

**DIVISION OF HEALTH PLANNING AND
RESOURCE DEVELOPMENT
AUGUST 2007**

**CON REVIEW: FSF-NIS-0307-003
SOUTHERN MEDICAL IMAGING GULFCOAST, LLC
ACQUISITION OF STAND-UP MRI EQUIPMENT
& ESTABLISHMENT OF MRI SERVICES
CAPITAL EXPENDITURE: \$1,847,000
LOCATION: BILOXI, HARRISON COUNTY, MISSISSIPPI**

STAFF ANALYSIS

I. PROJECT SUMMARY

A. Applicant Information

Southern Medical Imaging GulfCoast, LLC (SMIG) is a proprietary Mississippi limited liability company located in Biloxi, Harrison County, Mississippi. SMIG members and governing board are Barry Monday, Eric Graham, M.D., Eric Wolfson, M.D., and Victor Bazzone, M.D. SMIG was formed on March 31, 2005, by the filing of a Certificate of Formation with the Office of the Mississippi Secretary of State. SMIG has entered into a contract for management, billing and collection services with The Lincoln Group II, LLC. SMIG will participate in the Medicare and Medicaid programs.

B. Project Description

SMIG requests Certificate of Need authority to acquire a stand-up magnetic resonance imaging (MRI) scanner and establish MRI services at its offices at 1721 Medical Park Drive, Biloxi, Harrison County, Mississippi 39532. SMIG proposes to operate Monday through Friday, ten (10) hours per day, and four (4) hours on Saturday. The project includes the lease of a new FONAR Stand-Up MRI scanner and rent of approximately 2,000 square feet of space. The applicant proposes to use a FONAR Stand-Up MRI scanner, which is a whole-body Open MRI system operating at field strength of 0.6 Tesla. The applicant states that the establishment and use of the FONAR Stand-Up MRI scanner will be a state of the art open MRI in Biloxi, Mississippi, and will provide patients and physicians with additional MRI options, including weight bearing scans and flexion extension scans, which are currently unavailable in the state.

The applicant proposes that the FONAR Stand-Up MRI scanner is the only scanner currently available that will allow for true unrestricted motion for flexion and extension studies. This MRI can scan spines and joints in an actual weight-bearing state, helping provide physicians more accurate diagnostic studies than the traditional MRI scanner which scans the patient lying down.

The applicant submitted a proposed 10 year monthly lease agreement between SMIG and CVDD, LLC to lease the 2,000 square feet of space at an annual rent of \$50,000, paid in 12 monthly installments of \$4,166.67. To acquire the equipment, the applicant provided a 60 month lease agreement (with the option to purchase at the end of the lease term) between the SMIG and Banc of America Leasing & Capital, LLC. The lease provides for a stair-stepped payment schedule over its term with rental adjustment payments based on treasury yields.

The applicant provided a detailed quotation on the specifications and description of the Stand-Up MRI prepared by FONAR Corporation. The applicant submitted a site plan for the proposed lease space and the Mississippi Department of Health, Division of Licensure and Certification, issued site approval to SMIG on May 27, 2005, for the proposed out-patient MRI provider location of 1721 Medical Park Drive, Biloxi, Harrison County, Mississippi 39532.

SMIG submitted a three year Projected Operating Statement and a letter from Hancock Bank indicating good standings and available line of credit for this project, if needed. The applicant indicates that 8.00 FTE personnel will be hired as a result of this project. SMIG anticipates using the company's cash reserves to fund the project and a loan from Hancock Bank, if necessary. The applicant expects that the capital expenditure will be obligated in September 2007, and the project will be completed in November 2007, or within 90 days from the issuance of the Certificate of Need.

II. TYPE OF REVIEW REQUESTED

The Mississippi State Department of Health reviews applications for major medical equipment acquisition and offering of MRI services in accordance with Sections 41-7-173; 41-7-191, subparagraph (1)(d)(xii),(f), and (i), and 41-7-193, Mississippi Code 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 of 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 September 4, 2007.

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

A. State Health Plan (SHP)

The *FY2007 State Health Plan* contains 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.

Acquisition or Otherwise Control of MRI Equipment

SHP Criterion 1- Need

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

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 application contains 17 letters of support and affidavits from 8 physicians indicating that they will refer approximately 3,648 procedures the first year of operation (nurse practitioner referrals and one of the referring physician's estimated referrals are not included in this figure). One physician's projected procedures are excluded due to the physician's recent request on June 26, 2007, to rescind the affidavit; thereby withdrawing approximately 300 referrals per year. Further, 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
2,000	2,400	2,800

The applicant states that the affidavits contained in this application indicate that physicians will refer between 120 and 600 patients per physician per year.

Upon careful examination of affidavits submitted by the applicant, staff determined that some of the numbers appear to have been altered. Therefore, it is questionable as to whether the referral numbers represent actual referral by the physicians during the year. If the questionable affidavits are excluded (2,688 procedures), the projected procedures total 1,860; which exceeds the 1,700 minimum procedures per year.

According to the *FY 2007 State Health Plan*, there were 12 providers operating 13 MRI service locations for 2004 utilizing 16.2 full time equivalent (FTE) units, and 11 providers operating MRI services at 12 locations for 2005 in General Hospital Service Area 7 (GHS 7) utilizing 15.2 FTE units. As reported in the *State Health Plan*, the units (mobile/fixed) performed a total of 33,705 procedures in 2004 for an average of 2,081 procedures per FTE unit. In 2005, the units performed a total of 33,407 procedures for an average of 2,198 procedures per FTE unit. The 2006 updated information shows that there were 15.6 FTE units (excluding one non-operational unit) performing approximately 34,284 procedures, with an average of

2,198 procedures (see attachment 1).

The applicant submits that there is a need in Harrison County for the proposed Stand-Up MRI scanner, and assert that the existing scanners in the area do not have the ability to perform the array of tests that the FONAR Stand-up MRI could perform, such as true weight bearing and flexion extension exams. Based on 2007 population figures, SMIG believes that the facility will provide between 2,000; 2,400, and 2,800 MRI procedures in Biloxi for the succeeding three years.

According to the *FY 2007 State Health Plan*, in 2004, there were 12 MRI providers operating 16.2 FTE units in General Hospital Service Area 7. Also, there were two non-operational CON MRI providers approved in 2004. The 16.2 operational FTE units reportedly performed a total of 33,705 procedures for an average of 2,081 procedures per FTE unit. In 2005, the 15.2 FTE units performed a total of 33,407 procedures, or an average of 2,198 procedures per FTE unit. Updated information shows that in FY 2006, GHSA 7 had a total of 15.6 FTE units performing a total of 34,284 procedures, or an average of 2,198 procedures per FTE unit. Should the number of procedures remain constant for FY 2007, the 15.6 FTE units and 1 CON approved unit, totaling 16.6 FTE units, could perform approximately 2,065 procedures on average per FTE unit.

SHP Criterion 2 - Assurances

The application includes a certificate from the United States Public Health Service classifying and giving FDA approval of the FONAR Corporation, MRI scanner. The scanner will operate 10 hours per day, Monday through Friday, and 4 hours on Saturday. The applicant states that the MRI technician will be supervised by a radiologist who has experience in MRI. Also, the MRI technician will be trained and experienced in MRI studies and will adhere to State and professional licensure and certification requirements.

SHP Criterion 3 - Information Recording/Maintenance

SMIG affirms that they will record and maintain the information required by this criterion and shall make the data available to the Mississippi State Department of Health within fifteen (15) business days of request.

SHP Criterion 4 - Authorized Entity

SMIG was formed on March 31, 2005, by the filing of a Certificate of Formation with the Office of the Mississippi Secretary of State. SMIG has designated Barry L. Monday of 3688 Veterans Memorial Drive, Ste. 318, Hattiesburg, Mississippi 39401, as its manager.

SHP Criterion 5 - Authorization to Provide MRI

The application seeks CON approval from the Mississippi State Department of Health, Division of Health Planning and Resource Development, for the acquisition/establishment of MRI equipment/services in General Hospital Service Area 7.

Criteria for Offering of MRI Services

SHP Criterion 1- Need

An entity desiring to offer MRI services must document that the equipment shall perform a minimum of 1,700 procedures per year using the procedures estimation methodology presented in the Plan. The Plan provides, however, that: "If the MRI unit in question is presently utilized by more than one provider of MRI services, the actual number of procedures performed by them during the most recent 12-month period may be used instead of the formula projections". In addition, the Plan requires that if a particular MRI unit is utilized by more than one provider of MRI services, all existing or proposed providers of MRI services must jointly meet the required service volume of 1,700 procedures annually.

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.

Based on the referral figures in the affidavits, excluding the ones in question, staff calculated approximately 1,860 MRI procedures will be performed utilizing the FONAR Stand-Up MRI scanner, which exceeds the 1,700 minimum procedures per year.

According to the *FY 2007 State Health Plan*, in 2004 there were 12 MRI providers operating 16.2 FTE units in General Hospital Service Area 7. Also, there were two non-operational CON MRI providers approved in 2004. The 16.2 operational FTE units reportedly performed a total of 33,705 procedures for an average of 2,081 procedures per FTE unit. In 2005, the 15.2 FTE units performed a total of 33,407 procedures, or an average of 2,198 procedures per FTE unit.

As stated earlier, updated projections indicate that there were 15.6 FTE fixed/mobile operational units and one CON authorized MRI unit in GHSA 7 during FY 2006. The number of procedures performed was 34,284, with an average of 2,198 procedures per FTE unit. If the number of procedures remains the same, the 15.6 FTE operating units and one CON authorized unit, could be expected to perform approximately 2,065 procedures on average per FTE unit.

SHP Criterion 2 - Documentation of Diagnostic Imaging Modalities

SMIG affirms that a full range of diagnostic imaging modalities for verification and complimentary studies will be available through either itself or other providers with whom its members have staff privileges. Among these modalities are computed tomography, ultrasound, angiography, nuclear medicine and conventional radiology.

SHP Criterion 3- Accessibility

SMIG states in the CON application that it serves all of the population, including low income, racial and ethnic minorities, women, and handicapped persons. SMIG provides health care services to patients in need of the service regardless of age, creed, sex, race or ability to pay.

SHP Criterion 4 - Staffing

The applicant affirms that a Director, Board Certified radiologist or a nuclear medicine imaging physician, or other board eligible licensed physician, and an MRI Technologist/Radiographer will be on site during the hours of operation to ensure the center functions properly and provide interpretation of clinical images.

SHP Criterion 5 - Research Staffing

SMIG affirms that the facility does not anticipate using MRI equipment for experimental procedures if the procedures are performed by a formal/approved MRI staff.

SHP Criterion 6 -Recording of Data

SMIG affirms that the facility will record and maintain the information required by this criterion and shall make the data available to the Mississippi Department of Health regarding the operation of the MRI equipment. Also, the facility states it will record source of payment for procedures and the total amounts charged during the fiscal year.

SHP Criterion 7 - CON Approval

The applicant seeks CON approval to acquire MRI equipment.

B. General Review (GR) Criteria

Chapter 8 of the *Mississippi Certificate of Need Review Manual, (November 12, 2006, as amended)* addresses general criteria by which all CON applications are reviewed.

GR Criterion 2 - Long Range Plan

According to the applicant, the long range development plan of SMIG is to provide state of the art equipment and improved treatment modalities, including weight bearing and flexion extension scans, to the patients in its service area.

GR Criterion 3- Availability of Alternatives

The applicant asserts that the Stand-Up MRI scanner is a technology that is not currently being offered elsewhere in Mississippi. Its medical applications and modalities provide the most effective form of magnetic resonance imaging available, and are in high demand in the health care industry. SMIG asserts that the operation of the proposed unit would be cost effective and an efficient way to provide such technology and medical services to the patients in GHSA 7. According to the applicant, while existing MRI units in GHSA 7 are not specifically the same type and application of the proposed unit, such other units are performing well above the optimum level that is required under the State Health Plan. SMIG asserts that in considering current utilization of current units in GHSA 7, there is a need for an additional provider of magnetic resonance imaging in the service area.

GR Criterion 4 - Economic Viability

The applicant states that the proposed charges for MRI scans shall be comparable to the charges of other providers for similar services statewide based upon Medicare and private reimbursement rates.

SMIG asserts that the projected levels of utilization for the proposed service are reasonable and consistent with those experienced by similar facilities and the need within the service area.

The applicant projects net income of \$1,817,409; \$2,118,200; and \$2,561,366 for the first, second and third year of operation, respectively.

GR Criterion 5 - Need for the Project

In addressing the need for additional MRI services in GHSA 7, the applicant points out that Harrison County contains the second largest population in the state, according to the 2010 population projections list in the *2007 State Health Plan*.

Due to the fact that existing providers are averaging above the 1,700 procedures required, the applicant determined that there is a need for another MRI provider in GHSA 7. Also, the applicant notes that on average the units are performing above the optimum utilization as identified by the *State Health Plan*.

For 2006, staff identified 12 fixed FTE units (excluding the fixed unit at Memorial Hospital at Gulfport, Orange Grove) and 3.6 mobile FTE units, for a total of 15.6 FTE MRI units in existence in GHSA 7. For FY 2007 operational and approved units 10.2 of the 15.6 FTE units are, or will be, located in Harrison County.

Eighteen (18) endorsement letters, two (2) from area physicians making referrals, were included in the CON application. Also, nine (9) affidavits from physicians were included in the application to estimate future referrals for MRI services. However, one of the physicians submitted a letter on June 26, 2007, requesting to rescind her affidavit.

The remaining physicians project 1,860 procedures annually, which exceeds the 1,700 minimum required to justify the need.

SMIG states in the CON application that it serves all of the population, including low income, racial and ethnic minorities, women, and handicapped persons. SMIG provides health care services to patients in need of the service regardless of age, creed, sex, race or ability to pay.

However, letters of opposition were received from Memorial Hospital at Gulfport and Open MRI, LLC (Cedar Lake Open MRI, LLC, and Compass Imaging, LLC). All facilities claim that the application filed by SMIG represents a duplication of services and that the establishment of an additional unit will cause an adverse impact on the existing providers in the area.

GR Criterion 6- Access to the Facility

The applicant affirms that the facility will provide services to all persons, and will do so on an equal basis. SMIG projects that 4% of the patients served at the center will be medically indigent patients. The applicant indicates the expected payor mix by type payor will be as follows: Medicaid will be 5%, Medicare 20%, and Private Pay 75%, which includes insurance and self-pay.

The applicant contends that SMIG complies with all applicable federal regulations concerning community service, access by under-served groups and handicapped persons, and the provision of uncompensated care.

The applicant asserts that it will provide services to Medicare and Medicaid patients. The applicant further asserts that medically indigent patients shall be treated on a reduced fee or no charge based upon the hardship policy implemented at SMIG.

The applicant affirms that it will provide services to any person referred to SMIG in need of services regardless of age, sex, race, or ability to pay.

GR Criterion 7- Information Requirement

SMIG affirms that they will record and maintain the information required by this criterion and shall make the data available to the Mississippi State Department of Health within fifteen (15) business days of request.

GR Criterion 8 - Relationship to Existing Health Care System

SMIG does not believe that approval of the proposed MRI unit will have an adverse affect on existing facilities because they are not providing similar services and existing MRI providers are operating at high levels of utilization.

As previously indicated, Memorial Hospital at Gulfport and Open MRI, LLC submitted letters of opposition.

GR Criterion 9 - Availability of Resources

The applicant affirms that a Director, Board Certified radiologist or nuclear medicine imaging physician, or other board eligible licensed physician, and an MRI Technologist/Radiographer will be employed at the facility. The applicant indicates that 8.00 FTE personnel will be hired from within the local community of certified physicians, radiological technologists or new graduates from the local schools of radiographic technology. SMIG will use the company's cash reserves and a loan from Hancock Bank to fund the project.

GR Criterion 10 - Relationship to Ancillary or Support Services

SMIG asserts that the addition of the FOMAR Stand-Up MRI scanner, and its capabilities of providing flexion extension and true weight bearing scanning services, will complement the existing services in GHSA 7 and will not materially affect current ancillary or support services.

IV. FINANCIAL FEASIBILITY

A. Capital Expenditure Summary

	Capital Expenditure	Percentage
New Construction		
Renovation Construction	210,000	11%
Capital Improvements		
Fixed Equipment	1,500,000	81%
Non-Fixed Equipment	7,000	1%
Land Cost		
Site Preparation		
Fees (Architectural, Consultant, etc)	15,000	1%
Contingency Reserve	40,000	2%
Capitalized Interest		
Other (legal & Acct. fees)	75,000	4%
Total Proposed Capital Expenditure	1,847,000	100%

The Lease of the Stand-Up MRI is a capital lease in the amount of \$1,500,000.

B. Method of Financing

SMIG will use the company's cash reserves and lines of credit to fund the project.

C. Effects on Operating Costs

The applicant's three-year projected operating statement is provided in Attachment 2. The applicant's projections include: expenses, utilization, and results from operation for the first three years following completion of the project.

D. Cost to Medicaid/Medicare

Payor	Utilization Percentage	First Year Expense
Medicaid	5%	\$146,500
Medicare	20%	\$586,000
Other	75%	\$2,197,500
Total	100%	\$2,930,000

The applicant projects 10% percent bad debt. Medically indigent and charity care are approximately 4% of gross patient revenues.

V. RECOMMENDATION OF OTHER AFFECTED AGENCIES

The Division of Medicaid was provided a copy of this application for comment. No written comment has been received as of publication date.

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 for offering of MRI services as contained in the *FY 2007 Mississippi State Health Plan*, and Chapter 8 of the *Mississippi Certificate of Need Review Manual*, revised November 2006.

The Division of Health Planning and Resource Development recommends approval of the application submitted by Southern Medical Imaging GulfCoast, LLC for the acquisition/establishment of MRI equipment/services.

ATTACHMENT 1
General Hospital Service Area 7
Location and Number of MRI Procedures

Facility	Location	Type / No. of Equipment	Number of Procedures 2004	Number of Procedures 2005	Updated Numbers 2006*	Days of Operation	FTE Unit
Biloxi Regional Medical Center	Biloxi	F	4,384	5,212	5,005	M-F	1.0
Coastal County Imaging	Gulfport	F	CON	CON	98	M & F	0.4
Coastal MRI – Bienville Orthopaedic	Bienville	M	1,647	0	0	M-F	1.0
Garden Park Medical Center	Gulfport	F	1,520	1,668	1,569	M-F	1.0
George County Hospital	Lucedale	F	598	614	727	M-F	1.0
Gulf Coast Medical Center	Biloxi	F	1,578	1,532	1,051	M-F	1.0
Hancock Medical Center	Bay St. Louis	F	2,159	1,943	64	M-Sun	1.4
L.O. Crosby Memorial Hospital/Highland Community Hospital	Picayune	M	964	901	370	M-F	1.0
Memorial Hospital at Gulfport	Gulfport	F(2)	5,961	6,121	5,976	M-F	2.0
Memorial Hospital at Gulfport	Orange Grove	F	CON	CON	CON	N/A	0.0
Ocean Springs Hospital	Ocean Springs	F	2,975	3,516	3,888	M-F	1.0
Open MRI – Cedar Lake	Gulfport	F/M	2,662	3,373	4,904	M-F	2.0
Open MRI – Compass Site	Gulfport	F	3,882	3,182	4,709	M-Sat	1.2
OMRI, Inc. d/b/a Open MRI	Gulfport	M(2)	1,240	1,485	2,001	M-Thur	1.6
Singing River Hospital	Pascagoula	F	4,135	3,860	3,922	M-F	1.0
Total			33,705	33,407	34,284	-	-
Full Time Equivalent Units			16.2	15.2	15.6	-	16.6
Average Number of Procedures (operating units)			2,081	2,198	2,198	-	-

Source: FY 2007 State Health
 *FY 2006 Survey and Hospital Report
 F/M Fixed/Mobile MRI unit
 FTE – Full Time Equivalent Unit

ATTACHMENT 2

**Southern Medical Imaging GulfCoast, LLC
 Acquisition of MRI Equipment and Service, Gulfcoast, MS
 Three-Year Operating Statement**

	Year 1	Year 2	Year 3
Revenue			
Gross Patient Care Revenue	\$4,100,000	\$4,920,000	\$5,740,000
Deduction From Revenue	(\$1,050,000)	(\$1,260,000)	(\$1,470,000)
Charity	(\$120,000)	(\$144,000)	(\$168,000)
Net Patient Care Revenue	\$2,930,000	\$3,516,000	\$4,102,000
Total Operating Revenue	<u>\$2,930,000</u>	<u>\$3,516,000</u>	<u>\$4,102,000</u>
Operating Expenses			
Salaries	\$84,375	\$88,594	\$93,024
Benefits	21,094	22,149	23,256
Supplies	33,000	39,600	47,520
Services	477,360	570,960	666,120
Lease	200,000	380,000	421,200
Depreciation	221,428	221,428	221,428
Interest	25,334	25,069	18,086
Other	50,000	50,000	50,000
Total Operating Expense	<u>\$1,112,591</u>	<u>\$1,397,800</u>	<u>\$1,540,634</u>
Net Operating Income	<u>\$1,817,409</u>	<u>\$2,118,200</u>	<u>\$2,561,366</u>
Assumptions			
Number of Scans	2,000	2,400	2,800
Charge per Scan	\$ 2,050	\$ 2,050	\$ 2,050
Cost per Scan	\$556	\$582	\$550