MISSISSIPPI STATE DEPARTMENT OF HEALTH DIVISION OF HEALTH PLANNING AND RESOURCE DEVELOPMENT MARCH 2016

CON REVIEW C-NIS-1115-026 ADVANCED VASCULAR ACCESS CENTER, LLC PROVISION OF DIGITAL SUBTRACTION ANGIOGRAPHY SERVICES AND PERIPHERAL VASCULAR CATHETEIZATION PROCEDURES CAPITAL EXPENDITURE: \$64,500 LOCATION: SENATOBIA, TATE COUNTY, MISSISSIPPI

STAFF ANALYSIS

I. PROJECT SUMMARY

A. <u>Applicant Information</u>

Advanced Vascular Access Center, LLC is a Mississippi limited liability company, formed on October 27, 2015 whose sole member is John L. Herzog, M.D.

On October 27, 2015, the Secretary of State issued the entity a Certificate of Good Standing.

B. <u>Project Description</u>

Advanced Vascular Access Center, LLC ("Advanced") or ("AVAC") requests Certificate of Need (CON) authority to provide in-office digital subtraction angiography ("DSA") services and peripheral vascular catheterization procedures to patients in and around Senatobia, Mississippi. The applicant indicates that the project does not involve new construction, repair or renovation, and Advanced will purchase fixed equipment at a cost of \$64,500.

The applicant submits that there is a high prevalence of peripheral vascular disease or "PVD" in the State of Mississippi and a low number of providers/facilities capable of performing treatment procedures in General Hospital Service Area 1 ("GHSA1") where Senatobia is located. The applicant states that the prevalence and devastating effects of PVD are reflected in the extremely high rate of limb amputations in Mississippi; therefore, the applicant proposes to perform DSA services and peripheral vascular catheterization procedures for the treatment of PVD before the disease process progresses to the point at which amputation is required.

The applicant's stated final objectives for the project are: to improve health care quality and patient safety for residents of GHSA 1, and especially Tate County; to help reduce the growth of health care costs while promoting high value, effective care; and, to ensure access to quality, competent care for vulnerable populations in GHSA 1 suffering from or at high risk of developing PVD.

HP&RD (03/16) C-NIS-1115-026 Advanced Vascular Access Provision of DSA Services & PVCP Page 2 The project will require 3.0 FTE personnel at an estimated cost of \$197,000 the first year.

The total proposed capital expenditure is \$64,500 for fixed equipment. The applicant projects that the project will be completed and all capital expenditures will be incurred within 4-6 months of final CON approval.

On February 29, 2016, the MSDH, Bureau of Health Facilities, Licensure and Certification approved the site for the improvements to 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 March 24, 2016.

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

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

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 Advanced will be conducted by a cardiologist with the necessary specialized training. The applicant does not propose to perform procedures involving the heart or the brain. The applicant states that prior arrangements have been made for consultation/backup from a vascular surgeon for interventional peripheral vascular procedures.

SHP Criterion 2 - CON Approval/Exemption

Advanced Vascular Access Center, LLC acknowledges 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 Advanced's long-range plans are to improve health care quality and patient safety for residents of GHSA 1; to help reduce the growth of health care costs while promoting high-value, effective care; and to ensure access to quality, competent care for vulnerable populations in GHSA 1 suffering from or at risk of developing PVD. The applicant believes that the proposed project is consistent with the applicant's long-term plans because DSA and peripheral vascular catheterization procedures are minimally invasive, relatively low-risk and low-cost, and will be performed by a qualified physician.

GR Criterion 3 – Availability of Alternatives

The applicant states that there are no less costly or more effective alternative methods of providing the proposed services.

The applicant stated it considered partnering with a hospital but decided that a better way to promote patient safety and convenience would be to allow patients to receive and recuperate from the proposed services in a private atmosphere that is more relaxed that a hospital setting. The applicant states that the proposed project will save both time and money.

GR Criterion 4 - Economic Viability

Based on the income statement contained in the application, the project will be economically viable by the second year of operation. Advanced projects a net loss of \$119,170 the first year, with net income of \$49,475 the second year and \$344,712 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. The applicant further asserts that the charges and profitability estimated by Advanced are comparable to the existing providers in GHSA1.

Advanced projects that it will perform approximately 250 DSA procedures in the first year of operation with that number increasing to 500-750 procedures in the second and third years of operation. In addition, the applicant projects to perform 36 peripheral vascular interventions the first year, 72 the second and 108 the third year. The applicant affirms that the projected levels of utilization are reasonably consistent with those experienced by the other two service providers in GHSA 1, as well with the need level of GHSA 1.

GR Criterion 5 - Need for the Project

Advanced submits that the proposed project will provide health care services primarily to a patient population suffering from PVD. The applicant states that the need for additional diagnostic and therapeutic vascular services is significant as there are only two other providers in GSA 1 and both are located in Southaven, approximately 26 miles north of Senatobia. Advanced believes that making the proposed services available in Tate County will be especially helpful for residents of Tate, Panola, Tunica and Marshall counties that traditionally have trouble traveling, such as low income persons, racial and ethnic minorities, handicapped persons and other underserved groups, and the elderly.

The applicant states that it will serve all patients who come seeking care and confirms that there are no policies or procedures in place which would exclude patients based on race, color, age, sex, ethnicity, or income.

GR Criterion 6 - Access to the Facility or Service

Advanced 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 \$37,479 in gross patient revenue from charity care patients in Projected Year 1 and \$74,958 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 submits that there are two existing providers located in Southaven, Desoto County, Mississippi. No comparable services are available in Senatobia and/or Tate County.

The applicant states that the proposed project is unique because Advanced will be the only DSA provider in Tate County. It will be a closer and more convenient option for many who live in GHSA 1 and need access to peripheral arterial disease treatment services.

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

GR Criterion 9 - Availability of Resources

Advanced expects to recruit additional personnel through traditional methods of advertising and networking, as necessary.

GR Criterion 14 - Construction Projects

This project does not require construction.

GR Criterion 16 - Quality of Care

Advanced expects that the project will improve the quality of care by improving health outcomes in GHSA 1 and by delivering services from an in-office setting in a manner that maximizes resource use and avoids waste.

IV. FINANCIAL FEASIBILITY

Capital Expenditure Summary

The total estimated capital expenditure is allocated as follows:

	ltem	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	64,500	100.0
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>\$64,500</u>	<u>100.00</u>

The above capital expenditure represents the overall estimated total capital expenditure for the DSA service.

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

The project will be financed with a bank loan from Metropolitan Bank with interest rate of 5.25% over a term of 5 years.

C. Effect on Operating Cost

The applicant'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	48	\$ 359,796
Medicaid	21	157,411
Commercial	26	194,890
Self Pay	0	0
Charity Care	5	37,479
Other	<u>0</u>	<u>0</u>
Total	100	\$ 749,576

V. RECOMMENDATIONS OF OTHER AFFECTED AGENCIES

The Division of Medicaid was provided a copy of this application for review and comment; however, 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 Advanced Vascular Access Center, LLC for the provision of Digital Subtraction Angiography (DSA) Services and Peripheral Vascular Catheterization Procedures.

Attachment 1

Advanced Vascular Access Center, LLC Three-Year Operating Statement (Project Only)							
Inree-Yea		ear I	Year 2	Year 3			
Revenue							
Patient Revenue:							
Inpatient							
Outpatient	<u>\$</u>	749,876	<u>\$ 1,499,152</u>	<u>\$ 2,248,615</u>			
Gross Patient Revenue	\$	749,576	\$ 1,499,152	\$ 2,248,615			
Charity Care	\$	37,479	74,958	112,431			
Deductions		<u>150,665</u>	<u>301,329</u>	<u>451,972</u>			
Net Patient Revenue	\$	561,432	\$ 1,122,865	\$ 1,684,212			
Other Operating Revenue		0	0	0			
	\$	561,432	÷				
Total Operating Revenue	φ	301,432	\$ 1,122,865	\$ 1,684,212			
Expenses							
Operating Expenses:							
Salaries	\$	170,000	\$ 270,000	\$ 270,000			
Benefits	+	27,000	45,000	45,000			
Supplies		8,400	8,400	8,400			
Services		0	0	0			
Lease		50,695	50,695	50,695			
Depreciation		12,900	12,900	50,000			
Interest		0	0	0			
Other		412,175	686,395	952,505			
Total Expenses	<u>\$</u>	<u>681,170</u>	<u>\$ </u>	<u>\$ 1,339,500</u>			
Net Income (Loss)	\$	(119,738)	\$49,475	\$ 344,712			
	Ψ	(110,100)	ψ+0,+10	ψ 044,112			
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		\$2,246	\$2,246	\$2,246			
Cost per inpatient day		0	0	0			
Cost per outpatient day		\$2,725	\$2,147	\$ 1,786			