MISSISSIPPI STATE DEPARTMENT OF HEALTH DIVISION OF HEALTH PLANNING AND RESOURCE DEVELOPMENT SEPTEMBER 21, 2023

CON REVIEW NUMBER: FSF-NIS-0823-009 SOUTHERN VASCULAR, LLC OFFERING INVASIVE DIGITAL ANGIOGRAPHY IN A FREE-STANDING FACILITY CAPITAL EXPENDITURE: \$0.00 LOCATION: FLOWOOD, RANKIN COUNTY, MISSISSIPPI

STAFF ANALYSIS

I. PROJECT SUMMARY

A. <u>Applicant Information</u>

Southern Vascular, LLC ("Southern Vascular", "SV", or the "Applicant") is a Mississippi limited liability company and an office-based laboratory located at 120 Stone Creek Boulevard, Suite 300 Flowood, Rankin County, Mississippi. The Applicant has two (2) members (Rishi A. Roy, M.D., PLLC, and Danon Garrido, M.D., PLLC) who also serve as managing members. The Applicant states SV and Strategic Solutions ("Strategic") are currently negotiating a management agreement.

The application contains a Certificate of Good Standing from the Office of the Secretary of State, Jackson, Mississippi, indicating as of August 1, 2023, Southern Vascular, LLC is in good standing with the State of Mississippi.

B. <u>Project Description</u>

Southern Vascular requests certificate of need ("CON") authority to offer invasive digital angiography (DA) services at an office-based laboratory (OBL) located at 120 Stone Creek Boulevard, Suite 300, Flowood, Rankin County, Mississippi, in General Hospital Service Area ("GHSA") 5. The Applicant proposes to lease approximately 6,500 square feet of space at this location to offer invasive DA and other vascular and endovascular services, including diagnostic angiography, Arterial-Iliac, Femoral Popliteal ("Fem Pop"), Tibial Peroneal Revascularization and Dialysis Circuit-Fistulograms. The Applicant proposes to lease the building and equipment from the owner of the building – Plus Properties, LLC ("Plus"). The application contains a copy of a "Written Assurance of Intent to Enter Lease Agreement" between SV and Plus dated August 3, 2023.

The Applicant states the OBL will be managed by Strategic, a healthcare management company with over fifty-five (55) years of combined healthcare management experience in managing physician practices, OBLs, and ambulatory surgery centers.

Southern Vascular states the primary physician operators of the OBL will be Dr. Rishi Roy and Dr. Danon Garrido both of whom are highly experienced vascular and endovascular surgeons. The application contains the curriculum vitae ("CV") for each doctor.

The Applicant states the final objectives of the project are to increase access to care and provide patients with another option to receive necessary DA services in a convenient and cost-efficient manner.

The Applicant affirms that SV will comply with all applicable State statutes and regulations for the protection of the environment, including 1) approved water supplies; 2) sewage and water disposal; 3) hazardous waste disposal; 4) water pollution control; 5) air pollution control; and 6) radiation control.

The Applicant projects twenty-two (22) full-time equivalent (FTE) staff will be hired at an annual cost of \$750,000.00 the first year.

The Applicant affirms the project will not require a capital expenditure; therefore, the project should be complete within six (6) months of the Department's approval.

The application contains a letter dated July 7, 2023, documenting the Mississippi State Department of Health ("MSDH"), Division of Fire Safety and Construction, Bureau of Health Facilities Licensure and Certification's approval of the site for the project.

II. TYPE OF REVIEW REQUIRED

The Mississippi State Department of Health ("MSDH") will review applications for a CON under the statutory requirements of Sections 41-7-173, 41-7-191, and 41-7-193, Mississippi Code of 1972 Annotated, as amended. MSDH will also review applications for CON according to the general criteria listed in the *Mississippi Certificate of Need Review Manual*, all adopted rules, procedures, and plans of MSDH, and the specific criteria and standards listed below.

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 ten (10) days of publication of the staff analysis. The opportunity to request a hearing expires on October 2, 2023.

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

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

The FY 2022 Mississippi State Health Plan, Third Edition ("MSHP") contains policy statements and criteria and standards regarding Certificate of Need Applications for the Offering of Invasive Digital Angiography Services. The application complies with the policy statements, criteria, and standards stated in the MSHP as follows:

<u>Policy Statement 1 – Digital Angiography Equipment and Services in</u> <u>Ambulatory Surgery Centers</u>

The Applicant requests a CON to offer DA services to be performed in an officebased laboratory.

Certificate of Need Criteria and Standards for Invasive Digital Angiography (DA) in a Freestanding Facility

SHP Need Criterion 1: Staffing Requirements

- a. Proper protocols for screening and medical specialty backup. The Applicant certifies no DA services will be provided by personnel other than those with specialized training and that the proposed DA services will be performed by Dr. Rishi Roy and Dr. Danon Garrido, each of whom is a fellowship-trained vascular surgeon.
- **b. Physician(s) identify and certification**. The Applicant states that Dr. Rishi Roy and Dr. Danon Garrido will perform intravascular interventions using DA and certifies that each doctor will maintain medical staff privileges at a full-service hospital.

SHP Need Criterion 2: Types of Procedures

- **a.** Non-emergent or life-threatening nature. The Applicant affirms Southern Vascular's understanding of and compliance with Need Criterion 2.a.i – 2.a.iii.
- b. Percutaneous endovascular interventions of peripheral vessels not excluded in a.iii.1 (major blood vessels). The Applicant affirms Southern Vascular's understanding of and compliance with Need Criterion 2.b.

SHP Need Criterion 3: Transfer Agreement

The Applicant certifies that the facility will have a formal transfer agreement with a full-service hospital to provide services that are required beyond the scope of the freestanding facility's programs.

SHP Need Criterion 4: CON Exemption

The Applicant affirms its understanding and compliance with this criterion.

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

Chapter 8 of the *Mississippi Certificate of Need Review Manual, Revised September 1, 2019,* addresses the general criteria by which all CON applications are reviewed. This application is in substantial compliance with the general review criteria contained in the manual.

GR Criterion 1 – State Health Plan

The application was reviewed for consistency with the *FY 2022 Mississippi State Health Plan, Third Edition,* in effect at the time of submission. The project substantially complies with the criteria and standards for DA services stated in the State Health Plan.

GR Criterion 2 – Long Range Plan

Southern Vascular states that it developed the proposal to provide convenient, timely, and cost-effective access to DA services to individuals who reside in the Jackson, Mississippi, Metropolitan area and to increase access to care. The Applicant asserts that the project is consistent with SV's long-range plans to provide the highest quality DA services possible.

GR Criterion 3 – Availability of Alternatives

- a. Advantages and Disadvantages: The Applicant states the only alternative to the project as proposed would be to not do the project. Based on the need in the area for additional DA services, the Applicant states SV did not identify any advantages to this alternative.
- **b. New Construction Projects:** The Applicant affirms the project does not involve new construction.
- c. Beneficial Effects to the Health Care System: The Applicant submits the project will increase access to patient care by providing an additional access point for patients to receive vascular and intravascular procedures in a more convenient office-based setting.

d. Effective and Less Costly Alternatives:

- i. Unnecessary Duplication of Services: The Applicant states that there is not an effective and less costly alternative to the proposed project available in the area; therefore, it will not be an unnecessary duplication of services.
- **ii. Efficient Solution:** The Applicant submits there is no effective and less costly alternative to the proposed project.
- e. Improvements and Innovations: The Applicant asserts that OBLs promote a more patient-centered experience compared to the traditional hospital or facility setting and generally offer more convenient access to care, lower costs, and shorter waiting times compared to a traditional hospital setting.
- f. Relevancy: The Applicant states that as technology continues to advance, peripheral vascular procedures are increasingly being performed in nonhospital settings such as ambulatory surgery centers and OBLs. Southern Vascular states it projects that this trend will continue, and SV's proposed OBL offering DA services will be well-positioned to provide these necessary services in the future.

GR Criterion 4 - Economic Viability

- a. **Proposed Charge:** The Applicant states that in establishing chargemaster rates for the procedures to be offered in the OBL, SV considered Centers for Medicare and Medicaid Services ("CMS") reimbursement rates, historical data from other vascular laboratories, and the actual expenses expected for each procedure.
- **b. Projected Levels of Utilization:** The Applicant states that based on Strategics' management experience with similar OBLs in the State, the projected levels of utilization are consistent with those of similarly situated facilities and consistent with the need level of the service area.
- **c. Financial Feasibility Study:** The Applicant affirms this criterion is not applicable as the proposed project costs less than \$2,000,000.00.
- **d.** Financial Forecasts: The Applicant affirms this criterion is not applicable as SV is a new facility.
- e. Means of Covering Expenses in the Event of Failure to Meet Projections: The Applicant states that SV will cover expenses incurred by the proposed project through additional capital contributions by its members, if necessary.

f. Impact of Proposed Project on Health Care Cost: The Applicant states SV does not anticipate that the project will impact the cost of health care.

GR Criterion 5 - Need for the Project

a. Access by Population Served: The Applicant states that according to the American Diabetes Association, Mississippi has one of the highest rates of diabetes in the nation, with approximately 14.4% of the adult population having been diagnosed with diabetes. The Applicant further states that according to the Department's FY 2018 Diabetes Action Plan, diabetes also disproportionately affects African Americans, the poor, and other underserved communities.

The Applicant states that CMS has recognized that peripheral vascular interventions to treat diabetes complications and other forms of peripheral arterial disease can be performed safely, effectively, and efficiently in an office-based setting.

Southern Vascular states SV's services will be open and accessible to all members of the community, including low-income persons, racial and ethnic minorities, disabled persons, the elderly, and other underserved.

- **b.** Relocation of Services: The Applicant affirms this criterion is not applicable.
- **c.** Current and Projected Utilization of Comparable Facilities: The Applicant asserts the MSDH does not publish utilization statistics regarding the number of DA procedures performed by other facilities in the State.
- d. Probable Effect on Existing Facilities in the Area: The Applicant states SV does not anticipate that the proposed service will affect existing facilities providing similar services.
- e. Community Reaction: The application contains six (6) letters of support from health care providers in the area.

GR Criterion 6 - Access to the Facility or Service

a. Access to Services. The Applicant certifies that all residents of the health planning service area, hospital service area, or patient service area, including Medicaid recipients, charity/medically indigent patients, racial and ethnic minorities, women, disabled persons, and the elderly, will have access to the services proposed.

The following table shows the projected percentage of gross patient revenue and the actual dollar amount of health care proposed to be provided to medically indigent patients and/or charity patients.

	Medically* Indigent (%)	Medically Indigent (\$)	Charity Care (%)	Charity Care (\$)
Historical Year 2020	N/A	N/A	N/A	N/A
Historical Year				
2021	NA	NA	NA	NA
Projected Year 1	NA	NA		
			0.45	\$32,000.00
Projected Year 2	NA	NA	0.45	\$36,800.00

Note: The Applicant notes as a new facility, SV does not have historical utilization data or indigent/charity care data. The Applicant confirms that the figures in the above table are projections of indigent/charity care in the first two (2) years of operation of SV, and for purposes of these projections, SV does not separate medically indigent cases from charity care.

- **b.** Existing Obligations: The Applicant certifies the facility has no existing obligations under any federal regulation.
- c. Unmet Needs of Medicare/Medicaid and Medically Indigent Patients: The Applicant affirms the proposed services will be fully open and accessible to all patients, including Medicare, Medicaid, and medically indigent patients.
- **d.** Access to Proposed Facility: The Applicant affirms that Medicare, Medicaid, and medically indigent patients will have access to the services offered by SV.
- e. Access Issues
 - i. <u>Transportation and Travel</u>: The Applicant asserts there are no access issues to the facility.
 - **ii.** <u>Restrictive Admissions Policy:</u> The Applicant submits SV will not have an admissions policy as it will be operated as a physician office; however, SV will comply with applicable Federal and State civil rights laws and will not discriminate on the basis of race, color, national origin, age, disability, gender, or any other prohibited characteristics.

- iii. <u>Access to Care by Medically Indigent Patients</u>: The Applicant states SV will be fully open and accessible to all patients, including medically indigent patients.
- iv. <u>Operational Hours of Service</u>: The Applicant certifies Southern Vascular will operate during normal business hours Monday through Friday. The Applicant further certifies SV will not provide services on an emergency basis.

GR Criterion 7 - Information Requirement

The Applicant affirms Southern Vascular will record and maintain, at a minimum, the required information regarding charity care to the medically indigent and Medicaid populations and make it available to the Department within fifteen (15) business days of request.

GR Criterion 8 - Relationship to Existing Health Care System

- **a. Comparable Services:** The Applicant states invasive DA services are generally provided in full-service hospitals; however, offering these services in an OBL offers patients greater accessibility, efficiency, and convenience.
- **b.** Effect on Existing Health Services: The Applicant asserts the proposed project will complement existing services by offering an additional point of care for patients to obtain invasive DA and offer vascular interventions in a convenient office-based setting.
- **c.** Adverse Impact: The Applicant asserts that failure to grant the proposed CON would be detrimental to patients in the Jackson, Mississippi, area by decreasing access to care for necessary DA services and other vascular interventions.
- **d. Transfer/Referral/Affiliation Agreements:** The Applicant submits Southern Vascular does not have any transfer, referral, or affiliation agreements but will obtain a transfer agreement prior to the beginning of operations.

GR Criterion 9 - Availability of Resources

- **a. New Personnel:** The Applicant asserts new personnel necessary to operate the OBL will be recruited through public and private means to target and recruit qualified staff.
- **b.** Contractual Services: The Applicant submits this criterion is not applicable.

- c. Existing Facilities or Services: The Applicant submits this criterion is not applicable.
- **d.** Alternative Uses of Resources: The Applicant submits this criterion is not applicable.

GR Criterion 10 – Relationship to Ancillary or Support Services

- a. Support and Ancillary Services: The Applicant states no support or ancillary services are necessary for the proposed project.
- **b.** Changes in Costs or Charges: The Applicant states SV does not anticipate any change in costs or charges for the proposed project.
- **c.** Accommodation of Changes in Cost or Charges: The Applicant states the financial tables and three-year projected operating statement consider projected changes in cost and charges.

GR Criterion 11 – Health Professional Training Programs

The Applicant states this criterion is not applicable to the proposed project.

GR Criterion 12 – Access by Health Professional Schools

The Applicant affirms this criterion is not applicable.

GR Criterion 13 – Access by Individuals Outside Service Area

The Applicant submits that although SV anticipates providing services to individuals not residing in the service area, SV is unaware of any special needs or circumstances that should be considered.

GR Criterion 14 - Construction Projects

The proposed project does not require construction.

GR Criterion 15 – Competing Applications

There are no competing applications filed with the MSDH for the provision of invasive DA services.

GR Criterion 16 - Quality of Care

a. Past Quality of Care: The Applicant asserts this criterion is not applicable because the proposed project will be a new facility.

- **b. Improvement of Quality of Care:** The Applicant asserts that having another freestanding provider of DA services in the area will increase the accessibility, continuity, and quality of vascular medical care and provide more efficient and convenient service for patients.
- c. Accreditations and/or Certifications: The Applicant indicates the facility has no accreditations or certifications.

IV. FINANCIAL FEASIBILITY

A. <u>Capital Expenditure Summary</u>

The proposed project does not require a capital expenditure.

B. <u>Method of Financing</u>

The Applicant does not propose a capital expenditure; however, the Applicant proposes to lease the building for a ten (10) year term at a zero (0) percent interest rate for \$136,500 per year. In addition, the Applicant proposes to lease equipment for a ten (10) year term at three (3) percent interest for \$105,600 per year.

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

The three-year projected operating statement for Southern Vascular is presented in Attachment 1.

D. Cost to Medicaid/Medicare

Southern Vascular projects gross patient revenue cost (Project Only) to third-party payors as follows:

Payor Mix	Utilization *Percentage (%)	First Year Revenue (\$)
Medicare	34.54%	\$ 2,424,060.00
Medicaid	3.51 %	246,630.00
Commercial	56.65 %	3,977,151.00
Self Pay	4.84%	340,000.00
Charity Care	0.46%	32,000.00
Other	0.00%	0.00
Total	100.00%	\$ 7,020,101.00

Note: Staff's calculation differs from the Applicant's due to rounding.

V. RECOMMENDATIONS OF OTHER AFFECTED AGENCIES

The Division of Medicaid was provided a copy of this application for review and comment. As of September 21, 2023, no comments had been received from the Division of Medicaid.

VI. CONCLUSION AND RECOMMENDATION

This project is in substantial compliance with the FY 2022 Mississippi State Health Plan, Third Edition; the Mississippi Certificate of Need Review Manual, September 1, 2019, Revision; and duly adopted rules, procedures, and plans of the Mississippi State Department of Health.

Therefore, the Division of Health Planning and Resource Development recommends approval of the application submitted by Southern Vascular, LLC, for the Offering of Invasive Digital Angiography Services in a Freestanding Facility.

Attachment 1

Southern Vascular, LLC Offering of Invasive Digital Angiography Service Three-Year Operating Statement (Project Only)									
		Year I		Year 2	-	Year 3			
Revenue									
Patient Revenue:									
Inpatient	\$	0.00	\$	0.00	\$	0.00			
Outpatient		7,020,101.00		8,073,116.00		8,880,428.00			
Gross Patient Revenue		7 ,020,101.00	\$	8,073,116.00	\$	8,880,428.00			
Charity Care		20,000.00		23,920.00		26,312.00			
Deductions from Rev.		4,542,266.00		5,223,605.00		5,745,966.00			
Net Patient Revenue	\$	2,457,035.00	\$	2,825,591.00	\$	3,108,150.00			
Other Operating Revenue		0.00		0.00		0.00			
Total Operating Revenue	\$	2,457,035.00	\$	2,825,591.00	\$	3,108,150.00			
Expenses									
Operating Expenses:									
Salaries	\$	750.000.00	\$	795,000.00	\$	818,860.00			
Benefits		150.000.00		159,000.00		163,770.00			
Supplies		517,683.00		595,335.00		654,868.00			
Service		346,750.00		318,500.00		395,768.00			
Lease		242,100.00		246,195.00		250,412.00			
Depreciation									
Interest									
Other									
Total Expenses	<u>\$</u>	2,006,533.00	<u>\$</u>	2,114,030.00	<u>\$</u>	2,283,668.00			
					•				
Net Income (Loss)	\$	450,502.00	\$	711,561.00	\$	824,482.00			
Assumptions									
Inpatient days									
Outpatient days		250		250		250			
• •		1,000		1,250		1,500			
Procedures Charge/inpatient day		1,000		1,200		1,500			
Charge per outpatient	\$	28,080.00	\$	32,292.00	\$	35,522.00			
Charge per procedure		7,020.00	\$	6,458.00	ֆ \$	5,920.00			
Cost per inpatient day	\$	1,020.00	Ψ	0,400.00	Ψ	5,920.00			
Cost per outpatient day	\$	8 026 00	\$	8,456.00	\$	0 125 00			
		8,026.00				9,135.00			
Cost per procedure	\$	2,007.00	\$	1,691.00	\$	1,522.00			