

**MISSISSIPPI STATE DEPARTMENT OF HEALTH
DIVISION OF HEALTH PLANNING AND RESOURCE DEVELOPMENT
OCTOBER 17, 2022**

**CON REVIEW NUMBER: POB-NIS-0822-014
NORTH MISSISSIPPI VASCULAR CARE, LLC
PROVISION OF INVASIVE DIGITAL ANGIOGRAPHY SERVICES
CAPITAL EXPENDITURE: \$0.00
LOCATION: COLUMBUS, LOWNDES COUNTY, MISSISSIPPI**

STAFF ANALYSIS

I. PROJECT SUMMARY

A. Applicant Information

North Mississippi Vascular Care, LLC (the “Applicant” or “North MS Vascular Care”) is a Mississippi limited liability company which owns and operates a physician office located at 425 Hospital Drive, Suite 4A, Columbus, Lowndes County, Mississippi. The application indicates North MS Vascular Care has two (2) managing members (AVA Columbus Mississippi Holdings, LLC and Jomad Cardiovascular, LLC) and is managed by American Vascular Associates, located at 3001 Palm Harbor Blvd. Ste. A, Palm Harbor, Florida.

The application contains a Certificate of Good Standing from the Office of the Secretary of State, Jackson, Mississippi, indicating as of July 22, 2022, North Mississippi Vascular Care, LLC is in good standing with the state of Mississippi.

B. Project Description

North MS Vascular Care requests Certificate of Need (“CON”) authority to offer invasive digital angiography services at its physician office facility, located in Columbus, Lowndes County, Mississippi, in General Hospital Service Area (“GHSA”) 4. The Applicant states North MS Vascular Care currently leases equipment which has the capability to perform the proposed service; therefore, there are no additional building costs or capital expenditures associated with the project. The application contains a copy of the lease agreement with Siemens Medical Solutions.

The Applicant states North MS Vascular Care currently provides non-digital angiography services at its facility for viewing arteries and veins with the use of fluoroscopy. The Applicant states the service requires the injection of contrast material into the patient which highlights the blood vessels through the artery or vein. The Applicant further states due to world-wide supply-chain disruptions involving contrast material, North MS Vascular Care is unable to obtain contrast material. According to the Applicant, the only alternative to the now unavailable contrast material is CO₂. The Applicant states using CO₂ requires the use of invasive digital angiography to properly observe the blood vessels. The Applicant states, because of the world-wide shortage in contrast material and in order to continue to serve its patients, North MS Vascular Care urgently needs to provide the proposed service.

The Applicant states the final objectives of their project are: to ensure access to necessary medical procedures during the time of the global supply shortage of contrast material; to improve health care quality and patient safety for residents of Lowndes County and GHSA 4; to reduce health care costs while promoting high-value, effective care; to ensure the accurate diagnosis and provision of treatment of patients with chronic limb-threatening ischemia (“CLTI”); and to ensure access to quality and competent care for vulnerable populations in GHSA 4.

The Applicant projects two (2) additional full-time equivalent (FTE) staff will be hired at an annual cost of \$130,000.00 the first year. The Applicant projects the project will not require a capital expenditure, construction, or renovation. The Applicant anticipates the service to begin immediately following the receipt of final CON approval by the Department.

The application contains a letter dated August 18, 2022, documenting the project does not require site approval by the Mississippi State Department of Health (“MSDH”), Division of Health Facilities Licensure and Certification.

II. TYPE OF REVIEW REQUIRED

The Mississippi State Department of Health 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 a Certificate of Need 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 27, 2022.

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, Second Edition* (“MSHP”) contains policy statements and criteria and standards regarding CON applications for the Offering of Invasive Digital Angiography Services. The application is in compliance 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 states this Policy Statement is not applicable as the digital angiography (“DA”) services will be performed in a physician’s office.

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

SHP Need Criterion 1 - Staffing Requirements

- a. **The applicant for invasive DA services shall demonstrate that proper protocols for screening and medical specialty backup are in place before services are rendered by personnel other than those with specialized training. The protocols shall include, but are not limited to, having prior arrangements for consultation/backup from a vascular surgeon, cardiologist, radiologist or nephrologist credentialed and accredited for interventional peripheral vascular procedures.**

The Applicant certifies that North MS Vascular Care will not perform any procedures involving the heart or the brain. Additionally, the Applicant indicates the DA services will not be performed by personnel other than those with specialized training. The Applicant states the proposed DA services (interventional peripheral vascular procedures) will be performed by Dr. John King, who has all the necessary specialized training to perform interventional peripheral vascular procedures.

- b. **Identify physicians in the group and state which physician(s) will perform intravascular interventions using invasive DA. Certify that:**
 - i. **Each physician will maintain medical staff privileges at a full-service hospital; or**
 - ii. **At least one member of the physician group has staff privileges at a full-service hospital and will be available at the facility or on call within a 30-minute travel time of the full-service hospital during the hours of operation of the facility.**

The Applicant states Dr. John King will perform intravascular interventions using invasive DA and certifies that Dr. King will maintain medical staff privileges at a full-service hospital.

SHP Need Criterion 2 - Types of Procedures

- a. **Procedures in a freestanding facility are generally non-emergent nor life threatening in nature and require a patient stay of less than 24 consecutive hours. The procedures shall not be of a type that:**

- i. **Generally, result in blood loss of more than ten percent of estimated blood volume in a patient with a normal hemoglobin.**
- ii. **Require major or prolonged intracranial, intrathoracic, abdominal, or major joint replacement procedures, except for laparoscopic procedures; or**
- iii. **Involve major blood vessels.**
 1. **Major blood vessels are defined as the group of critical arteries and veins including the aorta, coronary arteries, pulmonary arteries, superior and inferior vena cava, pulmonary veins, carotid arteries, and any intracerebral artery or vein.**

The Applicant affirms the proposed invasive DA procedures are generally non-emergent and non-life-threatening in nature and require a patient stay of less than twenty-four (24) consecutive hours. In addition, the Applicant certifies the procedures will not be of a type that meets any of the criteria listed in Need Criterion 2.a.i – 2.a.iii.

- b. **Percutaneous endovascular interventions of the peripheral vessels not excluded in a.iii.1. above are permitted to be performed in a freestanding facility. These procedures are defined as procedures performed without open direct visualization of the target vessel, requiring only needle puncture of an artery or vein followed by insertion of catheters, wires, or similar devices which are then advanced through the blood vessels using imaging guidance. Once the catheter reaches the intended location, various maneuvers to address the diseased area may be performed which include, but are not limited to, injection of contrast for imaging, ultrasound of the vessel, treatment of vessels with angioplasty, atherectomy, covered or uncovered stenting, intentional occlusion of vessels or organs (embolization), and delivering of medications, radiation, or other energy such as laser, radiofrequency, or cryo.**

The Applicant affirms its understanding of and compliance with Need Criterion 2.b.

SHP Need Criterion 3 - Transfer Agreement

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

The Applicant certifies North MS Vascular Care will have a formal transfer agreement with a full-service hospital to provide services which are required beyond

the scope of the freestanding facility's programs.

SHP Need Criterion 4 - CON Exemption

Before utilizing or providing the equipment or service, the applicant desiring to provide the digital angiography equipment or invasive DA services shall have CON approval or written evidence that the equipment or service is exempt from CON approval as determined by MSDH through a determination of reviewability.

The Applicant affirms its understanding and compliance with this criterion. In addition, the Applicant provided a letter dated January 19, 2021, as evidence that the equipment is exempt from CON review as determined by MSDH.

B. General Review (GR) Criteria

Chapter 8 of the *Mississippi Certificate of Need Review Manual, Revised September 1, 2019*, addresses 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, Second Edition* in effect at the time of submission. The Applicant asserts the project satisfies all four (4) general goals of the State Health Plan.

GR Criterion 2 – Long Range Plan

The Applicant states North MS Vascular Care's long-range plans are: to continue to improve health care quality and patient safety for residents of Lowndes County and GHSA 4; to reduce health care costs while promoting high-value, effective care; to ensure the accurate diagnosis and provision of treatment of patients with chronic limb threatening ischemia ("CLTI"); and to ensure access to quality, competent care for vulnerable populations in GHSA 4.

GR Criterion 3 – Availability of Alternatives

- a. **Advantages and Disadvantages:** The Applicant states there are no less costly or more effective alternative methods other than providing the proposed services. The Applicant further states, in order to continue to serve its patients during the contrast material global supply shortage, the proposed project is the only identified 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 most effectively benefit the health care system by ensuring continued quality and accessible care for the Applicant's patients and for GHSA 4. The Applicant further states, without adopting this alternative method to provide services, its patients would remain unserved during the global supply chain shortage and patients who suffer from CLTI will be without a necessary provider of services to treat their condition.
- d. **Effective and Less Costly Alternatives:**
 - i. **Unnecessary Duplication of Services:** The Applicant states North MS Vascular Care is unaware of any other providers in its service area replacing non-digital angiography services with invasive digital angiography. In addition, the Applicant states it is unaware of other physician practices performing invasive DA procedures for the diagnosis of CLTI. The Applicant submits the operation of a clinic-based DA provider will meet a need in GHSA 4 and increase access to services to those who need it most. The Applicant also notes its patient population will not have access to the proposed service without the granting of the CON. Therefore, the Applicant indicates the project is not a 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 the proposed project fosters innovations in the delivery of health services in the face of a global supply chain deficit. According to the Applicant, the use of catheter-based endovascular techniques is minimally invasive and allows for necessary fluoroscopic procedures to continue to occur while the shortage of contrast material continues. The Applicant states invasive DA is very helpful in the care of peripheral arterial disease patients with CLTI. The Applicant states the increasing prevalence of CLTI is also fueling the Applicant's need for vascular imaging to accurately diagnose and provide treatment.
- f. **Relevancy:** The Applicant asserts, considering the global supply-chain disruption involving contrast material, North MS Vascular Care is utilizing the only present alternative to replace the unavailable contrast material.

GR Criterion 4 - Economic Viability

- a. **Proposed Charge:** The Applicant asserts the proposed charges are similar to other DA services provided in the State by the same type of facility as the Applicant.
- b. **Projected Levels of Utilization:** The Applicant states the projected levels of utilization are reasonably consistent with those experienced by similar

facilities in GHSA 4, as well as with the need level of GHSA 4.

- c. **Financial Feasibility Study:** The Applicant affirms this criterion is not applicable as the proposed capital expenditure is less than \$2,000,000.00.
- d. **Financial Forecasts:** The Applicant affirms the financial forecasts do not deviate significantly from the three-year historical period financial statements.
- e. **Means of Covering Expenses in Event of Failure to Meet Projections:** The Applicant states North MS Vascular Care is an office-based practice and does not have the same high overhead costs associated with an acute care hospital where DA procedures are normally performed. The Applicant further states it has projected realistic revenues for the project based on current performance. However, the Applicant asserts it could fall short of its revenue projections and still satisfy the requirement for economic viability for the proposed project.
- f. **Impact of Proposed Project on Health Care Cost:** The Applicant asserts North MS Vascular Care is confident that the proposed project will reduce overall health care costs for all aspects of the health care system, including Mississippi Medicaid. The Applicant states the proposed services will be performed from an office-based setting, which will be significantly less expensive for the Medicaid program than equivalent services performed in a hospital setting. In addition, the Applicant states the services will prevent the development of more serious and life-threatening issues and complications that are more expensive to treat.

GR Criterion 5 - Need for the Project

- a. **Access by Population Served:** The Applicant states Lowndes County's population is comprised of the elderly, of ethnic and racial minorities, the economically underprivileged and medically underserved populations. The Applicant notes the operation of a clinic-based DA provider will meet a need in the service area and increase access to services to those in the State who need it most.
- b. **Relocation of Services:** The Applicant affirms this criterion is not applicable.
- c. **Current and Projected Utilization of Comparable Facilities:** The Applicant notes North MS Vascular Care currently provides non-digital angiography services at its facility for viewing arteries and veins with the use of fluoroscopy. The Applicant states the methodology North MS Vascular Care used for projecting utilization is based on the Applicant's previous utilization of non-digital angiography and the conversion of non-digital angiography services to invasive DA services.

- d. **Probable Effect on Existing Facilities in the Area:** The Applicant asserts, based on the need previously described, there will be no significant adverse impact to existing service providers as the service will only be used to treat North MS Vascular Care’s existing patients.
- e. **Community Reaction:** The application contains fourteen (14) letters of support from health care providers and community leaders.

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, handicapped persons, and the elderly will have access to the services proposed.

The following table shows the projected percentage of gross patient revenue and 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 (\$)
Projected Year 1	1%	\$55,986.00	N/A	N/A
Projected Year 2	1%	106,865.00	N/A	N/A

- 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 available to all patients, including Medicare, Medicaid, and medically indigent patients.
- d. **Access to Proposed Facility:** The Applicant submits North MS Vascular Care does not discriminate against and will provide free access to the poor, physically handicapped, women, elderly, and members of ethnic and racial minorities.
- e. **Access Issues**
 - i. **Transportation and Travel:** The Applicant submits North MS Vascular Care is located at 425 Hospital Drive in Columbus, Mississippi and is easily accessible to all patients.
 - ii. **Restrictive Admissions Policy:** The Applicant submits North MS Vascular Care has always provided and will continue to provide free

access to its services for all segments of Lowndes County and the surrounding area population. The Applicant notes the facility does not have an admissions policy as it is a physician practice.

- iii. **Access to Care by Medically Indigent Patients:** The Applicant states North MS Vascular Care is committed to serving the needs of the diverse population of GHSA 4, including medically indigent patients who come to the clinic seeking care.
- iv. **Operational Hours of Service:** The Applicant certifies North MS Vascular Care operates and will continue to operate Monday through Friday from 8:00 am until 4:00 pm.

GR Criterion 7 - Information Requirement

The Applicant affirms North MS Vascular Care will record and maintain, at a minimum, the required information regarding charity care, care to the medically indigent, and Medicaid populations and will 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 North MS Vascular Care is currently unaware of any other providers in its service area replacing non-digital angiography services with digital angiography. The Applicant submits, without the granting of the CON, its patient population will not have access to the proposed service. In addition, the Applicant states it is unaware of any other physician practices performing DA procedures for the diagnosis of CLTI.
- b. **Effect on Existing Health Services:** The Applicant asserts the proposed project will have no adverse impact on existing health services as it is purely designed to continue to provide quality care to its existing patient base by using the only alternative to contrast material currently available. The Applicant states failure to utilize this alternative treatment will result in North MS Vascular Care being unable to care for its patient base.
- c. **Adverse Impact:** The Applicant asserts there is no alternative to the use of contrast material, which is largely unavailable due to the current global shortage. The Applicant further states failure to grant the proposed CON would result in an adverse impact to the Applicant's patients.
- d. **Transfer/Referral/Affiliation Agreements:** The Applicant submits North MS Vascular Care does not have any transfer, referral or affiliation agreements but will obtain a transfer agreement prior to operations beginning, if required.

GR Criterion 9 - Availability of Resources

- a. New Personnel:** The project will require the addition of one (1) registered nurse and one (1) radiological technician. The Applicant asserts new personnel will be recruited through public and private means to target qualified staff.
- b. Contractual Services:** The Applicant submits currently there are no related contractual services.
- c. Existing Facilities or Services:** The Applicant states the proposed service is currently being provided at North MS Vascular Care subject to an emergency authorization and will continue if the project is approved.
- d. Alternative Uses of Resources:** The Applicant states the proposed service is the only known alternative to the use of contrast materials, which are not presently available due to a global shortage and supply chain disruption.

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 asserts there should be no material change in costs or charges as a result of the project.
- c. Accommodation of Changes in Cost or Charges:** The Applicant states there will be no change in costs or charges for the proposed project.

GR Criterion 11 – Health Professional Training Programs

The Applicant states North MS Vascular Care does not anticipate an impact on the clinical needs of health professional training programs.

GR Criterion 12 – Access by Health Professional Schools

The Applicant states this criterion is not applicable.

GR Criterion 13 – Access by Individuals Outside Service Area

The Applicant submits the project focuses on the needs of those residing in the service area.

GR Criterion 14 - Construction Projects

The Applicant states the proposed project does not require construction.

GR Criterion 15 – Competing Applications

There are no competing applications filed with the Mississippi State Department of Health for the provision of invasive DA services.

GR Criterion 16 - Quality of Care

- a. **Past Quality of Care:** The Applicant asserts North MS Vascular Care is committed to the provision of prompt, efficient, high-quality service to all patients who present for digital angiography procedures.
- b. **Improvement of Quality of Care:** The Applicant asserts the proposed project will improve the quality of care delivered to the target population because North MS Vascular Care serves patients who are at high risk for limb amputation. The Applicant further states the provision of invasive digital angiography services also assist in determining whether amputation is necessary or can be avoided.
- c. **Accreditations and/or Certifications:** The Applicant submits the facility has no accreditations or certifications.

IV. FINANCIAL FEASIBILITY

A. Capital Expenditure Summary

The proposed project does not require a capital expenditure.

B. Method of Financing

This criterion is not applicable as the Applicant does not propose a capital expenditure.

C. Effect on Operating Cost

The three-year projected operating statement for North Mississippi Vascular Care, LLC is presented at Attachment 1.

D. Cost to Medicaid/Medicare

North MS Vascular Care projects gross patient revenue cost (Project Only) to third party payors as follows:

Payor Mix	Utilization Percentage (%)	First Year Revenue (\$)
Medicare	59.00%	\$ 3,359,188.00
Medicaid	10.00%	559,865.00
Commercial	25.00%	1,399,662.00
Self Pay	5.00%	279,932.00
Charity Care	1.00%	55,986.00
Other	0.00%	0.00
Total	100.00%	\$ 5,654,633.00

V. RECOMMENDATIONS OF OTHER AFFECTED AGENCIES

The Division of Medicaid was provided a copy of the Applicant's application for review and comment. As of October 17, 2022, no comments have been received from the Division of Medicaid.

VI. CONCLUSION AND RECOMMENDATION

This project is in substantial compliance with the criteria and standards for the provision of invasive digital angiography services contained in the *FY 2022 Mississippi State Health Plan, Second Edition*; the *Mississippi Certificate of Need Review Manual, September 1, 2019, Revision*; and the 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 North Mississippi Vascular Care, LLC for the provision of invasive digital angiography services in a freestanding facility.

Attachment 1

North Mississippi Vascular Care, LLC Provision 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	5,654,633.00	10,793,365.00	11,761,200.00
Gross Patient Revenue	\$ 5,654,633.00	\$ 10,793,365.00	\$ 11,761,200.00
Charity Care	(38,071.00)	(72,668.00)	(80,784.00)
Deductions from Rev.	3,807,080.00	7,266,820.00	8,978,400.00
Net Patient Revenue	*\$ 1,809,482.00	\$ 3,453,877.00	\$ 3,763,584.00
Other Operating Revenue	0.00	0.00	0.00
Total Operating Revenue	*\$ 1,809,482.00	\$ 3,453,877.00	\$ 3,763,584.00
Expenses			
Operating Expenses:			
Salaries	\$ 57,000.00	\$ 105,500.00	\$ 106,250.00
Benefits	16,000.00	29,500.00	29,750.00
Supplies	582,400.00	1,020,800.00	1,170,000.00
Service	85,500.00	177,875.00	193,150.00
Lease			
Depreciation			
Interest			
Other	75,850.00	122,000.00	131,750.00
Total Expenses	\$ 816,750.00	\$ 1,455,675.00	\$ 1,630,900.00
Net Income (Loss)	*\$ 992,732.00	\$ 1,998,202.00	\$ 2,132,684.00
Assumptions			
Inpatient days			
Outpatient days			
Procedures	212	319	360
Charge/inpatient day			
Charge per outpatient			
Charge per procedure	\$ 26,673.00	\$ 33,835.00	\$ 32,670.00
Cost per inpatient day			
Cost per outpatient day			
Cost per procedure	\$ 3,853.00	\$ 4,563.00	\$ 4,530.00

*Note. Net Patient Revenue, Net Operating Revenue, and Net income are off by \$1.