MISSISSIPPI STATE DEPARTMENT OF HEALTH DIVISION OF HEALTH PLANNING AND RESOURCE DEVELOPMENT MARCH 17. 2017

CON REVIEW NUMBER: C-NIS-0117-002

VASCULAR ACCESS CENTER OF BOLIVAR, LLC

PROVISION OF DIGITAL SUBTRACTION ANGIOGRAPHY SERVICES AND

PERIPHERAL VASCULAR CATHETERIZATION SERVICES

CAPITAL EXPENDITURE: \$504,501.00

LOCATION: CLEVELAND, BOLIVAR COUNTY, MISSISSIPPI

STAFF ANALYSIS

I. PROJECT SUMMARY

A. Applicant Information

Vascular Access Center of Bolivar, LLC is a Mississippi Limited Liability Company (LLC), located at 810 East Sunflower Road, Suite 100E; Cleveland, Mississippi 38732. The applicant indicates that Vascular Access Center of Bolivar, LLC is governed by a four member Board of Directors and Officers.

The applicant provided a Certificate from the Secretary of State, verifying that the LLC was registered on January 11, 2010 and received a Certificate of Good Standing on January 11, 2017. The document indicates that the business is a LLC in the State of Mississippi.

B. Project Description

Vascular Access Center of Bolivar, LLC (VAC Bolivar) 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 Cleveland, Bolivar County, Mississippi.

According to the applicant, there is a high prevalence of both peripheral vascular disease (PVD) and diabetes in the State of MS with few provider facilities performing DSA procedures in General Hospital Service Area (GHSA) 3. Staff determined that General Hospital Service Area 3 is comprised of eight (8) counties: Bolivar, Coahoma, Humphreys, Leflore, Quitman, Sunflower, Tallahatchie and Washington. The applicant states that currently, there are two (2) hospital-based DSA Service providers located in GHSA 3: Bolivar Medical Center (Cleveland, Bolivar County, Mississippi) and Greenwood Leflore Hospital (Greenwood, Leflore County, Mississippi). Bolivar Medical Center and Greenwood Leflore Hospital offer DSA services in a hospital setting.

The applicant submits that the project will provide services from an in-office setting as opposed to an acute care hospital. Therefore, the applicant states that VAC Bolivar will be the only facility in GHSA 3 to offer DSA services in a freestanding facility. VAC Bolivar believes that by providing in office DSA services, procedures will be more accessible, convenient and comfortable for patients.

The applicant states that the final objective of the proposed project is to improve the health care quality and patient safety for residents of Bolivar County and GHSA 3.

VAC Bolivar is currently providing services pursuant to the terms and conditions of the Confidential Consent Order, which was approved by MSDH prior to the submission of the proposed CON application.

The applicant affirms that the proposed project requires a capital expenditure of \$504,501 for the renovation of 4,320 square feet of space it currently leases.

The applicant states that the proposed project will require .5 additional full time equivalents (FTEs) personnel for 2017 at an estimated cost of \$50,195 for the first year (for project only).

The applicant further states that the services to be offered pursuant to the CON will require 9 full time equivalents (FTEs) personnel at an estimated cost of \$695,614. The applicant confirms that VAC Bolivar will lease all equipment to perform the proposed services.

The applicant anticipates that the offering of CON approved services will begin immediately following receipt of final CON approval.

The applicant submitted a request for site approval to the MSDH Division of Health Facilities Licensure and Certification on January 27, 2017.

II. TYPE OF REVIEW REQUIRED

This project is reviewed in accordance with Sections 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 of 1972, Annotated, as amended, any affected person may request a public hearing on this project within 10 days of publication of the staff analysis. The opportunity to request a hearing expires on March, 27, 2017.

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 states that VAC Bolivar will not perform any procedures involving the heart or brain. The applicant submits that the proposed DSA services (interventional peripheral vascular procedures) will be performed by three board-certified physicians and will possess the necessary specialized training. The physicians are as follows: Dr. Salil Joshi, Dr. Jorge Salazar and Dr. Michael Cohen.

The application contains Curricula Vitae for Dr. Salil Joshi, Dr. Jorge Salazar and Dr. Michael Cohen. The application also contains a copy of a signed Medical Director Agreement of Bennie Wright, M.D. confirming an arrangement for consultation/backup from a vascular surgeon has been made for all interventional vascular procedures. The applicant states that Mr. Bennie Wright, M.D. will not perform procedures from start to finish at VAC Bolivar. The applicant further states, that in the event a patient goes into distress during a procedure being performed at VAC Bolivar, the backup vascular surgeon (Bennie Wright, M.D.) would be available to provide the needed treatment.

SHP Criterion 2 - CON Approval/Exemption

The applicant acknowledges that CON approval or written evidence that the equipment or service is exempt from CON approval is required. VAC Bolivar is currently providing services pursuant to the express permission of the Department. VAC Bolivar will cease the provision of those services in the event the Department directs it to do so or if the Department disapproves this CON application.

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 offering of digital subtraction angiography services and peripheral vascular catheterization services.

GR Criterion 2 – Long Range Plan

The applicant states that DSA services are a necessary part of VAC Bolivar's long term plan to continue to improve health care quality and patient safety for residents of General Hospital Service Area (GHSA) 3. The applicant further states that VAC Bolivar's goal is 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 suffering from or at high risk of developing PVD, as well as those who require VAC Bolivar's services related to their dialysis treatments. The applicant states that the proposed project is consistent with the applicant's long term plans of providing quality healthcare to the citizens of Cleveland, Bolivar County, Mississippi and GHSA 3 by offering patients convenient access to DSA and peripheral vascular catheterization procedures.

GR Criterion 3 – Availability of Alternatives

The applicant affirms that VAC Bolivar considered not going forward with the proposed project; however, that option would leave the residents of GHSA 3 with a growing unmet need for the services. The applicant states that VAC Bolivar also considered partnering with a local hospital to provide the proposed services, but decided that a better way to promote patient safety and convenience would be to allow patients to receive and recuperate in a private atmosphere. The applicant believes an office setting would provide a more relaxed environment than a hospital setting. The applicant believes since the proposed project will not involve hospitalization, the cost of care will be lower, turnaround times between procedures will be much faster and scheduled procedure times are less likely to be delayed due to an emergency that may occur in a hospital setting.

According to the applicant, there are no less costly or more effective alternative methods of providing the proposed services. Based on this conclusion, VAC Bolivar believes that the proposed project is the best solution to providing more accessible, convenient and comfortable access to the citizens of GHSA 3.

GR Criterion 4 - Economic Viability

The applicant submits that the cost for allocated DSA Services will be \$4,180 per procedure for the first year of operation. VAC Bolivar contends that the proposed charges and profitability estimates are comparable to the existing providers in GHSA 3. VAC Bolivar projects net income of \$76,000 the first year with CON approval, \$84,000 the second year with CON approval, and \$93,000 the third year of operation with CON approval (see Attachment 1).

The applicant asserts that it is an office-based practice and does not have the high overhead normally associated with hospitals where acute care is traditionally performed. Nonetheless, VAC Bolivar submits that while not anticipated, the applicant could fall short of the proposed revenue projections and still satisfy the requirement for economic viability based on the realistic revenues projected.

The applicant affirms that the proposed project requires a capital expenditure of \$504,501.00.

GR Criterion 5 - Need for the Project

The applicant states that the needs for additional diagnostic and therapeutic vascular services in GHSA 3 are significant. The applicant asserts there are two hospital based DSA Service providers located in GHSA 3: Bolivar Medical Center and Greenwood Leflore Hospital. The *FY 2015 MS SHP* states that Bolivar Medical Center performed 724 DSA procedures and Greenwood Leflore Hospital performed 2,597 DSA procedures for a total of 3,321 in FY 2013 for GHSA 3.

The FY 2015 State Health Plan shows that the 2020 projected population for GHSA 3 will be 181,292. The FY 2015 MSHP verifies that there were a total of 42, 885 DSA procedures statewide for FY 2013.

The following table shows the performed and projected DSA services provided for the proposed project:

Prior Year (Performed)	Projected Year (Projected)	Digital Subtraction Angiography Services (DSA)
FY 2015	-	924
FY 2016	-	896*
-	1	900
-	2	900
-	3	900

Note: *Annualized for calendar year 2016

VAC Bolivar confirms that the 900 projected procedures for years one through three in the proposed application is a conservative projection, including no growth in VAC

Bolivar's historical utilization numbers. The applicant states that VAC Bolivar will initiate the provision of additional services, not presently offered, which will increase revenues in the future.

The applicant confirms that GHSA 3 is comprised of eight (8) counties: Bolivar, Coahoma, Humphreys, Leflore, Quitman, Sunflower, Tallahatchie and Washington; six (6) of which do not have DSA providers. Along with Bolivar County, the applicant believes that the counties in direct need of more accessible DSA services are Coahoma, Humphreys, Quitman, Sunflower, Tallahatchie and Washington. The applicant states that there is a high prevalence of both peripheral vascular disease and diabetes in the State of MS and a low number of providers capable of performing treatment procedures in GHSA 3. The applicant affirms that VAC Bolivar will offer these urgently needed DSA services for patients in GHSA 3. The applicant further states that the high population of diabetic patients require an access line in which frequently becomes clogged, impaired and require services that VAC Bolivar provides in order to repair, clear or replace the access line.

The applicant suggests that the proposed service area is well known to have a population primarily composed of ethnic minorities, economically underprivileged and medically underserved persons. The applicant believes that providing the clinic-based DSA service, they will unquestionably meet a need in the service area as well as increase access to services to those most in need.

The applicant states that VAC Bolivar is currently providing services pursuant to the MSDH's express permission. The applicant confirms that VAC Bolivar anticipates no adverse impact to the existing service providers because the approval of the proposed CON application will not add any additional services to the proposed service area. The applicant further states that the level of services provided at VAC Bolivar will remain status quo.

The applicant states that presently there are no office-based endovascular lab offering DSA in GHSA 3. Therefore, the applicant affirms that VAC Bolivar will continue to be the only freestanding DSA provider in the entire eight (8) county service area.

The application contains 11 letters of support from Cleveland, Mississippi's Mayor; the Executive Director of BCCOA (Bolivar County Council on Aging, Inc.); Health and Wellness Board Member from the Washington County Economic Alliance; and various GHSA 3 residents for the proposed project.

GR Criterion 6 - Access to the Facility or Service

According to the applicant, all patients in the service area, including Medicaid recipients, charity/medically indigent patients, racial and ethnic minorities, women, handicapped persons, and the elderly, will have access to the services of the facility.

The following table shows the projected estimated gross patient revenues of health care provided to charity/medically indigent patients for years one and two for the proposed project:

Projected Year	Medically Indigent	Charity Care
1	\$0.00 (0%)	\$37,479.00 (5%)
2	\$0.00 (0%)	\$74,958.00 (5%)

The applicant submits that the proposed facility will operate five (5) days per week. However, VAC Bolivar will offer additional operating hours and days as the patient population increases.

The applicant submits that VAC Bolivar has no obligations under any federal regulations requiring provision of uncompensated care, community service, or access by minority/handicapped persons.

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

VAC Bolivar is located in General Hospital Service Area 3. As previously stated, there are two hospital based DSA Service providers located in GHSA 3: Bolivar Medical Center and Greenwood Leflore Hospital and are limited to hospital settings, and a private office setting is not available in GHSA 3. These providers performed 3,321 digital subtraction angiography procedures in FY 2013.

The applicant affirms that there are no comparable services available in the six (6) remaining counties. The applicant confirms that patients in Coahoma, Humphreys, Quitman, Sunflower, Tallahatchie and Washington have no provider in their counties; however they are able to travel to Bolivar County more easily compared to leaving GHSA 3 in order to receive care. The applicant believes the non-hospital setting allows patients to receive comfortable quality care in a close proximity to their homes.

The applicant suggests that the proposed project will not affect existing health services in the target area because no other in-office DSA services are currently offered.

The applicant states that due to the constant aging population in GHSA 3, risks of PVD are increasing. The applicant affirms that the need for peripheral interventions

in northern Mississippi increases each year and the proposed project is necessary to serve the vascular health needs of the service area. The application included a Transfer Agreement with Bolivar Medical Center.

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

GR Criterion 9 - Availability of Resources

The applicant asserts additional personnel will be recruited by VAC Bolivar through traditional advertising and networking, if necessary.

GR Criterion 10 - Relationship to Ancillary or Support Services

The applicant asserts that Criterion 10 is not applicable to the proposed DSA project.

GR Criterion 14 - Construction Projects

This applicant confirms that the project does not require new construction; however, the applicant provided information asserting a renovation of 4,320 square feet would be required at a cost of \$116.78 per square foot.

GR Criterion 16 - Quality of Care

The applicant states that the proposed project will continue the provision of the highest quality of care to patients in GHSA 3 by delivering services from an in-office setting in a manner that maximizes resource use and avoids waste. Additionally, the applicant confirms that the services will be delivered in a way that takes into account each patient's preferences and aspirations.

VAC Bolivar believes that the proposed project will improve the quality of care being delivered to the target population area, and make DSA services more convenient and accessible in the GHSA 3 area.

IV. FINANCIAL FEASIBILITY

Capital Expenditure Summary

The applicant affirms that the capital expenditure associated with the proposed project is \$504,501.00. The applicant states that the cost is for the renovation of 4,320 square feet of space at a cost of \$116.78 per square foot.

Method of Financing

Since the proposed project does not require a capital expenditure as stated above, no funding source is needed.

C. Effect on Operating Cost

VAC of Bolivar'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	82%	\$3,170,000	
Medicaid	7%	285,000	
Commercial	10%	400,000	
Self Pay	1%	25,000	
Charity Care	0%	0	
Other	0%	0	
Total	100	\$ 3,880,000	

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 Vascular Access Center of Bolivar, LLC for in-office digital subtraction angiography (DSA) services and peripheral vascular catheterization procedures.

Attachment 1

Vascular Access Center of Bolivar, LLC Three-Year Operating Statement (with Project)					
I hree-Yea	Year I	ent (with Project) Year 2	Year 3		
Revenue					
Patient Revenue:					
Inpatient					
Outpatient	\$3,880,000	\$3,960,000	<u>\$4,040,000</u>		
Gross Patient Revenue	3,880,000	3,960,000	4,040,000		
Charity Care	0	0	0		
Deductions	0	0	0		
Net Patient Revenue	\$3,880,000	<u>\$3,960,000</u>	\$4,040,000		
Other Operating Revenue	\$ 0	\$ 0	\$ 0		
Total Operating Revenue	\$3,880,000	\$3,960,000	\$4,040,000		
Total Operating Revenue	<u>ψ3,000,000</u>	<u>\$5,900,000</u>	<u>\$4,040,000</u>		
Expenses					
Operating Expenses:					
Salaries	\$1,640,000	\$1,685,000	\$1,730,000		
Benefits	105,000	110,000	115,000		
Supplies	1,445,000	1,460,000	1,475,000		
Services	352,000	355,000	357,000		
Lease	120,000	122,000	124,000		
Depreciation	45,000	45,000	45,000		
Interest	0	0	0		
Other	<u>97,000</u>	<u>99,000</u>	<u>101,000</u>		
Total Expenses	\$3,804,000	\$3,876,000	\$3,947,000		
Net Income (Loss)	\$ 76,000	\$ 84,000	\$ 93,000		
Assumptions					
Inpatient days	0	0	0		
Outpatient visits	0	0	0		
Procedures	910	930	950		
Charge/outpatient day	N/A	N/A	N/A		
Charge per inpatient day	N/A	N/A	N/A		
Charge per procedure	\$ 4,264	\$ 4,258	\$ 4,253		
Cost per inpatient day	N/A	N/A	N/A		
Cost per outpatient day	\$ 4,180	\$ 4,168	\$ 4,155		