

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

SEPTEMBER 27, 2024

**CON REVIEW: FSF-R-NIS-0824-010
SINGING RIVER HEALTH SYSTEM
ACQUISITION OF CARDIAC-ONLY PET EQUIPMENT
AND OFFERING OF CARDIAC-ONLY PET SERVICES
CAPITAL EXPENDITURE: \$2,322,703.00
LOCATION: OCEAN SPRINGS, JACKSON COUNTY, MISSISSIPPI**

STAFF ANALYSIS

I. PROJECT SUMMARY

A. Applicant Information

Singing River Health System (“SRHS” or the “Applicant”) is a 501(c)(3) non-profit community hospital system owned by Jackson County Mississippi. SRHS currently operates three (3) acute care hospitals: Singing River – Pascagoula, a 435-bed general acute care facility located in Pascagoula, Mississippi (“SRP”); Singing River – Ocean Springs, a 136-bed general acute care facility located in Ocean Springs, Mississippi (SROS”); and Singing River – Gulfport, 130-bed acute care hospital located in Gulfport, Mississippi (“SRG”).

According to the Applicant, SRHS offers a robust cardiology service line. SRP and SROS have established open heart surgery programs and offer a full array of cardiac catheterization services. SRG also operates a cardiac catheterization laboratory offering both diagnostic and PCI services. SRHS currently employs four (4) interventional cardiologists: Dr. Ahmad Agha; Dr. Cherie Champagne; Dr. Michael Cunningham; and Dr. Matthew Han (the “SRHS Cardiologists”). In addition, Dr. Scott Laura will be joining Singing River Cardiology in September of 2024.

The Applicant states the SRHS Cardiologist currently utilize a provider-based clinic located at 2 Doctor’s Drive, Ocean, Springs, Mississippi.

The Applicant states SRHS recently acquired a medical office building located at 1270 Ocean, Springs Road, Ocean Springs, Mississippi currently called Ocean Springs Professional Center (the “Center”). SRHS plans to change the name of the Center to the “Singing River Health- Multi- Specialty Clinic” (“MSC”).

The Center consists of three (3) medical office suites, two (2) of which are built out and leased to medical provider tenants (one of which is affiliated with SRHS), and a third suite which consist of shell space which has not been built out (the "Cardiology Suite").

B. Project Description

Singing River Health System ("SRHS") requests Certificate of Need ("CON") authority to acquire Cardiac-Only PET equipment and offer Cardiac-Only PET Services. SRHS proposes to establish a free-standing cardiology clinic in the Cardiology suite, which will require the renovation of approximately 3,525 square feet of existing shell space and construction of approximately 3,323 square feet of additional space. Following completion of the renovations and construction, SRHS will relocate the SRHS Cardiologists to the Cardiology Suite, which will be operated as a free-standing clinic.

The Applicant states SRHS will renovate over 3500 square feet of existing space for cardiology clinic space and expand the building by approximately 3,000 square feet of new space of which 1,215 square feet of space will be utilized to operate the Cardiac PET/CT scanner.

The application contains architectural schematics for the project attached as Exhibit A. The application also contains a cost estimate for the proposed Cardiac PET unit which Applicant states, for the purposes of this CON Application, only includes those cost related to the Cardiac PET portion of the project. SRHS estimates the total capital expenditure for the Cardiac-Pet portion of the project to be \$2,322,703.00.

The Applicant proposes to purchase an Omni Legend PET/CT Scanner. A copy of the Equipment Quote along with a copy of the Omni Legend PET/CT Scanner brochure is included in the application.

The Applicant projects to acquire two (2) full-time equivalent (FTE) personnel during the first year of operation at a cost of \$163,800.00.

The Applicant states SRHS anticipates that its Board of Trustees will approve the capital budget related to this project in August or September of 2024. The anticipated date the project will be complete is August 2025.

The Application included the site approval letter from the MSDH Division of Health Facilities Licensure and Certification, dated June 11, 2024, indicating that site approval is not required for the proposed project.

SRHS states through the offering of Cardiac PET services, Singing River Cardiology will be able to offer the highest standard of advanced nuclear cardiac imaging to the patient population they serve. The Applicant states the final objective of this project is to successfully bring Cardiac PET Services to the patients that Singing River Cardiology serves. Furthermore, the Applicant states SRHS will implement this service in an efficient and convenient manner.

The applicant submits SRHS has completed the six (6) additional projects over the past two (2) years which required a capital expenditure in excess of \$200,000.00.

The Applicant Affirms that SRHS will comply with all state and local building codes, zoning ordinances, and/or appropriate regulatory authority.

SRHS affirms that it 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.

SRHS affirms that it will obtain approval from the Division of Radiological Health prior to commencing cardiac PET services.

II. TYPE OF REVIEW REQUIRED

This project is reviewed in accordance with Section 41-7-173, 41-7-191 (1)(d)(xv), and 41-7-193 of the Mississippi Code of 1972, Annotated, as amended. MSDH will also review applications for a CON according to the general criteria listed in the *Mississippi Certificate of Need Review Manual, November 11, 2023*; all adopted rules, procedures, plans, criteria, and standards of 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 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 7, 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, Third Edition* contains policy statements, criteria and standards that the applicant is required to meet before receiving CON authority for the acquisition or otherwise control of a Positron Emission Tomography (PET) Scanner and related equipment, including Cardiac only PET scanner and the offering of fixed or mobile PET services including Cardiac Only PET services. This application is in substantial compliance with the applicable policy, criteria and standards stated in the *Plan as follows*:

SHP Policy Statement 1 – CON Review Requirements

SRHS acknowledges this requirement, but the estimated cost of scanner and related equipment is less than \$1,500,000.00.

SHP Policy Statement 2 – Indigent/Charity Care

The Applicant states as a publicly owned 501(c)(3) non-profit charitable organization, SRHS will provide a “reasonable amount” of indigent/charity care.

SHP Policy Statement 3 – Service Areas

The applicant states the services are proposed to be offered in Ocean Springs, Jackson County, Mississippi which is located in (“GHSA”) 9.

SHP Policy Statement 4 – Equipment to Population Ratio

The Applicant states the proposed project is not applicable to this policy because SRHS proposes only to offer cardiac-only PET services.,.

SHP Policy Statement 5 – Access to Supplies

SRHS affirms that it has direct access to appropriate radio-pharmaceuticals.

SHP Policy Statement 6 – Services and Medical Specialties Required

The Applicant states to the extent applicable to a Cardiac only PET unit, SRHS affirms that it will have these modalities available at its facilities except with respect

to neurosurgery for which SRHS maintains transfer arrangements with other local facilities.

SHP Policy Statement 7 – Hours of Operation

SRHS proposed hours of operation are 8am – 5pm Monday through Thursday; 8am. to – noon on Friday.

SHP Policy Statement 8 – CON Approval Preference

The Applicant affirms this proposal does not involve mobile and/or shared equipment.

SHP Policy Statement 9 – CON Requirements

SRHS acknowledges this policy statement. The Applicant states this project involves a fixed PET scanner.

SHP Policy Statement 10 – CON Exemption

The Applicant states this policy inapplicable to the proposed project.

SHP Policy Statement 11 – Addition of a Health Care Facility

The Applicant states this project does not involve mobile equipment.

SHP Policy Statement 12 – Equipment Registration

SRHS affirms that it will provide the registration/serial number of the PET scanner to the Department of Health prior to commencing services.

SHP Policy Statement 13 – Certification

The Applicant states this project does not involve mobile equipment. Therefore, this policy does not apply to the proposed project.

SHP Policy Statement 14 – Conversion from Mobile to Fixed Service

The Applicant states this project does not involve the conversion of a mobile unit. Therefore, this policy does not apply to the proposed project.

SHP Policy Statement 15 – Applicants with Accredited Cancer Center:

The Applicant states this policy statement is inapplicable to the proposed project.

Criteria and Standards for Acquisition or Otherwise Control of a PET Scanner including Cardiac only PET Scanner

SHP Need Criterion 1 – Minimum Procedures/Population

- a. **The entity desiring to acquire or to otherwise control the PET scanner must project a minimum of 1,000 clinical procedures per year and must show the methodology used for the projection.**

The Applicant states for the purpose of this application SRHS conservatively projects that it will perform 1040 cardiac PET procedures in Year One (1); 1092 procedures in Year Two (2); and 1147 procedures in Year Three (3).

SRHS states Singing River Cardiology management reviewed historical cardiac nuclear annual volumes and applied a conversion factor to the historical volumes of the current Singing River Cardiology Providers. The Applicant states financial projections are based on a 5% increase in volume for years two (2) and three (3). SRHS believes this is a conservative estimate. SRHS has also discussed projected volumes and obtained affidavits from employed cardiologist who project that they will refer 1,250 procedures per year.

- b. **The applicant shall document a minimum of 300,000 per PET scanner unit. The Division of Health Planning and Resource Development population projections shall be used. In the case of a Cardiac only PET scanner, this criterion will not apply.**

The Applicant states this project involves cardiac-only PET services; therefore, this criterion does not apply.

SHP Need Criterion 2 – Business Registration

The Applicant states SRHS is a publicly owned Mississippi community hospital established pursuant to the Mississippi Code Section 41-13-10 *et seq.* duly authorized to do business in Mississippi.

SHP Need Criterion 3 – Approval of Additional PET Equipment

At the time this application was submitted, there were no operational cardiac-only PET facilities in Service Area 9; however, on February 22, 2024, the MSDH issued a CON to Southern Mississippi Heart Clinic (“SMHC”), located at 3704 Bienville Blvd., Ocean Springs, MS. According to SMHC, SMHC’s facility is located less than 1.5 miles from the Applicant’s proposed facility. As SMHC’s facility only opened in August 2024, the Department has no utilization statistics to compare.

SHP Need Criterion 4 – Division of Radiological Health Approval

The Applicant affirms that SRHS shall receive approval from the Division of Radiological Health prior to the commencement of services.

SHP Need Criterion 5– Data Requirements

The Applicant affirms that SRHS will maintain the above data and make it available to the MSDH upon request.

SHP Need Criterion 6 - Fixed/Minimum Volume Requirement

The Applicant states SRHS does not propose to rent, lease, or otherwise allow other providers to use the equipment on a contractual basis.

SHP Need Criterion 7 – CON Approval/ Extension for PET Equipment

The Applicant states SRHS acknowledges this criterion and requests CON approval prior to utilizing the Equipment.

SHP Need Criterion 8 – Applicants with an Accredited Cancer Center

The Applicant states this policy does not apply to the proposed project.

Certificate of Need Criteria and Standards for Offering of Fixed or Mobile Positron Emission Tomography (PET) Services including Cardiac only PET Scanner

SHP Criterion 1 – Minimum Procedures

The application contains affidavits from four (4) physicians, as follows, projecting to refer a total of 1,050 procedures per year:

<u>Physician</u>	<u>Projected Procedures</u>
Matthew Hann, MD	250
Cherie Champagne, MD	250
Ahmed Aghan, MD	250
Michal Cunningham, MD	<u>300</u>
<u>Total</u>	<u>1,050</u>

SHP Criterion 2 – PET Equipment Utilized by Multiple Providers

The Applicant states this project does not propose that the PET unit will be utilized by more than one provider of PET services.

SHP Criterion 3 – Quality Control and Environmental Requirements

SRHS affirms that the cardiac PET services will be offered in a physical environment that conforms to federal standards, manufacturer’s specifications and licensing agencies’ requirements, manufacturer’s specifications, and licensing agencies’ requirements, including the areas listed described above.

SHP Criterion 4 – Division of Radiological Health Approval

SRHS affirms that it will receive approval from the Division of Radiological Health prior to commencing services.

SHP Criterion 5 – Provision of On-Site Medical Cyclotron

SRHS affirms that it will be provided an on-site rubidium-82 generator and elution system from a third-party entity situated within a one (1) hour drive from the proposed PET location.

SHP Criterion 6 – Staffing Requirements

- a. SRHS affirms that it will meet this requirement utilizing one or more of its existing radiology providers

- b. Not applicable - SRHS states that it will not operate cyclotron on-site
- c. SRHS affirms that it will meet this requirement and will contract with a qualified third-party company to provide service engineers and physicists.
- d. The Applicant employs an experienced and trained Radiation Safety Officer and affirms it will meet this requirement. The Applicant stated SRHS will not operate a medical cyclotron on-site.
- e. SRHS affirms that it will employ sufficient nuclear medicine technologist in compliance with this requirement.
- f. SRHS affirms that it will have necessary qualified staff available to operate the proposed unit, and that such staff shall include all of the above-listed personnel with appropriate training, qualifications, and experience.

SHP Criterion 7 – Management of Medical Emergencies

The Applicant states MSC shall maintain appropriate policies and procedures for the management of any medical emergencies which occur within the PET unit, including the arrangement for emergency transportation of patients to SROS or another appropriate SRHS facility. The application states SROS operates an emergency department less than (1) mile away from MSC, patients experiencing a medical emergency will benefit from a coordinated and seamless transfer process.

SHP Criterion 8 – Accommodating Referred Patients

SRHS affirms that it will accept appropriate referrals from other local provider and that these patients shall be accommodated to the fullest extent possible, by extending hours of service and prioritizing patients according to standards of need and appropriateness rather than the source of the referral.

SHP Criterion 9 – Medical Necessity

SRHS affirms, that it will establish protocols to assure that all clinical PET procedures performed are medically necessary and cannot be performed by other less expensive, established modalities.

SHP Criterion 10 –Notification of Procedures Offered

SRHS affirms that it will maintain current listings of appropriate PET procedures for use by referring physicians.

SHP Criterion 11 – Data Requirements

SRHS affirms that the required data will be maintained and made available to the Mississippi State Department of Health upon request.

SHP Criterion 12 – CON Approval/Exemption for PET Equipment

The Applicant acknowledges this need criterion and will obtain CON approval prior utilizing the PET equipment.

B. General Review (GR) Criteria

Chapter 8 of the *Mississippi Certificate of Need Review Manual, Revised November 11, 2023*; addresses general criteria by which all CON applications are reviewed. This application is in substantial compliance with general review criteria contained in the manual.

GR Criterion 1- State Health Plan

The Applicant states this project's compliance with the State Health Plan specific criteria listed in Section III A. above.

GR Criterion 2 – Long Range Plan

The Applicant states this proposed project is aligned with Singing River Health's mission to "Improve Health and Save Lives". The applicant also states they are a not-for-profit county owned health system providing over \$70,000,000.00 annually in uncompensated care, which includes indigent care. The applicant further states they serve the residents of Jackson County, Harrison County and the surrounding areas. According to the application, SRHS operates a large network of medical clinics and three (3) Emergency Rooms in the communities. The Applicant states through these facilities alone, they currently see a high demand for advanced cardiac diagnostic services. The Applicant expects the demand to continue to grow as the average age of the population continues to increase in the local and surrounding areas. SRHS believes that making advanced cardiac imaging modalities such as Cardiac PET available will allow it to advance its mission and improve the health of its patient population.

GR Criterion 3 – Availability of Alternatives

- a. **Advantages and Disadvantages of Alternatives:** The Applicant states at the current time Singing River Cardiology group treats a substantial panel of patients in the communities. The applicant also states when utilizing diagnostic tool to identify potential cardiovascular blockages, the traditional Nuclear Medicine stress test can unfortunately result in both false negative or false positive results. SRHS proposes to add the latest available technology with state-of-the-art Digital Cardiac Pet Unit, which provides higher resolution and enhanced diagnostic accuracy compared to prior generation nuclear equipment. SRHS proposes to utilize the GE Omni Legend, which is an all-Digital unit that utilizes precision DL image learning and enhanced efficiency allowing our patients to spend less time in the scanner. The applicant affirms this concept brings convenience for patients while still producing the highest quality digital images for diagnosing heart disease in the patient population.
- b. **New Construction Projects:** The applicant states this project involves the renovation and expansion of an existing healthcare facility.
- c. **Beneficial Effects to the Health Care System:** The applicant states this new technology provides digital high precision quality studies to help the cardiologist more accurately diagnose cardiac disease. The Applicant states this will allow improved diagnostic accuracy for identifying heart disease, which in turn allows better clinical outcomes for patients.
- d. **Effective and Less Costly Alternatives:**
 - i. **Unnecessary Duplication of Services:** The applicant states Cardiac- only PET is not currently available in SRHS's service area, therefore this is not an unnecessary duplication of services.
 - ii. **Efficient Solution:** The applicant states this equipment will be contiguous with the Cardiology Clinic, allowing convenience and efficiency along with seamless integration with the patient care plan. The applicant asserts, , the digital unit utilizes a highly advanced software (DL) that allows a quicker scan which is better for the patient.
- e. **Improvements and Innovations:** The applicant states with this higher accuracy, new generation nuclear diagnostic platform, SRHS can reduce false positives/false negatives, which may remain undetected utilizing prior generation technology. The Applicant states the pinnacle improvement from this technology though is the fact it will allow a more accurate and quicker

diagnosis of heart disease. SRHS states this will enable the Cardiologist to intervene with the medical plan earlier rather than later. The applicant asserts that this in turn can improve the life expectancy for those patients as cardiologists will now be able to identify their underlying heart disease earlier in the disease process.

- f. **Relevancy:** The applicant states the current medical literature around Cardiac PET clearly justifies the trend with progressive health care systems implementing Cardiac PET technology. Singing River Cardiology desires this technology so it will be readily and efficiently available for the patients they serve.

GR Criterion 4 - Economic Viability

- a. **Proposed Charge:** The applicant states Singing River consulted with its finance and reimbursement experts within SRHS. The Applicant states the finance team utilizes the most recent information on insurance allowable when adding a new procedure to our charge master. SRHS believes that its proposed charges are reasonable and consistent with other providers in the state.
- b. **Projected Levels of Utilization:** The Applicant states as referenced above, the only cardiac-only PET services listed in the current MSHP is Cardiology Associates of North Mississippi, located in Lee County, Mississippi and which performed 1,170 procedures in FY 2020.
- c. **Financial Feasibility Study:** The application contains a letter from SRHS's Chief Financial Officer, attesting to the financial feasibility of the project.
- d. **Financial Forecasts:** The Applicant states this criterion is not applicable to this application. SRHS's projections do not deviate significantly from the financial statements of three (3) year historical period.
- e. **Covered Expenses:** The Applicant states SRHS will cover expenses incurred by the proposed project utilizing its existing cash reserves.
- f. **Impact of Proposed Project on Health Care Cost:** The Applicant states with the ability for this technology to detect heart disease earlier in the disease process, Cardiologists can create treatment plans on an outpatient basis. The Applicant states, in contrast, if heart disease is not identified early and progresses, the cost is significantly higher (e.g. Open Coronary Bypass or other interventions) which will result in substantially higher cost to the healthcare system.

GR Criterion 5 - Need for the Project

- a. Access by Population Served:** The Applicant states SRHS operates as a not-for-profit community owned health system. The Applicant states with that status, they provide a significant level of uncompensated care to their patients, which includes charity and indigent care. The Applicant asserts that SRHS' total uncompensated care provided in FY 2023 was in excess of \$75,000,000.00. The Applicant states Cardiac PET will be an available option for all patients meeting the clinical criteria, regardless of income status, age, or race.

The Applicant states as a 501(c)(3) non-profit hospital, SRHS is required to regularly conduct a community health needs assessment ("CHNA") which defines the community SRHS serves and assesses the healthcare needs of its community. SRHS is also required to develop an implementation strategy to address to community needs identified in the CHNA.

The application contains the most recent CHNA identifying the diverse community served by SRHS and their healthcare needs, and SRHS' implementation strategy to address the need identified in the CHNA.

- b. Relocation of Services:** The Applicant states this criterion is not applicable.
- c. Current and Projected Utilization of Like Facilities:** The Applicant states at the time of this application, there were no existing cardiac-only PET units operating in the service area. However, on February 22, 2024, the MSDH issued a CON to Southern Mississippi Heart Clinic ("SMHC"), located at 3704 Bienville Blvd., Ocean Springs, MS. According to SMHC, SMHC's facility is located less than 1.5 miles from the Applicant's proposed facility. As SMHC's facility only opened in August 2024, the Department has no utilization statistics to compare.

The Applicant referenced a case *Open MRI, LLC v Mississippi State Department of Health*, 939, So. 2d 813 (Miss. Ct. App. 2006), wherein it was held that:

“The Department, the applicant, and contestants are bound by the numbers as reflected in the State Health Plan in effect at the time of the application.”

- d. Probable Effect on Existing/Similar Facilities:** The Applicant states Singing River Cardiology group currently treats a large portion of the residents in the area. The Applicant further states these patients will now have access to Cardiac PET as an integrated offering in its Cardiology Clinic.

The applicant states in the event that another facility begins offering Cardiac PET CT services, there should be no adverse impact on such facility because SRHS projects vast a majority of Cardiac PET CT scans it will perform will result from referrals from its employed cardiologists.

- e. Community Reaction to Service:** The application contained three (3) letters of support from Jack Norris Director, Government Affairs of Ingalls Shipbuilding, George L. Freeland, Jr., Executive Director of Jackson County Economic Development Foundation and the Mayor of Ocean Springs Kenny Holloway.

In addition, MSDH received a letter from Southern Mississippi Heart Clinic (“SMHC”), opposing the proposed project. SMHC opposes the application, citing concerns that the project does not comply with Need Criterion 3, requiring existing facilities to be performing 1,500 procedures per year and duplication of services, as it will be located less than 1.5 miles from an existing facility offering cardiac-only PET services.

GR Criterion 6 - Access to the Facility or Service

a. Access to Services:

1. The Applicant affirms 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 minorities, women, handicapped persons, and the elderly have access to the services of the existing facility.

2. The Applicant affirms that the above-listed residents will continue to have access to the proposed services and/or facility as described in the application.
3. The Applicant asserts that SRHS does not separate indigent care (as defined in this Application) from charity care. The applicant states the projected charity care for Years 1 and 2 are higher than the historical year figures because in FY 2024, SRHS changed the method by which SRHS classifies charity care, resulting in significantly increased charity care and reduced bad debt.

Gross Patient Revenue

	Medically Indigent (%)	Charity Care (%)	Medically Indigent (\$)	Charity Care (\$)
Historical Year 2022	--	2%	--	\$83,338,986.00
Historical Year 2023	--	2%	--	\$75,369,890.00
Projected Year 1	--	4%	--	\$137,711,28
Projected Year 2	--	4%	--	\$141,842,620

- b. **Existing Obligations:** The Applicant affirms that Singing River does not have any existing obligations under any 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 asserts SRHS will provide cardiac PET services to Medicare, Medicaid and medically indigent patients.
- d. **Access to Proposed Facility:** The Applicant states SRHS is a participating provider in the Medicare, Medicaid programs. The Applicant affirms that SHHS is also a publicly owned 501 (c)(3) non-profit organization and maintains a robust financial assistance and charity care program for indigent care program for indigent and low-income patients.
- e. **Access Issues:**

- i. **Transportation and Travel:** The Applicant states the Multi-Specialty Clinic (MSC) will be located at 1270 Ocean Springs Road, Ocean Springs, MS which is conveniently accessible from US Highway 90.
- ii. **Restrictive Admissions Policies:** The Applicant asserts as a free-standing clinic, the MSC will not have an admission policy.
- iii. **Access to Care by Medically Indigent Patients:** The Applicant states SRHS maintains a financial assistance policy
- iv. **Operational Hours of Service:**
 1. **Regular Operation.** The Applicant states Singing River MSC regular hours of operations are from 8:00 am until 5:00 pm, Monday through Thursday. 8am to noon on Friday.
 2. **Emergency Operation.** The Applicant asserts this criterion is not applicable to the proposed project.

GR Criterion 7 - Information Requirement

Singing River affirms that it will record and maintain the above information and make it available to the Mississippi State Department of Health within fifteen (15) business days of its request.

GR Criterion 8 - Relationship to Existing Health Care System

- a. **Comparable Services:** The Applicant states based on information contained in the FY 2022 State Health Plan, Third Edition, there are currently no existing providers of cardiac- only PET services in GHSA 9.

Staff notes, however, that the Department issues a CON on February 22,2024, to Southern Mississippi Heart Clinic for cardiac-PET services, SMHC began operating in August 2024.

- b. **Effects on Existing Health Services:**

- i. **Complement Existing Services:** The Applicant states Singing River cardiac PET service is not currently offered. Singing River Cardiology proposes to offer this service in a convenient manner as a diagnostic tool integrated with the plan of care.

- ii. **Provide Alternative or Unique Services:** The Applicant states Singing River cardiac PET service is not currently offered. Singing River Cardiology proposes to offer this service in a convenient manner as a diagnostic tool integrated with the plan of care.
- iii. **Provide Services for a Specific Target Population:** The Applicant states Singing River cardiac PET service is not currently offered. Singing River Cardiology proposes to offer this service in a convenient manner as a diagnostic tool integrated with the plan of care.
- iv. **Provide services for Which There is an Unmet Need:** The Applicant states Singing River cardiac PET service is not currently offered. Singing River Cardiology proposes to offer this service in a convenient manner as a diagnostic tool integrated with the plan of care.

Adverse Impact: The Applicant states Cardiac PET offers substantial advantages over traditional nuclear medicine diagnostic tools. The Applicant state if SRHS is unable to implement this technology, it will be detrimental to the patients we serve who would clinically benefit from this technology.

- c. **Transfer/ Referral/ Affiliation Agreements:** The Applicant states this criterion is not applicable.

GR Criterion 9 - Availability of Resources

- a. **New Personnel:** The Applicant SRHS currently employs four (4) interventional cardiologist and will soon employ a fifth cardiologist. You state SRHS is a large regional healthcare system and will recruit any new personnel required using its existing human resources and recruitment processes.
- b. **Contractual Services:** The Applicant states SRHS is a full service general acute care hospital system and will provide any necessary support services for the proposed service.
- c. **Existing Facilities or Services:** The Applicant states that SRHS currently staffs three (3) acute ae hospitals and numerous other outpatient facilities and will continue to do so.
- d. **Alternative Uses of Resources:** The Applicant states this criterion is not applicable.

GR Criterion 10 – Relationship to Ancillary or Support Services

- a. Support and Ancillary Services:** The Applicant states that SRHS will make available all necessary support and ancillary services for the project.
- b. Changes in Costs or Change:** The Applicant states this service is currently not offered. The Applicant states cost and charges for this procedure are developed within the financial department in the customary manner in compliance with all charge master rules and regulations. You also state this is an FDA approved procedure.
- c. Accommodation of Changes in Costs or Charges:** The Applicant states the financial section of this application reflects projected costs and charges in implementing this service.

GR Criterion 11 – Health Training Programs

The Applicant states SRHS Nuclear Technicians are trained in all the principles of radiopharmaceuticals and equipment operation. The Applicant submits as an example, some of the Nuclear Technicians currently scan patients on outpatient Cancer PET equipment.

GR Criterion 12 - Access by Health Professional Schools

The Applicant states the Nuclear Technologists must receive adequate training and competency with nuclear medicine procedures prior to working independently providing procedures with this equipment. The Applicant also states relative to Radiology Technology training, SRHS affiliated with the area Radiology Schools and a training site in order to grow future Radiology Technologist.

According to the Applicant, SRHS maintains clinical affiliations with over seventy (70) educational institutions including Mississippi Gulf Coast Community College (including the School of X-ray) Delta State University, Mississippi State University, Jackson State University, Pearl River Community College (Includes Radiology Ultrasound School), Mississippi University for Women, Mississippi College, and Mississippi Delta Community. The Applicant states this volume of affiliation arrangements demonstrates Singing River's commitment to supporting training of our future health care workers.

The Applicant affirms SRHS does not at this time have any tangible plans to specifically utilize the Cardiac PET CT Scanner in healthcare professional training programs.

GR Criterion 13 Access to Individuals Outside Service Area

The Applicant states it is not uncommon for surrounding areas providers to order diagnostic testing within SRHS facilities.

GR Criterion 14 - Construction Projects

The Applicant states this criterion has been included in Economic Viability.

GR Criterion 15 – Competing Applications

There are no competing applications on file with the Department for cardiac-PET equipment and services.

GR Criterion 16 - Quality of Care

a. Past Quality of Care: The Applicant states although the proposed project involves the initiation of a new service, SRHS is an America College of Radiology (“ACR”) certified in nuclear medicine. The Applicant states Ocean Springs Hospital was also recently awarded an American Heart Association “Gold” Award for its treatment of coronary artery disease in patients with Type 2 Diabetes, and Singing River Gulfport was awarded a “Silver” Award for the same.

b. Improvement of Quality of Care: The Applicant states this new technology provides digital high precision quality studies to help the Cardiologist more accurately diagnose cardiac disease. The Applicant states this will allow improved diagnostic accuracy for identifying heart disease, which in turn allows better clinical outcomes for our patients.

c. Accreditation and/or Certificates: The Applicant states that SRHS is certified by the America College of Radiology (ACR) in Nuclear Medicine.

IV. FINANCIAL FEASIBILITY

A. Capital Expenditure Summary

The total estimated capital expenditure is allocated as follows:

	Item	Cost (\$)	Percent (%) of Total
a.	Construction Cost -- New	\$1,046,115.00	45.04%
b.	Construction Cost -- Renovation	0	0%
c.	Capital Improvements	0	0%
d.	Total Fixed Equipment Cost	\$1,050,143.00	45.21%
e.	Total Non-Fixed Equipment Cost	0	0%
f.	Land Cost	0	0%
g.	Site Preparation Cost	0	0%
h.	Fees (Architectural, Consultant, etc.)	\$84,837.00	3.65%
i.	Contingency Reserve	\$85,050.00	3.66%
j.	Capitalized Interest	0	0%
j.	Legal and accounting fees	0	0%
k.	Other	\$56,558.00	2.44%
	Total Proposed Capital Expenditure	\$2,322,703.00	100.00%

B. Method of Financing

The Applicant proposes to finance the proposed capital expenditure with cash reserves. The application contains a letter from the Chief Executive Officer confirming that Singing River Health System has sufficient cash reserves to fund the project.

C. Effect on Operating Cost

The Hospital's three-year projected operating statement is presented in 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	43%	\$5,772,687.00
Medicaid	8%	\$847,577.00
Commercial	10%	\$1,007,930.00
Self-Pay	5%	\$503,965.00
Charity Care	0%	-
Other	22%	\$2,267,841.00
Total	100%	\$10,400,000.00

V. RECOMMENDATIONS OF OTHER AFFECTED AGENCIES

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

VI. CONCLUSION AND RECOMMENDATION

This project is in substantial compliance with the policy statements, criteria, and standards for acquisition or otherwise control of cardiac-only PET equipment and provision of cardiac-only PET 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 Singing River Health System for the Offering of Cardiac-Only PET Services and Acquisition of Cardiac-Only PET Equipment.

Attachment 1

Jackson Heart Clinic Three-Year Operating Statement (Project Only)			
	Year 1	Year 2	Year 3
Revenue			
Patient Revenue:			
Inpatient	\$0	\$0	\$0
Outpatient	<u>\$10,400,000.00</u>	<u>\$10,920,000.00</u>	<u>\$11,466,000.00</u>
Gross Patient Revenue	<u>\$10,400,000.00</u>	<u>\$10,920,000.00</u>	<u>\$11,466,000.00</u>
Charity Care	\$197,600.00	\$207,480.00	\$217,854.00
Deductions from Revenue	\$8,465,876.00	\$8,889,169.00	<u>\$9,333,627.00</u>
Net Patient Revenue	\$1,736,524.00	\$1,823,351.00	\$1,914,519.00
Other Operating Revenue	\$0	\$0	\$0
Total Operating Revenue	\$1,736,524.00	\$1,823,351.00	\$1,914,519.00
Expenses			
Operating Expenses:			
Salaries	\$131,040.00	\$134,971.00	\$139,020.00
Benefits	\$32,760.00	\$33,743.00	\$34,755.00
Supplies	\$490,000.00	\$504,700.00	\$519,841.00
Services	\$0	\$0	\$0
Lease	\$0	\$0	\$0
Depreciation	\$228,000.00	\$234,840.00	\$241,885.00
Interest	\$0	\$0	\$0
Other	<u>\$0</u>	<u>\$0</u>	<u>\$0</u>
Total Expenses	<u>\$881,800.00</u>	<u>\$908,254.00</u>	<u>\$935,502.00</u>
Net Income (Loss)	\$854,724.00	\$915,097.00	\$979,018.00
Assumptions			
Inpatient days*	0	0	0
Outpatient days*	0	0	0
Procedures	1,040	1,092	1,147
Charge/outpatient day	\$0	\$0	\$0
Charge per inpatient day	N/A	N/A	N/A
Charge per procedure	\$10,000.00	\$10,000.00	\$9,997.00
Cost per inpatient day	NA	NA	NA
Cost per outpatient day	\$0	\$0	\$0
Cost per procedure	\$848.00	\$832.00	\$816.00

*Calculations may differ due to rounding.