

**MISSISSIPPI STATE DEPARTMENT OF HEALTH
DIVISION OF HEALTH PLANNING AND RESOURCE DEVELOPMENT
SEPTEMBER 23, 2024**

**CON REVIEW NUMBER: FSF-NIS-0824-009
LOWERY A. WOODALL SURGERY FACILITY, LLC
D/B/A LOWERY A. WOODALL OUTPATIENT SURGERY CENTER
OFFERING OF INVASIVE DIGITAL ANGIOGRAPHY SERVICES
IN A FREESTANDING FACILITY
CAPITAL EXPENDITURE: \$0.00
LOCATION: HATTIESBURG, FORREST COUNTY, MISSISSIPPI**

STAFF ANALYSIS

I. PROJECT SUMMARY

A. Applicant Information

Lowery A. Woodall Surgery Facility, LLC d/b/a Lowery A. Woodall Outpatient Surgery Center ("LAW or Applicant") is a Mississippi Limited Liability Company (LLC), located at 1 Lincoln Parkway Suite 100, Hattiesburg, Mississippi, 39401, and authorized to do business in Mississippi. The Applicant asserts LAW, a licensed and certified multi-specialty is owned by Hattiesburg Clinic Professional Association ("Hattiesburg Clinic"), a medical group with over 450 physicians and providers located in 17 counties in South Mississippi. Furthermore, the Applicant states in 2015, Hattiesburg Clinic received certificate of need ("CON") approval to offer invasive digital angiography ("DA") services at its primary clinic in Hattiesburg. Since that time, Hattiesburg Clinic's vascular surgeons and cardiologists have provided DA services to patients in the Clinic's office-based laboratories. The Applicant submits in May of 2024, LAW commenced operations in a newly renovated, state-of-the-art facility located at the Lincoln Center in Hattiesburg.

The Applicant provided a Certificate of Good Standing dated August 7, 2024, from the Secretary of State verifying the LLC was registered on July 21, 1998. The document indicates that the business is authorized to do business in the State of Mississippi.

B. Project Description

Lowery A. Woodall Surgery Facility, LLC requests Certificate of Need (CON) authority for the Offering of Digital Angiography (DA) Services in a Freestanding Facility, to patients in Hattiesburg, Forrest County, Mississippi. This application proposes the relocation of Hattiesburg Clinic's vascular DA service line to LAW's new facility in Hattiesburg. Existing equipment used for the provision of vascular DA services also will be relocated. LAW will become the provider of vascular DA

services, which will continue to be performed by Hattiesburg Clinic's vascular surgeons. Hattiesburg Clinic will continue to provide cardiology-related DA services at its primary clinic.

The *FY 2022 MS State Health Plan (3rd Edition)*, defines Invasive Digital Angiography ("DA") as "a diagnostic and catheter based therapeutic intravascular intervention imaging procedure that combines a digital processing unit with equipment similar to that used for standard fluoroscopic procedures." As defined, the Mississippi State Department of Health (MSDH) now regulates DA as a diagnostic and therapeutic practice.

The Applicant states following completion and approval of the project, the project will enable LAW and Hattiesburg Clinic physicians to perform vascular DA services in a new, state-of-the-art facility that was designed with multiple enhancements to elevate the standard of care for patients. The Applicant state Vascular Institute anticipates offering DA services within thirty (30) to sixty (60) days following CON approval.

The Applicant affirms LAW will comply with state and local building codes, zoning ordinances, and/or other appropriate regulations.

The Applicant affirms LAW 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's application included the site approval letter from the MSDH Division of Health Facilities Licensure and Certification, dated September 20, 2024.

The Applicant states, the proposed project does not require a capital expenditure.

II. TYPE OF REVIEW REQUIRED

This project is reviewed in accordance with Sections 41-7-173, 41-7-191, 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 ten (10) days of publication of the staff analysis. The opportunity to request a hearing expires on October 3, 2024.

III. CONFORMANCE WITH THE STATE HEALTH PLAN AND OTHER ADOPTED

CRITERIA AND STANDARDS

A. State Health Plan (SHP)

The *FY 2022 State Health Plan (3rd Edition)* contains criteria and standards which the applicant is required to meet before receiving CON authority for the 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 twelve (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 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 states LAW hereby certifies that it will maintain proper protocols for patient screening and that medical specialty consultation/backup will be available through Hattiesburg Clinic's vascular surgeons, cardiologists, radiologists, and nephrologists credentialed and accredited for interventional peripheral vascular procedures. Furthermore, the Applicant states the same highly experienced vascular surgeons and staff who currently provide vascular DA services at Hattiesburg Clinic will continue to provide the services at the LAW facility.

- b. **Identify physicians in the group and state which physician(s) will perform intravascular interventions using 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 the following Hattiesburg Clinic vascular surgeons will

perform DA services at LAW: Humayun Bakhtawar, MD, FACS, RPVI; J. Branson Harrison, MD; and Sourabh Mukherjee, MD, FACS, RPVI. The Applicant affirms all of the physicians have medical staff membership and clinical privileges at Forrest General Hospital in Hattiesburg.

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 twenty-four (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 certifies that the DA procedures performed at the LAW facility will comply with the above-stated guidelines. The Applicant affirms the same highly experienced and credentialed vascular surgeons who perform these procedures at Hattiesburg Clinic will continue to perform them at LAW.

- 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, artherectomy, 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 states LAW acknowledges that the above-described procedures are permitted to be performed in a freestanding facility. The Applicant affirms LAW will maintain clinically appropriate protocols with respect to the provision of vascular DA services.

SHP Need Criterion 3- Transfer Agreement

The Applicant confirms LAW currently has and will maintain a Patient Transfer Agreement with Forrest General Hospital.

SHP Need Criterion 4 - CON Approval/Exemption

The Applicant confirms in this application, LAW requests CON approval to offer DA services.

B. General Review (GR) Criteria

Chapter 8 of the *Mississippi Certificate of Need Review Manual, Revised November 11, 2023 ("Manual")*, 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 project is in substantial compliance with all criteria, standards, and policies of the *FY 2022 Mississippi State Health Plan (3rd Edition)* applicable to the acquisition or control of digital angiography equipment and the offering of digital angiography services in a freestanding facility.

GR Criterion 2 – Long Range Plan

The Applicant states following the completion of LAW's newly renovated ambulatory surgery center, the management teams of LAW and Hattiesburg Clinic determined that the relocation of vascular DA services to the new LAW facility would greatly enhance the clinical experience of patients in need of this service. The Applicant affirms the proposed project is consistent with LAW's and Hattiesburg Clinic's mission of providing quality health care in an efficient and cost-effective manner, with an emphasis on excellence and service to the patient.

GR Criterion 3 – Availability of Alternatives

- a. **Advantages and Disadvantages:** The Applicant states the only alternative to the proposed project would be to continue to provide vascular DA services at Hattiesburg Clinic's primary clinic location; however, that alternative was rejected as not being in the best interests of patients served by Hattiesburg Clinic's physicians.
- b. **New Construction Projects:** The Applicant affirms this criterion is not applicable.
- c. **Beneficial Effects to the Health Care System:** The Applicant states the relocation of vascular DA services to LAW will enable Hattiesburg Clinic and LAW to continue to provide these services to patients in an efficient, cost-effective and clinically superior environment.
- d. **Effective and Less Costly Alternatives:**
 - i. **Unnecessary Duplication of Services:** The Applicant states the proposed project does not involve a duplication of services because Hattiesburg Clinic currently provides vascular DA services and merely proposes to relocate those services to LAW.
 - ii. **Efficient Solution:** The Applicant states The LAW facility is a more clinically efficient environment than the current location of vascular DA services and will provide improved access to patients.
- e. **Improvements and Innovations:** The Applicant affirms, Vascular DA services will continue to be provided by Hattiesburg Clinic's highly experienced vascular surgeons in a cost-effective outpatient setting
- f. **Relevancy:** The Applicant states there is a clear industry trend in which health services are being moved to more efficient, accessible and less costly outpatient facilities. The proposed project is directly responsive to this trend.

GR Criterion 4 - Economic Viability

- a. **Proposed Charge:** The Applicant states the proposed charges for the services to be offered by LAW are presented in the accompanying financial analysis tables and are based on Hattiesburg Clinic's historical charge structure for the services.

- b. **Projected Levels of Utilization:** The Applicant states LAW's current and projected levels of utilization reflect the need for the proposed project.
- c. **Financial Feasibility Study:** The proposed project requires a capital expenditure of \$0.00; therefore, a financial feasibility study is not required for the proposed project.
- d. **Financial Forecasts:** The Applicant states that LAW does not project that its financial forecasts will deviate significantly from the facility's historical financial experience.
- e. **Covered Expenses:** The Applicant affirms LAW does not anticipate that the project will fail to meet projected revenues but has financial resources available to cover expenses.
- f. **Impact of Proposed Project on Health Care Cost:** The Applicant states the proposed project's impact on Medicare, Medicaid and other payors is reflected in the financial analysis tables which are part of this Application.

GR Criterion 5 - Need for the Project

- a. **Population Needs for Service:** The Applicant submits Hattiesburg Clinic currently provides vascular DA services in response to community health needs, and upon the relocation of these services to LAW, medically underserved groups, including those noted above, will continue to have access to DA services in Hattiesburg.
- b. **Relocation of Services:** The Applicant states following the relocation of vascular DA services to LAW, the existing space at Hattiesburg Clinic will be utilized for other clinical services.
- c. **Current and Projected Utilization of Comparable Facilities:** The Applicant states, the proposed project does not involve the initiation of new or additional health services. Vascular DA services currently being performed at Hattiesburg Clinic will be relocated to the LAW facility.
- d. **Probable Effect:** The Applicant states the proposed relocation of existing vascular DA services will not adversely impact other existing providers.
- e. **Community Reaction to Service:** The application included a joint letter of support signed by Physicians at Hattiesburg Clinic.

GR Criterion 6 - Access to the Facility or Service

- a. **Access to Services for Medically Underserved:** The Applicant states LAW provides elective (non-trauma/non-life threatening) surgical procedures that serve medically indigent patients through its participation in the Mississippi Medicaid program, and the chart reflects both historical and projected Medicaid revenue at LAW as a percentage and total dollar amount of gross patient revenue. Furthermore, the Applicant states due to the fact that most medically indigent patients receiving surgical services at LAW qualify for Medicaid, there is not a separate category of “charity care,” per se. which is similar to the situation in nursing homes, in which medically indigent residents qualify for Medicaid and there is no need for a provision of charity care. The Applicant affirms LAW projects that it will continue to serve a substantial number of Medicaid beneficiaries following the implementation of the proposed project.

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:

Gross Patient Revenue

| | Medically Indigent (%) | Charity Care (%) | Medically Indigent (\$) | Charity Care (\$) |
|-----------------------|------------------------|------------------|-------------------------|-------------------|
| *Historical Year 2022 | 18.3% | N/A | \$6,819,650 | N/A |
| *Historical Year 2023 | 19.4% | N/A | \$7,997,440 | N/A |
| Projected Year 1 | 21% | N/A | \$8,281,836 | N/A |
| Projected Year 2 | 21% | N/A | \$8,530,291 | N/A |

- b. **Existing Obligations:** The Applicant confirms there are no existing or remaining obligations under any federal regulation requiring provision of uncompensated care, community service, or access by minority and handicapped persons.
- c. **Unmet Needs of Medicare, Medicaid, and medically indigent patients:** The Applicant affirms LAW currently serves and will continue to serve Medicare, Medicaid and medically indigent patients.
- d. **Access to the Proposed Facility:** The Applicant states the services offered by LAW are accessible to residents of the area served by the facility.
- e. **Access Issues:**

- i. **Transportation and Travel:** The Applicant states LAW is located at Lincoln Center in Hattiesburg, which is easily accessible from U.S. Highway 49 and Interstate 59.
- ii. **Restrictive Admission Policy:** The Applicant submits this is not applicable to the proposed project as it will not be an inpatient facility.
- iii. **Access to Care by Medically Indigent Patients:** The Applicant states that LAW is currently accessible to Medically Indigent Patients.
- iv. **Operational Hours of Service:** The Applicant states the current operating hours of LAW are Monday through Friday, 7:00 a.m. to 5:00 p.m.

GR Criterion 7 - Information Requirement

The Applicant affirms that it will record and maintain the information required by this criterion and make it available to the Mississippi State Department of Health within fifteen (15) business days of request.

GR Criterion 8 - Relationship to Existing Health Care System

- a. **Comparable Services:** The Applicant states DA services are currently offered by hospitals in Hattiesburg and surrounding areas. Hattiesburg Clinic has provided these services in a freestanding, outpatient setting, and will continue to do so through the relocation of vascular DA services to LAW.
- b. **Effects on Existing Health Services:**
 - i. **Complement Existing Services:** The Applicant states Vascular DA services are part of the extensive continuum of outpatient care offered by Hattiesburg Clinic and its affiliated health facilities.
 - ii. **Providing Alternative or Unique Services:** The Applicant asserts the proposed project will allow patients to continue to access vascular DA services in an outpatient setting.
 - iii. **Provide a Service for a Specific Target Population:** The Applicant states the proposed project will provide access to patients in need of vascular DA services and who are in a lower-risk

category, thereby freeing up hospital-based services for more critical vascular patients.

- iv. **Provide Services for Which There is an Unmet Need:** The applicant states, the utilization of vascular DA services at Hattiesburg Clinic demonstrates the continuing need for this service.
- c. **Adverse Impact:** The Applicant states, if the project is not implemented, patients will be deprived of the benefits of receiving vascular DA services in a clinically superior environment.
- d. **Transfer/Referral/Affiliation Agreements:** The Applicant affirms, LAW has a Patient Transfer Agreement with Forrest General Hospital.

GR Criterion 9 - Availability of Resources

- a. **New Personnel:** The Applicant asserts, LAW will staff vascular DA services with existing personnel. Hattiesburg Clinic's vascular surgeons will continue to perform the vascular DA procedures.
- b. **Contractual Services:** The applicant states LAW has a Medical Director Agreement with Hattiesburg Clinic.
- c. **Existing Facilities or Services:** The Applicant affirms LAW is licensed by the Mississippi State Department of Health, and fully complies with applicable regulations on staffing.
- d. **Alternative Uses of Resources:** The Applicant states the proposed project is the best alternative for the provision of health services in response to community needs.

GR Criterion 10 – Relationship to Ancillary or Support Services

- a. **Support and Ancillary Services:** The Applicant affirms LAW is a licensed and Medicare/Medicaid certified facility that currently has all necessary support and ancillary services needed for the proposed project.
- b. **Changes in Costs or Charges:** The Applicant submits, LAW does anticipate a material change in costs or charges as a result of this project. Furthermore, the Applicant states cost and charge information is included in the financial tables which accompany the Application.

- c. Accommodation of Proposed Costs or Charges:** The Applicant states this item is not applicable to the proposed project.

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 states this criterion is not applicable to the proposed project.

GR Criterion 13 – Access to Individuals Outside Service Area

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

GR Criterion 14 – Construction Projects

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

GR Criterion 15 – Competing Applications

The Applicant acknowledges this criterion. There are no competing applications for DA services on file with the Department.

GR Criterion 16- Quality of Care

- a. Past Quality of Care:** LAW is licensed by the Mississippi State Department of Health and certified for participation in the Medicare and Medicaid programs.
- b. Improvements of Quality of Care:** The Applicant states the proposed project will allow patients in need of vascular DA services to receive these services in an improved clinical environment.
- c. Accreditation and/or Certificates:** The Applicant states LAW is Medicare and Medicaid certified.

IV. FINANCIAL FEASIBILITY

A. Capital Expenditure Summary

The Applicant affirms there is no Capital Expenditure associated with the proposed project.

B. Method of Financing

This criterion is not applicable to the proposed project as there is no Capital Expenditure associated with this project.

C. Effect on Operating Cost

Vascular Institute's (3) 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 | 72.00% | \$ 31,714,211.00 |
| Medicaid | 9.00% | 4,140,450.00 |
| Commercial | 16.00% | 7,224,151.00 |
| Self Pay | 1.00% | 38,007.00 |
| Charity Care | 0.00% | 0.00 |
| Other | 2.00% | 1,037,158.00 |
| Total | 100% | \$44,153,977.00 |

*Note: Staff's calculations differ from Applicant's calculations by 1%, probably due to rounding.

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 as of September 23, 2024.

VI. CONCLUSION AND RECOMMENDATION

This project is in substantial compliance with the criteria and standards for the provision of digital angiography services contained in the *FY 2022 Mississippi State Health Plan (3rd Edition)*; the *Mississippi Certificate of Need Review Manual, (November 11, 2023, 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 Lowery A. Woodall Surgery Facility, LLC for the Offering of Digital Angiography Services in a Freestanding Facility.

Attachment 1

Lowery A. Woodall, LLC
Three-Year Operating Statement (Project Only)

| | Year 1 | Year 2 | Year 3 |
|------------------------------------|---------------------|---------------------|--------------------|
| Revenue | | | |
| Patient Revenue: | | | |
| Inpatient | | | |
| Outpatient | \$44,153,977 | \$45,478,596 | \$46,842,954 |
| Gross Patient Revenue | 44,153,977 | 45,478,596 | 46,842,954 |
| Charity Care | | | |
| Deductions | 36,097,007 | 37,179,917 | 38,295,314 |
| Net Patient Revenue | \$8,056,970 | \$8,298,679 | \$8,547,640 |
| Other Operating Revenue | 0 | 0 | 0 |
| Total Operating Revenue | \$8,056,970 | *\$8,298,679 | \$8,547,640 |
| Expenses | | | |
| Operating Expenses: | | | |
| Salaries | \$487,914 | \$502,551 | \$517,627 |
| Benefits | 136,616 | 140,714 | 144,936 |
| Supplies | 2,029,944 | 2,090,842 | 2,153,567 |
| Services | 750,000 | 750,000 | 750,000 |
| Lease | | | |
| Depreciation | 19,370 | 19,370 | 19,370 |
| Interest | 6,064 | 6,064 | 6,064 |
| Other | 47,855 | 47,855 | 47,855 |
| Total Operating Expenses | \$3,477,763 | \$3,557,395 | \$3,639,419 |
| Net Operating Income (Loss) | *\$4,579,207 | \$4,741,284 | \$4,908,221 |
| Assumptions | | | |
| Inpatient days | 0 | 0 | 0 |
| Outpatient visits | 253 | 253 | 253 |
| Procedures | 768 | 791 | 815 |
| Charge/outpatient day | \$174,522 | \$179,757 | \$185,150 |
| Charge per inpatient day | N/A | N/A | N/A |
| Charge per procedure | \$57,492 | \$57,495 | \$57,476 |
| Cost per inpatient day | N/A | N/A | N/A |
| Cost per outpatient day | \$13,746 | \$14,061 | \$14,385 |
| Cost per procedure | \$4,528 | \$4,497 | \$4,466 |

*Note: Staff's calculations differ from Applicant's calculations by \$2.00, probably due to rounding.