DIVISION OF HEALTH PLANNING AND RESOURCE DEVELOPMENT MAY 2014

CON REVIEW HG-NIS-0613-007 RIVER OAKS, LLC d/b/a RIVER OAKS HOSPITAL ESTABLISHMENT OF A DIAGNOSTIC CATHETERIZATION AND PCI SERVICES AND ACQUISITION OF RELATED EQUIPMENT LOCATION: FLOWOOD, RANKIN COUNTY, MISSISSIPPI CAPITAL EXPENDITURE: \$448,000

STAFF ANALYSIS

I. PROJECT SUMMARY

A. APPLICANT INFORMATION

River Oaks Hospital, LLC d/b/a River Oaks Hospital is located at 1030 River Oaks Drive, Flowood, Rankin County, Mississippi and its parent company is Health Management Associates, Inc (HMA). The hospital is a short-term, licensed 160-bed, general medical/surgical facility owned by a limited liability company.

River Oaks is certified to participate in the Medicare and Medicaid programs and is listed in good standing with the Secretary of State's Office. Six officers and directors govern the facility. The applicant included a Certificate from the Secretary of State's Office dated May 13, 2013 indicating that River Oaks Hospital, LLC is a limited liability company incorporated in Mississippi and is in good standing with the State of Mississippi.

The occupancy rates, average lengths of stay (ALOS), and the Medicaid utilization rates for River Oaks Hospital, Flowood are as follows for the years 2010, 2011, and 2012:

Fiscal Year	Occupancy Rate (%)	ALOS (DAYS)	Medicaid Utilization Rate		
2010	65.55	3.73	25.53		
2011	45.78	3.76	28.75		
2012	37.58	3.59	8.58		

Source: Division of Health Facilities Licensure and Certification, MSDH

B. PROJECT DESCRIPTION

River Oaks Hospital, LLC d/b/a River Oaks Hospital (ROH) proposes to become a new provider by establishing a diagnostic cardiac catheterization (cath.) service and also provide primary and elective percutaneous coronary intervention (PCI) services at the hospital. The applicant states that the proposed PCI services will not provide open heart surgery capabilities as opposed to other hospitals in Cardiac Catheterization/Open Heart Surgery Planning Area (CC/OHSPA) 5. The applicant states the proposed PCI service will be based on the exception listed in the *FY 2013 Mississippi State Health Plan (MSHP)*.

Briefly, Rankin Cardiology Center, LLC (RCC) of Jackson received Certificate of Need (CON) Authority on June 28, 2001 under CON Review Number HG-NIS-0900-070 to establish a diagnostic cardiac catheterization service. The center listed above is shown in the *FY 2013 Mississippi State Health Plan* as providing only diagnostic cardiac catheterization services to Rankin Medical Center, Women's Hospital and River Oaks Hospital patients at the River Oaks Hospital Campus.

If the proposed project is approved, Rankin Cardiology Center, LLC will cease to provide diagnostic cardiac catheterization service and surrender its CON at the same time the proposed project is CON approved. The applicant asserts that ROH has one diagnostic cath. lab as well as one special procedures operating room. The applicant plans to purchase a hemodynamic monitoring equipment, a ballon pump, contrast delivery system and flex cardio imaging equipment. River Oaks Hospital indicates that the existing lab and special procedures room referenced above will be equipped to perform diagnostic caths and PCIs.

The total proposed project cost is \$448,000. Since River Oaks Hospital, LLC, Jackson was approved through a Determination of Reviewability ruling on July 10, 2012 to renovate two operating rooms at a cost of \$1,943,550; the proposed project will not involve any new construction or renovation or other expenses except the cost of \$50,000 for equipment and fees. The applicant does not anticipate renovating the existing facility or plans for the provision of radiation therapy services. The project will entail purchasing non-fixed equipment.

The applicant includes a capital expenditure summary, a three-year projected operating statement, and audited financial statements ending 2012. As a result of this project, the applicant projects that 5.0 full-time equivalents (FTEs) will be required for the proposed project at a cost of \$256,560.

The applicant received site approval for the proposed facility from the Mississippi State Department of Health, Division of Licensure and Certification. To fund the project, River Oaks Hospital, LLC will use cash reserves in the amount of \$448,000. Upon CON approval, the applicant anticipates that the capital expenditure will be obligated within one month of final CON approval and the proposed project to be complete within three months of obligation of the capital expenditure.

II. TYPE OF REVIEW REQUIRED

The Mississippi Department of Health reviews applications for the construction, development and relocation of a healthcare facility or portion thereof, or major medical equipment involving a capital expenditure in excess of \$2,000,000, establishment of Cardiac Catheterization Services and Open-Heart Surgery Services and the Acquisition or Otherwise Control of Cardiac Catheterization Equipment and/or the Offering of Cardiac Catheterization Services under the applicable statutory requirements of Sections 41-7-173, 41-7-191 (1)(d)(ii), 41-7-193 and 41-7-195, Mississippi Code of 1972, 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 18, 2014.

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

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

The FY 2013 Mississippi State Health Plan (MSHP) contains criteria and standards for Cardiac Catheterization Services and Open-Heart Surgery Services and the Acquisition or Otherwise Control of Cardiac Catheterization Equipment and/or the Offering of Cardiac Catheterization Services

The *Plan* gives guidelines for all health planning in Mississippi. The *Plan* states that: Mississippi's planning and health regulatory activities have the following purposes:

- To prevent unnecessary duplication of health resources;
- To provide cost containment;
- To improve the health of Mississippi residents; and
- To increase the accessibility, acceptability, continuity, and quality of health services.

This project is consistent with the above stated goals of health planning.

The cardiac catheterization narrative in Chapter 5 of the *MSHP* under 114 discusses cardiac catheterization and its two disciplines: cardiac catheterization and angiography. The various therapeutic interventions are listed in the *MSHP*. It also states that any facility performing diagnostic cardiac catheterizations <u>without</u> open-heart surgery capability must:

- maintain formal referral agreements with a nearby facility to provide emergency cardiac services, including open-heart surgery
- must also delineate the steps it will take to ensure that high-risk or unstable patients are not catheterized in the facility
- must document that more complex procedures are not performed in the facility such procedures include, but are not limited to:

percutaneous coronary interventions (PCI) transseptal puncture transthoracic left ventricular puncture myocardial biopsy.

The *MSHP* provides a numbered list of Joint Policy Statements under 115.01 for the criteria and standards referenced above relating to the proposed project. The narrative lists two goals and five standards MSDH adopted to further the goals.

The hospital is proposing to establish diagnostic cardiac catheterization (cath.) service and also provide primary and elective percutaneous coronary intervention (PCI) services at the hospital. River Oaks Hospital states that the proposed PCI services will <u>not</u> provide open-heart surgery capabilities as the other hospitals in CC/OHSPA 5.

Based on the population data for each county in the *FY 2013 MSHP*, staff determined that there are 15 counties in CC/OHSPA 5 and the population base is **787,626. Thus, the population base standard for** CC/OHSPA 5 exceeds the minimum 100,000 listed in the first standard shown.

Under section 115.02 of the *MSHP*, there are 11 items listed under the policy section. The applicant states that River Oaks Hospital recognizes and <u>complies with the definitions and statements under items</u> <u>1 through 5</u>; however, in Policy Statement (PS) 5, the applicant asserts that River Oaks <u>will not provide</u> the proposed diagnostic cath and PCI services to neonates, infants or young children.

PS 6 - Present Utilization of Cardiac Catheterization Equipment/Services

As previously mentioned under the *Project Description* section, Rankin Cardiology Center, LLC is located in ROH and is equipped with a diagnostic catheterization lab with equipment controlled by and services provided through a joint venture between ROH and two other hospitals. Also, the purpose of the proposed project is to <u>transfer ownership and</u> <u>control of RCC's equipment to River Oaks Hospital</u>. In turn, the services provided through RCC will be terminated and the CON that was granted to RCC will be surrendered to the Department.

The applicant uses the *FY 2013 MSHP* as a reference to report that there are six existing hospitals in CC/OHSPA 5. The applicant states that if the proposed project is approved, the number of hospitals, which received CON approval for cardiac catheterization equipment/services within the service area, will remain unchanged.

The applicant provided a utilization of the service area from 2007 through 2011 and it ranges from 13,025 to 17,193. The applicant admits that RCC adult cardiac catheterizations at the facility declined each year after 2007 because PCI services weren't available and the group of cardiologists left the River Oaks Hospital. If the proposed project is approved, the applicant asserts that cardiologists from UMMC have agreed to provide coverage at River Oaks Hospital in addition to the coverage provided by other cardiologists, including other interventional cardiologists.

The applicant states that the proposed project will allow access to care and by ROH establishing cath and PCI services at the hospital, the implementation of the project will decrease travel time for many residents in CC/OHSPA 5. The applicant points out that practice standards have surfaced to lessen the door-to-ballon time from 90 minutes or less to closer to 60 minutes. The applicant projects the following outcomes relating to ROH proposed project in CC/OHSPA 5:

- An ambulance will most likely not bypass ROH because the facility will offer PCI services;
- Patients with signs of a heart attack will be triaged and stabilized at ROH instead of being transported to another hospital;
- Regarding existing adult cardiac cath programs offering PCI services in CC/OHSP 5 and the proposed project, geographic accessibility will greatly improve for the residents of Rankin County and 6 counties to the north and east of Rankin County;

- Active heart attack patients who travel by private vehicles to the hospital will save 12.5 minutes of traveling time to access PCI services at the hospital; and
- The transfer of patients for PCI have a delay in the door-to-ballon time and the median time for 3 scenarios listed in the application can range from 88 minutes to 121 minutes and can be increased by 45 minutes.

The median time for three scenarios for transferring patients to another facility is 88 minutes.

PS 7 - CON Application Analysis and PS 8 - Minimum CC/OHSPA Population

To comply with PS 7 and PS 8, the applicant provided market share information in the CON application for the acquisition or otherwise control of cardiac catheterization equipment and/or the offering of cardiac catheterization services.

Also, the applicant states that ROH meets the minimum population base of 100,000 as required for applications proposing to establish cardiac catheterization services. To determine the need for services, the applicant indicates that the 2012 population estimate is 746,263 inhabitants in CC/OHSPA 5; however, the *FY 2013 MSHP* reports a total 2015 population of **787,626 for the same area.** As a part of PS 8, ROH provides patient origin data, the hospital's primary and secondary service areas and reports the population outside the hospital's CC/OHSPA to verify the need only for the proposed project.

The application includes a 12-month chart to report the number of discharges and patient origin data from CC/OHSPA 5. Based on the information, the counties and percentages are shown below by category:

	Discharge	Hospital Patient	Patient Orgin
County	Percentages	Orgin by County	Percentages
Rankin	39.10%	Rankin	39.10%
Hinds	21.90%	Hinds	21.90%
Madison	10.60%	Madison	10.60%
Scott	3.70%	Scott	3.70%
Leake	3.40%	Leake	3.40%
Simpson	2.60%	Simpson	2.60%
Copiah	1.80%	Copiah	1.80%
Attala	1.70%	Attala	1.70%
Yazoo	1.50%	Yazoo	1.50%
Warren	1.30%	Warren	1.30%
Holmes	0.90%	Lincoln	1.10%
Smith	0.50%		
Claiborne	0.10%		
Sharkey	0.10%		
Issaquena	0.00%		
All Others	10.80%	All Others	11.40%
Total Percentage	100.00%	Total Percentage	100.10%

The applicant also provides a chart in the application to show an analysis of all patient encounters (inpatient discharges, observation discharges, emergency room visits, and outpatient visits) during a 12-month period.

Hinds, Rankin, and Madison counties create a large percentage of inpatient and all encounters for a total of 67,333 encounters and of that number, 66,328 (98.5 percent) were among Mississippi residents.

From the list of counties shown in the table above, ROH states that the estimated 2012 population in CC/OHSPA 5 is 746,253 and the estimated, projected population for 2015 will be 766,691. The applicant also determined that Hinds, Rankin, and Madison counties account for two thirds of the total population in the area and are projected to be greater through 2020.

For CC/OHSPA 5, the application provides tables, which report population estimates from 2012 through 2020; population by age for 2015; and data for ROH's Primary and Secondary service areas. One table shows that the population will increase from 746,263 to 793,632 for 2012 through 2020. The applicant also discusses the population trends attributed to the aging "baby boomers," people living longer, how the aging population relates to the provision of healthcare and the need for ROH to offer the proposed services.

River Oaks affirms that the average age of the elderly population over the next 40 years will move from 85 years of age reported in 2000 to a higher

number by 2040. Since the existing healthcare delivery system is inadequate to handle the aging population, the applicant states that the average age change could affect healthcare and long-term care significantly. The applicant reports that persons age 45 years and older are affected by coronary heart disease (CHD). Based on the Census Bureau's population estimates for 2012, River Oaks Hospital asserts that the population in CC/OHSPA 5 is expected to increase from 273,302 in 2011 to 298,420 for age 45 and 82,933 to 107,661 for age 65. The table below shows the population increases for ROH's service areas.

Primary Service Secondary Service Area Area 2012 2020 2012 2020 520,526 563,585 209,962 218,792 Rankin Leake Simpson Hinds Madison Copiah Scott Attala Yazoo Warren Lincoln

River Oaks Hospital

For each of ROH's services areas, River Oaks Hospital also examined the 2012 through 2017 populations for the following: the hospital's overall zip code levels, aged 45 and older residents, and aged 65 and older population. The applicant asserts that each of the population categories listed above is projected to be well over 100,000 residents with expected increases each year compared to previous years.

PS 9 - Minimum Caseload

If an applicant is proposing to provide adult diagnostic cardiac catheterization service, the *FY 2013 MSHP* states that an applicant must be able to project a caseload of at least 300 diagnostic catheterizations per year. If an applicant is proposing to offer adult therapeutic cardiac catheterization services, the applicant must project a caseload of at least 450 catheterizations, diagnostic and therapeutic, per year.

Since River Oaks Hospital is proposing to establish adult diagnostic cardiac catheterization (cath.) service and also provide therapeutic cardiac catheterization through (PCI) services, the applicant projects that

the hospital will exceed 450 catheterizations, diagnostic and therapeutic, per year. The applicant used the following Centers for Disease Control (CDC) factors to project 518, 658, and 887 catheterizations, diagnostic and therapeutic procedures for year 1, 2, and 3 relating to CC/OHSPA 5 and the remaining Mississippi counties:

- Increasing need for cardiovascular services among Mississippi's aging population based on the prevalence of CHD by age;
- Residents who had heart attacks in the past;
- Residents who have recurrent heart attacks; and
- Number of health and behavioral factors (hypertension, obesity, cigarette smoking, and regular physical activity).

The applicant points out that past and current *MSHPs* report the number of adult cardiac cath procedures for 2007 to 2011 increased from 13,025 to 17,193. Also, the population estimates and rates for the same time frame increased from 732,279 to 744,181, while the rate per procedure per 1,000 inhabitants increased from 17.79 to 23.10. The applicant asserts that seven variables listed in the application determined the projected number of cardiac caths in CC/OHSPA 5 and the hospital's service areas.

Using estimates and cardiac cath rates/1,000 CC/OHSPA 5, the applicant provides the total adult cardiac cath procedures discusses the incidence rates for 2007 through 2011 and shows percentage increases from 17.79 to 23.10. Based on the adult population estimates and cardiac cath rates/1,000 CC/OHSPA 5, incidence percentage rates increased from 24.11 through 31.02. Other calculations, various methodologies, and studies were analyzed by ROH to project cardiac caths by different ages, the facility's service area, patient origin information, etc from 2014 through 2020. The data is presented in the application.

PS 10 - Residence of Medical Staff

River Oaks Hospital affirms that the facility shall perform cardiac catheterizations under the control of and by personnel living and working within the specific hospital area. The applicant states that ROH will not use traveling teams to provide services.

PS 11 - Hospital-Based

River Oaks Hospital asserts that the facility that the proposed diagnostic catheterizations and PCI services will be located in an acute care hospital.

The FY 2013 Mississippi State Health Plan (MSHP or SHP) does contain criteria and standards for Certificate of Need Criteria and Standards for the Acquisition or Otherwise Control of <u>Diagnostic</u> Cardiac Catheterization Equipment and/or the Offering Of <u>Diagnostic Cardiac Catheterization Services</u>.

SHP Criterion 1 - Need

River Oaks Hospital documented a minimum population base of 100,000 in the CC/OHSPA 5 regarding the proposed diagnostic cardiac catheterization equipment/service to be located in the service area listed above. The application discusses population estimates above under Policy Statement 7 and 8. The Division of Health Planning and Resource Development population projection for CC/OHSPA 5 is 787,626 based on the 2015 population projection listed in the *FY 2013 MSHP*.

SHP Criterion 2 - Minimum Procedures

The criterion states that if an applicant establishes diagnostic cardiac catheterization services only shall demonstrate that the proposed equipment/service utilization will be a minimum of 300 diagnostic cardiac catheterizations per year by its third year of operation.

The applicant is proposing to establish diagnostic cardiac catheterization (cath.) service and also provide primary and elective percutaneous coronary intervention (PCI) services at River Oaks Hospital.

Based on data and factors analyzed by ROH and discussed in *Policy Statement 9*, the applicant projects the following diagnostic cardiac catheterizations in CC/OHSPA 5 for year 1, 2, and 3, respectively 404, 514, and 692.

SHP Criterion 3 - Impact on Existing Providers

The applicant proposing to acquire or otherwise control diagnostic cardiac catheterization equipment and/or offer diagnostic cardiac catheterization services must document that each existing unit, which is (a) in the CC/OHSPA and (b) within forty-five (45) miles of the applicant, has been utilized for a minimum of 450 procedures (both diagnostic and therapeutic) per year for the two most recent years.

The table below from the *FY 2013 MSHP* shows the number of procedures reported by each facility in CC/OHSPA 5. An updated table is also shown below to display data for FY 2012. The applicant asserts that ROH meets the requirement listed under this criterion.

River Oaks Hospital states that the utilization for the facility is due to: the hospital not offering PCI services, a lack of referrals by physicians, and a deficiency in scheduling by cardiologist. The hospital projects that with PCI services, with hospital's diagnostic cath, the data below, ROH's projections will increase the number of diagnostic caths performed at the facility.

Table 5-10Cardiac Catheterizations by Facility and Typeby Cardiac Catheterization/Open Heart Planning Area (CC/OHSPA)FY 2010, FY 2011, and FY 2012

Facility	County	Total Adult Procedures		Total Pediatric Procedures		Total PTCA Procedures		# Labs
		2010	2011	2010	2011	2010	2011	2011
CC/OHSPA 5		15,918	17,193	1,036	924	2,575	2,756	24
Central Mississippi Medical Center	Hinds	630	1,200	0	0	221	250	3
Mississippi Baptist Medical Center	Hinds	3,627	4,203	0	0	958	1,039	5
Rankin Cardiology Center*•	Rankin	8	22	0	0	0	0	1
River Region Health System	Warren	1,102	1,157	0	0	285	283	4
St. Dominic-Jackson Memorial Hospital	Hinds	2,939	2,743	0	0	1,079	1,153	6
University Hospital & Health Systems	Hinds	7,612	7,868	1,036	924	32	31	5

Facility	County	Total . Proce		Pedi	tal iatric dures	Total PTCA Procedures		# Labs
		2011	2012	2011	2012	2011	2012	2012
CC/OHSPA 5		17,193	16,434	924	570	2,756	2,944	23
Central Mississippi Medical Center	Hinds	1,200	1,180	0	0	250	289	3
Mississippi Baptist Medical Center	Hinds	4,203	4,326	0	0	1,039	1,143	5
Rankin Cardiology Center*•	Rankin	22	120	0	0	0	0	1
River Region Health System	Warren	1,157	1,230	0	0	283	314	4
St. Dominic-Jackson Memorial Hospital	Hinds	2,743	6,661	0	0	1,153	1,163	6
University Hospital & Health Systems	Hinds	7,868	2,917	924	570	31	35	4

Sources: FY 2013 MSHP, FY 2014 MSHP

*Diagnostic Catheterizations only

•Provides Diagnostic Cardiac Catheterizations for Rankin Medical Center, Women's Hospital, and River Oaks Hospital patients, at River Oaks Hospital Campus

The applicant provided three cardiac cath calculation rates by age group/population, and based on methodologies listed in the application to project the impact of the proposed comprehensive cardiac cath program by the hospital. The data reported an increase for years 1 through year 3 of 732 cardiac caths. The projected volume among existing facilities in CC/OHSPA 5 will increase from 17,193 to 18,780 for 2011 through 2016 (see table below).

CCOHSPA-5 Estimates and Projections by Facility Methodology Based on Average Projected Volume of Three Methodologies

		2011 Market		2016 Market
Facility	2011	Share %	2016	Share %
Central MS Medical Center	1,200	7.0	1,251	6.7
MS Baptist Medical Center	4,203	24.4	4,382	23.3
Rankin Cardiology	22	0.1	-	-
River Oaks Hospital	-	0.0	887	4.7
River Region Health System	1,157	6.7	1,206	6.4
St. Dominic-Jackson Memorial Hospital	2,743	16.0	2,860	15.2
University Hospitals and Health System -UMC	7,868	45.8	8,194	43.7
TOTAL	17,193	100.0	18,780	100.0

The hospital states that the existing providers will encounter a slight decrease in market share; however, the number of adult cardiac caths at each facility should increase based on the projected increase in the number of adult caths to be performed. The hospital is not owned and/or operated by the state or its agencies.

SHP Criterion 4 - Staffing Standards

The applicant affirms that ROH has or can obtain the ability to administer the proposed services, provide sufficiently trained and experienced professional staff, and evaluate the performance of the programs. The Mississippi State Department of Health staff shall use guidelines presented in *Optimal Resources for Examination of the Heart and Lungs: Cardiac Catheterization and Radiographic Facilities*, published under the auspices of the Inter-Society Commission for Heart Disease Resources, as resource materials when reviewing these items in an application.

SHP Criterion 5 - Recording and Maintenance of Data

River Oaks Hospital affirms that the facility will provide, as required under licensure standards, written assurance that they will record and maintain utilization data for diagnostic cardiac catheterization procedures (e.g., morbidity data, number of diagnostic cardiac catheterization procedures performed, and mortality data, all reported by race, sex, and payor status) and make such data available to the Mississippi State Department of Health annually.

SHP Criterion 6 -Referral Agreement

Regarding the proposed project, establishment of diagnostic cardiac catheterization services only, the applicant documents that a formal referral agreement with a facility for the provision of emergency cardiac

services (including open-heart surgery) will be in place and operational at the time of the inception of cardiac catheterization services. SHP Criterion 7 - Patient Selection

River Oaks Hospital proposing to provide diagnostic cardiac catheterization services asserts that the facility will (a) delineate the steps which will be taken to insure that high-risk or unstable patients are not catheterized in the facility, and (b) certify that therapeutic cardiac catheterization services will not be performed in the facility unless and until the applicant has received CON approval to provide therapeutic cardiac catheterization services.

SHP Criterion 8 - Regulatory Approval

Before utilizing or providing the equipment or service, River Oaks Hospital is proposing to provide diagnostic cardiac catheterization equipment or service and is seeking CON approval from the Mississippi State Department of Health.

The FY 2013 Mississippi State Health Plan (MSHP) does contain criteria and standards for Certificate of Need Criteria and Standards for the Acquisition or Otherwise Control of <u>Therapeutic</u> Cardiac Catheterization Equipment and/or the Offering Of <u>Therapeutic Cardiac Catheterization</u> <u>Services</u>.

SHP Criterion 1 - Need

River Oaks Hospital documented a minimum population base of 100,000 in the CC/OHSPA, where the proposed therapeutic cardiac catheterization equipment/service is to be located. The application discusses population estimates above under Policy Statement 7 and 8. The Division of Health Planning and Resource Development population projection for CC/OHSPA 5 is 787,626 based on the 2015 population projection listed in the *FY 2013 MSHP*.

SHP Criterion 2 - Minimum Procedures

An applicant proposing the establishment of therapeutic cardiac catheterization services shall demonstrate that the proposed equipment/service utilization will be a minimum of 450 cardiac catheterizations, both diagnostic and therapeutic, per year by its third year of operation and a minimum of 100 total PCIs.

River Oaks Hospital discusses the requirement listed above and provides documentation to show ROH will meet the utilization required above in SHP Policy Statement 9 - Minimum Caseload. The applicant asserts that

ROH projects the following for 2014, 2015, and 2016 relating to CC/OHSPA 5:

- □ 404, 514, and 692 diagnostic cardiac catheterizations.
- □ 114, 145, and 195 total PCIs

(Primary PCIs included in total number of PCIs -16, 20, and 27)

□ 518, 658, and 887 total adult procedures

SHP Criterion 3 - Impact on Existing Providers

An applicant proposing to acquire or otherwise control therapeutic cardiac catheterization equipment and/or offer therapeutic cardiac catheterization services shall document that each existing unit which is (a) in the CC/OHSPA and (b) within 45 miles of the applicant, has been utilized for a minimum of 450 procedures (both diagnostic and therapeutic) per year for the two most recent years as reflected in data supplied to and/or verified by the Mississippi State Department of Health.

The applicant discusses the impact under *SHP Criterion 3 - Impact on Existing Providers* listed above. The hospital states that the existing providers will encounter a slight decrease in market share; however, the number of adult cardiac caths at each facility should increase based on the projected increase in the number of adult caths

The hospital is not owned and/or operated by the state or its agencies.

SHP Criterion 4 - Staffing Standards

The applicant affirms that ROH has, or can obtain, the ability to administer the proposed services, provide sufficiently trained and experienced professional staff, and evaluate the performance of the programs. Mississippi State Department of Health staff shall use guidelines presented in *Optimal Resources for Examination of the Heart and Lungs: Cardiac Catheterization and Radiographic Facilities*, published under the auspices of the Inter-Society Commission for Heart Disease Resources, as resource materials when reviewing these items in an application.

SHP Criterion 5 - Staff Residency

The applicant asserts that medical staff performing therapeutic cardiac catheterization procedures will be onsite within thirty (30) minutes.

SHP Criterion 6 - Recording and Maintenance of Data

River Oaks asserts that the facility shall provide, as required under licensure standards, written assurance that they will record and maintain separate utilization data for diagnostic and therapeutic cardiac catheterization procedures (e.g., morbidity data, number of diagnostic and therapeutic cardiac catheterization procedures performed and mortality data, all reported by race, sex and payor status) and make that data available to the Mississippi State Department of Health annually. **SHP Criterion 7 - Open-Heart Surgery**

The criterion states that an applicant proposing the establishment of therapeutic cardiac catheterization services shall document that open-heart surgery services are available or will be available on-site where the proposed therapeutic cardiac catheterization services are to be offered before such procedures are performed. However, qualified applicants may submit an application to perform percutaneous coronary intervention (PCI) services in a hospital without on-site cardiac surgery.

To qualify, River Oaks Hospital asserts that the facility will meet the current American College of Cardiology (ACCF), American Heart Association Task Force on Practice Guidelines (AHA) and the Society of Cardiovascular Angiography and Interventions (SCAI)-ACCF/AHA/SCAI Guideline for Percutaneous Coronary Intervention and the following:

- a. River Oaks Hospital assert the facility will comply with performing a minimum of 50 total PCIs per year/per primary operator (physicians), including 12 primary PCIs per year/per facility.
- b. The applicant states that qualified operators will have a lifetime experience of greater than 150 total PCIs with acceptable outcomes as primary operator after completing fellowship or have completed an Interventional Cardiology fellowship.
- c. The facility asserts that it will use a minimum of less than 120 minutes to accomplish transfer from the onset of PCI complications to cardiopulmonary bypass. The facility's program affirms that ROH will have a formal emergency transfer agreement with a hospital providing open heart surgery. While transporting a patient to the receiving hospital, ROH affirms that it will ensure the availability of an intra-aortic balloon pump (IABP). The application includes a transfer agreement with UMMC.

- d. River Oaks Hospital provides projections to show that the facility will annually perform a minimum of 100 total PCIs per year (see below):
 - □ 114, 145, and 195 total PCIs

(Primary PCIs included in total # of PCIs -16, 20, and 27)

- e. The applicant affirms that the proposed ROH program will participate in the STEMI ("ST"-Segment Elevation Myocardial Infarction) Network.
- f. The applicant asserts that ROH will perform primary and elective PCI procedures.

SHP Criterion 8 - Regulatory Approval

Before utilizing or providing the equipment or service, River Oaks Hospital is proposing to provide cardiac catheterization equipment or service and is seeking CON approval by the Mississippi State Department of Health.

SHP Criterion 9 - Provision of Diagnostic Catheterization Services

As stated in the Project Description above, Rankin Cardiology Center, LLC (RCC) of Jackson received Certificate of Need (CON) Authority to establish a diagnostic cardiac catheterization service. The center only provides diagnostic cardiac catheterization services to Rankin Medical Center, Women's Hospital and River Oaks Hospital patients at the River Oaks Hospital Campus. Upon approval, RCC will cease to provide diagnostic cardiac catheterization service and surrender its CON at the same time the proposed project is CON approved.

Since River Oaks Hospital is not an existing provider of diagnostic cardiac cath services, ROH does not have data to demonstrate that a diagnostic cardiac catheterization unit has been utilized for a minimum of 300 procedures per year for the two most recent years. As a note, RCC did not perform as well as projected regarding the service the center offered (see RCC's utilization shown in the table under SHP Criterion 3 - Impact on Existing Providers).

Physician Referrals/Affidavits

Regarding Table I below, ROH states in the application that the number of cardiac cath procedures at ROH will originate from four sources: persons who are admitted to ROH in the emergency department; referrals from HMA-owned primary care clinics to cardiologists on the hospital's active medical staff; anticipated procedures from affiliated cardiologists; and patents referred from other sources to cardiologists on the hospital's medical staff.

For the third year of operation, River Oaks Hospital affirms that the proposed cardiac cath laboratory will perform the projected 2016 numbers shown in Table I.

Table IRiver Oaks HospitalProjected Adult Coronary Angiography and AngioplastyProcedures

Туре	2014	2015	2016
Total Adult Procedures	518	658	887
Diagnostic Cardiac			
Catheterizations	404	514	692
Total PCIs	114	145	195
Primary PCIs *	16	20	27

*Primary PCIs included in total number of PCIs

Under number 2 of the Application for a Certificate of Need, the Substantive Review form, the applicant states the ROH is proposing diagnostic cardiac catheterization (cath.) service and will also provide primary and elective percutaneous coronary intervention (PCI) services.

The applicant indicates that ROH is not an existing provider of the services and submitted utilization projections for the services based on physician referrals. The physician affidavits of commitment from the referring physicians include the actual number of referrals from the prior year(s), the projected number of referrals and/or the number of procedures or treatments to be rendered (see Table II below).

Table IIRiver Oaks Projected UtilizationBased on Physician Referrals/Affidavits

-	Diagnostic Catheterizations		Cls	PCIs Performed		
2012	2013	2012	2013	Greather than 150 as the Primary Operator		
<u>1,373</u>	<u>1,374</u>	<u>518</u>	534	<u>1,200</u>		

The applicant indicates that the physician referrals/affidavits in Table II support the 2016 numbers projected for the third year of operation in Table I.

B. <u>General Review (GR) Criteria</u>

Chapter 8 of the *Mississippi Certificate of Need Review Manual, 2011 Revision,* addresses general criteria by which all CON applications are reviewed.

GR Criterion 1 - State Health Plan (SHP)

The *State Health Plan* contains criteria and standards for the following regarding the proposed ROH project within Rankin County: establishment of a diagnostic catheterization and PCI services and acquisition of related equipment.

Staff contends that the establishment of the services listed above and acquisition of related equipment in Rankin County does foster the health planning purpose of increasing the accessibility, acceptability, continuity, and quality of health services.

GR Criterion 2 - Long Range Plan

The applicant states that ROH initially conversed about offering PCI services on a previous occasion; however, determined it was not going to be feasible to do so because of the prior limitation requiring open heart surgery.

River Oaks Hospital asserts that proposing to operate and offer diagnostic cath and PCI services will allow the hospital to accomplish its long range plan of providing a full complement of acute services.

Based on the application, ROH asserts that the proposed project is consistent with ROH's long-range goals/objectives. The proposed project seeks to establish diagnostic catheterization and PCI services and acquire related equipment.

GR Criterion 3 - Availability of Alternatives

Rankin Cardiology Center, LLC of Jackson was CON approved to establish a diagnostic cardiac catheterization service at the River Oaks Campus for three facilities. The applicant indicated that ROH considered continuing to offer cath services only through RCC; however, this option would persist in posing a problem for the patients and physicians. For example, if patients need PCI services during a cath procedure, patients will have to be transferred.

By providing a full complement of services to appropriately screened patients, the applicant believes this will:

- Permit ROH to meet its goals and the needs of its physicians and patients; and
- Assist patients presented to ROH's emergency department timely access to PCI services in relation to what is required for door-todoor balloon time.

The proposed project does not require ROH to modernize the existing facility or new construction. Again, a full complement of services at ROH will allow patients to receive all care at one location. Based on the *FY 2013 MSHP*, staff determined that the following facilities provide Cardiac Catheterizations in CC/OHSPA 5:

Facility/County	
Central Mississippi Medical Center	Hinds
Mississippi Baptist Medical Center	Hinds
Rankin Cardiology Center*•	Rankin
River Region Health System	Warren
St. Dominic-Jackson Memorial Hospital	Hinds
University Hospital & Health Systems	Hinds

*•As previously mentioned, RCC is the only center that provides diagnostic catheterizations only for Rankin Medical Center, Women's Hospital, and River Oaks Hospital patients, at River Oaks Hospital Campus.

The applicant asserts that if the proposed project is approved, ROH will enhance services already provided at the hospital and believes the project will improve patient's continuity of care. Since PCI services without open heart backup was approved by the American Health Association and practice guidelines and adopted/approved to be listed in the *FY 2013 MSHP*, ROH believes that the expansion at the facility will increase access to both diagnostic cath and PCI services to all Mississippians especially to those who reside in CC/OHSPA 5.

GR Criterion 4 - Economic Viability

The applicant provided a three-year projected operating statement. The total operating revenue over a projected three year period, any income increases or decreases or net losses are shown in Attachment 1 of this document.

Based on the applicant, there are no hospitals in Mississippi that offer PCI services <u>without</u> open-heart surgery backup. To determine the projected charges for the proposed project, ROH asserts that it analyzed ROH

Medicare and Medicaid (payor mix); inpatient and outpatient reimbursement levels; and inquiry of other hospital's program specifics. Expected reimbursements and supply costs, human resource needs, insight from other hospitals were used to determine profitability of the project.

As stated previously, there are no hospitals in Mississippi that offer PCI services <u>without</u> open-heart surgery backup. Thus, ROH's projected levels of utilization are based on several sources the applicant explored (see application). Their results determined that ROHs projections are reasonable, represent the current utilization and forecast what will be expected in GSHA 5. The applicant asserts that Health Management Associates, Inc. will support the service in case the project fails.

The applicant states that the proposed project will not have an impact on the overall cost of healthcare nor gross revenues or Medicaid expenses per procedure.

The proposed project does not have a capital expenditure that exceeds \$2,000,000; however, since Health Management Associates, Inc. is ROH's parent organization, the applicant provided HMA's consolidated financial documents and statements for December 31, 2012 and December 31, 2011. Based on the financial documents, the proposed project appears to be economically viable.

GR Criterion 5 - Need for the Project

The applicant affirms that the population in Flowood, Rankin County, Mississippi and GHSA 5 residents (including low income persons, racial and ethnic minorities, women, handicapped persons and other underserved groups, and the elderly) will have access to ROH proposing to establish a diagnostic cardiac catheterization (cath.) service and also providing primary and elective percutaneous coronary intervention (PCI) services at the hospital.

As previously mentioned, the proposed project is <u>not</u> an establishment of a new facility or relocation of an existing facility. In CC/OHSPA 5, the applicant affirms that there are four hospitals located less than 4 to 6 miles from ROH which have an existing PCI program <u>with</u> surgical backup. River Oaks Hospital asserts that neither the facility nor other hospitals in the facility's defined service area offer PCI services with<u>out</u> open heart surgery. Thus, the applicant asserts that there are no existing facilities providing similar services. The applicant states ROH does not have any current utilization for the proposed service; however, the facility provided utilization projections based on the following sources:

- Population growth and aging
- Incidence growth
- Current market share for River Oaks Health System
- Physician comments and support
- Number of patients presented to the hospital with cardiac problems

The narrative and tables under the first heading for *SHP Criterion 3 - Impact on Existing Providers* discusses three methodologies used and the results from the methodologies.

The applicant submitted about 43 letters of endorsement from community officials and individuals expressing their reaction to the proposal.

GR Criterion 6- Accessibility

River Oaks Hospital affirms that the proposed facility will be in compliance with federal and state regulations in regard to serving all patients in CC/OHSPA 5 regardless of race, creed, sex, or ability to pay.

The applicant projects that 2% of the patients served at ROH will be medically indigent and charity care patients. As a note, the hospital doesn't separate the numbers for each of those categories. The applicant indicates that the expected payor mix by type payor will be as follows: Medicaid, 12%, Medicare, 28%, Commercial, 55%, Self Pay, 3%, Charity care, 2%; and other, 0%.

If the proposed project is approved, ROH states patients will be able to access a full range of cardiac services, inclusive of cath and PCI services at one location. The application includes ROH's admission policy and indicates that the facility in Flowood is accessible to CC/OHSPA 5 residents 24 hours per day. The applicant asserts that operational hours for cath and PCI services will be 9 am to 5 pm, five days per week; however, primary or emergency PCI services will be available after traditional hours.

GR Criterion 7- Information Requirement

The applicant affirms that ROH 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

The applicant indicates that hospitals in CC/OHSPA 5 provide Cath and PCI services with open-heart surgery capabilities; however, the proposed project will establish diagnostic catheterization and PCI services along with acquiring related equipment. For a list of facilities that provide Cardiac Catheterizations in CC/OHSPA 5, see GR Criterion 3.

Although the proposed cath and PCI services would be comparable to other facilities in the area, ROH believes that hospitals in the area should continue to perform more complicated procedures relating to their larger open-heart surgery program. If the proposed project is approved, ROH will be the first hospital that will provide cath and PCI services without open-heart backup and trusts that the program will be a model of how these services can safely be offered at other facilities without open heart programs.

River Oaks affirms that implementation of the proposed project will affect existing health services in the region or statewide in some of the following ways:

- Improve continuity and Quality a patient's hospital choice relating to their care encourages a patient-physician relationship;
- Increase in accessibility hospitals with larger programs will be able to accommodate more complicated procedures while ROH handles PCIs;
- Improve Health in MS expansion of PCI service without openheart backup will improve the health of patients in state encountering significant heart disease;
- Access Point patients with heart issues will be able to utilize another entry point to cardiac services;
- Improve Time in Emergency Room PCI services at ROH will improve door-to-door balloon times that will result in better outcomes; and
- Minimize Transport patients would be able to receive services based on where they choose and won't have to be moved to another provider.

Based on the population of service area, ROH projects an increase in cath procedures over the next three years and anticipates decrease of accessibility to patients if the proposed project is not approved. The applicant believes this will cause a negative impact on the patients who are presented to the ER department with cardiac issues, patients who would like to have their healthcare provided by ROH and physicians who want their patients care provided by ROH. The applicant states that ROH has an emergency transfer agreement with University of Mississippi Medical Center.

GR Criterion 9 - Availability of Resources

The applicant asserts that ROH demonstrated a successful staffing history before it closed and asserts that sufficient personnel will be available to ensure proper implementation of this project. Also, ROH states that current staff is able to provide cath services and assist in more invasive hospital procedures. Through ROH affiliation with UMMC, it will allow its staff to learn from UMMC interventional cardiologist and nurses. River Oaks Hospital affirms that the facility will continue to utilize services provided by UMMC fellows in interventional cardiology to provide cardiac services at the facility. The applicant projects that 5.0, full-time equivalents (FTEs) will be required for the proposed project at a cost of \$256,560.

GR Criterion 10 - Relationship to Ancillary or Support Services

The applicant asserts ROH currently provides ancillary and support services and there will be no increase in the utilization of ancillary and support services as a result of this project.

GR Criterion 11- Health Professional Training Programs

The applicant states UMMC provides cardiac services at River Oaks and ROH anticipates that UMMC students will assist in providing cardiac services at the facility. River Oaks Hospital asserts that the facility currently works with other health training programs in the area to provide clinical and hospital experience for students. Thus, staff believes it appears that the proposed relocation of ROH will not have an adverse effect upon the health professional training programs in CC/OHSPA 5.

GR Criterion 12- Access by Health Professional Schools

The applicant asserts it currently works with health professional training programs in the area (See response under GR 11).

GR Criterion 14 - Construction Projects

The applicant contends no new construction or renovation is associated with the proposed project; however, under the project description, ROH indicated that River Oaks, LLC was approved to renovate two operating rooms at a cost of \$1,943,550.

GR Criterion 15 – Competing Applications

Since there are no competing applications, no additional information is required to adhere to this criterion.

GR Criterion 16 - Quality of Care

By the implementation of the proposed project, the applicant believes that the project will improve and enhance the delivery of care by increasing services and providing a more thorough cardiac program. River Oaks Hospital participates in the Medicare and Medicaid programs and is accredited by The Joint Commission.

IV. FINANCIAL FEASIBILITY

Cost Item	Estimated Cost	% of the Total
Construction Cost -New	\$0	0.00%
Construction Cost-Renovation	0	0.00%
Capital Improvements, i.e. (minor painting and repairs, refurbishing)	0	0.00%
Total Fixed Equipment Cost	0	0.00%
Total Non-Fixed Equipment Cost	398,000	88.84%
Land Cost	0	0.00%
Site Preparation Cost	0	0.00%
Fees (Architectural and Consultant Fees)	0	0.00%
Fees (Legal and Accounting)	25,000	5.58%
Contingency Reserve	0	0.00%
Capitalized Interest	0	0.00%
Other Cost (Consulting)	25,000	5.58%
Other Cost	-	0.00%
TOTAL PROPOSED CAPITAL EXPENDITURE	\$448,000	100%

A. Capital Expenditure Summary

As stated previously, no new construction or renovation is associated with the proposed project.

B. Method of Financing

To fund the project, River Oaks Hospital, LLC will use cash reserves in the amount of \$448,000.

C. Effects on Operating Costs

The applicant's projections of gross revenues for the first, second, and third year of operation, expenses, and net income are shown in Attachment 1. Utilization, cost, and charges are also included in the applicant's Three-Year Projected Operating Statement (See Attachment 1).

D. Cost to Medicaid/Medicare

In the application, River Oaks Hospital provides the following revenue source projections for each payor category listed below:

River Oaks, LLC d/b/a River Oaks Hospital							
Payor	Utilization Percentage	First Year Revenue					
Medicaid	12.00%	\$104,051,235.72					
Medicare	Medicare 28.00% \$242,786,216.68						
Self Pay	3.00%	\$26,012,808.93					
Commercial	55.00%	\$476,901,497.05					
Charity	2.00%	\$17,341,872.62					
Other	0.00%	\$0.00					
Total 100% \$867,093,631.00							
ROH states that bad debt is included into deductions from gross patient revenue. Charity care will be percentage of gross patient revenues; ranging from 1.75% to 2.50%. Medically indigent is approximately 2% of gross patient revenues.							

V. RECOMMENDATION OF OTHER AFFECTED AGENCIES

The Division of Medicaid was provided a copy of this application and the Department received written comments from the agency. The Division states that effective September 1, 2012, it changed the methodology by which it reimburses <u>outpatient services</u> so that the cost incurred, subsequent to that date, will no longer affect outpatient payments.

In addition, effective October 1, 2012, the Division changed the methodology by which it reimburses <u>inpatient services</u> so that the cost incurred, subsequent to that date, will only affect cost outlier payments. Based on the Division of Medicaid's analysis, the estimated increase in cost outlier payments resulting from this project cannot be determined at this time. The Division of Medicaid opposes this project.

VI. CONCLUSION AND RECOMMENDATION

This project is in substantial compliance with the overall objectives of the 2013 *Mississippi State Health Plan;* Chapter 8 of the *Mississippi Certificate of Need Review Manual, 2011 Revision;* and all adopted rules, procedures, and plans of the Mississippi Department of Health.

Consequently, the Division of Health Planning and Resource Development recommends approval of this application submitted by River Oaks Hospital, LLC dba River Oaks Hospital for the establishment of a diagnostic catheterization and PCI services and acquisition of related equipment.

ATTACHMENT 1

River Oaks, LLC d/b/a River Oaks Hospital Establishment of a Diagnostic Catheterization and PCI Services and Acquisition of Related Equipment

Three-Year Projected Operating Statement (With Project)

		Latest Actual	Proposed Year 1	Propose Year 2	d	Proposed Year 3		
Revenue								
Inpatient Care Revenue	\$	340,713,193 \$	370,689,897 \$	389,172	,420 \$	408,083,934		
Outpatient Care Revenue		469,510,194	496,403,734	518.079	,093	537.437.117		
Gross Patient Care Revenue	\$	810,223,387 \$	867,093,631 \$	907,251,	,513 \$	945,521,051		
Charity Care	\$	14,178,909 \$	15,362,066 \$	16,040	,908 \$	16,578,986		
Deductions from Revenue		656,455,471	702,702,325	735,342	,166	766,662,160		
Net Patient Care Revenue	\$	139,589,007 \$	149,029,240 \$	155,868,	,439 \$	162,279,905		
Other Operating Revenue	\$	7,928,198 \$	7,928,198 \$	7,928	,198 \$	7,928,198		
Total Operating Revenue	\$	147,517,205 \$	156,957,438 \$	5 163,796 ,	,637 \$	170,208,103		
Operating Expense								
Salaries	\$	32,869,490 \$	34,370,168 \$	35,732	.722 \$	36,867,154		
Benefits	Ŧ	8,656,571	9,028,424	9,381	, ,	9,668,377		
Supplies		25,952,147	26,551,753	27,046	,	27,335,852		
Services		8,562,504	8,667,999	8,733		8,721,605		
Lease		5,742,219	5,799,641	5,857	,638	5,916,214•		
Depreciation		7,822,333	7,862,133	7,862	,133	7,862,133		
Interest		300,547	300,547	300	,547	300,547		
Other		18,518,984	18,739,433	18,963	,940	19,016,862		
Total Operating Expense	\$	108,424,795 \$	111,320,098	5 113,878 ,	,455 \$	115,688,743		
Net Operating Income (Loss)	\$	39,092,410 \$	45,637,340	6 49,918,	,182 \$	54,519,361		

	 Latest	F	Proposed Year 1	Proposed Year 2	Proposed Year 3
Inpatient days	 22,142		25,052	26,366	27,981
Outpatient visits	52,680		56,640	58,968	61,438
Procedures	791,896		848,059	882,148	917,737
Charge per outpatient day	\$ 8,912	\$	8,764	\$ 8,786 \$	8,748
Charge per inpatient day	\$ 15,388	\$	14,797	\$ 14,760 \$	14,584
Charge per procedure	\$ 1,023	\$	1,022	\$ 1,028 \$	1,030
Cost per inpatient day	\$ 4,897	\$	4,444	\$ 4,319 \$	4,134
Cost per outpatient day	\$ 2,058	\$	1,965	\$ 1,931 \$	1,883
Cost per procedure	\$ 137	\$	131	\$ 129 \$	126