

**DIVISION OF HEALTH PLANNING  
AND RESOURCE DEVELOPMENT  
NOVEMBER 2004**

**CON REVIEW: MU-NIS-0904-032  
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 managed, limited liability company located in Gulfport, Mississippi. GCDI is managed by one physician. 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 board member enclosed Certification to indicate the managing member is endorsing the project. The company will be certified to participate in the Medicare and Medicaid programs.

**B. PROJECT DESCRIPTION**

GCDI requests CON 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 Vantage AGV Highfield MRI System and permanently park the trailer at the proposed site to provide outpatient MRI services.

The applicant enclosed a proposed 20 year, monthly lease agreement between Affiliated Physicians, LLC and Gulf Coast Diagnostic Imaging, LLC. The applicant included a quotation submitted by Performance Medical Group listing the description of the MRI equipment, outlining its capabilities, and a lease cost of \$25,800.00 per month.

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 submitted a letter to the Mississippi State Department of Health, Division of Licensure and Certification, requesting site approval.

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 to fund the project and debts will be retired from operations. 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 State 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 State 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 December 6, 2004.

## **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, utilizing the procedures estimation methodology contained in the Plan.

Because the procedures estimation methodology was intended for use by hospitals and not clinics, the MSDH 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 eight physicians indicating that they will refer in excess of 1,800 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:

<b>Projected MRI Procedures</b>		
<b>Year 1</b>	<b>Year 2</b>	<b>Year 3</b>
1,860	2,046	2,250

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	No. of Proc. 2001	No. Proc. 2002	No. Proc. 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
<b>Total</b>			<b>24,535</b>	<b>28,731</b>	<b>31,831</b>

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 FY 2004 were provided by MSDH.

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 14; 11 fixed units (including one non-operational unit at Orange Grove) and 4 mobile units (see the following table).

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

**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 between 1,800 and 2,200 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, an application is pending before the Department 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 number of referrals by each physician appear to be somewhat overstated. Also, staff's examination of the affidavits submitted by previous applicants for MRI services in GHSA 7 show estimates of 60 to 240 referrals per physician. Affidavits contained in this application indicate that physicians will refer between 140 and 400 patients per year.

In addition, the physician affidavits contained in the application indicate that referring physicians saw a total of 9,972 patients from January 1, 2003 through December 31, 2003. 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 that the applicant can expect only 598 referrals annually, far less than the minimum 1,700 procedures required to document need.

#### **SHP Criterion 2 - Assurances**

The application includes specification and description information on the Toshiba Vantage AGV 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, Hitachi 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 State 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. At this time, GCDI does not have any boards or committees, advisory boards or groups or other representative forums.

#### **SHP Criterion 5 - Authorization to Provide MRI**

GCDI 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**

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 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 14; 11 fixed units (including one non-operational unit at Orange Grove) and 4 mobile units.

Eight endorsement letters from various community officials were included in the CON application dated September 1, 2004. Also, eight affidavits from physicians were included in the application to verify future referrals for MRI services.

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 State 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 for the MRI vendor to acquire an MRI instrument as determined by the Mississippi State Department of Health.

### **B. General Review (GR) Criteria**

Chapter 8 of the *Mississippi Certificate of Need Review Manual, 2000 revisions*, addresses general criteria by which all CON applications are reviewed.

#### **GR Criterion 2 - Long Range Plan**

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 equaled a cost estimate of \$793,600 to \$800,000; 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 \$1,781,780 the first year, \$2,354,142 the second year, and \$2,945,214 the third year of operation. Given that GHSA 7 has 15 approved units and one additional unit pending approval, staff is concerned that the applicant cannot 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, an application is pending approval for an additional fixed unit in Harrison County. If approved, 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.

Eight endorsement letters from various community officials were included in the CON application dated September 1, 2004. The applicant further submitted copies of affidavits from eight physicians indicating that they will refer between 140 to 400 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 somewhat 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 Memorial Hospital at Gulfport (MHG) and Open MRI, LLC (OMRI). Both 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 only 1% of the patients served at the center will be medically indigent patients. The applicant indicates the expected payer 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 State 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, and one CON pending for an additional unit staff contends that the project cannot be viable without causing an adverse impact on existing providers in the area. As previously indicated, 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. Information provided by existing providers indicates that GCDI will not provide a full range of radiological services; thus, the patient's imaging needs will be far less than the standard of care appropriate for interpreting complex imaging studies in a mobile trailer. GCDI will use the company's cash reserves to fund the project and debts will be retired from operations.

#### **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 to fund the project and debts will be retired from operations.

**C. Effects on Operating Costs**

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

	<b>First Year</b>	<b>Second Year</b>	<b>Third Year</b>
Patient Volume	1,860	2,046	2,250
Patient Charges	3,348,000	4,191,300	5,062,500
Less Contractual Adjustments	(\$1,004,400)	(\$1,258,290)	(\$1,518,750)
Net Patient Charge	2,343,600	2,933,010	3,543,750
<b>Expenses:</b>			
Equipment Lease	309,600	309,600	309,600
Space Lease	40,000	40,000	40,000
Personnel	111,250	117,844	123,736
Utilities	11,000	11,500	12,000
Supplies	74,660	86,686	95,450
Telephone	3,200	3,200	3,200
Linen Expenses	3,000	3,400	3,800
Employee Training	3,500	3,500	4,000
Transcription	5,580	6,138	6,750
<b>Total Expenses</b>	<b>561,790</b>	<b>581,868</b>	<b>598,536</b>
Net Income (Loss)	\$1,781,810	\$2,351,142	\$2,945,214

The applicant states the following: one treatment per patient, the average number of procedures-1,860 per annum, the charge per procedure- \$1,260.00, and the cost per procedure- \$302.

**D. Cost to Medicaid/Medicare**

Payor	Utilization Percentage	First Year Expense
Medicaid	13.5%	\$ 75,841.65
Medicare	48.5%	\$ 272,468.15
Other	38%	\$ 213,480.20
<b>Total</b>	100%	\$ 561,790.00

GCDI projects 5% percent bad debt. Medically indigent and charity care are approximately 1% and 3% 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 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 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 staff 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, should it be approved, 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.