

**Division of Health Planning and
Resource Development
February 2006**

**CON Review: HG-MME-0605-017
Forrest General Hospital-Hattiesburg
Acquisition of a Radiosurgery System
Capital Expenditure: \$5,300,000
Location: Hattiesburg, Forest County, Mississippi**

Staff Analysis

I. PROJECT SUMMARY

A. Application Information

Forrest General Hospital (FGH or Forrest General) currently operates 512 beds. The license category of these beds is listed below.

Forrest General Hospital Licensure Category and Number of Beds	
License Category	Bed Capacity
General Medical Surgery	404
Adult Psychiatric*	40
Adult Chemical Dependency*	32
Adolescent Psychiatric	16
Rehabilitation	<u>20</u>
Total Licensed Bed Capacity	512

*Pine Grove Recovery Center (separately licensed division of Forrest General Hospital)

Forrest General Hospital is a county owned, not-for-profit, tax exempt institution governed by a board of trustees appointed by the Forrest County Board of Supervisors.

The occupancy rates, average length of stay (ALOS), and the Medicaid utilization rates for the three most recent fiscal years are as follows (medical/surgical beds only).

Forrest General Hospital Utilization Data			
Fiscal Year	Occupancy Rate (%)	ALOS (Days)	Medicaid Utilization Rate
2002	64.70	4.72	23.6
2003	61.24	4.59	16.4
2004	61.99	4.61	16.3

Source: The Division of Health Facility Licensure and Certification, MDH

B. Project Description

Forrest General Hospital seeks Certificate of Need authority to construct a third vault and to purchase Accuray Cyberknife Stereotactic Radiosurgery (SRS) equipment for the therapeutic radiation department. Currently, Forrest General Cancer Center uses two Varian Linear Accelerators to deliver therapeutic radiation to patients diagnosed with cancer. The delivery of radiation is determined by a comprehensive treatment plan based on diagnostic exams, such as CT and MRI. The information from the diagnostic exams is used by the dosimetrist, physicist, and radiation oncologist to determine the amount and location of radiation to be delivered in multiple fractionated doses. Common treatment plans require the patient to have daily treatments over a few to several weeks. The use of intensive modulated radiation therapy (IMRT) and multi-leaf collimation (MLC) has increased the amount of radiation delivered to the tumor while sparing the surrounding healthy tissue, according to the applicant.

Forrest General Hospital will continue to use the two existing linear accelerators to provide IMRT and MLC treatment options. The proposed SRS unit will provide the latest technology or radiation therapy and SRS. Construction of a third vault will be required to house the new SRS unit, according to the applicant.

The proposed purchase of SRS equipment is requested to improve patient outcomes and to provide an option for treatment that is not offered in General Hospital Service Area 6 (GHSA 6). The term “radiosurgery” comes from the results of a tumor being treated by stereotactic radiosurgery. The effect is so dramatic that the tumor appears to have been surgically removed. Radiosurgery uses computer-guided linear accelerator beams to deliver a single dose of radiation to a specific area of the brain or body. With linear accelerator beams, the physicians are able to treat patients with brain disorders and brain and body tumors. At times, the disorders or tumors may be too difficult or dangerous to treat with traditional surgery. Stereotactic radiosurgery is commonly used to treat benign conditions to the brain, such as arteriovenous malformation (AVM), a tangle of blood vessels in the brain, or to treat multiple small, well-defined, malignant tumors, according to the applicant.

The benefits of SRS over the linear accelerator include the ability to:

- Treat larger or more numerous lesions;
- Target the entire lesion while avoiding nearby healthy tissue and critical structures, such as the brain stem, nerves, and eyes;
- Provide radiation doses precisely to the borders of irregularly shaped tumors; and
- Perform procedures on an outpatient basis with minimal recovery time.

In addition to the benefits of brain disorders and tumors of the brain, SRS is used to treat tumors in other parts of the body. Typical tumors of the body are:

- Primary lung
- Lung metastases
- Prostate
- Pancreas
- Liver
- Liver metastases
- Kidney
- Spinal Cord

The proposed project will require the recruitment of 13 additional physicians at a first-year additional personnel cost of \$262,223.

II. TYPE OF REVIEW REQUIRED

The Mississippi Department of Health will review Certificate of Need applications for the acquisition or otherwise control of therapeutic radiation equipment and/or the offering of therapeutic radiation services under the applicable statutory requirements of Sections 41-7-173, 41-7-191 (1)(f), and 41-7-193, Mississippi Code of 1972, as amended. The MDH 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 of the Mississippi Department of Health; and the specific criteria and standards listed below. The acquisition or otherwise control of therapeutic radiation equipment is reviewable if the equipment cost exceeds \$1,500,000.

In accordance with Section 41-7-197 (2) of the Mississippi Code of 1972 Annotated, as amended, any person may request a public hearing on this project within 20 days of publication of the staff analysis. The opportunity to request a hearing expires on March 7, 2006.

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

A. State Health Plan (SHP)

The FY 2006 *State Health Plan* contains criteria and standards which an applicant is required to meet before receiving CON authority for the acquisition or otherwise control of therapeutic radiation equipment involving a capital expenditure in excess of \$2,000,000. The applicant is not in substantial compliance with these criteria.

SHP Criterion 1 - Need

- a. Need Methodology: *The State Health Plan* states the need of one therapeutic unit per 148,148 population. The FY 2005 *State Health Plan* indicates a 2010 projected population for GHSA 6 as 319,616. The calculated need for therapeutic radiation units for GHSA 6 is 2.16 ($319,616/148,148 = 2.157$). A total of three therapeutic radiation units presently operate in GHSA 6; (Forrest General Hospital operates two and South Central Mississippi Cancer Center in Laurel operates one), therefore, only three therapeutic radiation therapy units are justified.
- b. Averaged 8,000 Procedures per Therapeutic Radiation Unit: A total of 15,698 therapeutic radiation procedures were conducted on the three machines in GHSA 6, for an average 5,233 procedures per unit. ($15,698/3 = 5,233$) --short of the average of 8,000 procedures per year as required in the FY 2005 *State Health Plan*.

- c. Applicant Must Exceed 320 Patients per Year/Unit or 8,000 Treatments per Year/Unit: Forrest General Hospital operated two therapeutic radiation units during the last two years. During this time these units together produced 12,190 treatments in 2003 and 12,420 in 2004. The average number of treatments per unit for 2003 and 2004 were 6,095 and 6,210, respectively.
- d. Located Outside a Forty-Mile Radius from an Existing Therapeutic Radiation Provider: The nearest therapeutic radiation provider from Forrest General Hospital is located in Laurel which is approximately 29 miles from Hattiesburg.

SHP Criterion 2 - Back-Up Services

Forrest General Hospital has diagnostic x-ray, CT scan, and ultrasound services within the facility, according to the applicant.

SHP Criterion 3 – Professional Capability

Forrest General Hospital has all professional personnel required to operate therapeutic radiation equipment on staff or under contract, including: board-certified radiation oncologist-in-chief, dosimetrist, radiation therapy technologist certified by the American Registry of Radiation Technologists, and registered nurses.

SHP Criterion 4 – Access to Support Staff

The applicant affirms that the facility will be accessible to brachytherapy staff, treatment aides, social workers, dietitians, and physical therapists.

SHP Criterion 5 – Physician Availability

The applicant affirms that all physicians who are responsible for therapeutic radiation services at Forrest General Hospital, including the radiation oncologist-in-chief, shall reside within 60 minutes of the facility.

SHP Criterion 6 – Access to a Modern Simulator

The applicant affirms that a modern simulator capable of precisely producing the geometric relationships of treatment equipment to a patient and capable of producing high-quality diagnostic radiographs will be available on site. The applicant also stipulates that protocols will be in place to assure that the radiation oncologist who performs the patient's simulation will also be the same radiation oncologist who performs the treatment on the patient and that personnel performing the fluoroscopy have received appropriate training in the required techniques related to simulation procedures.

SHP Criterion 7 – Computerized Treatment Planning System

The applicant affirms that a comprehensive computerized treatment planning system with the capability of simulation of multiple external beams, display isodose distribution in more than one plane, and performing dose calculations for brachytherapy implants is present on site at the hospital.

SHP Criterion 8 – Board Certified Radiation Oncologist Oversight

The applicant affirms that a board certified radiation oncologist is on staff at Forrest General Hospital.

SHP Criterion 9 - Approval by the Division of Radiological Health

The applicant affirms that the Division of Radiological Health will be involved during the planning and implementation of the proposed project and the site, plans, and equipment shall receive approval from that Division before any radiosurgery services are delivered.

SHP Criterion 10 – Quality Assurance Program

The applicant affirms that a quality assurance program for stereotactic radiosurgery will be established and followed and that, at a minimum, it will include the following:

- 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 12 months of initiation of the service, and
- b. The services shall establish a quality assurance program which will meet, at a minimum, the standards established by the ACR.

SHP Criterion 11 – Compliance with GR Criterion 10(a) and (b)

The applicant affirms understanding of and agrees that failure to comply with criterion #10 (a) and (b) may result in revocation of the CON (after due process) and subsequent termination of authority to provide stereotactic radiosurgery services.

B. General Review (GR) Criteria

Chapter 8 of the *Mississippi Certificate of Need Review Manual*, May 13, 2000, (as amended) addresses general criteria by which all CON applications are reviewed. The applicable criteria are as follows:

GR Criterion 1 – State Health Plan

The *Mississippi State Health Plan* contains two sets of standards and criteria for the acquisition and implementation of therapeutic radiation equipment and services. These include 1) the GammaKnife® and 2) other than GammaKnife®. The FY 2005 State Health Plan provides no equipment specific criteria and standards for the Accuray Cyberknife Stereotactic Radiosurgery® equipment. The definition of stereotactic radiosurgery as contained in the *FY 2005 State Health Plan* means a non-invasive therapeutic procedure in which narrow beams of radiant energy are directed at the treatment target in the head so as to produce tissue destruction, using computerized tomography (CT), radiography, magnetic resonance imaging (MRI) and angiography for localization. The Accuray Cyberknife Stereotactic Radiosurgery® equipment, although designed to deliver therapeutic radiation therapy throughout the whole body, falls within this definition. Therefore, the

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 Gamma Knife®) are applicable to this request.

Based upon evaluation, the proposed equipment, in accordance with criteria and standards for therapeutic radiation equipment (other than Gamma Knife®), is not justified.

GR Criterion 2 – Long Range Plan

The applicant affirms that this project has been approved by Forrest General Hospital's Board of Trustees and is consistent with the Board's long range plan.

GR Criterion 3 – Availability of Alternatives

According to the applicant, one alternative is to do nothing and continue to treat patients with existing equipment. This idea was considered and found to be unacceptable for the Cancer Center of Excellence. This new equipment will not only provide the most current treatment but will provide out-of-area patients the ability to receive SRS.

GR Criterion 4 -- Economic Viability

According to the applicant, the project has been determined to be financially feasible by the hospital's management staff. The economic viability of the proposed project is demonstrated in the financial analysis section and the three-year projected operating statement, herein.

- a. Proposed Charges: According to the applicant, Forrest General Hospital's charges for similar services are comparable to those charges established by other facilities within the state.
- b. Level of Utilization: According to the applicant, projected levels of SRS utilization are equal to those experienced by other large tertiary providers who are not a "regional hub." The excellent utilization levels are expected to continue due to growth of the aging population and increased market share through managed care contracts.
- c. Financial Feasibility Study: The application contains a financial feasibility study, conducted by the Chief Financial Officer, which demonstrated that the hospital could meet operating expenses and other requirements of the project for the first three years after implementation and that the project will be funded by operating funds of Forrest General Hospital.

GR Criteria 5 – Need for the Project: (a) Population to be Served, b) Projected Utilization, and (c) Effect on Similar Facilities

According to the applicant, Forrest General Hospital will continue treating patients without regard to any unique situation, such as age, race, national origin, or ability to pay.

The disease incidence model provided by the applicant includes the typical functional disorders such as: epilepsy, Parkinson's disease, intractable pain, and trigeminal neuralgia. The anticipated utilization, determined by the disease incidence model, is as follows:

Procedures	Number	Procedures	Number
Meningioma	31	Acoustic Neuroma	2
Intracranial Metastases	77	Head/neck Malignant tumor	21
Primary AVM, Spinal Cord, Bone, etc.	1	Intracranial (Primary and Met.) New Cases	131

The applicant does not expect any adverse impact to any hospital as a result of this proposal.

The application contains letters of support and committal. No letters of opposition were received.

GR Criteria 6 – Access to the Facility or Service

The applicant affirms that Forrest General Hospital maintains no institutional barriers to medically underserved populations receiving medical care or other clinical services. The percentage of underserved populations receiving care at Forrest General Hospital reasonably reflects their percentage in the service area population.

GR Criteria 7 – Information Requirement

The applicant states that it will record and maintain the requested information stated in the above criterion and make it available to the Mississippi Department of Health within 15 working days of request.

GR Criteria 8 – Relationship to Existing Health Care System

No stereotactic radiosurgery capability presently exists within GHSA 6. Therefore, Forrest General Hospital would serve as a referral base for patients needing SRS services, according to the applicant.

GR Criteria 9 – Availability of Resources

According to the applicant, Forrest General Hospital currently maintains a full compliment of professional and support staff for the provision of radiation therapy services. The application contains documentation demonstrating that Forrest General Hospital possesses the health management and financial resources necessary to carry forward with this project.

GR Criteria 10 – Relationship to Ancillary or Support Services

According to the applicant, this project does not involve the offering of new health care; therefore, it will not affect existing ancillary or support services.

GR Criteria 11 – Effect on Health Professional Training Programs

Forrest General Hospital provides reasonable access to health professional training programs in the area, according to the applicant.

GR Criteria 14 – Construction Projects

The application contains cost estimates and schematic drawings of the radiosurgery vault. The vault is to be constructed next to the existing two vaults located in the Radiation Therapy Department of the cancer center. According to the applicant, this is the only feasible location for the third vault.

Using the Department’s formula for calculating the cost per square foot of hospital construction, the 2,900 square feet of vault construction will cost \$1,575,000 or \$543.10 per square foot.

GR Criteria 16 – Quality of Care

Applicant is accredited by the Joint Commission on Accreditation of Healthcare Organizations and provides quality care to all of its patients.

IV. FINANCIAL FEASIBILITY

A. Capital Expenditure Summary

The total estimated capital expenditure of \$5,300,000 is allocated as follows:

			Percent
a.	Construction Cost -- New	\$ 1,150,000	21.70
b.	Construction Cost -- Renovation	0	0
c.	Capital Improvements	25,000	0.47
d.	Total Fixed Equipment Cost	0	0
e.	Total Non-Fixed Equipment Cost	3,700,000	69.81
f.	Land Cost	0	0
g.	Site Preparation Cost	242,500	4.58
h.	Fees (Architectural, Consultant, etc.)	125,000	2.36
i.	Contingency Reserve	57,500	1.08
j.	Capitalized Interest	0	0
k.	Other Cost	0	0
l.	Total Proposed Capital Expenditure	<u>\$5,300,000</u>	<u>100.00</u>

The major expenditures are dedicated to the construction of an additional radiosurgery vault containing 2,900 square feet and the purchase and installation of Accuray Cyberknife Stereotactic Radiosurgery equipment.

B. Method of Financing

The project will be financed through Forrest General Hospital’s accumulated cash reserve.

C. Effects on Operating Cost

The application projects the following expense and revenue results from operation for the first three years following completion of the project:

Forrest General Hospital Cyberknife Feasibility Analysis			
Revenue	<u>Year 1</u>	<u>Year 2</u>	<u>Year 3</u>
Gross Charges	\$ 4,856,170	\$ 5,597,570	\$ 6,450,180
Revenue Deductions:	-3,253,780	-3,750,540	-4,321,815
Net Patient Revenue	\$ 1,602,390	\$ 1,847,030	\$ 2,128,365
Operating Expenses			
Maintenance/Equipment	\$ 0	\$ 425,000	\$ 425,000
Treatment Supplies	18,989	21,888	25,222
Salaries	206,000	216,300	227,115
Fringe Benefits	41,200	43,260	45,423
Indirect Administration	50,000	52,500	55,125
Marketing	75,000	45,000	30,000
Insurance	50,000	52,500	55,125
Utilities	25,000	26,250	27,563
Maintenance/Building	5,000	5,250	5,513
Depreciation	812,051	812,051	812,051
Total Operating Expense	\$ 1,283,240	\$ 1,699,999	\$ 1,708,137
Operating Margin	\$ 319,150	\$ 147,031	\$ 420,228
Margin Percent	6.6	2.6	6.5
Statistics			
Outpatient Admissions	131	151	174
Charges Per Patient	\$ 37,070	\$ 37,070	\$ 37,070
Cost Per Patient	\$ 9,796	\$ 11,258	\$ 9,817

D. Cost to Medicaid

Forrest General Hospital Cyberknife Radiosurgery First Year Payor Allocation			
Payor	Utilization Rate	Patients	First Year Cost
Medicaid	15.50	20	\$ 752,706
Medicare	45.00	59	\$ 2,185,276
Other	<u>39.50</u>	<u>52</u>	<u>\$ 1,918,188</u>
Totals	<u>100.00</u>	<u>131</u>	<u>\$ 4,856,170</u>

V. RECOMMENDATION OF OTHER AFFECTED AGENCIES

The Division of Medicaid takes no position on this application.

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 as contained in the FY 2005 Mississippi State Health Plan; Chapter 8 of the *Mississippi Certificate of Need Review Manual*, Revised 2000; and all adopted rules, procedures, and plans of the Mississippi Department of Health. Particularly, the applicant was unable to demonstrate a need for additional therapeutic radiation therapy capacity in General Hospital Service Area 6 as required by the *State Health Plan*, based on the need for therapeutic radiation equipment (other than GammaKnife®).

The Division of Health Planning and Resource Development recommends disapproval of this application submitted on behalf of Forrest General Hospital for the acquisition of Accuray Cyberknife Radiosurgery equipment and the construction of a radiosurgery vault to house the equipment.