

**MISSISSIPPI STATE DEPARTMENT OF HEALTH
DIVISION OF HEALTH PLANNING AND RESOURCE DEVELOPMENT
JULY 25, 2022**

**CON REVIEW NUMBER: HG-NIS-0522-010
NORTH MERIDIAN CANCER CENTER, LLC
ACQUISITION OF LINEAR ACCELERATOR AND PROVISION OF
THERAPEUTIC RADIATION SERVICES
CAPITAL EXPENDITURE: \$1,835,410.00
LOCATION: MERIDIAN, LAUDERDALE COUNTY, MISSISSIPPI**

STAFF ANALYSIS

I. PROJECT SUMMARY

A. Applicant Information

North Meridian Cancer Center, LLC (the "Applicant" or the "Cancer Center") is a Mississippi limited liability company registered on January 21, 2022. The Applicant states North Meridian Cancer Center, LLC will be located on a lot North of Meridian Plastic Surgery Center, which is located at 5002 Highway 39 North, Meridian, Mississippi 39301. The Cancer Center is governed by R. Scott Anderson, M.D., and Charlene Moore Anderson.

The application contains a Certificate of Good Standing from the Office of the Secretary of State indicating as of February 23, 2022, North Meridian Cancer Center, LLC is in good standing with the state of Mississippi.

B. Project Description

North Meridian Cancer Center, LLC requests certificate of need ("CON") authority to acquire a linear accelerator and provide therapeutic radiation services in Lauderdale County. The Applicant states the proposed project entails acquiring an Accuray Model HADA Tomo linear accelerator and placing it in a building (Legacy Coach System) specifically designed by the manufacturer of the unit. The Applicant further states the project will require the construction of a 20-foot-wide by 60-foot-long concrete pad with adequate weight-bearing capability to support the unit, as well as adequate power and water to support operation of the unit. The Applicant affirms North Meridian Cancer Center will be an active freestanding radiation facility.

The Applicant asserts the site for the proposed unit will be located adjacent to the front door of Meridian Plastic Surgery Center. The Applicant states North Meridian Cancer Center will be "sited" by a crane on vacant space north of Meridian Plastic Surgery Center. The Applicant further states a precise fiscal address will be issued after the linear accelerator is placed on the lot and power is connected to the unit. The Applicant affirms the proposed site is appropriate for the construction of the pad and operation of the Tomo unit. The Applicant states the unit will be transported to Meridian and placed into operation in cooperation with the Radiation Safety Division

of the Mississippi State Department of Health to ensure appropriate exposure levels are achieved. The Applicant states the survey for Radiation Safety will be conducted "on-site".

According to the Applicant, the Cancer Center will utilize an "in and out" treatment concept for treatment delivery. The Applicant states, when a patient arrives, staff will direct them to the dressing room, and the patient will be treated and returned to their vehicle. The Applicant states Painless Skin Cancer Treatment Center, LLC, an affiliate of North Meridian Cancer Center, leases a suite inside Meridian Plastic Surgery Center with four (4) restrooms and a waiting room that the Cancer Center patients may utilize.

In addition, the Applicant states once the unit arrives, shielding will be installed, which complies with all state and local building codes, zoning ordinances, and appropriate regulatory authority. The Applicant states the shielding will be installed pursuant to the manufacturer's site planning guide.

The Applicant states the final objective of the project is to treat cancer patients with advanced therapeutic radiation and provide patients of General Hospital Service Area 6 and west Alabama a choice in the selection of radiation oncology care providers within the region. The Applicant states North Meridian Cancer Center will offer comparable services to the existing provider in GHSA 6 with more modern equipment.

The Applicant states the Cancer Center will comply with all state and local building codes, zoning ordinances, and/or appropriate regulatory authority. Further, the Applicant affirms the Cancer Center 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.

North Meridian Cancer Center projects 5.0 full-time equivalent (FTE) staff will be hired at an annual cost of \$555,000.00 the first year. The Applicant projects a total capital expenditure of \$1,835,410.00, as itemized in Section IV of this Staff Analysis. The Applicant proposes to finance the project with a sixty (60) month loan financed at four percent (4%) interest.

North Meridian Cancer Center expects to obligate the capital expenditure within thirty (30) days of CON approval and anticipates the project will be complete within eight (8) months following receipt of the CON.

The application contains a letter dated July 1, 2022, documenting MSDH Division of Health Facilities Licensure and Certification's approval of the site for the facility.

II. TYPE OF REVIEW REQUIRED

The Mississippi State Department of Health (“MSDH”) will review applications for a CON under the statutory requirements of Sections 41-7-173, 41-7-191, and 41-7-193, Mississippi Code of 1972 Annotated, as amended. MSDH will also review applications for a CON according to the general criteria listed in the *Mississippi Certificate of Need Review Manual*, all adopted rules, procedures, and plans of MSDH, and the specific criteria and standards listed below.

In accordance with Section 41-7-197(2) of the Mississippi Code of 1972 Annotated, as amended, any affected person may request a public hearing on this project within ten (10) days of publication of the staff analysis. The opportunity to request a hearing expires on August 4, 2022.

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

A. State Health Plan (SHP)

The *FY 2022 Mississippi State Health Plan, Second Edition* (“MSHP”) contains policy statements, criteria, and standards which the applicant is required to meet before receiving CON authority for the acquisition or otherwise control of a linear accelerator and the provision of therapeutic radiation services. In addition, therapeutic radiation services are reviewable if the proposed provider has not provided such services on a regular basis within twelve (12) months prior to the time such services would be offered. This application is not in compliance with the applicable policy statements, criteria, and standards stated in the *Plan* as discussed below.

Policy Statements Regarding Certificate of Need Applications for the Acquisition or Otherwise Control of Therapeutic Radiation Equipment, and/or the Offering of Therapeutic Radiation Services (Other than Stereotactic Radiosurgery)

Policy Statement 1 – Service Areas:

The application indicates the proposed unit will be located in Lauderdale County, General Hospital Service Area (GHSA) 6. In addition, the Applicant states the unit will also serve five (5) Alabama counties.

Policy Statement 2 – Equipment to Population Ratio:

The Applicant submits, as shown on Map 5-1 of the *FY 2022 MSHP*, the 2025 population projection for GHSA 6 is 181,725. The Applicant notes need in the *Plan* is defined as one (1) unit per 117,380 population. In addition, the Applicant

acknowledges MSDH will consider out-of-state population in determining the need for equipment under certain circumstances.

Staff determined that GHSA 6 has two (2) operational units and one (1) unit that is currently being replaced for a total of three (3) units. Therefore, the project as proposed does not meet the equipment to population ratio requirement.

Policy Statement 3 – Limitation of New Services:

The Applicant acknowledges, when the therapeutic radiation unit-to-population ratio reaches one (1) to 117,380 in a given GHSA, no new therapeutic radiation services may be approved unless the utilization of all the existing machines in the given GHSA averaged 8,000 treatments or 320 patients per year for the two (2) most recent years as reported on the “Renewal of Hospital License and Annual Hospital Report”. The Applicant submits Anderson Cancer Center reported 7,996 treatments in 2019 and 8,522 treatments in 2020, which average exceeds 8,000 treatments per year.

Staff reviewed documentation submitted by Anderson Regional Cancer Center (the “Center”) confirming the Center utilized two (2) units to perform radiation services during fiscal years 2019, 2020, and 2021. Considering data published in Table 5-5 of the *MSHP*, the Center’s two (2) units performed a combined average (for fiscal years 2019 and 2022) of 8,259 treatments or 4,125.5 treatments per unit.

Therefore, the Applicant is not in compliance with this policy statement

Policy Statement 4 – Expansion of Existing Services:

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

Policy Statement 5 – Equipment Designated for Backup

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

Policy Statement 6 – Definition of a Treatment:

As defined for health planning and CON purposes, the Applicant agrees to the definition of a patient “treatment”. A patient “treatment” is defined as one individual receiving radiation therapy during a visit to a facility which provides megavoltage radiation therapy regardless of the complexity of the treatment or the number of “fields” treated during the visit.

Policy Statement 7 – Use of Equipment or Provision of Service:

The Applicant states the CON application submitted seeks the approval of the

Mississippi State Department of Health for the acquisition of one (1) Accuray Model HADA Tomo Therapeutic Radiation System.

Certificate of Need Criteria and Standards for the Acquisition or Otherwise Control of Therapeutic Radiation Equipment and/or the Offering of Therapeutic Radiation Services (other than Stereotactic Radiosurgery)

Need Criterion 1: Project Need

The Plan states the applicant shall document a need for therapeutic radiation equipment/service by complying with any one of the following methodologies:

a. The need methodology as presented in the *Plan*;

1. Project Annual Number of Cancer Patients:

$$\text{New Cancer Cases} = \frac{\text{General Hospital Area}}{6 \text{ Population}} \times \frac{6.06 \text{ cases}^*}{1,000 \text{ pop.}}$$

*Mississippi Cancer Incidence Rate

$$181,725 \times \frac{6.06}{1,000} = \mathbf{1,101.25 \text{ new cancer cases}}$$

2. Project the Annual Number of Radiation Therapy Patients:

New Cancer Cases X 45% = Patients Who Will Likely Require Radiation Therapy

$$1,101.25 \times 45\% = \mathbf{495.56 \text{ radiation therapy patients}}$$

3. Estimate Number of Treatments to be Performed Annually:

Radiation Therapy Patients X 25 Treatments per Patient (Avg.) = Estimated Number of Treatments

$$495.56 \times 25 = \mathbf{12,389 \text{ treatments}}$$

4. Project Number of Megavoltage Radiation Therapy Units Needed:

Estimated No. of Treatments = Projected Number of Units Needed
8,000 Treatments per Unit

$$\frac{12,389}{8,000} = \mathbf{1.548 \text{ units needed}}$$

5. Determine Unmet Need (if any):
Projected Number of Units Needed – Number of Existing Units =
Number of Units Required (Excess)

Unmet Need: 1.548 – 3 = (1.452)

The Applicant does not satisfy this methodology for Mississippi's population only. However, the Applicant states North Meridian Cancer Center will also serve the following counties in Alabama for a total population of 73,493: Choctaw (12,665); Lamar (13,972); Pickens (19,123); Sumter (12,345); and Washington (15,388). Adding the Alabama service area population to the Mississippi service area population, the total population to be served is 255,218.

When applying the same formula to the combined population, this need methodology is still not met as demonstrated below.

1. $255,218 \times \frac{6.06}{1,000} = 1,546.62$ **new cancer cases**
 2. $1,546.62 \times 45\% = 695.98$ **radiation therapy patients**
 3. $695.98 \times 25 = 17,399.47$ **treatments**
 4. $17,399.47 \div 8,000 = 2.175$ **units needed**
 5. **Unmet Need: 2.175 – 3 = (0.825)**
- b. **Demonstrating that all existing machines in the service area in question have averaged 8,000 treatments per year or all machines have treated an average of 320 patients per year for the two most recent consecutive years;**

The Applicant submitted information from the *FY 2022 MSHP* indicating Anderson Regional Cancer Center (the only provider of radiation therapy services in GHSA 6) had 7,996 visits in FY 2019 and 8,522 visits in FY 2020 for a combined average of 8,259 visits for the two (2) most recent years for which data was reported in the *MSHP*.

The Applicant asserts that although the current provider has three (3) linear accelerators, only one (1) unit is primarily in use. The Applicant submits the Varian Clinac 23 EX unit is decommissioned and has had a padlock on the breaker box for the past three (3) years. In addition, the Applicant states the current provider reported a single number for treatments performed on the Varian Clinac iX on their "Renewal of Hospital License and Annual Hospital Report"; therefore, the Applicant states, by application of the regulations, the unit is a "backup" unit and is unable to be counted in the CON inventory. The

Applicant further surmises that this means only the Tomotherapy HDA unit is in use at the Center for the 181,725 patients in GHSA 6. The Applicant submits Chapter 5, Section 509.01, Policy Statement 5, states: “Therapeutic Radiation equipment designated by an applicant as ‘backup’ equipment shall not be counted in the inventory for CON purposes. Any treatments performed on the ‘backup’ equipment shall be attributed to the primary equipment for CON purposes.”

Based on information contained in the Department’s files there are three (3) approved radiation therapy units at Anderson Regional Cancer Center. According to Anderson Regional Cancer Center, two (2) are currently operating and one (1) received approval for replacement from the Department on April 12, 2022, through a Determination of Non-Reviewability. Considering the data published in Table 5-5 of the *MSHP* and information submitted by Anderson Regional Cancer Center, the Center has two operational (2) units which performed a combined average of 8,259 treatments or an average of 4,125.5 treatments per unit for FY 2019 and FY 2020. Therefore, staff finds the Applicant has also not met this need methodology.

In addition to the above, an affidavit signed by Caleb R. Dulaney, M.D., Anderson Regional Cancer Center’s Medical Director, indicates the two (2) operational units at the Center performed a total of 8,495 treatments in FY 2019, 8,403 treatments in FY 2020, and 6,947 treatments in FY 2021 (see table below). Dr. Dulaney affirms the treatment numbers for fiscal years 2019, 2020, and 2021 were pulled from the Cancer Center’s MOSAIQ® patient data management system.

Linear Accelerator	FY 2019 10/1/18-9/30/19	FY 2020 10/1/19-9/30/20	FY 2021 10/1/20-9/30/21
Clinac iX	5,578	3,217	2,450
Tomotherapy HDA	2,917	5,186	4,497
MOSAIQ Total	8,495	8,403	6,947

The affidavit submitted by Dr. Dulaney also states the following: “The Clinac iX and the Tomotherapy HDA linear accelerators have been in active use for the treatment of patients for each of these years and also in 2022. Neither machine was designated by the Cancer Center during that time, nor is either unit presently designated as a backup unit.” Dr. Dulaney certifies both units are fully operational and are used on the same days at the same times to treat patients independently.

- c. Demonstrating that the applicant’s existing therapeutic equipment has exceeded the expected level of patients’ service, i.e., 320 patients per year/unit, or 8,000 treatments per year/unit for the most recent 24-month period.**

The Applicant submits this methodology is not applicable to the proposed project.

Using the methodologies described in this Need Criterion, staff finds the Applicant has not demonstrated a need for an additional therapeutic radiation unit in GHSA 6.

Need Criterion 2: Presence of Readily Available Services

The Applicant submits North Meridian Cancer Center has access to diagnostic X-Ray, CT scan, and ultrasound services within fifteen (15) minutes normal driving time of the proposed facility.

Need Criterion 3: Staffing Requirements

- a. The Applicant submits the services will have, at a minimum, the following full-time dedicated staff:
 - i. One board-certified radiation oncologist-in-chief. The Applicant states R. Scott Anderson, M.D. will serve North Meridian Cancer Center as the radiation oncologist.
 - ii. One dosimetrist. The Applicant states North Meridian Cancer Center will have one (1) or more dosimetrists.
 - iii. One certified radiation therapy technologist certified by the American Registry of Radiation Technologists. The Applicant states Georgerine M. Conner, RRT will serve as the Chief Radiation Therapy Technologist for North Meridian Cancer Center.
 - iv. One registered nurse. The Applicant asserts North Meridian Cancer Center will have one (1) or more registered nurses.
- b. The Applicant submits the service will have at a minimum, access to a radiation physicist certified or eligible for certification by the American Board of Radiology. The Applicant states Paul L. King, M.S., MPH, DADR will serve North Meridian Cancer Center, LLC as the radiation physicist.

Need Criterion 4: Access to Additional Staff

The Applicant affirms North Meridian Cancer Center has access to brachytherapy staff, treatment aides, social workers, dietitians, and physical therapists.

Need Criterion 5: Physician Location

The Applicant states R. Scott Anderson, the Radiologist in Chief, resides within fifteen (15) driving minutes of the Cancer Center.

Need Criterion 6: Access to a Modern Simulator

The Applicant affirms North Meridian Cancer Center has access to a modern simulator capable of precisely producing the geometric relationships of the treatment equipment to a patient. Further, the Applicant states the Accuray HADA Tomo Therapy Linear Accelerator is capable of performing the patient's simulation on site, and Dr. Anderson, the radiation oncologist performing the patient simulator, will also be the same radiation oncologist performing the treatment on the patient.

- a. If the simulator is located at a site other than where the therapeutic radiation equipment is located, protocols will be established which will guarantee that the radiation oncologist who performs the patient's simulation will also be the same radiation oncologist who performs the treatments on the patient.**

The Applicant affirms the simulator and therapeutic radiation equipment will be located at North Meridian Cancer Center.

- b. If the simulator uses fluoroscopy, protocols will be established to ensure that the personnel performing the fluoroscopy have received appropriate training in the required techniques related to simulation procedures.**

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

Need Criterion 7: Access to Computerized Treatment Planning System

The Applicant affirms North Meridian Cancer Center will have a computerized treatment planning system with the capability of simulating multiple external beams, display isodose distributions in more than one plane, and perform dose calculations for brachytherapy implants.

The Applicant assures the proposed computerized treatment plan system has the capacity of CT based planning.

Need Criterion 8: Supervision of Treatment

The Applicant affirms North Meridian Cancer Center will be under the control of R. Scott Anderson, M.D., a board-certified oncologist.

Need Criterion 9: MSDH Division of Radiological Health Approval

The Applicant states the proposed site, plans, and equipment have been submitted to the Mississippi State Department of Health Division of Radiological Health for approval.

Need Criterion 10: Quality Assurance Program

- a. The therapeutic radiation program shall meet, at a minimum, the physical aspects of quality assurance guidelines established by the American College of Radiology (ACR) within twelve (12) months of initiation of the service.**

The Applicant affirms North Meridian Cancer Center will establish a quality assurance program which complies, at a minimum, with the standards established by the American College of Radiology.

- b. The service shall establish a quality assurance program which complies, at a minimum, with the standards established by the American College of Radiology.**

The Applicant affirms North Meridian Cancer Center will establish a quality assurance program which complies with the standards established by the American College of Radiology.

Need Criterion 11: Failure to Comply

The Applicant states North Meridian Cancer Center shall comply with Need Criterion 10(a) and (b) and affirms its understanding that failure to comply may result in the revocation of the CON.

B. General Review (GR) Criteria

Chapter 8 of the *Mississippi Certificate of Need Review Manual, Revised September 1, 2019* addresses general criteria by which all CON applications are reviewed. This application is not in substantial compliance with the general review criteria contained in the Manual.

GR Criterion 1- State Health Plan

The application was reviewed for consistency with the *FY 2022 Mississippi State Health Plan, Second Edition ("MSHP")* in effect at the time of submission. The Applicant asserts the project substantially complies with the four (4) General CON Policies stated in the *MSHP*.

Staff finds that the project is not in substantial compliance with the *FY 2022 MSHP* policies and criteria for the acquisition or otherwise control of therapeutic radiation equipment and the offering of therapeutic radiation services.

GR Criterion 2 – Long Range Plan

The Applicant submits the long-range plan for North Meridian Cancer Center is to provide high quality care for cancer patients in the most cost-effective manner. The

Applicant states use of the Accuray HADA Tomo Therapy unit provides the capability to upgrade equipment quickly and cost-effectively at the appropriate time.

GR Criterion 3 – Availability of Alternatives

- a. **Advantages and Disadvantages:** The Applicant asserts there is only one other option for services in GHSA 6, the present provider of radiation services.
- b. **New Construction Projects:** The Applicant states this criterion is not applicable.
- c. **Beneficial Effects to the Health Care System:** The Applicant submits an additional provider of therapeutic radiation services will meet the needs of underserved populations, which benefits the entire patient population.
- d. **Effective and Less Costly Alternatives:**
 - i. **Unnecessary Duplication of Services:** The Applicant states meeting the needs of the underserved and the need shown in the *MSHP* is evidence the proposed project is not an unnecessary duplication of services.
 - ii. **Efficient Solution:** The Applicant submits utilization of a Tomo modular unit in a Legacy Coach, which can be placed into service within ninety (90) days following approval of the CON, is a more efficient solution to the identified need. The Applicant further states the acquisition of the Accura Tomo Therapy HADA System is the most efficient solution to meet the identified need.
- e. **Improvements and Innovations:** The Applicant asserts utilization of a Accuray Mobile Tomo Therapy HADA System in a Legacy 50' x 10' Coach System promotes both health care quality assurance and the delivery of healthcare services.
- f. **Relevancy:** The Applicant asserts the proposed project addresses changing trends in both service delivery and community health care needs by providing Meridian and the surrounding area with an additional provider of therapeutic radiation services.

GR Criterion 4 - Economic Viability

- a. **Proposed Charge:** The Applicant states North Meridian Cancer Center's charges will be similar to other centers in the region and based on CMS' reimbursement rates for the region. The Applicant states, because radiation oncology is currently undergoing a bundling of services by CMS, it is hard to predict what reimbursement levels will be in the future; however, the

Applicant states a small free-standing center of the type proposed by the Cancer Center will be exempt from those concerns for approximately five (5) years. The Applicant further states based on historical data, nine (9) patients under treatment per day will meet all expenses and retire all sources of debt.

- b. Projected Levels of Utilization:** The Applicant estimates the Cancer Center will become profitable within six (6) months of commencement of services. The Applicant projects to perform 3,000 procedures the first year, 4,500 the second year, and 6,000 the third year. Therefore, the Applicant's projected levels of utilization appear to be consistent with the utilization levels of the existing provider in GHSA 6.
- c. Financial Feasibility Study:** This criterion is not applicable to this project.
- d. Financial Forecasts:** The Applicant states North Meridian Cancer Center's financial forecasts do not deviate significantly from their proposed three-year historical period financials.
- e. Means of Covering Expenses in Event of Failure to Meet Projections:** The Applicant states North Meridian Cancer Center has obtained a line of credit from BankPlus, which will provide some of the funding needed for the project.
- f. Impact of Proposed Project on Health Care Cost:** The Applicant asserts the project will have no adverse impact on gross revenues per patient day. The Applicant states any impact on gross revenues will be a beneficial impact. Furthermore, the Applicant states the implementation of the project will not result in an increase in charges for any service. The Applicant states any increase will occur as a result of inflation, reimbursement issues, and more sophisticated procedures.

GR Criterion 5 – Need for the Project

- a. Access by Population Served:** The Applicant states there is a need for an additional provider of therapeutic radiation therapy treatment in GHSA 6, considering the population and geographic service area. The Applicant submits Dr. Anderson has never denied a patient access to his services and North Meridian Cancer Center will provide care to underinsured cancer patients.
- b. Relocation of Services:** This criterion is not applicable.
- c. Current and Projected Utilization of Comparable Facilities:** The

Applicant submits studies have shown in general, delays of more than seven (7) weeks result in a clear rate of diminished clinical outcomes in cancer treatment, both due to local recurrence and metastatic spread. The Applicant states often the patient is three (3) to four (4) weeks from the initial biopsy by the time the patient is referred to radiation oncology. The Applicant further states the concern with the current sole provider of services in GHSA 6 is the provider's practices, which substantially slow the initiation of patient treatment including holding both underinsured patients and veterans over insurance issues, deliberately slowing planning times for all providers by limiting throughput in the dosimetry department and delaying physics certification and validation of dose increasing the risk for bad outcomes for patients.

- d. **Probable Effect on Existing Facilities in the Area:** The Applicant asserts Anderson Regional Cancer Center (current provider of radiation therapy services in GHSA 6) currently exceeds the 8,000 annual treatments required in the *MSHP*. The Applicant expects very little to no impact on the utilization of Anderson Regional Cancer Center.

However, affidavits submitted by Robert J. Guasco, LCSW, MHA, Director of the Anderson Regional Cancer Center, and Caleb R. Dulaney, M.D., Medical Director of Anderson Regional Cancer Center, refutes the Applicant's assertion that the current radiation therapy services in GHSA 6 exceeds the 8,000 annual treatments required per unit in the *MSHP*.

Based on information contained in the Department files and affidavits submitted by Anderson Regional Cancer Center, staff finds there is excess need for therapeutic radiation equipment/services in GHSA 6 as defined in the *MSHP*.

- e. **Community Reaction:** The application contains seven (7) letters of support from physicians, health care providers, and community leaders.

In addition, the application received three (3) letters opposing the project from Anderson Regional Cancer Center and other physicians. Two (2) affidavits refuting the projections of the Applicant were also submitted.

GR Criterion 6 - Access to the Facility or Service

- a. **Access to Services.** The Applicant certifies that all residents of the health planning service area, hospital service area, or patient service area, including Medicaid recipients, charity/medically indigent patients, racial and ethnic minorities, women, handicapped persons, and the elderly will have access to the services proposed.

The following table shows the projected percentage of gross patient revenue and actual dollar amount of health care proposed to be provided to medically

indigent patients and/or charity patients.

	Medically* Indigent (%)	Medically Indigent (\$)	Charity Care (%)	Charity Care (\$)
Historical Year 2020	N/A	N/A	N/A	N/A
Historical Year 2021	N/A	N/A	N/A	N/A
Projected Year 1	0.00%	\$0.00	2.00%	\$60,000.00*
Projected Year 2	0.00%	\$0.00	2.00%	\$90,000.00*

*Note: Staff finds the projections for Year 1 and Year 2 do not reflect 2% of gross patient revenue as stated in the Applicant's Projected Income Statement for Year 1 and Year 2.

- b. **Existing Obligations:** The Applicant certifies this criterion is not applicable to this project.
- c. **Unmet Needs of Medicare/Medicaid and Medically Indigent Patients:** The Applicant submits the Cancer Center will treat all radiation therapy patients presenting for cancer care regardless of payor source.
- d. **Access to Proposed Facility:** The Applicant submits all patients in need of radiation therapy will have access to the proposed facility.
- e. **Access Issues**
 - i. **Transportation and Travel:** The Applicant submits the proposed facility is located on Highway 39 in Meridian, which provides patients quick and easy access to the Cancer Center.
 - ii. **Restrictive Admissions Policy:** The Applicant submits North Meridian Cancer Center is an outpatient service which does not admit patients.
 - iii. **Access to Care by Medically Indigent Patients:** The Applicant certifies all patients, including medically indigent patients, presenting to North Meridian Cancer Center will have access to care.
 - iv. **Operational Hours of Service:** The Applicant certifies the Cancer Center's regular hours of operation are eight (8) hours per day, five (5) days per week.

GR Criterion 7 - Information Requirement

The Applicant affirms North Meridian Cancer Center will record and maintain, at a minimum, the required information regarding charity care, care to the medically indigent, and Medicaid populations and make it available to the Department within fifteen (15) business days of request.

GR Criterion 8 - Relationship to Existing Health Care System

- a. Comparable Services:** The Applicant states North Meridian Cancer Center will offer services comparable to the existing provider with more modern equipment. The Applicant asserts the Clinac 23EX, placed in service in April 2004 at Anderson's Cancer Center, was removed from service in January 2016 and totally pad locked three years ago. The Applicant further states the Clinac IX was placed in service in April 2008 and is currently being used as a "backup" unit although fully functional.

Anderson Regional Cancer Center submitted affidavits from the Director of the Cancer Center and the Cancer Center's Medical Director certifying the Clinac IX has never been used as a backup unit. Anderson Regional Cancer Center further affirmed there are two (2) radiation therapy units currently in use at their Center with the third unit expected to be replaced and put back into service shortly.

b. Effect on Existing Health Services

- i. Complement Existing Services:** The Applicant states the proposed project will provide patients with treatment choice.
- ii. Provide Alternative or Unique Service:** The Applicant states North Meridian Cancer Center proposes a unique alternative service (electronic brachytherapy) to cancer patients of East Central Mississippi. The Applicant states Dr. Anderson worked with Accuray to develop planning algorithms allowing SBRT delivery similar to Cyberknife using Tomotherapy. The Applicant states North Meridian Cancer Center plans to offer these therapies.
- iii. Provide a service for a specified target population:** The Applicant states services will be provided to "elderly and debilitated" cancer patients.
- iv. Provide services for which there is an unmet need:** The Applicant asserts no other provider in the state provides electronic brachytherapy.
- c. Adverse Impact:** The Applicant asserts, if the proposed project is not

implemented, patients who receive a cancer diagnosis will have an “extraordinary” wait time for their treatment.

- d. **Transfer/Referral/Affiliation Agreements:** The Applicant submits North Meridian Cancer Center has transfer/referral/affiliation agreements with Ochsner-Rush Hospital.

GR Criterion 9 - Availability of Resources

- a. **New Personnel.** The Applicant asserts North Meridian Cancer Center has all the required personnel to staff the proposed project.
- b. **Contractual Services.** The Applicant submitted a service agreement with Accuray for the project.
- c. **Existing Facilities or Services.** The Applicant notes the proposed project is the establishment of a new facility.
- d. **Alternative Uses of Resources.** The Applicant states the acquisition of the Accura Tomo Therapy HADA System is the most efficient solution to meet the identified need.

GR Criterion 10 – Relationship to Ancillary or Support Services

- a. **Support and Ancillary Services.** The Applicant states all necessary support and ancillary services will be in place at North Meridian Cancer Center.
- b. **Changes in Costs or Charges.** The Applicant asserts there will be no change in proposed charges as a result of the implementation of this project. The Applicant states any increases in future charges for existing services will occur as a result of inflation and reimbursement issues and the provision of more sophisticated procedures.
- c. **Accommodation of Changes in Cost or Charges.** The Applicant asserts North Meridian Cancer Center anticipates increased patient revenue.

GR Criterion 11 – Health Professional Training Programs

The Applicant states North Meridian Cancer Center will consider each request made by any health professional training program that is in its service area. The Cancer Center will review each request based on the merits of the training and the participants and will take appropriate action.

GR Criterion 12 – Access by Health Professional Schools

As stated above, North Meridian Cancer Center states it will consider each request made by any health professional training program that is in its service area. The Cancer Center will review each request based on the merits of the training and the participants and will take appropriate action.

GR Criterion 13 – Access by Individuals Outside Service Area

The Applicant states North Meridian Cancer Center proposes to provide services to individuals in West Alabama, including the counties of Choctaw, Washington, Sumter, Pickens, and Lamar, which are not in GHSA 6. The Applicant states Alabama providers offering therapeutic radiation services are located in Tuscaloosa (95 miles away) and Birmingham (146 miles away), which are several hours away. The Applicant believes that because of the time and distance to the Alabama facilities, patients from Pickens, Sumter, Choctaw, and Washington counties which are proximal to the Cancer Center would seek therapeutic radiation treatment in Meridian.

GR Criterion 14 - Construction Projects

The Applicant submits the project does not include construction.

GR Criterion 15 – Competing Applications

There are no competing applications filed with the Mississippi State Department of Health for radiation therapy services.

GR Criterion 16 - Quality of Care

- a. Past Quality of Care.** The Applicant asserts the physicians associated with North Meridian Cancer Center have a history of providing high quality medical care to residents of the service area and will have in place a quality improvement program to ensure the delivery of high-quality care to its patients in the most efficient manner with the resources available.
- b. Improvement of Quality of Care.** The Applicant asserts the addition of another provider will improve the target population's access and will improve quality of care.
- c. Accreditations and/or Certifications.** The Applicant submits North Meridian Cancer Center will apply for Medicare and Medicaid Certification and the American Society of Radiation Oncology – Astro Accreditation when it becomes operational.

IV. FINANCIAL FEASIBILITY

A. Capital Expenditure Summary

Cost Item	Projected Cost	Percentage of Cost (%)
Construction – New	\$ 0.00	0.00%
Construction (Renovation)	0.00	0.00%
Capital Improvement	0.00	0.00%
Fixed Equipment	1,120,000.00	61.02%
Non-fixed Equipment	66,350.00	3.61%
Land Cost	0.00	0.00%
Site Preparation	29,730.00	1.62%
Fees (Architectural)	93,330.00	5.09%
Capitalized Interest	0.00	0.00%
Contingency Reserve	117,000.00	6.37%
Other (Rigging/MS Power)	274,000.00	14.93%
Other Project Development Costs	135,000.00	7.36%
Total Capital Expenditure	\$ 1,835,410.00	100.00%

B. Method of Financing

The Applicant proposes to finance \$1,500,000 of the project with a loan at a rate of four percent (4%) interest for a term of sixty (60) years. In addition, the Applicant proposes equity contributions of \$335,410.00. The application includes a letter from BankPlus regarding financing for the project.

Additionally, the Applicant proposes to lease the land for an annual cost of \$9,000.00 at a rate of three percent (3%) interest for a period of five (5) years.

C. Effect on Operating Cost

The three-year projected operating statement for North Meridian Cancer Center is presented at Attachment 1.

D. Cost to Medicaid/Medicare

North Meridian Cancer Center projects gross patient revenue cost (project only) to third party payors as follows:

Payor Mix	Utilization Percentage (%)	First Year Revenue (\$)
Medicare	40.21%	\$ 1,500,000.00
Medicaid	12.06%	450,000.00
Commercial	40.21%	1,500,000.00
Self Pay	5.36%	200,000.00
Charity Care	2.15%	80,000.00
Other	0.00%	0.00
Total	*99.99%	\$ 3,730,000.00

Note: Staff's calculation of utilization % differs from the Applicant's.

V. RECOMMENDATIONS OF OTHER AFFECTED AGENCIES

The Division of Medicaid was provided a copy of this application for review and comment. As of July 25, 2022, no comments have been received from the Division of Medicaid.

VI. CONCLUSION AND RECOMMENDATION

This project is not in substantial compliance with the criteria and standards for the acquisition or otherwise control of therapeutic radiation equipment and the offering of therapeutic radiation services as contained in the *FY 2022 Mississippi State Health Plan, Second Edition*; the *Mississippi Certificate of Need Review Manual, September 1, 2019, Revision*; and the duly adopted rules, procedures, and plans of the Mississippi State Department of Health.

The Applicant fails to sufficiently prove a need for an additional therapeutic radiation unit in GHSA 6. The Applicant's application fails to meet the Equipment to Population Ratio requirement as described in Chapter 5, Section 509.01, Policy Statement 2, the Limitation of New Services requirement as described in Section 509.01, Policy Statement 3, and Need Criterion 1 as described in Section 509.02 of the *MSHP*.

Because the Applicant based its need projection on the premise that only one (1) radiation therapy unit currently exists in GHSA 6, the Applicant failed to justify a need for an additional unit in that service area. The Division of Health Planning and Resource Development received sworn affidavits and verified that the existing provider in GHSA 6 has three (3) approved radiation therapy units, two (2) of which were in operation in FY 2019, FY 2020, and FY 2021. As described in Section III.A. (Need Criterion 1) of this Staff Analysis, the Applicant does not meet the therapeutic radiation equipment/service need methodology for this project.

Therefore, the Division of Health Planning and Resource Development recommends disapproval of the application submitted by North Meridian Cancer Center for the Acquisition of Therapeutic Radiation Equipment and the Offering of Therapeutic Radiation Services.

Attachment 1

North Meridian Cancer Center Acquisition of Linear Accelerator and the Provision of Therapeutic Radiation Services Three-Year Operating Statement (Project Only)			
	Year 1	Year 2	Year 3
Revenue			
Patient Revenue:			
Inpatient	\$ 0.00	\$ 0.00	\$ 0.00
Outpatient	3,730,000.00	5,595,000.00	7,460,000.00
Gross Patient Revenue	3,730,000.00	5,595,000.00	7,460,000.00
Charity Care	60,000.00	90,000.00	120,000.00
Deductions from Rev.	2,170,000.00	\$ 3,255,000.00	\$ 4,340,000.00
Net Patient Revenue	\$ 1,500,000.00	\$ 2,250,000.00	\$ 3,000,000.00
Other Operating Revenue	0.00	0.00	0.00
Total Operating Revenue	\$ 1,500,000.00	\$ 2,250,000.00	\$ 3,000,000.00
Expenses			
Operating Expenses:			
Salaries	\$ 555,000.00	\$ 779,500.00	\$ 1,110,000.00
Benefits	0.00	0.00	0.00
Supplies	12,000.00	18,000.00	24,000.00
Service	275,000.00	275,000.00	275,000.00
Lease	9,000.00	9,000.00	9,000.00
Depreciation	249,428.00	391,292.00	243,289.00
Interest	59,405.00	49,663.00	39,499.00
Other	90,000.00	135,000.00	180,000.00
Total Expenses	\$ 1,249,833.00	\$ 1,657,455.00	\$ 1,880,788.00
Net Income (Loss)	\$ 250,167	\$ 592,545.00	\$ 1,119,212.00
Assumptions			
Inpatient days			
Outpatient days	300	300	300
Procedures	3,000	4,500	6,000
Charge/inpatient day	\$ NA	\$ NA	\$ NA
Charge per outpatient	\$ 12,433.00	\$ 18,650.00	\$ 24,867.00
Charge per procedure	\$ 1,243.00	\$ 1,243.00	\$ 1,243.00
Cost per inpatient day	\$ NA	\$ NA	\$ NA
Cost per outpatient day	\$ 4,166.00	\$ 5,525.00	\$ 6,269.00
Cost per procedure	\$ 417.00	\$ 368.00	\$ 313.00