MISSISSIPPI STATE DEPARTMENT OF HEALTH DIVISION OF HEALTH PLANNING AND RESOURCE DEVELOPMENT MAY 2015

CON REVIEW C-NIS-0215-004 CARDIOVASCULAR SOLUTIONS OF MISSISSIPPI, LLC PROVISION OF DIGITAL SUBTRACTION ANGIOGRAPHY SERVICES CAPITAL EXPENDITURE: \$250,000

LOCATION: GRENADA, GRENADA COUNTY, MISSISSIPPI

STAFF ANALYSIS

I. PROJECT SUMMARY

A. Applicant Information

Cardiovascular Solutions of Mississippi, LLC is a limited liability company and its sole members are Ashwani Sastry, MD, Ali Aboufares, MD, and Foluso Fakorede, MD.

On February 19, 2015, the Secretary of State issued the entity a Certificate of Good Standing.

B. Project Description

Cardiovascular Solutions of Mississippi, LLC ("Cardiovascular Solutions") or ("CSM") requests Certificate of Need (CON) authority to provide in-office digital subtraction angiography ("DSA") services to patients in and around Grenada, Mississippi. The applicant states that the project does not involve new construction, repair or renovation, and CSM already owns all equipment necessary to perform DSA procedures.

The applicant submits that DSA may be performed on a repeat basis in cases where risk and cost of conventional angiography might otherwise preclude a series of follow-up studies. Such studies can provide valuable information regarding the natural history of a variety of vascular diseases and the long-term results of various therapeutic interventions. DSA also allows safer screenings of the elderly, who have a high risk of cerebrovascular disease. In addition, the applicant states that most DSA studies can be performed in less than one hour and are appropriate as an outpatient procedure, whereas conventional angiography usually requires a hospital stay of one or two days.

The applicant's final objective for the project is to provide DSA services from an inoffice setting, thereby making DSA procedures more accessible, convenient and comfortable for patients in the Grenada, Mississippi, which according to the applicant, is an area of the state that is currently underserved by DSA providers.

The project will require 5.0 FTE personnel at an estimated cost of \$55,000 per FTE the first year.

The total proposed capital expenditure is \$250,000 for fixed equipment, including improvements and other expenses necessitated by the equipment and installation. The applicant projects that the project will be completed and all capital expenditures will be incurred upon approval and receipt of CON or 30 days thereafter.

The MSDH Division of Health Facilities Licensure and Certification has approved the site for the improvements for the physician's practice.

II. TYPE OF REVIEW REQUIRED

This project is reviewed in accordance with Section 41-7-173, 41-7-191 (1)(d)(vii), and 41-7-193 of the Mississippi Code of 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 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 on June 8, 2015.

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

A. State Health Plan (SHP)

The FY 2015 State Health Plan contains criteria and standards which the applicant is required to meet before receiving CON authority for offering of diagnostic imaging services of an invasive nature, i.e. invasive digital angiography, if those services have not been provided on a regular basis by the proposed provider of such services within the period of 12 months prior to the time such services would be offered. This application is in substantial compliance with the applicable criteria stated in the Plan as follows:

SHP Criterion 1 - Need

The applicant for DSA services shall demonstrate that proper protocols for screening, consultation, and medical specialty backup are in place before services are rendered by personnel other than those with specialized training.

The applicant submits that all of the DSA services provided by CSM will be conducted by physicians with the necessary specialized training. CSM will not allow DSA procedures to be conducted except by physicians with necessary qualifications to meet the specialized training requirements as outlined in the *State Health Plan*. The physicians shall be a single specialty group of interventional cardiologists with

specialized interest, training and expertise in the diagnosis and treatment of vascular disease, who have spent dedicated time above and beyond that required for interventional cardiology, learning and developing skills in endovascular intervention.

SHP Criterion 2 - CON Approval/Exemption

Cardiovascular Solutions of Mississippi, LLC recognizes that CON approval is necessary before DSA services may be provided, and affirmed that it will not provide DSA services until CON approval is obtained.

B. General Review (GR) Criteria

Chapter 8 of the *Mississippi Certificate of Need Review Manual, Revised September 1, 2011;* addresses general criteria by which all CON applications are reviewed. This application is in substantial compliance with general review criteria contained in the manual.

GR Criterion 1- Consistency with the State Health Plan

The project is in substantial compliance with all criteria, standards, and policies of the FY 2015 Mississippi State Health Plan applicable to the provision of digital subtraction angiography services.

GR Criterion 2 – Long Range Plan

The applicant states that DSA services are a necessary part of Cardiovascular Solutions of Mississippi, LLC's long term plan to perform endovascular procedures in an in-office setting. DSA services are essential to CSM's business model, and were a focus when planning a safe and effective process to perform endovascular procedures in an in-office setting. Cardiovascular Solutions of Mississippi, LLC identified General Hospital Service Area IV (GHSA 4) as an underserved area of the State with regards to the availability and amount of DSA procedures currently being conducted in that region. The applicant states that this determination ultimately played a major role in CSM's decision to open the clinic in Grenada.

GR Criterion 3 – Availability of Alternatives

The applicant states that there are no alternative approaches to the project.

GR Criterion 4 - Economic Viability

Based on the income statement contained in the application, the project will be economically viable. CSM projects net income of \$109,875 the first year, \$334,751 the second year, and \$559.626 the third year of operation.

The applicant asserts that proposed charges were calculated based upon the appropriate CPT codes in existence for the procedures as listed in the Medicare database, specific to the service area in question. The applicant further states that the only similar services provided in the service area are provided at Baptist Memorial Hospital-North Mississippi, located in Oxford, and Baptist Memorial Hospital-Golden Triangle, located in Columbus, and the charges and profitability estimated by CSM are believed to be comparable to these two facilities.

Cardiovascular Solutions of Mississippi, LLC projects to perform approximately 250 DSA services in the first year with that number increasing to 500-750 procedures in the second and third year of operation. Although these numbers are higher than those experienced in GHSA 4, CSM believes that it can meet its projected numbers because numbers indicate that the need level of patients in GHSA 4 is not currently being met. The applicant submits that in 2013 there were a total of 42,885 DSA procedures statewide; with a state population of 3,156,054 that equates to a DSA usage rate of .0136, or 136 procedures per 10,000 population. Grenada County has a population of 22,668. After multiplying the usage rate times the Grenada population, the applicant determined that the need level was approximately 308 DSA procedures in Grenada County alone. Further, CSM submits that the need for DSA procedures in GHSA 4 is approximately 4,651 per year, based on a total population of 341,996 for the General Hospital Service Area multiplied by the usare rate of .0136.

GR Criterion 5 - Need for the Project

Cardiovascular Solutions of Mississippi, LLC contends that there is a definite need for DSA services in Grenada County, based on the high prevalence of peripheral vascular disease and the low number of providers/facilities capable of performing endovascular procedures in the area. The applicant states that the prevalence and devastating effects of vascular disease are reflected in the extremely high rate of limb amputations in Mississippi and particularly in the Delta. CSM proposes to perform endovascular procedures to treat peripheral vascular disease before the disease process progresses to the point that amputation is required. According the applicant, providing these services in Grenada County, where no DSA provider is currently registered, will be especially helpful for citizens that traditionally have trouble traveling, such as low income persons, racial and ethnic minorities, women, handicapped persons and other underserved groups, and the elderly, all of which groups are substantially represented in Grenada County and the Delta.

The project is not expected to have an effect on existing facilities providing DSA services since there are none located in the Grenada area.

GR Criterion 6 - Access to the Facility or Service

Cardiovascular Solutions affirms that all residents of the health planning service area, hospital service area, patient service area, including Medicare, Medicaid recipients, charity/medically indigent patients, racial and ethnic minorities, women, handicapped persons and the elderly will have access to the proposed services.

The applicant projects \$25,602 in gross patient revenue from charity care patients in Projected Year 1 and \$51,204 in Projected Year 2.

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 State Department of Health within 15 business days of request.

GR Criterion 8 - Relationship to Existing Health Care System

The applicant reiterates that currently the only registered DSA providers in GHSA 4 are Baptist Memorial Hospital with locations in Oxford and Columbus, Mississippi. CSM will be located in Grenada, Mississippi, and the closest DSA provider in the service area is over 50 miles away in Oxford. The applicant states it will be able to provide DSA services to Medicare, Medicaid, and medically indigent patients located around Grenada more efficiently than the two Baptist Memorial Hospital branches. Additionally CSM states it will be the only office-based provider of DSA services in the service area.

The applicant states that CSM's physicians have already established relationships with several physicians in the area, including internists and wound care specialists, to complement the services these physicians offer. The applicant further state that physicians of CSM are trained in internal medicine, and general cardiovascular disease, in addition to vascular medicine and interventional vascular procedures, and are dedicated to treating the risk factors and co-morbidities associated with cardiovascular disease in the community that they intend to serve.

The Department received no letters of opposition concerning the proposed project.

GR Criterion 9 - Availability of Resources

Cardiovascular Solutions expects to recruit additional personnel through traditional advertising and networking if necessary.

GR Criterion 14 - Construction Projects

This project does not require construction.

GR Criterion 16 - Quality of Care

Cardiovascular Solutions expects to improve the quality of care being delivered to the target population by making DSA services more convenient and accessible.

IV. FINANCIAL FEASIBILITY

Capital Expenditure Summary

The total estimated capital expenditure is allocated as follows:

	Item	Cost (\$)	Percent (%) of Total
a.	Construction Cost New	0	0
b.	Construction Cost Renovation	0	0
C.	Capital Improvements	0	0
d.	Total Fixed Equipment Cost ¹	\$250,000	100.00
e.	Total Non-Fixed Equipment Cost	0	0
f.	Land Cost	0	0
g.	Site Preparation Cost	0	0
h.	Fees (Architectural, Consultant, etc.)	0	0
i.	Contingency Reserve	0	0
j	Capitalized Interest	0	0
j.	Legal and accounting fees	0	0
k.	Other	<u>0</u>	<u>0</u>
	Total Proposed Capital Expenditure	<u>\$250,0000</u>	<u>100.00</u>

The above capital expenditure represents the overall estimated total capital expenditure for the DSA service. According to the applicant, the actual cost of the fixed equipment purchased by Cardiovascular Solutions of Mississippi, LLC is \$95,000.1 The additional \$155,000 is to account for improvements and "other" expenses necessitated by the equipment and installation of same.1

B. Method of Financing

The project does not require financing.

C. <u>Effect on Operating Cost</u>

The Hospital's three-year projected operating statement is presented at Attachment 1.

D. Cost to Medicaid/Medicare

The applicant projects the cost to third party payors as follows:

Payor Mix	Utilization Percentage (%)	First Year Revenue (\$)
Medicare	42	\$ 204,818
Medicaid	21	102,408
Commercial	32	153,613
Self Pay	0	0
Charity Care	5	25,602
Other	0	<u>0</u>
Total	100	\$ 486,441

V. RECOMMENDATIONS OF OTHER AFFECTED AGENCIES

The Division of Medicaid was provided a copy of this application for review and comment; the Department has not received a letter of comment on the proposed project.

VI. CONCLUSION AND RECOMMENDATION

This project is in substantial compliance with the criteria and standards for the provision of digital subtraction angiography services contained in the FY 2015 Mississippi State Health Plan; the Mississippi Certificate of Need Review Manual, 2011 Revision; and duly adopted rules, procedures, and plans of the Mississippi State Department of Health.

The Division of Health Planning and Resource Development recommends approval of the application submitted by Cardiovascular Solutions of Mississippi, LLC for the provision of Digital Subtraction Angiography (DSA) Services.

Attachment 1

Cardiovascular Solutions of Mississippi, LLC									
Three-Yea		ting Statem ar I		ect Only) ar 2	Year 3				
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Povonuo									
Revenue									
Patient Revenue:									
Inpatient	Φ.	400 444	Φ.	070.000	Φ.	4 450 202			
Outpatient	<u>\$</u>	486,441	<u>\$</u>	972,882		1,459,323			
Gross Patient Revenue	<u>\$</u>	486,441	\$	972,882	\$	1,459,323			
Charity Care	\$	25,602		51,204		76,806			
Deductions		<u>40,964</u>		81,927		122,891			
Net Patient Revenue	\$	419,875	\$	839,751	\$	1,259,626			
Other Operating Revenue		0		0		0			
Total Operating Revenue	\$	419,875	\$	839,751	\$	1,259,626			
Total operating iteration		110,010		000,101	<u> </u>	1,200,020			
Expenses									
Operating Expenses:									
Salaries	\$	100,000	\$	150,000	\$	200,000			
Benefits	· ·	10,000	· · · · · · · · · · · · · · · · · · ·	15,000		20,000			
Supplies		130,000		260,000		390,000			
Services		20,000		30,000		40,000			
Lease		0		0		0			
Depreciation		50,000		50,000		50,000			
Interest		0		0		0			
Other		<u>0</u>		<u>0</u>		0			
Total Expenses	<u>\$</u>	310,000	<u>\$</u>	505,000	<u>\$</u>	700,000			
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Net Income (Loss)	\$	109,875	\$	334,751	\$	559,626			
Assumptions									
Inpatient days*		0		0		0			
Outpatient days*		0		0		0			
Procedures		250		500		750			
Charge/outpatient day		0		0		0			
Charge per inpatient day		0		0		0			
Charge per procedure		\$1,946		\$1,946		\$1,946			
Cost per inpatient day		0		0		0			
Cost per outpatient day		\$1,240		\$1,010		\$ 933			