

**MISSISSIPPI STATE DEPARTMENT OF HEALTH
DIVISION OF HEALTH PLANNING AND RESOURCE DEVELOPMENT**

REVISED - JUNE 21, 2021

**CON REVIEW: FSF-NIS-0421-003
HIFIDELITY IMAGING, LLC
ESTABLISHMENT OF FREESTANDING FIXED MRI SERVICES
CAPITAL EXPENDITURE: \$113,103.00
LOCATION: HATTIESBURG, FORREST COUNTY, MISSISSIPPI**

STAFF ANALYSIS

I. PROJECT SUMMARY

A. Applicant Information

HiFidelity Imaging, LLC (“HiFidelity”), is an imaging facility formed on January 1, 2020, as a Mississippi Limited Liability Company. The entity consists of two (2) members, Jory Scott and Jared Carlson, owners of Capes & Canes, LLC. On April 19, 2021, the Mississippi Office of the Secretary of State issued a Certificate of Good Standing for the entity certifying that it has continued authority to operate in Mississippi.

B. Project Description

HiFidelity Imaging, LLC (“HiFidelity” or the “Applicant”) requests certificate of need (“CON”) authority to establish a freestanding fixed magnetic resonance imaging (MRI) unit to provide services in Hattiesburg, Mississippi.

The Applicant affirms HiFidelity will provide services out of an existing medical office space located at 4 Willow Point, Suite 1A, Hattiesburg, Mississippi, for which HiFidelity has secured a sublease. The Applicant states HiFidelity seeks CON authority to control a leased fixed MRI unit and offer MRI services at the subleased medical office. HiFidelity affirms the MRI unit will provide service to the community up to five (5) days a week.

The Applicant states the current available services in General Hospital Service Area 8 (“GHSA 8”) are limited in image resolution, reducing effectiveness for more complicated and challenging diagnoses and post-therapeutic and post-surgical evaluation, particularly in neurological patients. The application also includes a support letter from Dr. Alan Kevin Cole stating HiFidelity’s proposed MRI unit will incorporate new technology using compressed sensing, with greater speed and high millimeter isotropic spatial resolution. Dr. Cole suggests this level of high homogeneity of images and a powerful gradient amplifier help maintain image quality throughout the field of view. Furthermore, Dr. Cole suggests this level of high-definition imaging with multiple settings allows it to assist with difficult diagnoses and more problematic issues of post treatment evaluation, follow-up therapy and prognosis for which he believes would benefit neurological patients.

The Applicant states this service will complement existing MRI services in GHSA 8 and meet the local diagnostic imaging needs of the Hattiesburg, Mississippi area.

HiFidelity proposes to renovate approximately 1,000 square feet of medical office space to accommodate the MRI equipment. According to the Applicant, renovation will include

the housing of the MRI unit with the appropriate shielding and provide a reception and waiting area for patients.

The Applicant asserts that the capital expenditure for the proposed project is \$113,103.00, which includes renovation costs to update the existing medical office space, the filing fee, legal fees for counsel, and contingency reserve to avoid any cost overrun of the project. The Applicant affirms HiFidelity proposes to fund the project with contributions to equity by HiFidelity's members. The Applicant states Capes & Canes, LLC is related to HiFidelity in that its members are also members of HiFidelity. The Applicant further states Capes & Canes, LLC will purchase the MRI machine directly from United Imaging for approximately \$1,000,897.00. The Application contained lease proposals from Capes & Canes, LLC to HiFidelity, for a United Imaging uMR 570 1.5T Superconducting Wide-Bore MRI unit and its inclusive equipment. The proposal indicated a ten (10) year lease term at \$8,500.00 payable in advance on the 1st day of each month and a lease from MS Pain and Migraine, LLC for the leased office space located at 4 Willow Point, Suite 1A, Hattiesburg, Mississippi 39402. The short-form commercial lease term indicated payment of \$1,000.00 payable in advance on the 1st of each month for five (5) years commencing as of February 1, 2021, and ending January 31, 2027, unless terminated sooner. In addition, HiFidelity will provide MS Pain and Migraine, LLC with a certificate reflecting acceptable liability insurance coverage not less than the amount of \$1,000.00, listing MS Pain and Migraine, LLC as an additional insured.

The Capital Expenditure Summary (*Section IV. FINANCIAL FEASIBILITY (A)*) gives an itemization of the total capital expenditure for the project. The Applicant further included a projected operating statement, which shows the first, second, and third years of operation (see Attachment 1).

The Applicant indicates that HiFidelity will add 2.0 additional full-time equivalent (FTE) personnel the first year of the project at an estimated annual cost of \$105,000.00. On November 9, 2020, the Mississippi State Department of Health ("MSDH"), Division of Health Facilities Licensure and Certification determined that a site approval was not necessary for the proposed project at the Hattiesburg location.

HiFidelity states it currently complies with all local building codes, zoning ordinances, and appropriate regulatory authority and will continue to do so. It further affirms that it will comply with all applicable state statutes and regulations for 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.

HiFidelity proposes to obligate the capital expenditure within one (1) month of CON approval and anticipates that the proposed project will be complete within three (3) months of CON approval.

II. TYPE OF REVIEW REQUIRED

The Mississippi State Department of Health will review applications for a Certificate of Need (CON) to acquire or otherwise control magnetic resonance imaging ("MRI") equipment and offer MRI services under the 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, September 1,*

2019; all adopted rules, procedures, plans, criteria and standards of the MSDH; and the specific criteria and standards listed below.

In accordance with Section 41-7-197 (2) of the Mississippi Code 1972 Annotated, as amended, any 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 June 21, 2021.

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

A. Mississippi State Health Plan (MSHP)

The *FY 2020 Mississippi State Health Plan* (“MSHP”) contains policy statements, criteria and standards, which an applicant is required to meet before receiving CON authority for the acquisition or otherwise control of MRI equipment and the offering of MRI services. This application is not in substantial compliance with the applicable policy statements, criteria and standards.

Policy Statements Regarding Certificate of Need Applications for the Acquisition or Otherwise Control of Magnetic Resonance Imaging (MRI) Equipment and/or the Offering of MRI Services

1. CON Review Requirements: The CON process regarding the acquisition or otherwise control of MRI equipment and/or the offering of MRI services involves separate requirements for CON review: (a) an entity proposing to acquire or otherwise control MRI equipment must obtain a CON to do so if the capital expenditure for the MRI unit and related equipment exceeds \$1,500,000; and (b) an entity proposing to offer MRI services which has not provided the service on a regular basis within the last twelve (12) months must obtain a CON before providing such services, regardless of the capital expenditure.

The Applicant states a Certificate of Need (“CON”) for the offering of MRI services is necessary because the Applicant has not provided these services on a regular basis within the last twelve (12) months. The Applicant further states though the capital expenditure for the MRI equipment itself will not exceed \$1,500,000, the Applicant has elected to include the control of the MRI equipment in this CON application.

2. CON Approval Preference: MSDH shall give preference to those applicants proposing to enter into joint ventures utilizing mobile and/or shared equipment. However, the applicant must meet the applicable CON criteria and standards provided herein and the general criteria and standards contained in the currently approved Mississippi Certificate of Need Review Manual.

Not applicable. The Applicant states this project involves a freestanding, fixed MRI unit that will be available and open to providers and their patients seeking medical services in the proposed service area.

3. Mobile MRI: For purposes of this Plan, a mobile MRI unit is defined as an MRI unit operating at two or more host sites and that has a central service coordinator. The mobile MRI unit shall operate under a contractual agreement for the provision of MRI services at each host site on a regularly scheduled basis.

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

4. Conversion to Fixed: The conversion from mobile MRI service to fixed MRI service is considered the establishment of a new MRI service and requires CON review.

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

5. Utilization of Existing Units: No new MRI services shall be approved unless all existing MRI service in the applicant's defined service area performed an average of 1,700 MRI procedures per existing and approved MRI scanner during the most recent twelve (12) month reporting period and the proposed new services would not reduce the utilization of existing providers in the service area.

HiFidelity submits, per the most recent *MSHP*, the average number of procedures performed per MRI unit was 2,813.93 ($31,516 \div 11.2$), and in 2016 the average number of procedures per MRI unit was 2,924.91 ($32,759 \div 11.2$). The Applicant affirms this calculation indicates that the existing MRI units in GHSA 8 average more than 1,700 procedures per existing and approved MRI scanner during the most recent 12-month reporting period. The Applicant further states the proposed new services will not adversely impact or significantly reduce the utilization of existing providers in the service area because the available data for GHSA 8 indicates the existing units are already scheduled beyond expected capacity. The Applicant further states the proposed project will provide MRI services needed by residents but are not currently available in GHSA 8.

6. Population-Based Formula: MSDH shall use a population-based formula as presented at the end of this chapter when calculating MRI need. Also, the formula will use historical and projected use rates by service area and patient origin data. The population-based formula is based on the most recent population projections prepared by the State Data Center (University of Mississippi Center for Population Studies). The applicant shall project a reasonable population base to justify the provision of 2,700 procedures (or 1,700 procedures for rural hospitals) by the second year of operation.

The Applicant states, based on the information contained in the *FY 2020 MSHP*, the Mississippi MRI Use Rate is 81.6 with an expected volume of 25,809 for GHSA 8. However, the Applicant states that the Population-Based Formula and its use of statewide MRI Use Rate does not adequately depict the need for MRI services in GHSA 8, particularly given that in 2016 GHSA 8's MRI scans exceeded the expected projected volume. The Applicant further calculated a GHSA specific use rate of 103.6; using this use rate, the applicant calculated an expected volume of 32,768 scans for GHSA 8.

The Applicant states it will demonstrate that GHSA 8 has a reasonable population base to justify the provision of 2,700 procedures by its second year of operation. HiFidelity projects a utilization of 2,183 in the first year, 2,725 in the second year, and 3,249 in the third year of operation.

7. Mobile Service Volume Proration: The required minimum service volumes for the establishment of services and the addition of capacity for mobile services shall be

prorated on a “site by site” basis based on the amount of time the mobile services will be operational at each site.

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

8. Addition of Health Care Facility: An equipment vendor who proposes to add a health care facility to an existing or proposed route must notify MSDH through the filing of a Determination of Non-Reviewability of any proposed changes, i.e., additional health care facilities or route deviations, from those presented in the Certificate of Need application prior to such change.

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

Certificate of Need Criteria and Standards for the Acquisition or Otherwise Control of Magnetic Resonance Imaging (MRI) Equipment and/or the Offering of MRI Services

MSDH will review applications for a CON for the acquisition or otherwise control of MRI equipment and/or the offering of MRI services under the applicable statutory requirements of Sections 41-7-173, 41-7-191, and 41-7-193, Mississippi Code of 1972, as amended. MSDH will also review applications for Certificate of Need according to the general criteria listed in the *Mississippi Certificate of Need Review Manual*; all adopted rules, procedures, and plans MSDH; and the specific criteria and standards listed below.

The acquisition or otherwise control of MRI equipment is reviewable if the equipment cost is in excess of \$1,500,000; if the equipment and/or service is relocated; and if the proposed provider of MRI services has not provided such services on a regular basis within the period of twelve (12) months prior to the time such services would be offered, regardless of the capital expenditure.

SHP Need Criterion 1: Minimum Procedures/Population

The *FY 2020 Mississippi State Health Plan* states: The entity desiring to acquire or otherwise control the MRI equipment shall demonstrate a minimum of 2,700 procedures per year by the end of the second year of operation. The applicant must show the methodology used for the projections.

The Applicant anticipates HiFidelity will perform over 2,725 scans by the end of the second year of operation. The Applicant states its projections are based on the affidavits from physicians who will refer patients to HiFidelity.

- a. Non-hospital based MRI facilities: Applicants for non-hospital based MRI facilities may submit affidavits from referring physicians. MRI procedures projected in affidavits shall be based on actual MRI procedures referred during the year.**

The application contains three (3) affidavits. The Applicant certifies the physicians providing the affidavits reviewed their patient or billing records over a certain time frame and annualized these number in order to project a reasonable number of MRI scans they believed they would refer to the proposed service area in Years 1, 2, and 3 of operation. The Applicant further states, the physicians concluded that in total they would refer 2,183 MRI scans in Year 1 of

operation, 2,725 MRI scans in Year 2 of operation, and 3,249 MRI scans in Year 3 of operation.

The Applicant's original application purported to include affidavits from three (3) referring physicians. However, the Applicant submitted additional information acknowledging one (1) of the physician affidavits was submitted by a nurse practitioner in error. The letter received by the Department states:

The original application included an affidavit from Rebecca Hollingsworth, in which Ms. Hollingsworth incorrectly and inadvertently indicated that she was a physician. Ms. Hollingsworth is a nurse practitioner licensed by the Mississippi Board of Nursing. Though she is not a physician, Ms. Hollingsworth is able to order MRI scans within the scope of her practice and has historically referred patients to receive MRIs.

Since Ms. Hollingsworth is not a referring physician, the Department will not consider her projections in its analysis. Therefore, the Applicant's revised projections are 1,493 MRI scans in Year 1 of operation, 1,844 MRI scans in Year 2 of operation, and 2,188 MRI scans in Year 3 of operation.

b. Reasonable population base:

The Applicant submits the population base for the service area is 316,290. Mississippi's MRI utilization rate is 81.6 scans per thousand per *FY 2020 MSHP* data (256,199 scans statewide in 2016 on a statewide population of 3,138,145). Using MSDH's population-based formula, the Applicant states the population base would support up to 25,809 scans per year ($316,290 \times 81.6$ scans per thousand = 25,809 scans). However, according to the Applicant, GHSA 8's MRI scans already exceeded this expected projected volume by 6,950 MRI scans in 2016.

As previously stated, the Applicant believes the population-based formula and a statewide MRI Use Rate does not adequately depict the need for MRI services in GHSA 8, particularly given that in 2016, GHSA 8's MRI scans already exceeded this expected projected volume by 6,950 MRI scans.

The Applicant further states their total calculated 2016 scans in GHSA 8 (32,759) divided by the 2023 projected GHSA 8 population (316,290) resulted in a GHSA 8 specific use rate of 103.6. The Applicant states using the GHSA 8 specific use rate, the expected volume is 32,768.

Applicant's Defined Services Area Population $(316,290) \times 103.6 \div 1000 = 32,768$.

Projected MRI Procedures

	Year 1	Year 2	Year 3

Applicant's Projections	2,183	2,725	3,249
Department's Revised Projections*	1,493	1,844	2,188

* See discussion under SHP Need Criterion 1a.

c. Utilization of existing units:

General Hospital Service Area 8 (MRI Procedures)

				2015	2016
Total				31,516	32,759
Forrest General Hospital	H	Forrest	F (2)	5,514	6,061
Hattiesburg Clinic, P.A.	FS	Forrest	F (4)	11,123	11,888
Jefferson Davis Community Hospital	MP	Jefferson Davis	M	121	105
Merit Health Wesley	H	Lamar	F	2,426	2,325
Open Air MRI of Laurel	FS	Jones	F	3,818	3,507
SMI-Marion General Hospital	MP	Marion	M	275	280
South Central Regional Medical Center	H	Jones	F	2,229	2,229
Southern Bone & Joint Specialist, PA	FS	Forrest	F (2)	6,010	6,364

The Applicant submits GHSA 8 currently has eleven (11) fixed MRI units and two (2) mobile MRI units. The applicant states the two (2) mobile MRI units each provide MRI services four (4) hours per week, for a combined eight (8) hours per week total. Therefore, the Applicant states in its calculations, it considered the mobile MRI units to provide the equivalent of 0.2 hours of the MRI services of a fixed unit, which assumes a forty (40) hour per week schedule of services. Therefore, the Applicant states their calculations assumed 11.2 full-time MRI units in GHSA 8.

The Applicant submits of the 11.2 units (11 fixed and 0.2 to represent the mobile units) in 2015, the average number of procedures performed per MRI unit was

2,813.93 (31,516 ÷ 11.2) and in 2016 that average number of procedures per MRI unit was 2,924.91 (32,759 ÷ 11.2). The Applicant affirms this calculation indicates the existing MRI units in GHSA 8 average more than 1,700 procedures per existing and approved MRI scanner during the most recent twelve (12) month reporting period. The Applicant further states the proposed new services will not adversely impact or significantly reduce the utilization of existing providers in the service area because the available data for GHSA 8 indicates the existing units are already scheduled beyond expected capacity.

SHP Need Criterion 2: Equipment Requirements

The Applicant submitted documents for FDA approval and a proposed lease agreement. The Applicant affirms HiFidelity will only permit qualified personnel to operate the proposed MRI equipment.

SHP Need Criterion 3 – Data Requirements

The Applicant certifies HiFidelity will record and timely provide such information.

SHP Need Criterion 4: Business Registration

The application contains documentation from the Mississippi Secretary of State to support the formation of the limited liability company. HiFidelity Imaging, LLC, is listed in good standing with the State of Mississippi as of April 19, 2021.

SHP Need Criterion 5: CON Approval/Exemption for MRI Equipment

The Applicant states it recognizes this requirement and in response submits this application. The Applicant also affirms that it will not utilize the MRI equipment until obtaining a CON or written evidence from the Department that the equipment is exempt from CON approval.

The Applicant states the equipment HiFidelity proposes to lease does not meet the capital expenditure threshold to require a Certificate of Need (CON); however, HiFidelity is including the equipment in this application for CON authority to control the equipment and provide MRI services.

Certificate of Need Criteria and Standards for the Offering of Fixed or Mobile MRI Services

CON - MRI Need Criterion 1: Minimum Procedures/Population

The entity desiring to offer MRI services must document that the equipment shall perform A minimum of 2,700 procedures (or 1,700 procedures for rural hospitals) by the end of the second year of operation. This criterion includes both fixed and mobile MRI equipment. The application must show the methodology used for the projections.

a. Non-hospital-based MRI facilities

The application contains three (3) affidavits. See discussion above under SHP Need Criterion 1a.

b. Reasonable population base

The Applicant submits HiFidelity considers GHSA 8 as its potential service area. The Applicant states HiFidelity anticipates the MRI service will draw residents throughout the Hattiesburg area as well as areas around Hattiesburg that are not located in GHSA 8.

The Applicant submits the population base for GHSA 8 is 316,290. Mississippi's MRI utilization rate is 81.6 scans per thousand per *FY 2020 Mississippi State Health Plan* data (256,199 scans statewide in 2016 on a statewide population of 3,138,145). Using MSDH's population-based formula, the Applicant states that population base would support up to 25,809 scans per year ($316,290 \times 81.6$ scans per thousand = 25,809 scans). However, GHSA 8's MRI scans already exceeded this expected projected volume by 6,950 MRI scans in 2016.

The Applicant believes the population-based formula and its use of a statewide MRI Use Rate does not adequately depict the need for MRI services in GHSA 8, particularly given that in 2016, GHSA 8's MRI scans already exceeded this expected projected volume by 6,950 MRI scans.

The Applicant further states their total calculated 2016 scans in GHSA 8 (32,759) divided by 2023 projected GHSA 8 population (316,290) resulted in a GHSA 8 specific use rate of 103.6. The Applicant states using the GHSA 8 specific use rate, the expected volume is 32,768.

Applicant's Defined Service Area Population (316,290) $\times 103.6 \div 1000 = 32,768$.

c. Utilization of existing units.

Applicant submits GHSA 8 currently has eleven (11) fixed MRI units and two (2) mobile MRI units. The two (2) mobile MRI units each provide MRI services four (4) hours per week, for a combined eight (8) hours per week. Therefore, the Applicant states in its calculations, it considered the mobile MRI units to provide the equivalent of 0.2 of the MRI services of a fixed unit, which assumes a forty (40) hour per week schedule of services. Therefore, the Applicant states their calculations assumed 11.2 full-time MRI units in GHSA 8.

The Applicant submits of the 11.2 units (11 fixed and 0.2 to represent the mobile units) in 2015, the average number of procedures performed per MRI unit was 2,813.93 ($31,516 \div 11.2$) and in 2016 that average number of procedures per MRI unit was 2,924.91 ($32,759 \div 11.2$). The Applicant states this calculation indicates that the existing MRI units in GHSA 8 average more than 1,700 procedures per existing and approved MRI scanner during the most recent twelve (12) month reporting period available. The Applicant further states the proposed new services will not adversely impact or significantly reduce the utilization of existing providers in the service area because the available data for GHSA 8 indicates the existing units are already scheduled beyond expected capacity.

CON - MRI Need Criterion 2: Availability of Diagnostic Imaging Modalities

HiFidelity states a full range of diagnostic imaging modalities are currently available in

GHSA 8 and used by referring providers. The Applicant states these modalities are available for referring physicians to verify the MRI equipment's scan as the physicians deem necessary and will enable those referring physicians to order any complementary studies, they deem necessary.

The Applicant also states the modalities listed in Need Criterion 2 are currently available in GHSA 8 and are regularly used by the referring providers that submitted affidavits. The Applicant further states the proposed MRI machine itself can perform non-invasive angiography in 4D (a modality which the applicant states is currently not available in GHSA 8). The Applicant also plans to provide x-ray with fluoroscopy, CT, and ultrasound at the location where the MRI service will be located.

CON - MRI Need Criterion 3: Non-Discrimination

The Applicant certifies that it and its participating medical personnel shall have no policies or procedures which would exclude patients because of race, color, age, sex, ethnicity, or ability to pay.

CON - MRI Need Criterion 4: Staffing Requirements

The Applicant must document that the following staff will be available:

a. Director

The Applicant affirms that upon receipt of a CON, it will recruit and hire or contract with a board eligible radiologist or other board eligible licensed physician to serve as Medical Director of the freestanding MRI service.

b. One Full-time MRI Technologist-Radiographer

The Applicant states upon receiving CON approval, the Applicant intends to hire or contract with Andrew Maxwell, an MRI technologist-radiographer who meets the required qualifications. The Applicant has submitted a support letter and credentials for Mr. Maxwell for the MRI technologist-radiographer position.

CON - MRI Need Criterion 5: Experimental Procedures

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

CON - MRI Need Criterion 6: Data Requirement

The Applicant affirms HiFidelity will keep and timely provide the data listed under this need criterion to the Department upon request.

CON - MRI Need Criterion 7: CON Approval/Exemption for MRI Equipment

The Applicant states though the equipment that HiFidelity proposes to lease does not meet the capital expenditure threshold to require a CON, HiFidelity is including the equipment in this application for CON authority to control the equipment and provide MRI services.

B. General Review (GR) Criteria

Chapter 8 of the *Mississippi Certificate of Need Review Manual, September 1, 2019*, addresses general criteria by which all CON applications are reviewed. This application is in substantial compliance with general review criteria.

GR Criterion 1 –State Health Plan:

All projects will be reviewed for consistency with the State Health Plan in effect at the time of submission.

The application was reviewed for compliance with the *FY 2020 Mississippi State Health Plan* as discussed above.

GR Criterion 2 - Long Range Plan:

The Applicant states the proposed project is consistent with HiFidelity's long range strategic plan of providing needed MRI services to GHSA 8 and the provision of those services in a high quality, accessible, cost effective and an efficient manner. HiFidelity states its principal, Jory Scott, became familiar with the unique images available through the United Imaging unit and believed a need for such images existed in GHSA 8. The Applicant states HiFidelity reviewed the *FY 2018 MSHP* and the *FY 2020 MSHP* and confirmed the need for additional MRI services existed in GHSA 8. HiFidelity affirms several possible locations for MRI services were explored in the Hattiesburg area and the plans were finalized on the proposed location of 4 Willow Point, Suite 1A, in Hattiesburg, Mississippi.

GR Criterion 3- Availability of Alternatives:

- a. **Advantages and Disadvantages of Alternatives:** The Applicant states there is no better alternative for the project. The Applicant asserts the status quo was taken into consideration but believes the need in GHSA 8 and the innovative equipment proposed for the project make it the best alternative. The Applicant states the project will meet a need in GHSA 8 for neurological scans. Furthermore, the Applicant states failing to move forward with the project will cause a continued need for additional MRI capacity, continued wait times for patients and the unavailability in GHSA 8 for MRI services that this equipment is capable of providing, causing residents to continue leaving the area to receive services.
- b. **New Construction Projects:** The Applicant states this project does not involve new construction. HiFidelity will modernized the existing medical office space to accommodate the proposed MRI unit.
- c. **Beneficial Effects to the Health Care System:** The Applicant states the project addresses an existing need evidenced by their response to CON Need Criterion 1: Minimum Procedures/Population. The Applicant also states the project addresses this need by providing MRI services that are complementary to existing MRI services in GHSA 8, rather than duplicating the offerings of services.
- d. **Effective and Less Costly Alternatives:** The Applicant states there is no better alternative for the proposed project.

- i. Unnecessary Duplication of Services:** The Applicant states HiFidelity will offer services that are needed by residents but are not currently available in GHSA 8. The Applicant states the proposed MRI unit will incorporate new technology using compressed sensing, with greater speed and high millimeter isotropic spatial resolution. The Applicant states HiFidelity believes the residents of GHSA 8 will forego or travel outside of GHSA 8 in order to receive MRI services that HiFidelity proposes to provide. HiFidelity further states the proposed MRI services are complementary to those already offered in GHSA 8, rather than duplicative.
 - ii. Efficient Solution:** The applicant asserts HiFidelity does not believe an effective and less costly alternative for the proposed project is currently available in the area. The Applicant further states the services HiFidelity will offer are needed and are not currently available in GHSA 8.
- e. Improvements and Innovations:** The Applicant asserts the proposed project fosters improvements and innovations in the delivery of health services in GHSA 8. The Applicant states the project promotes health care quality assurance and cost effectiveness by providing services that are needed by residents but not currently available in GHSA 8. The Applicant states the proposed project will offer a type of MRI service that is not currently available in the area, improving the availability of certain types of neurology scans. As stated above, Dr. Cole (a MS licensed physician) states the addition of the proposed new technology to the assets of the local area will enable physicians to evaluate more accurately, with objective measurements, post-therapeutic progress and outcomes. Dr. Cole further suggests faster imaging with the proposed new MRI technology will allow greater access for patients.
- f. Relevancy:** The Applicant asserts in the *MSHP*, GHSA 8 MRI scans for 2016 exceeded expected volume using 2023 projected population figures, indicating a clear need in GHSA 8 for additional MRI services for the foreseeable future. The Applicant states the proposed project will increase capacity of MRI scans in GHSA 8 without duplicating services. The Applicant further states this proposed project will address a need for neurological scans that are not currently available in GHSA 8.

GR Criterion 4 - Economic Viability:

Based on the Applicant's three-year projections, this project will have net income of \$857,000.00 the first year, \$1,401,000.00 the second year, and \$1,575,000.00 the third year of operation.

- a. Proposed Charge:** The Applicant states charges for MRI services will be approximately \$1,205.00 per scan depending on the nature of the exam. The Applicant states the charges are comparable to charges for MRI services at other facilities in the planning area and in the State.

- b. Projected Levels of Utilization:** The Applicant states the levels of utilization of the MRI service are projected to be reasonably consistent with those experienced by other facilities in GHSA 8 and with the levels of utilization required by Chapter 5 of the Plan. The Applicant further states the projected MRI utilization is supported by physician affidavits projecting the number of MRI referrals they would anticipate sending to HiFidelity, if CON approved, based upon examination of referral histories and patient diagnoses of their practices in the past.
- c. Financial Feasibility Study:** This criterion is not applicable as the capital expenditure is less than \$2,000,000.00.
- d. Financial Forecasts:** The Applicant asserts HiFidelity has not offered services within the last three (3) years, the financial forecasts reflect revenue arising out of projected MRI services.
- e. Covered Expenses:** The Applicant asserts should the project fail to meet projected revenues, the members of HiFidelity are prepared to make additional capital contributions to the business to allow it to cover operating and other expenses.
- f. Impact of Proposed Project on Health Care Cost:** The Applicant asserts the cost of healthcare should not be impacted by the proposed project, as the charges to both Medicare and Medicaid will remain similar to other providers.

GR Criterion 5 - Need for the Project

- a. Access by Population Served:** The Applicant affirms HiFidelity intends to make its services available to all residents of GHSA 8 who are referred to the service by an ordering physician.
- b. Relocation of Services:** This criterion is not applicable as the Applicant does not propose to relocate services.
 - i. Replacement Facility:** The applicant affirms this criterion is not applicable to the proposed project.
 - ii. Utilization of Existing Space Post Relocation of Services:** The applicant affirms this criterion is not applicable to the proposed project.
- c. Current and Projected Utilization of Comparable Facilities:** The Applicant states the available data indicates the existing services will continue to have utilization at levels expected in the *MSHP* for MRI units including at levels of at least 2,700 per unit per year.
- d. Probable Effect on Existing Facilities in the Area:** The Applicant states the available data for GHSA 8 indicates the existing units are already scheduled beyond expected capacity; therefore, the proposed project should have no adverse effect on the existing services but by contrast will complement the existing services.

- e. **Community Reaction to Service:** The application contained two (2) letters of support and four (4) letters of opposition for the proposed project.

GR Criterion 6- Access to the Facility or Service

a. Access

- 1. **Access to Services:** The Applicant states HiFidelity is a recently formed Limited Liability Company; therefore, this criterion is not applicable.
- 2. **Access to the Proposed Services:** The Applicant states the residents of the proposed project will have access to the services.
- 3. **Gross Patient Revenues:** The Applicant states HiFidelity has not previously provided services. However, the Applicant further states HiFidelity plans to adopt a financial need policy to ensure that appropriate care is provided to all residents of GHSA 8, to the extent they are referred to MRI service. The Applicant states HiFidelity plans to provide charity care equal to about 3% of gross patient revenue each year.

The following table shows the projected estimated gross patient revenues of health care to medically indigent and charity care patients for Years 1 and 2 of the proposed project.

	Medically Indigent (%)	Charity Care (%)	Medically Indigent (\$)	Charity Care (\$)
Historical Year FY 2018	N/A	N/A	N/A	N/A
Historical Year FY 2019	N/A	N/A	N/A	N/A
Projected Year 1	0.0%	3.0%	\$0.00	\$89,000.00
Projected Year 2	0.0%	3.0%	\$0.00	\$134,000.00

- b. **Existing Obligations:** The Applicant indicates that HiFidelity has no existing obligations under federal regulation requiring provision of uncompensated care, community service, or access by minority or handicapped persons.
- c. **Unmet Needs of Medicare, Medicaid, and Medically Indigent Patients:** The Applicant states HiFidelity plans to participate in both Medicare and Medicaid to the extent its offered services are covered by these programs. The Applicant asserts HiFidelity plans to adopt a financial need policy to ensure that appropriate care is provided to all residents of GHSA 8, to the extent they are referred to the MRI service.
- d. **Access to Proposed Facility:** The Applicant submits HiFidelity will provide appropriate care to all residents of GHSA 8 to the extent they are referred to the MRI service by an ordering physician.

Access Issues:

- i. **Transportation and Travel:** The Applicant states the proposed project will be located centrally within the city limits of Hattiesburg, Mississippi, approximately one-half mile from Hardy Street/US Highway 98, near existing medical infrastructure. The Applicant further states the location of the proposed project will make accessibility easy and quick for the residents of GHSA 8.
- ii. **Restrictive Admission Policy:** The Applicant asserts this criterion is not applicable to the proposed project.
- iii. **Access to Care by Medically Indigent Patients:** The Applicant states HiFidelity plans to adopt a financial need policy to ensure appropriate care is provided to all residents of GHSA 8, to the extent they are referred to the MRI service.
- iv. **Operational Hours of Service:** The Applicant states its regular operating hours will be Monday – Friday, 8:00 a.m. to 5:00 p.m. The Applicant states emergency only operation is not applicable to this project.

GR Criterion 7- Information Requirement

The Applicant certifies that it will record and maintain, at a minimum, the information stated in this criterion regarding charity care, care to the medically indigent, and Medicaid populations, and make it available to the Mississippi State Department of Health within fifteen (15) days of request.

GR Criterion 8 - Relationship to Existing Health Care System

a. **Comparable Services:** The Applicant references the *FY 2020 MSHP*, where it reports eight (8) healthcare facilities operating thirteen (13) MRI units in GHSA 8. The Applicant states, those units are currently operating beyond the capacity required by the State Health Plan and are expected to continue to operate without any significant consequences from the provision of additional MRI services by HiFidelity.

b. Effect on Existing Health Services:

- i. **Complement existing services:** The Applicant states neurological scans of the type proposed by the project are not currently available in GHSA 8. The Applicant affirms the project will improve the availability of certain types of neurology scans and complement the types of MRI scans already available in GHSA 8.
- ii. **Provide Alternative or Unique Services:** The Applicant asserts the project will offer a type of MRI service that is not currently available in the area, improving the availability of certain types of neurology scans.
- iii. **Provide Services for a Specific Target Population:** The Applicant asserts the project will enable residents of GHSA 8 suffering from neurology concerns to receive these services without traveling out of GHSA 8.

- iv. **Provide Services for Which There is an Unmet Need:** The Applicant states the proposed MRI unit will incorporate new technology currently not available in GHSA 8.
- c. **Adverse Impact:** The Applicant asserts that failure to implement this project would leave GHSA 8 residents lacking in these services, requiring them to either forego such scans or travel outside of GHSA 8 to obtain the service.
- d. **Transfer/Referral/Affiliation Agreements:** The Applicant states to the extent that any transfer agreements are necessary, the Applicant will have such agreements in place prior to providing services. The Applicant further states HiFidelity does not intend to have any referral or affiliation agreements.

GR Criterion 9 - Availability of Resources

- a. **New Personnel:** The Applicant states HiFidelity intends upon receipt of a CON to hire or contract with Andrew Maxwell, an MRI technologist-radiographer that meets the required qualifications for providing the MRI service. The Applicant further states, to the extent that additional personnel are required, Mr. Maxwell has the experience and knowledge to assist in recruiting additional personnel.
- b. **Contractual Services:** The Applicant states this GR criterion is not applicable to the proposed project.
- c. **Existing Facilities or Services:** The Applicant states this GR criterion is not applicable to the proposed project.
- d. **Alternative Uses of Resources:** The Applicant states this GR criterion is not applicable to the proposed project.

GR Criterion 10 – Relationship to Ancillary or Support Services

- a. **Support and Ancillary Services:** The Applicant states all necessary support and ancillary services for this project area available in GHSA 8 inasmuch as the project requires them.
- b. **Changes in Costs or Charges:** The Applicant asserts this GR criterion is not applicable to this project.
- c. **Accommodation of Changes in Costs or Charges:** The Applicant asserts this GR criterion is not applicable to this project.

GR Criterion 11- Health Professional Training Programs

The Applicant states the proposed project will have no effect on the clinical needs of health professional training programs in the service area.

GR Criterion 12 – Access by Health Professional Schools

The Applicant states the proposed project will have no effect on the clinical needs of health professional training programs in the service area.

GR Criterion 13 – Access to Individuals Outside Service Area

The Applicant submits HiFidelity proposes to provide services to individuals who are not residing in the service area but chooses to access care from their facility.

GR Criterion 14 – Construction Projects

The proposed project does not involve new construction.

GR Criterion 15 – Competing Applications

There are no competing applications related to this project.

GR Criterion 16 - Quality of Care

- a. **Past Quality of Care:** The Applicant asserts this GR criterion is not applicable to the proposed project.
- b. **Improvement of Quality of Care:** The Applicant states HiFidelity will provide quality healthcare that permits residents of GHSA 8 to receive MRI services that are not currently available in the area. The Applicant further states increased capacity of MRI services should reduce wait times for residents to schedule necessary diagnostic services allowing them to receive their diagnosis and treatment in a timely fashion.
- c. **Accreditation and/or Certificates:** The Applicant asserts this GR criterion is not applicable to the proposed project.

IV. FINANCIAL FEASIBILITY

A. Capital Expenditure Summary

Cost Item	Estimated Cost
Construction Cost -New	\$ 0.00
Construction Cost-Renovation	\$78,103.00
Capital Improvements	0.00
Fees (Architectural, Consultant, etc.)	\$25,000.00
Contingency Reserve	\$10,000.00
Capitalized Interest	0.00
Other	0.00
TOTAL PROPOSED CAPITAL EXPENDITURE	\$113,103.00

B. Method of Financing

HiFidelity proposes to fund the proposed project with an equity contribution of \$113,103.00.

C. Effect on Operating Costs

See Attachment 1 for HiFidelity’s three-year projected operating statement for the proposed project.

The Applicant submits HiFidelity Imaging, LLC is a new entity whose sole operations will be the provision of MRI services. Therefore, there are no financial statements available for HiFidelity as it has no operations at this time. The Applicant included unaudited 3-year financial statements for VCT, LLC, which was previously owned by the Applicant’s member Jory Scott and the assets of which are now owned by Capes & Canes, LLC. The Applicant states HiFidelity’s current members, Jory Scott and Jared Carlson, also own Capes & Canes, LLC. The Applicant further states VCT, LLC has been in operation for several years providing various health related services in the Hattiesburg, Mississippi area.

D. Cost to Medicaid/Medicare

The applicant’s projection of charges to third party payors is as follows (based on gross patient revenue):

Payor	First Year Revenue	Utilization Percentage
Medicare	\$ 1,880,000.00	63.00%
Medicaid	0.00	0%
Commercial	723,000.00	24.00%
Self Pay	289,000.00	10.00%
Charity	89,000.00	3.00%
Other	0	0%
Total	2,981,000.00	<u>100.00%</u>

V. RECOMMENDATION OF OTHER AFFECTED AGENCIES

The Division of Medicaid was provided a copy of this application for review and comment. As of the date of this staff analysis, the Division has not provided any comments on the proposed project.

VI. CONCLUSION AND RECOMMENDATION

This project is not in substantial compliance with the criteria and standards for the acquisition or otherwise control of magnetic resonance imaging (MRI) equipment and offering of MRI services contained in the *FY 2020 Mississippi State Health Plan*; Chapter 8 of the *Mississippi Certificate of Need Review Manual, April 9, 2019*; and all adopted rules, procedures, and plans of the Mississippi State Department of Health.

The Applicant fails to sufficiently prove a need for an additional MRI unit in GHSA 8. The Applicant's application fails to demonstrate through its physician affidavits that HiFidelity will achieve a minimum of 2,700 procedures by the end of its second year of operation as required by Need Criterion 1a. in both Sections 512.01.03 and Section 512.01.04 of the *FY 2020 MSHP*. Thus, the Applicant is not in compliance with these criteria.

Therefore, the Division of Health Planning and Resource Development recommends disapproval of the application submitted by HiFidelity Imaging, LLC, for the Establishment of Freestanding Fixed MRI Services at 4 Willow Point, Suite 1A, Hattiesburg, MS 39402.

VII. FINAL CONCLUSION AND RECOMMENDATION

On June 11, 2021, The Division of Health Planning and Resource Development (the "Division") recommended disapproval of HiFidelity's CON application for the Establishment of Freestanding Fixed MRI Services. Following the Division's initial recommendation, the Applicant was allowed to submit additional material for further analysis to resolve the basis of the staff's recommendation of disapproval.

The Applicant submitted additional material for the Division's consideration on June 16, 2021. This material included an affidavit submitted by Dr. Alan Kevin Cole which the Applicant states verifies the projected numbers previously submitted by Ms. Rebecca Hollingsworth. The Applicant also submitted an additional affidavit from Dr. Paul Talbot, a physician practicing in Hattiesburg, MS, and who the Applicant states is also a potential referral source for the HiFidelity project. The Applicant notes, Dr. Talbot's projections are in excess of Ms. Hollingsworth's projections. The Applicant lastly states the affidavits from Dr. Cole, Dr. Talbot, and Dr. Nelson support the numbers included in the Applicant's CON Application (Year 1: 2,183; Year 2: 2,725; and Year 3: 3,249), demonstrating that the Applicant will achieve a minimum of 2,700 procedures by the end of its second year of operation as required by Need Criterion 1a in Sections 512.01.03 and 512.01.04 of the *FY 2020 MSHP*.

After reviewing the Applicant's additional information, the Division of Health Planning and Resource Development maintains its staff recommendation of disapproval. Again, the Applicant fails to sufficiently prove a need for additional MRI services in GHSA 8. The Applicant's application also fails to demonstrate through its physician affidavits that HiFidelity will achieve a minimum of 2,700 procedures by the end of its second year of operation as required by Need Criterion 1a in both Sections 512.01.03 and Section 512.01.04 of the *FY 2020 MSHP*.

Need Criterion 1a states "Applicants for non-hospital based MRI facilities may submit affidavits from *referring physicians*." *FY 2020 Mississippi State Health Plan*, Sections 512.01.03 and 512.01.04 (emphasis added). Because Ms. Hollingsworth is not a physician, the Division will continue to exclude the numbers projected in her affidavit.

The Applicant also submitted an additional affidavit from Dr. Paul Talbot for the Division's consideration. However, Dr. Talbot's projections appear unreasonable considering the methodology described. Dr. Talbot states the following in his affidavit:

I have reviewed or caused to be reviewed the patient records or billing records for the periods of Jan 2020 – June 2021, with respect to the number of patients I have treated during those time periods and the number of patients for whom I have recommended magnetic resonance imaging as a diagnostic modality or found a condition which warranted referral for an MRI.

The number of patients that I have treated during those time frames for whom I have recommended magnetic resonance imaging is approximately 247.

I project that 712 is a reasonable minimum projection of the number of magnetic resonance imaging procedures for which I would have referred patients to the proposed HiFidelity MRI service.

Dr. Talbot projects referring 712 MRI procedures to HiFidelity in Year 1, 916 MRI procedures in Year 2, and 1074 MRI procedures in Year 3. However, when 247 is extrapolated and annualized over a period of seventeen (17) months, as explained by the Applicant, the projection does not yield the procedure numbers stated in the affidavit. Thus, the Division finds the Applicant is still not in substantial compliance with the criteria and standards for the acquisition or otherwise control of MRI equipment and the offering of MRI services.

Therefore, the Division of Health Planning and Resource Development recommends disapproval of the application submitted by HiFidelity Imaging, LLC, for the Establishment of Freestanding Fixed MRI Services at 4 Willow Point, Suite 1A, Hattiesburg, MS 39402.

**Attachment 1
HiFidelity Imaging, LLC
Three-Year Operating Statement (Project Only)**

	Year 1	Year 2	Year 3
Revenue			
Inpatient Care Revenue	0.00	0.00	0.00
Outpatient Revenue	\$ 2,981,000.00	\$ 4,472,000.00	\$ 4,969,000.00
Gross Patient Revenue	\$ 2,981,000.00	\$ 4,472,000.00	\$ 4,969,000.00
Charity	\$ (89,000)	\$ (134,000)	\$ (149,000)
Deductions from Revenue	\$1,821,000.00	\$2,732,000.00	\$3,036,000.00
Net Patient Care Revenue	\$ 1,249,000.00	\$ 1,874,000.00	\$ 2,082,000.00
Other Operating Revenue	0.00	0.00	0.00
Total Operating Revenue	\$ 1,249,000.00	\$ 1,874,000.00	\$ 2,082,000.00
Operating Expenses			
Salaries	\$87,000.00	\$90,000.00	\$94,000.00
Benefits	17,000.00	18,000.00	19,000.00
Supplies	96,000.00	147,000.00	166,000.00
Services	0	0	0
Lease Expenses	114,000.00	114,000.00	114,000.00
Depreciation	0	0	0
Interest	0	0	0
Other	78,000.00	104,000.00	114,000.00
Total Operating Expenses	\$ 392,000.00	\$ 473,000.00	\$ 507,000.00
Net Operating Income	\$857,000.00	\$1,401,000.00	\$1,575,000.00
	Proposed Year 1	Proposed Year 2	Proposed Year 3
Inpatient Days	0	0	0
Outpatient Visits	0	0	0
Procedures	2,400	3,600	4,000
Charge per Outpatient Day	0	0	0
Charge per Inpatient Day	0	0	0
Charge per Procedure	\$1,242.00	\$1,242.00	\$1,242.00
Cost per Inpatient Day	0	0	0
Cost per Outpatient Day	0	0	0
Cost per Procedure	\$163.00	\$131.00	\$127.00