

**MISSISSIPPI STATE DEPARTMENT OF HEALTH
DIVISION OF HEALTH PLANNING AND RESOURCE DEVELOPMENT
OCTOBER 6, 2023**

**CON REVIEW NUMBER: FSF-NIS-0823-011
ADVANCED VASCULAR AND VEIN ASSOCIATES, LLC
OFFERING INVASIVE DIGITAL ANGIOGRAPHY IN A FREE-STANDING FACILITY
CAPITAL EXPENDITURE: \$0.00
LOCATION: SOUTHAVEN, DESOTO COUNTY, MISSISSIPPI**

STAFF ANALYSIS

I. PROJECT SUMMARY

A. Applicant Information

Advanced Vascular and Vein Associates, LLC (“AVVA”, or the “Applicant”) is a Mississippi limited liability company and an office-based laboratory located at 60 Physicians Dr., Southaven, DeSoto County, Mississippi. The Applicant asserts AVVA has two (2) members (Rishi A. Roy, M.D., PLLC, and Danon Garrido, M.D., PLLC) who also serve as the managing members. The Applicant states that AVVA and Strategic Solutions (“Strategic”), located at 778 Liberty Road, Suite B, Flowood, Mississippi, 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 7, 2023, Advanced Vascular and Vein Associates, LLC is in good standing with the State of Mississippi.

B. Project Description

Advanced Vascular requests certificate of need (“CON”) authority to offer invasive digital angiography (DA) services at an office-based laboratory (OBL) located at 60 Physician Drive, Southaven, DeSoto County, Mississippi, in General Hospital Service Area (“GHSA”) 1. The Applicant proposes to lease equipment and approximately 7,000 square feet of space at the proposed 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 states AVVA proposes to lease the building and equipment from Plus Properties, LLC (“Plus”), the owner of the proposed building –. The application contains a copy of a “Written Assurance of Intent to Enter Lease Agreement” between AVVA and Plus dated August 7, 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.

Advanced Vascular states the primary physician operators of the OBL will be Dr. Rishi Roy, Dr. Danon Garrido, and Dr. Michelle Moe-Aiken, all of whom are highly experienced vascular and endovascular surgeons. The application contains each doctor's curriculum vitae ("CV").

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 AVVA 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 three (3) months of the Department's approval.

The application contains a letter dated August 21, 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 16, 2023.

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

A. State Health Plan (SHP)

The *FY 2022 Mississippi State Health Plan, Third Edition* (“MSHP”) contains policy statements, 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:

Policy Statement 1 – Digital Angiography Equipment and Services in Ambulatory Surgery Centers

The Applicant requests a CON to offer DA services to be performed in an office-based 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 that no DA services will be provided by personnel other than those with specialized training. The Applicant further certifies that the proposed DA services will be performed by fellowship-trained vascular surgeons.
- b. **Physician(s) identify and certification.** The Applicant certifies that AVVA surgeons will perform intravascular interventions using DA and that each doctor will maintain medical staff privileges at a full-service hospital and will be available at the facility or on call within a thirty (30) minute travel time of the full-service hospital during the hours of operation of the facility.

SHP Need Criterion 2: Types of Procedures

- a. **Non-emergent or life-threatening nature.** The Applicant affirms AVVA’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 AVVA’s understanding of and compliance with Need Criterion 2.b.

SHP Need Criterion 3: Transfer Agreement

The Applicant certifies that AVVA 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. General Review (GR) Criteria

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 as stated in the State Health Plan.

GR Criterion 2 – Long Range Plan

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

GR Criterion 3 – Availability of Alternatives

- a. **Advantages and Disadvantages:** The Applicant states the only alternative to the proposed project would be to not do the project. Based on the need in the area for additional DA services, the Applicant states AVVA 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 non-hospital settings such as ambulatory surgery centers and OBLs. The Applicant further states it projects that this trend will continue, and AVVA'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, AVVA 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 Mississippi, 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 AVVA is a new facility.
- e. Means of Covering Expenses in the Event of Failure to Meet Projections:** The Applicant states that AVVA will cover expenses incurred by the proposed project through additional capital contributions by its members, in the event of failed projections.

- f. **Impact of Proposed Project on Health Care Cost:** The Applicant states AVVA does not anticipate that the project will impact the cost of health care. The Applicant states that AVVA believes that the project will have a positive impact on the cost of healthcare as the procedures will be performed in the office-based setting versus the hospital and/or ambulatory surgery center setting.

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.

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

- b. **Relocation of Services:**

- i. **Replacement Facility:** The Applicant affirms this criterion is not applicable.
- ii. **Relocation of Services:** The Applicant states the proposed project does not involve the relocation of services.

- c. **Current and Projected Utilization of Comparable Facilities:** The Applicant asserts that MSDH does not publish utilization statistics regarding the number of DA procedures performed by other facilities in the State. Therefore, the Applicant affirms that the methodology used for projecting utilization was based on Strategics' management experience with similar OBLs in Mississippi.

- d. **Probable Effect on Existing Facilities in the Area:** The Applicant states AVVA does not anticipate that the proposed service will effect existing facilities providing similar services. Advanced Vascular notes that there

are twenty-nine (29) registered vascular surgeons in the state of Mississippi, per Medifind.com, and of those twenty-nine (29) registered vascular surgeons, only one (1) vascular surgeon practices in DeSoto County and the surrounding counties. The Applicant affirms based on those findings it makes the area a severely underserved population forcing patients to leave the State to receive adequate care.

- e. **Community Reaction:** The application contains seven (7) letters of support from health care providers for the proposed project.

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, AVVA does not have historical utilization data or indigent/charity care data.

- 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 that AVVA will be fully open and accessible to all patients, including Medicare, Medicaid, and medically indigent populations.
- d. **Access to Proposed Facility:** The Applicant affirms that Medicare, Medicaid, and medically indigent patients will have access to the services

offered by AVVA.

e. Access Issues

- i. Transportation and Travel:** The Applicant asserts there are no access issues to the facility.
- ii. Restrictive Admissions Policy:** The Applicant submits AVVA will not have an admissions policy as it will be operated as a physician office; however, AVVA 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. Access to Care by Medically Indigent Patients:** The Applicant states AVVA will be fully open and accessible to all patients, including medically indigent patients.
- iv. Operational Hours of Service:** The Applicant certifies Advanced Vascular will operate during normal business hours Monday through Friday. The Applicant further certifies that AVVA will not provide services on an emergency basis.

GR Criterion 7 - Information Requirement

The Applicant affirms Advanced 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 at a significantly lower cost.
- c. Adverse Impact:** The Applicant asserts that failure to grant the proposed CON would be detrimental to patients in the Desoto County, area by decreasing access to care for necessary DA services and other vascular interventions.

- d. **Transfer/Referral/Affiliation Agreements:** The Applicant submits Advanced 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 that AVVA will recruit personnel necessary to operate the OBL 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 that AVVA 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 AVVA anticipates providing services to individuals not residing in the proposed service area, AVVA is unaware of any special needs or circumstances that should be considered.

GR Criterion 14 - Construction Projects

The Applicant affirms the proposed project does not require construction.

GR Criterion 15 – Competing Applications

The Division of Health Planning and Resource Development affirms that there are no competing applications filed with 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. Capital Expenditure Summary

The Applicant affirms there is no capital expenditure associated with the proposed project.

B. Method of Financing

The Applicant states AVVA does not propose a capital expenditure for the proposed project. However, the Applicant proposes to lease the proposed 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 \$105,600.00 per year.

C. Effect on Operating Cost

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

D. Cost to Medicaid/Medicare

AVVA 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 October 6, 2023, no comments had been received from the Division of Medicaid.

VI. CONCLUSION AND RECOMMENDATION

This project substantially complies 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 Advanced Vascular and Vein Associates, LLC, for the Offering of Invasive Digital Angiography Services in a Freestanding Facility.

Attachment 1

Advanced Vascular and Vein Associates, LLC Offering of Invasive Digital Angiography Service Three-Year Operating Statement (Project Only)			
	Year 1	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	\$ 2,006,533.00	\$ 2,114,030.00	\$ 2,283,668.00
Net Income (Loss)	\$ 450,502.00	\$ 711,561.00	\$ 824,482.00
Assumptions			
Inpatient days			
Outpatient days	250	250	250
Procedures	1,000	1,250	1,500
Charge/inpatient day			
Charge per outpatient	\$ 28,080.00	\$ 32,292.00	\$ 35,522.00
Charge per procedure	\$ 7,020.00	\$ 6,458.00	\$ 5,920.00
Cost per inpatient day			
Cost per outpatient day	\$ 8,026.00	\$ 8,456.00	\$ 9,135.00
Cost per procedure	\$ 2,007.00	\$ 1,691.00	\$ 1,522.00