

**DIVISION OF HEALTH PLANNING AND
RESOURCE DEVELOPMENT
DECEMBER 2006**

**CON REVIEW: FSF-NIS-1006-031
STARKVILLE ORTHOPEDIC CLINIC, STARKVILLE
ACQUISITION OF MRI EQUIPMENT AND OFFERING OF MRI SERVICES
CAPITAL EXPENDITURE: \$802,061
LOCATION: STARKVILLE, OKTIBBEHA COUNTY, MISSISSIPPI**

STAFF ANALYSIS

I. PROJECT SUMMARY

A. Applicant Information

Starkville Orthopedic Clinic, LLC, a Mississippi limited liability company, combines a diverse group of orthopedic surgeons and professional staff to provide a full spectrum musculoskeletal treatment system in Starkville, Oktibbeha County, Mississippi. Managing members provide governance to the LLC. The application contains a letter of good standing from the Mississippi Secretary of State.

B. Project Description

Starkville Orthopedic Clinic or "the applicant" requests Certificate of Need (CON) authority to provide MRI services to its orthopedic patients five days a week using a 0.35 Tesla MRI unit leased from Siemens Medical Solutions USA, Inc. of Malvern, Pennsylvania. The applicant states that the present clinic has adequate space to house the proposed MRI equipment. However, due to rapidly expanding patient cliental, the applicant plans to construct a two-story 4,500 square foot office building/clinic. Once the new facility is constructed, the MRI unit will be moved to the new facility. According to the applicant, the construction of the new office/clinic facility is not contingent upon the approval of this proposal. Therefore, the applicant contends that this project requires no construction, renovation, or capital expenditure other than the MRI lease payments. The applicant proposes to employ a full-time MRI technologist-radiographer for a total personnel budget of \$95,000 during the first year of operation. The applicant anticipates the MRI scanner to become available for patient service within 12 months of approval.

The application contained a letter of site approval from the Department's Division of Health Facilities Licensure and Certification.

II. TYPE OF REVIEW REQUIRED

This project is reviewed in accordance with Section 41-7-191, subparagraphs 1 (d)(xii), (f), and (j) 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 of 1972, Annotated, 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 January 16, 2007.

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

A. State Health Plan (SHP)

The FY 2006 Mississippi State Health Plan, the plan in effect at the time this application was received, contains policy statements, criteria, and standards which an applicant must meet before receiving CON authority for the acquisition or otherwise control of MRI equipment and the offering of MRI services. This application submitted on behalf of Starkville Orthopedic Clinic substantially complies with the FY 2006 State Health Plan.

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 end of the second year of operation, using the procedures-estimation methodology contained in the State Health Plan. Applicants for non-hospital based MRI facilities may submit affidavits from referring physicians in lieu of the need estimation methodology required for hospital-based facilities. MRI procedures projected in affidavits shall be based on actual MRI procedures referred during the year (most recent 12 months). The application contained such affidavits from six physicians.

The application submitted on behalf of Starkville Orthopedic Clinic, a non-hospital facility, contains restated affidavits as demonstrated in the table below:

Starkville Orthopedic Clinic Acquisition of MRI Equipment		
Referring Physicians	First Year Referrals	Second-Year Referrals
William Billington	144 -180	144 -180
Allan Butler	660 -720	660 -720
Mike Cox*	0	480
Slater Lowery	180 -204	180 -204
Todd Smith	660 -720	660 -720
Ann Stokes	120 -144	120 -144
Total Physician Referrals	1,764 -1,968	2,244 -2,448

*Note: The Mississippi Supreme Court decision in *Mississippi State Department of Health v. Natchez Community Hospital*, 143 So. 2d 973 (Miss. 1999) provides that CON applications must be supported by substantial evidence and that unsupported statements by physicians do not provide the substantial evidence required to grant a CON. All physicians except Dr. Cox stated that based on their records and referral patterns they could reasonably expect to refer the indicated number of procedures. However, Dr. Cox, who lives out of state, based his referral estimation on the history of Starkville Orthopedic Clinic and not his actual personal referral history. Therefore, his referral estimation can not be accepted in demonstrating an

unmet need of 1700 scans, leaving a sworn estimation of between 1,764 and 1,968 scans for each the first and second year of operation of the open MRI unit

The applicant adequately demonstrates a need for the acquisition and control of an MRI unit at Starkville Orthopedic Clinic by using the need determination methodology outlined in the *FY 2006 State Health Plan (SHP)*.

SHP Criterion 2 – Quality Assurance

The applicant attested that according to the Food and Drug Administration (FDA), MRI units are Class II medical devices and that a finding of “substantially equivalent” is required to sell an MRI in the United States. The application contained documentation that the MAGNETOM C MRI equipment is a Class II medical device and is classified as “substantial equivalent” by the FDA. Starkville Orthopedic Clinic affirms that only qualified personnel will be allowed to operate the equipment. The equipment will not be rented, leased, or otherwise used by other providers, according to the applicant.

SHP Criterion 3 – Information Recording/Maintenance

The applicant affirmed that it will maintain, at a minimum, the information required by this criterion and will make it available to the Mississippi Department of Health within 15 days of request.

SHP Criterion 4 - Registration

The application contained documentation that Starkville Orthopedic Clinic is a registered entity authorized to do business in Mississippi.

SHP Criterion 5 – CON Approval

The applicant is requesting CON approval for the equipment stated in this application.

Criteria and Standards for the Offering of MRI Services

SHP Criterion 1 – Need

The applicant estimates that the professional staff of Starkville Orthopedic Clinic and referring physicians within the Starkville medical trade area will generate between 1,764 and 1,968 MRI scans by the end the first year of operation. The application contained affidavits from six referring physicians attesting that between 2,244 and 2,448 MRI procedures should be generated by the end of the second year. However, one physician did not project the number of expected referrals based on his past referral pattern and could not be used in projecting need. However, the applicant projected a number of referrals that is well within the 1,700 required by the *FY 2006 SHP*.

SHP Criterion 2 - Documentation of Diagnostic Imaging Modalities

Starkville Orthopedic Clinic submits that it will provide a full range of diagnostic imaging modalities for verification and complementary studies at the onset of

services. These modalities shall include, but not be limited to, full body computed tomography (CT), ultrasound, angiography, nuclear medicine, and conventional radiology.

SHP Criterion 3 – Accessibility

The applicant submits that Starkville Orthopedic Clinic and its affiliates or anyone providing services on its behalf, as well as those who contract with the facility, will provide services and ensure said services are available to all patients regardless of race, color, age, sex, ethnicity, or ability to pay.

SHP Criterion 4 – Staffing

Director: The application contains documentation that the clinic director and other staff physicians are fully qualified in the acquisition and interpretation of MRI images. The director will have knowledge through experience, training, and post graduate education, including a minimum of one week of full-time training with a functional MRI facility prior to the implementation of this project, according to the applicant.

MRI Technologist-Radiographer: Starkville Orthopedic Clinic affirms that a full-time MRI technologist-radiographer will be onsite at all times during operating hours of the MRI equipment.

SHP Criterion 5 – Research Staffing

The applicant does not anticipate any experimental procedures to be provided at the facility.

SHP Criterion 6 - Data Requirement

The applicant submits that all information required by this criterion will be maintained and made available to the MDH upon request.

SHP Criterion 7 – CON Approval

The applicant requests authority for the lease of MRI equipment and the offering of MRI imaging services at the Starkville Orthopedic Clinic.

B. General Review (GR) Criteria

Chapter 8 of the Mississippi Certificate of Need Review Manual, effective August 12, 2006, (as amended), addresses general criteria by which all CON applications are reviewed. The applicable criteria are discussed below:

GR Criterion 1 – Consistency with the State Health Plan

The applicant's proposed project is consistent with the *FY 2006 Mississippi State Health Plan*.

GR Criterion 2 – Long Range Plan

The applicant affirms that the establishment of an in-house orthopedic MRI imaging service is in conformance with its long-range plan.

GR Criterion 3 – Availability of Alternatives

The applicant states that through its years of experience it has recognized that MRI services are vital to the appropriate diagnosis and treatment of orthopedic maladies. The principals have found that the utilization of MRI services has continued to escalate and serves as an integral tool in the diagnosis and treatment of its patients. For this reason, the applicant began the planning process for implementing on-site open orthopedic MRI services.

The applicant affirms that local MRI services proved inadequate for the need of the clinic's orthopedic patients. They state that approximately half of the clinic's patients requiring MRI scan(s) are referred to MRI providers outside of Oktibbeha County. The applicant further affirms that approximately 20 percent of these referrals are for obese patients who are prone to orthopedic difficulties requiring shoulder, back, and hip procedures. The proposed open orthopedic MRI service would enable shortened diagnosis, treatment, and healing time for its patients. Therefore, the inclusion of an in-house open MRI service became part of the clinic's long-range plan, according to the applicant. The inclusion of PET or other imaging modalities were considered but tabled, according to the applicant.

GR Criterion 4 – Economic Viability

The project appears to be economically viable. The applicant projects net income of \$1,043,075 for the first year, \$1,424,850 for the second year, and \$1,387,500 for the third year of operation of the Starkville Orthopedic Clinic project. The applicant projects a cost of \$875 per scan for the first three years of operation of this project (staff calculates \$229 per scan for the first year of operation, \$186 during the second, and \$202 during the third year of operation) and a charge of \$1,250 per scan during the same period. The proposed charges are within the range of charges for MRI services charged by other providers in the state.

The applicant's proposed levels of utilization are reasonably consistent with those experienced by similar facilities in the service area and state. The applicant projected an average of 1,866, 2,346, and 2,346 scans during the first, second, and third year of operation, respectively.

The proposed capital expenditure is less than \$2,000,000; therefore, the project does not require a financial feasibility study.

GR Criterion 5 – Need for the Project

The application affirms that the proposed MRI unit located in Starkville Orthopedic Clinic would provide a one-stop imaging and treatment center of the area's orthopedic patients. The applicant further attests that the clinic does not now, nor will it in the future; deny treatment to any historically underserved group or individual. The proposed project involves a new institutional service with no

relocation of services involved. The application contained several letters of support of the proposed project from community and professional leaders. One letter of opposition to this project was received. See Attachment 1 for the location and number of MRI procedures in GHSA 1.

GR Criterion 6 – Access to Facility or Services

The applicant submits that all residents of the Starkville Orthopedic Clinic medical service area, including Medicaid recipients, charity/medically indigent patients, racial and ethnic minorities, women, handicapped persons, and the elderly, have access to the services of the clinic and will continue to have access to the MRI services. The applicant projects five percent of gross patient revenue toward bad debt and two percent toward medically indigent and charity care.

GR Criterion 7 – Information Requirement

The applicant affirmed that it will record and maintain the information required by this criterion and make it available to the Mississippi Department of Health upon request.

GR Criterion 8 – Relationship to Existing Health Care System

According to the applicant, 1.3 MRI units operate in Oktibbeha County: one mobile unit is located at Oktibbeha County Hospital, and Mississippi State University holds a CON for an MRI unit that will be capped at one-third in the number of private/non-research procedures it may perform. According to the *FY 2006 SHP*, Oktibbeha County Hospital performed fewer than optimum level of scans during the past two years: 1,368 in 2003 and 1,525 in 2004. The applicant explains that half of Starkville Orthopedic Clinic's patients required open MRI scans and could not use the MRI units located at the county hospital due to either the obesity and/or the claustrophobic conditions of the orthopedic patients.

The applicant further explains that, by nature, orthopedic patients are limited in mobility and that travel, repeated travel stops, and related delays impede the healing process for many of these patients. The applicant further states that the nearest open MRI unit is located in Lowndes County, some 30 miles from Starkville.

GR Criterion 9 – Availability of Resources

Starkville Orthopedic Clinic is currently staffed with professionals that include: two orthopedic surgeons specialized in treating bone and joint patients and two nurse practitioners, one currently on staff and one to be employed by the end of 2006. The applicant has successfully recruited another orthopedic surgeon who will join the clinic in early 2009. The application contains evidence that Imaging Specialists, PLLC of Brentwood, Tennessee, will provide on-site orthopedic radiology consultation to Starkville Orthopedic Clinic during the initial stage of open orthopedic MRI services.

The applicant confirmed that during 2004-2005, Starkville Orthopedic Clinic experienced 60 percent patient growth. Thus far in 2006, the clinic has experienced an additional 120 percent increase in patient clientele. The applicant attributes this growth to ongoing recruitment.

The application contained financial statements that demonstrate that adequate financial support should be available for the implementation of this project.

GR Criterion 10 – Relationship to Ancillary or Support Services

The applicant states that the proposed project will have no adverse impact on the existing ancillary or support services.

GR Criterion 16 – Quality of Care

The applicant plans to contract with Imaging Specialties, PLLC, a neuroradiology group of Brentwood, Tennessee, to provide professional guidance to maximize quality control and loss prevention during the initial phase of operation of the open MRI unit at the Starkville Orthopedic Clinic.

IV. Financial Feasibility

A. Capital Expenditure Summary

Construction Cost – New	\$0	0%
Construction Cost - Renovation	0	0%
Capital Improvements	0	0%
Total Fixed Equipment	0	0%
Total Non-Fixed Equipment	0	0%
Site Preparation Cost	0	0%
Fees (Architectural, Consultant, Etc.)	0	0%
Contingency Reserve	0	0%
Capitalized Interest	0	0%
Other Cost (Lease of Open MRI equipment)	802,061	100%
Total Proposed Capital Expenditure	\$802,061	100%

The above capital expenditure is proposed for the lease of an open MRI unit to be located at Starkville Orthopedic Clinic, Starkville.

B. Method of Financing

The applicant proposes that the project will be financed through the capital reserve of Starkville Orthopedic Clinic.

C. Effect on Operating Cost

The applicant projects the following results from operation for the first three years following completion of the project at the Starkville Orthopedic Clinic:

Three Year Projected Operating Statement Starkville Orthopedic Clinic			
	First Year	Second Year	Third Year
<u>Total Patient Revenue</u>	\$ 2,332,500	\$ 2,955,000	\$ 2,955,000
<u>Deductions from Revenue</u>			
Charity/Indigent Care	(\$ 46,650)	(\$ 59,100)	(\$ 59,100)
Contractual Adjustments	(\$ 699,750)	(\$ 886,500)	(\$ 886,500)
Bad Debt	(\$ 116,625)	(\$ 147,750)	(\$ 147,750)
Total Revenue Deductions	(\$ 863,025)	(\$1,093,350)	(\$ 1,093,350)
Net Revenue	\$1,469,475	\$1,861,650	\$ 1,861,650
<u>Operating Expenses</u>			
Salaries/Benefits	\$ 95,000	\$ 101,650	\$ 135,000
Supplies	\$ 20,000	\$ 20,000	\$ 20,000
Other Direct Cost	\$ 75,000	\$ 78,750	\$ 82,750
Building Cost	\$ 50,400	\$ 50,400	\$ 50,400
Equipment Lease	\$ 186,000	\$ 186,000	\$ 186,000
Total Operating Expense	\$ 426,400	\$ 436,800	\$ 474,150
Income from Operation	\$1,043,075	\$ 1,424,850	\$ 1,387,500
Procedures (average)	1,866	2,346	2,346
Charge Per Procedure	\$ 1,250	\$ 1,260	\$ 1,260
Cost Per Procedure*	\$ 875	\$ 875	\$ 875

*Staff calculations indicate a cost per of \$229, \$186, and \$202 during the first, second, and third years of operation, respectively using the formula: Total Operating Expense/ Projected Number of Scans = Cost per Scan.

D. Cost to Third Party Payors

The cost of the project to third party payors is as follows (based on net patient revenue):

Patient Mix by Payor Type	Utilization Rate Percent	First Year Cost
Medicare	35.0%	\$ 514,316
Medicaid	12.5%	\$ 183,684
Other Payors*	52.5%	\$ 771,475
Total	100.0%	\$1,469,475

The applicant projects five percent bad debt patients and two percent for charity care.

V. RECOMMENDATION OF OTHER AFFECTED AGENCIES

The Division of Medicaid was provided an opportunity to review and comment on this application. No written comments have been received.

VI. CONCLUSIONS AND RECOMMENDATION

This application is in substantial compliance with the criteria and standards for the acquisition or otherwise control of open MRI equipment and provision of open MRI services, as contained in the *FY 2006 Mississippi State Health Plan*; the *Mississippi Certificate of Need Review Manual, revived August 12, 2006, as amended*; and all adopted rules, procedures, and plans of the Mississippi Department of Health.

The Division of Health Planning and Resource Development recommends approval of the application submitted by Starkville Orthopedic Clinic.

ATTACHMENT 1
 Location and Number of MRI Procedures (GSHA-1)

Facility	Location	Type/No. of Equip.	Number of Procedures FY 2003	Number of Procedures FY 2004	*Number of Procedures 2005	Days Operated	FTE Unit
BMH-Booneville	Boonville	F	566	756	846	M-F	1
BMH- Golden Triangle	Columbus	F(2)	4,804	4,507	4,506	M-F	2
BMH- North Miss	Oxford	F(2)	4,400	3,676	3,888	M-F	2
BMH - Union County	New Albany	F	2,069	2,251	2,094	M-F	1
Gilmore Memorial Hospital,	Amory	M	1,295	1,461	1,461	M-F	1
Grenada Lake Medical Center	Grenada	F	1,828	2,502	3,024	M-F	1
Imaging Center of Columbus	Columbus	F(2)	1,135	1,928	4,243	M-F	2
Imaging Center for Excellence/ Inst – MSU	Starkville	F	-	-	CON (1/3 private)	-	0.33
Imaging Center of Gloster Creek Village	Tupelo	F	2,633	3,751	3,908	M-F	1
Magnolia Regional Health Center	Corinth	F(2)	4,238	4,216	4,216	M-F	2
North MS Medical Center, Iuka	Tishomingo	M	653	820	946	M,W,F	0.6
North MS Medical Center-West Point	West Point	M	666	678	778	Tu, Th	0.4
North MS Sports Medicine & Orthopedic Clinic, PLLC	Tupelo	M	-	-	181	M-F	1
North Miss Medical Center	Tupelo	F(4)	16,622	16,136	16,009	M-F	4
Oktibbeha County Hospital	Starkville	F/M	1,368	1,525	1,687	M-F	1
Pioneer Community Hospital	Aberdeen	M	-	-	CON	1day/week -	0.2
Preferred Imaging	Batesville	M	680	723	1,023	M,Tu,Th	0.6
SMI – North Oak Regional Hospital	Senatobia	M	0	72	72	M (AM)	0.2
Yalobusha General Hospital	Water Valley	M	276	463	463	W (PM)	0.2
SMI – Winston Medical Center	Louisville	M	-	CON	-	-	-
Trace Regional Hospital	Houston	M	136	243	225	F	0.2
Tri-Lakes Medical Center	Batesville	M	0	650	538	F	0.2
Webster Health Services,	Eupora	M	-	-	CON	2 day/week-	0.4
Total			43,369	46,382	50,332		
Full Time Equivalent Units			20.0	20.4	22.15	-	
Average Number of Procedures/per FTE Unit			2,168	2,274	2,272		