A MEDICAL IMAGING AT BARNES CROSSING

ACQUISITION OF MAGNETIC RESONANCE IMAGING (MRI)

EQUIPMENT AND OFFERING OF MRI SERVICES

CAPITAL EXPENDITURE: \$1,500,000 LOCATION: TUPELO, MISSISSIPPI

STAFF ANALYSIS

I. PROJECT SUMMARY

A. Applicant Information

Medical Imaging, LLC d/b/a Medical Imaging at Barnes Crossing (formerly Barnes Crossing Imaging, Inc.) is a private, for profit, professional, limited liability company authorized to do business in the state of Mississippi. The limited liability company was formed September 16, 2004. Medical Imaging, LLC has two owners: North Mississippi Joint Ventures, Inc., a subsidiary of North Mississippi Health Services owning 51 percent, and Premier Imaging, LLC, a private radiology practice owning 49 percent.

Medical Imaging, LLC recently opened two imaging centers in Tupelo, Mississippi. The first center, Medical Imaging on Crossover Road, currently offers MRI services. The second imaging center, Medical Imaging at Barnes Crossing, was constructed and owned by Medical Imaging, LLC.

The applicant indicates that Barnes Crossing Imaging, Inc. and Barnes Crossing, LLC are now known as Medical Imaging, LLC. The ownership has not changed, just the name.

Medical Imaging, LLC consists of the following corporate officers:

Gerald Wages, President Bruce Toppin, Secretary Marshall Edmondson, M.D., Treasurer

The registered office of Medical Imaging, LLC is located at:

201 South Spring Street Seventh Floor P.O. Box 1220 Tupelo, Mississippi 38804

Medical Imaging, LLC d/b/a Medical Imaging at Barnes Crossing is an 11,000 square foot facility located at 891 Mississippi Drive, Tupelo, Mississippi. The facility offers a broad scope of imaging services as an outpatient imaging center. Those services include, but are not limited to, the following: computed tomography (CT) scan, mammography, ultrasound, and traditional x-ray. The proposed project will expand services to include MRI services at the center.

B. Project Description

Medical Imaging, LLC requests Certificate of Need (CON) authority for the acquisition or otherwise control of magnetic resonance imaging (MRI) equipment and offering of MRI services at Medical Imaging at Barnes Crossing. Medical Imaging proposes to purchase a

GE "Excite HD" 1.5T Signa MRI system to offer the MRI services at Medical Imaging at Barnes Crossing. No construction or renovation will be needed to institute the MRI services.

Medical Imaging, LLC at Barnes Crossing's site, which will house the proposed MRI unit/services, has been approved by the MDH Division of Health Facilities Licensure and Certification.

According to Medical Imaging, LLC, the capital obligation, acquisition of the MRI system and offering of MRI services should be completed within 90 days of CON approval.

II. TYPE OF REVIEW REQUIRED

Projects which propose the acquisition or otherwise control of MRI equipment and offering of magnetic resonance imaging services are reviewed in accordance with Section 41-7-191, subparagraphs (1) (d)(xii), and (f) of the Mississippi Code of 1972, Annotated, as amended, and duly adopted rules, procedures, plans, criteria and standards of the Mississippi 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, 2005.

III. CONFORMANCE WITH THE <u>STATE HEALTH PLAN</u> AND OTHER ADOPTED CRITERIA AND STANDARDS

A. <u>State Health Plan (SHP)</u>

The FY 2005 State Health Plan (in effect at the time of submission of this application) addresses policy statements and specific criteria and standards which an applicant is required to meet before receiving CON authority to acquire or otherwise control MRI equipment and to offer MRI services. This application is not in compliance with the FY 2005 State Health Plan.

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

SHP Criterion 1 - Need

An entity desiring to acquire or otherwise control MRI equipment, or offer MRI services, must document that the equipment shall perform a minimum of 1,700 procedures per year by the second year of operation, utilizing the procedures estimation methodology contained in the **State Health Plan**.

Because the procedures estimation methodology was intended for use by hospitals and not clinics, however, the MDH allows freestanding applicants to use an alternative method to project the annual patient service volume for the facility. Medical Imaging, LLC at Barnes Crossing based the need for the proposed project on historical and projected MRI referrals of Medical Imaging, LLC's medical staff, and North Mississippi Medical Center's procedure estimation methodology for projecting MRI volume for the proposed project. As a result, 12.5 percent of North Mississippi Medical Center's outpatient MRI procedures will be shifted to the new imaging site. Medical Imaging asserts that the new imaging site would experience a three percent growth in the total number of procedures currently provided by North Mississippi Medical Center. The applicant projects 1,887 MRI procedures the first year.

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Based on NMMC's current total number of MRI procedures (16,136) for FY 2004, staff calculates that 2,017 of NMMC's outpatient MRI procedures will be shifted to Medical Imaging at Barnes Crossing.

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

Table 1
Projected MRI Procedures

Year 1	Year 2	Year 3
1,887	1,981	2,080

According to **the FY 2006 State Health Plan**, there were 19 providers of MRI services operating 25 units in General Hospital Service Area 1. As reported in the **Plan**, the 25 units performed a total of 43,369 procedures in 2003 for an average of 1,735 procedures per unit. In 2004, the 25 units performed a total of 46,382 procedures, or an average of 1,855 procedures per unit, according to the **Plan** (see table 2).

The **FY 2005 State Health Plan** indicates that the optimum utilization of a single MRI unit is between 2,000 and 2,500 procedures per year, or perhaps even higher when extended hours and additional days of operation are factored into a given MRI service. The 1,700 procedure threshold applies only to the acquisition of a new MRI unit and its projected performance of this volume of procedures by the end of the second year of operation. For FY 2004, eleven of the 25 MRI units did not meet the 1,700 procedure threshold. Need for additional MRI units or MRI providers in a given area would be indicated perhaps when all existing MRI units were operating at maximum capacity or procedure threshold. Such is not the case in General Hospital Service Area 1 (See Table 2).

Table 2

Location and Number of MRI

Procedures in General Hospital Service Area 1

Facility	Location	Type/No. of Equipment	No. of Procedures 2003	No. of Procedures 2004
Baptist Mem. Hosp.	Booneville	M	566	756
Baptist Mem. Hosp. – Golden Triangle	Columbus	F(2)	4,804	4,507
Baptist Mem. Hosp. – North Mississippi	Oxford	F(2)	4,400	3,676
Baptist Mem. Hosp. – Union County	New Albany	F	2,069	2,251
Clay County Med. Ctr.	West Point	M	666	678
Gilmore Mem. Hosp.	Amory	М	1,295	1,461
Grenada Lake Reg. Med. Ctr.	Grenada	М	1,828	2,502
Health South Radiology Clinic	Columbus	F	1,135	1,928
luka Hospital	Tishomingo	М	653	820
Magnolia Regional Health Center	Corinth	F(2)	4,238	4,216
Medical Imaging and Diagnostics, LLC	Tupelo	F	2,633	3,751
North Ms. Med. Ctr.	Tupelo	F(4)	16,622	16,136
Oktibbeha Co. Hosp.	Starkville	М	1,368	1,525
Preferred Imaging, LLC	Batesville	M	680	723
Trace Regional Hosp.	Chickasaw	M	136	243
Tri Lakes Med. Ctr.	Batesville	M	0	650
Yalobusha General Hospital	Water Valley	М	276	463
SMI – Winston Medical Center	Louisville	М	0	CON
SMI – North Oak Regional Hospital*	Senatobia	М	0	96
Total		25	43,369	46,382
Average			1,735	1,855

Source: **FY 2006 State Health Plan**, Applications for Renewal of Hospital License for Calendar Years 2004 and 2005, and Fiscal Years 2003 and 2004 Annual Hospital Reports.

Table 3, gives updated information, and the total number of operational/CON approved MRI units in GHSA 1 during FY 2003, 2004:

Table 3
MRI Units and Procedures for GHSA 1

# of Units	FY 2003	FY 2004	FY 2005	Approved CON
			Updated	
Fixed	13	13	2	
Mobile	12	11	1	
Total Operational	25	24	0	
CON Approved		1*	3*	1,700 (Each)
Total operational &	25	25	28	28
CON Approved				
Total Procedures	43,369	46,382	46,382	51,482
Average # of Procedures	1,735	1,855	1,657	1,839

According to updated information, there are three additional CON approved/non-operational MRI units/services in General Hospital Service Area 1 (Webster Health Services, Eupora, (mobile unit) Mississippi State University and Premeir Radiology, P.A., (fixed unit) and North Mississippi Sports Medicine & Orthopaedic Clinic, Tupelo (fixed unit). Should the number of procedures remain the same for FY 2005, the 24 operating units, and four CON approved/non-operational units, could be expected to perform approximately 1,839 procedures on an average per unit.

SHP Criterion 2 - Assurance

Medical Imaging, LLC submitted a preliminary proposal from GE Healthcare which provides detailed information on the proposed 1.5T Signa Excite HD MRI system. The applicant indicates that the proposed MRI unit is FDA approved.

According to the applicant, Robert Becker, M.D., is serving as medical director of MRI services at Medical Imaging at Barnes Crossing. Medical Imaging, LLC asserts that 1.4 technologists will be added to Medical Imaging at Barnes Crossing as a result of the proposed project.

SHP Criterion 3 – Information Recording/Maintenance

The applicant confirms the data listed in this criterion will be kept and made available to the MDH upon request.

SHP Criterion 4 – Authorized Entity

Medical Imaging, LLC was formed with the Secretary of State on September 16, 2004 as a Mississippi limited liability company authorized to do business in Mississippi.

SHP Criterion 5 – Authorization to Provide MRI

Medical Imaging, LLC is requesting Certificate of Need approval for the acquisition of magnetic resonance imaging equipment and offering of MRI services in General Hospital Service Area 1.

Criteria and Standards for the Offering of MRI Services

SHP Criterion 1 - Need

Medical Imaging, LLC at Barnes Crossing projects to perform 1,877 procedures the first year of operation, 1,981 the second year, and 2,080 the third year. These projections meet and exceed the minimum requirement of 1,700 procedures per year. However, based on the existing number of MRI units and utilization data in General Hospital Service Area 1 for the past two years, staff contends that an additional MRI unit in GHSA 1 cannot be viable without impacting a market already saturated with MRI units.

SHP Criterion 2 - Documentation of Diagnostic Imaging Modalities

Medical Imaging at Barnes Crossing asserts that the facility will provide CT, ultrasound, mammography and conventional radiology in addition to MRI at the Barnes Crossing site.

The applicant provided a copy of a letter from North Mississippi Medical Center advising that angiography services will be available at North Mississippi Medical Center for Medical Imaging at Barnes Crossing patient referrals. Angiography services, along with all other North Mississippi Medical Center's clinical services, are made available to all patients primarily through physician referrals.

SHP Criterion 3 - Accessibility

Medical Imaging, LLC d/b/a Medical Imaging at Barnes Crossing, confirms that it will meet the conditions required of this criterion. The applicant asserts that neither the facility nor its participating medical personnel shall have policies or procedures which would exclude patients because of race, color, age, sex, ethnicity, or ability to pay.

SHP Criterion 4 – Staffing

According to the applicant, Dr. Robert Becker, radiologist will serve as medical director of MRI services at Medical Imaging at Barnes Crossing. The applicant projects 1.4 MRI technologist will be added at Medical Imaging at Barnes Crossing. The applicant indicates that the required staff is fully trained and qualified to meet the requirements of this criterion.

SHP Criterion 5 – Research Staffing

According to the applicant, the requested MRI equipment will not be used for experimental procedures.

SHP Criterion 6 - Data Requirement

The applicant confirms that it will record and maintain the requested information and make it available to the Mississippi Department of Health.

SHP Criterion 7 - CON Approval

The applicant is requesting CON approval to acquire an MRI system and to offer MRI services.

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 - State Health Plan

This project was reviewed under the **FY 2005 State Health Plan** (in effect at the time of submission of this application). Staff contends that the project is not in substantial compliance with the projection of need as stated in the **Plan**.

GR Criterion 2 - Long Range Plan

According to the applicant, the long range plan of Medical Imaging at Barnes crossing is to provide affordable, state-of-the-art treatment for all patients.

GR Criterion 3 - Availability of Alternatives

According to the applicant, two alternatives to the proposed MRI services were considered and rejected for the following reasons shown below:

- Do not provide MRI services at the Medical Imaging at Barnes Crossing site (The applicant contends that this would result in patient inconvenience and delayed diagnosis.)
- Contract for a mobile MRI (The applicant contends that this would result in poor imaging quality, slower thru-put.)

GR Criterion 4 - Economic Viability

The applicant projects net income of \$1,105,553 the first year, \$1,184,169 the second year, and \$1,267,065 the third year of operation. See effect on operation cost, page 10. Given that GHSA 1 has 28 operational/CON approved MRI units, staff questions whether the applicant can meet the projections without encroaching on the ability of existing providers to provide these services.

Staff is concerned that if the project does not produce the required 1,700 MRI procedures per year, the project will not be economic viable.

GR Criterion 5 - Need for Services

The applicant asserts that MRI imaging offers perhaps the most useful information available for MRI patients. Care and treatment of patients at Medical Imaging, LLC d/b/a Medical Imaging at Barnes Crossing is non-discriminating.

According to the applicant, if the project is not approved, the MRI unit/services will not be available to many referring physicians. The service will be further delayed in making rapid and accurate diagnosis of their patients. The applicant projects that the project will have a five percent annual growth in MRI volume.

The applicant submits that implementing the proposed project will enable area residents to receive MRI services in a timely and accurate manner. The proposed project will greatly

enhance the ability of local physicians to effectively and efficiently care for their patients.

The application includes 26 letters of support and comments for the proposed project.

As previously noted, the optimum utilization of a single MRI unit has been identified by the **Plan** as being between 2,000 and 2,500 procedures per unit. The average for all units in GHSA 1 is not within this optimum range, and not all units in the service area are producing the required 1,700 MRI procedures per year. For FY 2003 and FY 2004, utilization of 11 of the 25 MRI units (fixed and mobile) in GHSA 1 performed less MRI procedures than required in the **Plan**. (See table 2).

Staff contends that General Hospital Services 1 currently has adequate MRI facilities to meet the needs of MRI patients in that services area.

GR Criterion 6 - Access to the Facility or Service

Medical Imaging LLC states that it serves all of the population, including: low income, racial and ethnic minorities, women, and handicapped persons. Medical Imaging asserts that it provides health care services to any individual referred to it in need of such services regardless of age, creed, sex, or race. The facility will provide a reasonable level of charity care, absorb bad debt, and accept governmental payments.

The applicant asserts that charity care offered by Medical Imaging, LLC will be 3 percent.

GR Criterion 7 - Information Requirement

Medical Imaging, LLC will record and maintain the requested information stated in the above criterion regarding charity care, care to the medically indigent and Medicaid populations.

GR Criterion 8 - Relationship to Existing Health Care System

As previously mentioned, there are 25 existing and three CON approved/non-operational MRI units in General Hospital Service Area 1. The 25 existing units performed an average of 1,855 MRI procedures per unit during FY 2004. However, 11 units in the service area did not perform at the minimum 1,700 procedure threshold (See table 2).

Given the number of units currently in the service area, staff believes that, if approved, this project will create unnecessary duplication of health services in GHSA 1.

The Imaging Center at Gloster Creek Village, Tupelo, Mississippi submitted a letter of opposition concerning the proposed project.

GR Criterion 9 - Availability of Resources

The applicant states that current training programs in place at North Mississippi Medical Center and area community colleges appear to adequately generate qualified personnel to meet the demand. Medical Imaging LLC d/b/a Medical Imaging at Barnes Crossing projects 1.4 full-time equivalent (FTE) staff to accommodate the new MRI service. The projected annual cost of the FTE staff is \$78,750.

GR Criterion 16 - Quality of Care

The applicant, Medical Imaging, LLC d/b/a Medical Imaging at Barnes Crossing, currently offers MRI services at another location (Medical Imaging on Crossover Road, Tupelo, Mississippi) in GHSA 1. The proposed project is for the acquisition of an MRI system and to offer MRI services at Medical Imaging at Barnes Crossing.

The applicant submits that it has consistently provided the highest level of medical services.

IV. FINANCIAL FEASIBILITY

A. <u>Capital Expenditure Summary</u>

The proposed cost of the MRI system (non-fixed equipment) is \$1,500,000.

B. Method of Financing

The applicant proposes to finance the project with a commercial bank loan in the amount of \$5,004,850 over a term of 5 years, at an interest rate of 5.44 percent. The application included a letter from Renasant Bank, Tupelo, Mississippi, indicating equipment financing and an operating line of credit for Medical Imaging, LLC.

C. <u>Effect on Operating Cost</u>

The applicant projects the following expenses, utilization, and results from operation for the first three years following completion of the project:

Three Year Projected Operating Statement

Expenses	Year 1	Year 2	Year 3
Supply Costs	\$ 25,666	\$ 26,693	\$ 27,760
Billing Costs	\$ 35,123	\$ 36,879	\$ 38,722
Total Variable Costs	\$ 60,789	\$ 63,572	\$ 66,482
Depreciation & Interest	\$ 318,000	\$ 318,000	\$ 318,000
Equipment Service	\$ 135,000	\$ 135,000	\$ 135,000
Staffing -Technical	\$ 78,750	\$ 81,900	\$ 85,176
Total Fixed Costs	\$ 531,750	\$ 534,900	\$ 538,176
Total Direct Costs	<u>\$ 592,539</u>	<u>\$ 598,472</u>	<u>\$ 604,658</u>

Annual Net Revenue	\$1,917,192	\$2,012,696	\$2,113,280
Net Contribution Margin	\$1,324,653	\$1,414,224	\$1,508,622
Allocated Overhead	\$ (219,100)	\$ (230,055)	\$ (241,557)
Net Income	\$1,105,553	\$1,184,169	\$1,267,065

Number of Scans	1,887	1,981	2,080
Cost/Scan	\$ 430	\$ 418	\$ 406
Charge/Scan	\$ 1,016	\$ 1,016	\$ 1,016

D. Cost to Medicaid/Medicare

Payor	Utilization Percentage	First Year Expense
Medicaid	8	\$ 47,403
Medicare	39	\$231,090
Other	<u>53</u>	<u>\$314,046</u>
Total	<u>100%</u>	<u>\$592,539</u>

Applicant projects 4.3 percent of gross revenue for bad debt patients, 3 percent for medically indigent patients and charity care patients.

V. RECOMMENDATIONS OF OTHER AFFECTED AGENCIES

The Division of Medicaid was provided a copy of this application for review and comment. According to the Division of Medicaid, outpatient services are paid as outlined in the **State Plan**. The Division takes no position on the application.

VI. CONCLUSION AND RECOMMENDATION

This project is not in substantial compliance with the criteria and standards for acquisition or otherwise control of MRI equipment and the offering of MRI services, as contained in the FY 2005 State Health Plan, and Chapter 8 of the Certificate of Need Review Manual, 2000 Revision. Specifically, staff contends that the applicant is not in compliance with the following criteria:

- SHP Criterion 1 and GR Criterion 5 Need: Based on the existing number of MRI units and utilization data in GHSA 1 for the past two years, there is no need for an additional MRI unit/services in GHSA 1 without impacting a market already saturated with MRI units. The average utilization for all MRI units in GHSA 1 is not within the optimum utilization range. Eleven MRI units in the service area are not producing the required minimum 1,700 MRI procedures per year. GHSA 1 currently has adequate MRI facilities to meet the need of MRI patients in that area. Staff contends that the project represents an unnecessary duplication of health resources.
- GR Criterion 4 Economic Viability: The application contains insufficient documentation
 that the facility will meet the projections without encroaching on the viability of existing
 providers of MRI services.
- GR Criterion 8 Relationship to Existing Health Care System: Staff contends that the project cannot be viable without causing an adverse impact on existing providers in the area.

Consequently, the Division of Health Planning and Resource Development recommends disapproval of the application submitted by Medical Imaging, LLC d/b/a Medical Imaging at Barnes Crossing for the acquisition/offering of MRI equipment/services.