

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

**CON REVIEW: FS-NIS-0305-007
GULF COAST DIAGNOSTICS IMAGING, LLC
ACQUISITION OF MRI UNIT AND ESTABLISHMENT OF MRI SERVICES
LOCATION: GULFPORT, MISSISSIPPI, HARRISON COUNTY
CAPITAL EXPENDITURE: \$0**

STAFF ANALYSIS

I. PROJECT SUMMARY

A. Applicant Information

Gulf Coast Diagnostic Imaging (GCDI), LLC is a limited liability company located in Gulfport, Mississippi. The entity is owned by Elias J. Gerth, M.D. of Key West, Florida. On September 22, 2004, GCDI filed a Certificate of Formation and Certificate of Existence with the Office of the Secretary of State and is presently governed by one board member. At this time, GCDI does not have any boards or committees, advisory boards or groups or other representative forums. The company will be certified to participate in the Medicare and Medicaid programs.

B. Project Description

GCDI requests Certificate of Need authority to acquire a magnetic resonance imaging (MRI) scanner and establish MRI services at its medical office facility. The office building is located at 1924 East Pass Road, Gulfport, Mississippi, in the Central Park subdivision. The applicant states that GCDI will provide a full range of diagnostic imaging modalities for verification and complementary studies, including but not limited to, computed tomography, ultrasound, angiography, nuclear medicine, and conventional radiology. GCDI has entered a lease with Affiliated Physicians, LLC to rent approximately 2,000 square feet of space on the ground floor of the building. Also, the applicant proposes to lease an FDA approved mobile trailer containing a new Toshiba Excelart Vantage/ AGV 1.5 Highfield MRI System and permanently park the trailer at the proposed site to provide outpatient MRI services.

The MRI scanner is an ultra-short, ultra-wide bore magnet that performs faster and non-claustrophobic exams (scans) while producing quality images at a reduced noise level of 90%. In addition, this new technology also performs vascular imaging or fresh blood imaging on patients without them being injected with contrast agents (dye) to diagnose problems or disease. This method prevents patients from becoming ill at the imaging center. Also, the applicant states that GCDI will charge a "global fee" of \$1,800 per scan including the radiologist's interpretation fee (\$200-\$400) while eliminating the cost of using contrast media, dye (\$200). This new technology drives down the potential exam or scan cost from \$2,300 to \$1,800 per scan.

The applicant enclosed a proposed 20-year, monthly lease agreement between Affiliated Physicians, LLC and Gulf Coast Diagnostic Imaging, LLC to lease the premises for \$40,000 per year. In addition, the applicant provided a 60-month lease between Gulf Coast Diagnostic Imaging, LLC and Toshiba America Medical Credit (TAMC) to lease the equipment for \$25,800 per month. The applicant included a quotation submitted by Performance Medical Group listing the description of the MRI equipment, outlining its capabilities, and the actual cost of the equipment.

The applicant provided a schematic drawing indicating that the mobile trailer is eight feet wide and 48 feet long consisting of an MRI Gantry area, Scan Room, a Patient Table, Control Room, Computer Equipment Room, and a Patient Lift. GCDI will not complete any new construction or renovation. The company received site approval on March 23, 2005 from the Mississippi Department of Health, Division of Licensure and Certification.

GCDI includes a capital expenditure summary, a three year Projected Operating Statement and a letter from the company's financial institution verifying the company's account status. The applicant indicates that 3.00 FTE personnel will be hired at an estimated annual cost of \$111,280. GCDI will use the company's cash reserves and lines of credit to fund the project. The applicant expects that the capital expenditure will be obligated within 30 days of approval and the project will be completed within six months.

II. TYPE OF REVIEW REQUESTED

The Mississippi Department of Health reviews applications for major medical equipment acquisition and offering of MRI services in accordance with Section 41-7-191, subparagraph (1)(d)(xii),(f), and (i) 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 June 6, 2005.

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

A. State Health Plan (SHP)

The *FY 2005 Mississippi 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 second year of operation, utilizing the procedures estimation methodology contained in the Plan.

Because the procedures estimation methodology was intended for use by hospitals and not clinics, the MDH allows freestanding applicants to use an alternative method to project the annual patient service volume for the facility. The applicant submitted copies of affidavits from 13 physicians indicating that they will refer in excess of 4,645 procedures the first year of operation. Further, the applicant makes the following projections of MRI procedures to be performed during the first three years of operation:

Projected MRI Procedures		
2005-Year 1	2006-Year 2	2007-Year 3
4,645	5,110	5,621

According to the *FY 2005 State Health Plan*, there were 11 providers of MRI services operating 12 units in General Hospital Service Area 7. Also, there was one non-operational CON approved MRI service at Orange Grove. As reported in the *Plan*, the 12 units performed a total of 28,731 procedures in 2002 for an average of 2,394 procedures per unit. In 2003, the 12 units performed a total of 31,831 procedures, or an average of 2,653 procedures per unit (see the following table).

**LOCATION AND NUMBER OF MRI
 PROCEDURES IN GENERAL HOSPITAL SERVICE AREA 7**

Facility	Location	Type /No. of Equipment	Number of Procedures 2001	Number of Procedures 2002	Number of Procedures 2003
Biloxi Regional Medical Center	Biloxi	F	3,668	4,419	5,578
Coastal MRI	Gautier	M	943	1,725	1,628
Garden Park	Gulfport	F	1,889	1,775	1,116
George County Hospital	Lucedale	M	146	7	495
Gulf Coast Medical Center	Biloxi	F	1,363	1,618	1,635
Hancock Medical Center	Bay St. Louis	F	1,806	1,955	1,981
L.O. Crosby Memorial Hospital	Pearl River	M	946	984	988
Memorial Hospital at Gulfport	Orange Grove	F	CON	CON	CON
Memorial Hospital at Gulfport	Gulfport	F(1) M(1)	4,956	5,706	5,458
Ocean Springs Hospital	Ocean Springs	F	2,238	2,304	2,804
Open MRI, Inc.*	Gulfport	M	4,029	4,993	6,659
Singing River Hospital	Pascagoula	F	2,551	3,245	3,489
Total			24,535	28,731	31,831

Source: *FY 2005 State Health Plan*, Applications for Renewal of Hospital License for Calendar Years 2003 and 2004, and Fiscal Years 2002 and 2003 Annual Hospital Reports.

*Note: Open MRI, Incorporated, converted two mobile sites, in Biloxi and Gulfport, Mississippi, to two fixed sites in the same cities. Hancock County Medical Center requested CON exemption to add one additional fixed MRI unit to their site. Updated projections for FY 2004 were provided by MDH.

Updated information indicates that Open MRI converted two of its mobile sites (Gulfport and Biloxi, Mississippi) to fixed sites pursuant to declaratory rulings issued August 15, 2002, and December 3, 2002. In addition, Hancock Medical Center acquired an additional fixed unit, by an operating lease, pursuant to a declaratory ruling issued July 31, 2003. Therefore, the total number of operational/CON approved MRI units in GHSA 7 during FY 2003 was 15; 11 fixed units (including one non-operational unit at Orange Grove) and 4 mobile units (see the following table).

MRI Units and Procedures for GHSA 7				
# of Units	FY 2002	FY 2003 (Reported)	FY 2003 (Updated)	FY 2004 (Estimate) Includes approved CON
Fixed	7	7	10	
Mobile	5	5	4	
Total Operational	12	12	14	
CON Approved*	1	1	1	1,700*
Total Operational & CON Approved	13	13	15	15
Total Procedures	28,731	31,831	31,831	33,531
Average # of Procedures	2,394	2,653	2,274	2,235

Note: The CON authorized unit at Orange Grove was included at 1,700 procedures per year for calculating the 2004 Estimate.

The applicant submits that there is a need in Harrison County for additional MRI services based on a state wide average of 60 MRI procedures for every 1,000 population. Based on 2003 population figures, GCDI believes that the facility will provide between 4,645 and 5,621 MRI procedures in Gulfport for the succeeding three years.

The *FY 2005 State Health Plan* also 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. As stated earlier, updated projections indicate that there were 11 fixed and 4 mobile operational/CON approved MRI units in GHSA 7 during FY 2003. In addition, on December 16, 2004 the Department issued a CON for an additional fixed unit in the service area. Should the number of procedures remain the same for FY 2004, the 14 operating units and one CON approved unit, operating at 1,700 procedures, could be expected to perform approximately 2,235 procedures.

Note: Staff's examination of the affidavits submitted reveal that the referrals projected by each physician appear to be overstated. For instance, staff's examination of the affidavits submitted by previous applicants for MRI services in GHSA 7 reveals estimates of 60 to 240 referrals per physician. Affidavits contained in this application indicate that physicians will refer between 65 and 1,000 patients per physician per year.

In addition, the physician affidavits contained in the application indicate that referring physicians saw a total of 51,200 patients from January 1, 2004 through December 31, 2004. Based on the number of patients seen by referring physicians and the statewide average incidence rate of 60 MRI procedures per 1,000 population established by the applicant, staff estimates a total of 3,072 referrals annually.

However, the staff must exclude Dr. Demond Hoda's affidavit from the 13 affidavits received because he reported 9,500 visits and failed to indicate the number of patients he referred from January 1, 2004 through December 31, 2004. Thus, the number of patients treated by the remaining 12 physicians in the time frame listed above would equal 41,700. At the statewide incidence rate of 60 per 1,000, staff estimates 2,502 procedures annually, but this estimation is based on referrals that appear to be somewhat overstated.

SHP Criterion 2 - Assurances

The application includes specification and description information on the Toshiba Excelart Vantage/ AGV 1.5 Highfield MRI System provided by Performance Medical Group. The company provided a service-maintenance agreement describing contract coverage and states the equipment will be in operation Monday through Friday, 10 hours per day. In addition, Toshiba states the MRI equipment is FDA approved. 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

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

SHP Criterion 4 - Authorized Entity

GCDI filed a Certificate of Formation and Certificate of Existence with the Office of the Secretary of State on September 22, 2004 and is presently governed by one board member.

SHP Criterion 5 - Authorization to Provide MRI

GCDI seeks CON approval from the Mississippi 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

According to the *FY 2005 State Health Plan 2003* reports, there were 11 MRI providers operating 12 units in General Hospital Service Area 7. Also, there was one non-operational CON approved MRI service at Orange Grove. The 12 units reportedly performed a total of 28,731 procedures in 2002 for an average of 2,394 procedures per unit. In 2003, the 12 units performed a total of 31,831 procedures, or an average of 2,653 procedures per unit.

Updated information indicates that Open MRI converted two of its mobile sites (Gulfport and Biloxi, Mississippi) to fixed sites pursuant to declaratory rulings issued August 15, 2002, and December 3, 2002. In addition, Hancock Medical Center acquired an additional fixed unit, by an operating lease, pursuant to a declaratory ruling issued July 31, 2003. Based on these changes in 2003, three fixed units were added to General Hospital Service Area 7. Therefore, the total number of operational/CON approved MRI units was 15; 11 fixed units (including one non-operational unit at Orange Grove) and 4 mobile units.

Five endorsement letters from various community officials were included in the CON application dated March 1, 2005. Also, 13 affidavits from physicians were included in the application to verify future referrals for MRI services, though one was excluded from analysis, as explained earlier.

The application states that community officials recognize that the GCDI complies with all federal regulations regarding community service and supports GCDI's efforts to serve all patients in GHSA 7 regardless of race, creed, sex, or ability to pay.

SHP Criterion 2 - Documentation of Diagnostic Imaging Modalities

The applicant certifies 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, ultrasound, angiography, nuclear medicine, and conventional radiology.

SHP Criterion 3- Accessibility

GCDI states in the CON application that the facility will not 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 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

GCDI 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

GCDI 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 an MRI instrument as determined by the Mississippi Department of Health.

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.

GR Criterion 2 - Long Range Plan

According to the applicant, the long range development plan of GCDI is to provide accessible MRI services to area residents of GHSA 7, as well as quality care and diagnostic treatments to patients.

GR Criterion 3- Availability of Alternatives

The applicant considered establishing MRI centers throughout the state of Mississippi or establishing a fixed site for an MRI unit. Both alternatives would not be financially feasible; however, the applicant believes that offering MRI services at a permanent location by using a mobile trailer to house the equipment would be less costly and more feasible. Thus, the applicant feels that the Harrison County site in Gulfport will be more accessible to area residents.

GR Criterion 4 - Economic Viability

The applicant projects net income of \$3,538,817 the first year, \$4,345,056 the second year, and \$5,288,866 the third year of operation. Given that GHSA 7 has 15 approved units, staff questions whether the applicant can meet the projections without encroaching on the ability of existing providers to provide these services.

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. The applicant further asserts that during 2003, the existing fixed and mobile MRI units in GHSA 7 collectively performed a total of 31,831 procedures, far in excess of the statewide average of 60 MRI procedures per 1,000 population.

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 the units are performing above the optimum utilization as identified by the *Plan*.

It should be noted that 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. While the average for all units in GHSA 7 is within this optimum range, not all units in the service area are performing at optimum levels. It should also be noted that utilization of two of the fixed units in GHSA 7 decreased during FY 2003.

As stated earlier, staff identified 11 fixed (including the non-operational unit at Orange Grove) and 4 mobile units in existence in GHSA 7. In addition, on December 16, 2004, the Department approved an additional fixed unit in Harrison County. If upheld by the courts, this will bring the potential total of operational units to 16, 7 of which are, or will be, located in Harrison County. Therefore, the staff contends that GHSA 7 currently has adequate facilities to meet the needs of MRI patients in that service area.

Five endorsement letters from various community officials were included in the CON application dated September 1, 2004. The applicant further submitted copies of affidavits from 13 physicians indicating that they will refer between 65 to 1,000 patients per year. The staff's examination of the affidavits submitted in the application reveals that the number of referrals by each physician appear to be overstated.

The application states that community officials recognize that the GCDI complies with all federal regulations regarding community service and supports GCDI efforts

to serve all patients in GSHA 7 regardless of race, creed, sex, or ability to pay. However, letters of opposition were received from Gulf Coast Medical Center (GCMC), Memorial Hospital at Gulfport (MHG), and Open MRI, LLC (OMRI). All facilities claim that the application filed by GCDI 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 residents of Harrison County. GCDI projects that 8% 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 13.5%, Medicare 48.5%, and Private Pay 38%.

GR Criterion 7- Information Requirement

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

GR Criterion 8 - Relationship to Existing Health Care System

Given the number of units present in the service area, staff contends that the project cannot be viable without causing an adverse impact on existing providers in the area. As previously indicated, Gulf Coast Medical Center (GCMC), Memorial Hospital at Gulfport (MHG), and Open MRI, LLC (OMRI) submitted letters of opposition to the project.

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 3.00 FTE personnel will be hired at an estimated annual cost of \$111,280. GCDI will use the company's cash reserves and lines of credit to fund the project.

GR Criterion 10 - Relationship to Ancillary or Support Services

The applicant states that GCDI will complement the existing MRI services in the GHSA 7. Thus, the MRI service will not have an effect on the support services.

IV. FINANCIAL FEASIBILITY

A. Capital Expenditure Summary

There is no capital expenditure associated with this project.

B. Method of Financing

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

C. Effects on Operating Costs

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

	First Year	Second Year	Third Year
Patient Volume	4,645	5,110	5,621
Patient Charges	8,361,000	9,964,500	11,804,100
Less Contractual Adjustments	(\$3,177,180)	(\$3,786,510)	(\$4,485,558)
Net Patient Revenue	5,183,820	6,177,990	7,318,542
Expenses:			
Professional Fee-Interpretation	418,050	459,900	505,890
Equipment Lease	309,600	321,600	324,600
Space Lease	40,000	44,000	48,400
Personnel	111,280	117,844	123,736
Utilities	28,381	31,222	32,145
Supplies	206,703	227,395	250,135
Telephone	3,200	3,520	3,872
Linen Expenses	8,129	8,942	9,207
Employee Training	3,600	4,800	6,000
Transcription	14,400	15,841	17,425
Management Fee	501,660	597,870	708,246
Total Expenses	1,645,003	1,832,934	2,029,656
Net Income (Loss)	\$3,538,817	\$4,345,056	\$5,288,886

The applicant states the following: one treatment per patient, the average number of procedures- 4,645 per annum, the charge per procedure- \$1,800.00, and the cost per procedure- \$355.

D. Cost to Medicaid/Medicare

Payor	Utilization Percentage	First Year Expense
Medicaid	13.5%	\$ 222,075
Medicare	48.5%	\$ 797,826
Other	38%	\$ 625,102
Total	100%	\$ 1,645,003
GCDI projects 3% percent bad debt. Medically indigent and charity care are approximately 8% and 2% of gross patient revenues, respectively.		

V. RECOMMENDATION OF OTHER AFFECTED AGENCIES

The Division of Medicaid was provided a copy of this application for comment. According to the Division of Medicaid, outpatient services are paid as outlined in the *State Medicaid Plan*.

VI. CONCLUSION AND RECOMMENDATION

This project is not 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 2005 Mississippi State Health Plan*, and Chapter 8 of the *Mississippi Certificate of Need Review Manual, 2000*. Specifically, staff contends that the applicant is not in compliance with the following criteria:

- **SHP Criterion 1 and GR Criterion 5- Need:** The application contains questionable documentation that the proposed facility will perform the required minimum 1,700 procedures by the second year of operation.
- **GR Criterion 4- Economic Viability:** The application contains insufficient documentation that the proposed facility will meet the projections without encroaching on the ability of existing providers to provide MRI services.
- **GR Criterion 8 - Relationship to Existing Health Care System:** Given the number of units present in the service area, and one CON pending for a unit, 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 Gulf Coast Diagnostic Imaging, LLC for the acquisition/establishment of MRI equipment/services.