

**MISSISSIPPI STATE DEPARTMENT OF HEALTH  
DIVISION OF HEALTH PLANNING AND  
RESOURCE DEVELOPMENT  
MARCH 2009**

**CON REVIEW FSF-NIS-1208-046  
MISSISSIPPI STATE UNIVERSITY AND PREMIER RADIOLOGY, P. A.  
DBA THE CANCER CENTER  
ACQUISITION OF THERAPEUTIC RADIATION EQUIPMENT AND  
OFFERING OF THERAPEUTIC RADIATION SERVICES  
CAPITAL EXPENDITURE: \$481,560  
LOCATION: STARKVILLE, OKITIBBEHA COUNTY, MISSISSIPPI**

**STAFF ANALYSIS**

**I. PROJECT SUMMARY**

**A. Applicant Information**

Mississippi State University (MSU) is a public institution and a component unit of the Mississippi Institutions of Higher Learning (IHL). The IHL, which governs Mississippi State University, consists of 13 members. MSU has seven officers and directors.

The Institute of Neuro-Cognitive Science and Technology (INST) is an affiliate organization of Mississippi State University that conducts neuro-cognitive research using MRI and MRI studies, and will be conducting research in radiation therapy and radiation therapy protocols.

Premier Radiology, P.A. (Premier) is a professional corporation consisting of seven officers and directors. Premier Radiology was founded in 1938, and the entity was originally incorporated in 1971. Premier states that it provides diagnostic, interventional, and therapeutic professional medical radiology services to hospital, clinic, outpatient facilities, and cancer treatment centers throughout North Mississippi. Premier Radiology includes eighteen (18) diagnostic radiologists and two (2) radiation oncologists who share research interests with the Institute for Neuro-Cognitive Science and Technology.

The Imaging Centers for Excellence, LLC (ICE) is an affiliate organization of Premier Radiology, P.A. that operates imaging equipment in Starkville, Mississippi including the MRI unit used for clinical and INST applications.

**B. Project Description**

MSU and Premier Radiology request certificate of need (CON) authority for the acquisition of therapeutic radiation equipment and offering of therapeutic radiation services. The applicants state that the proposed therapeutic radiation equipment and offering of therapeutic radiation services will be located at The Cancer Center, 500 Mallory Lane, Starkville, Mississippi. MSU's Institute for Neurocognitive Science and Technology and Premier propose to participate in a joint venture to conduct scientific research and provide biological imaging as authorized by House Bill 1345, 2004 Legislative Session. INST conducts multidisciplinary research, teaching, and service in the areas of cognitive neuroscience, computational biological imaging, and biomedical engineering. Premier's

biological imaging, and biomedical engineering. Premier's Imaging Center for Excellence, which actually houses the MRI, and The Cancer Center, a portion of which will house the proposed LINAC will be connected as part of the INST. The applicant states that participation by Premier Radiology, whose physicians have expertise in diagnostic radiology, add to MSU's research capabilities; make available biological imaging for diagnostic and therapeutic use to area physicians and their patients; and have a positive economic impact in the Starkville community. The applicants propose to acquire/lease a Clinac iX with OBI, PV, 120MLC, Eclipse, ARIA, Rapid ARC et al linear accelerator system, manufactured by Varian Medical Systems, Marietta, Georgia.

According to the applicants, the proposed LINAC is one of the most widely used accelerators in the world and enables nearly every area of the body to be treated. The proposed equipment will also include Varian's on-board imager. MSU and Premier assert that the proposed LINAC project will provide critical services to the community and the state of Mississippi by making available radiation therapy technology to area physicians and their patients. Pursuant to House Bill 1345 passed by the Mississippi Legislature in 2004, the LINAC will be utilized for research two-thirds (2/3) of the time it is in operation and will be available to the medical professionals for clinical use one-third (1/3) of the time it is in operation.

MSU and Premier Radiology project that the project will require 2.5 additional FTE personnel at an estimated cost of \$159,246 the first year.

The application contains a letter from the Division of Health Facilities Licensure and Certification approving the site for MRI services. The applicants assert that the LINAC and The Cancer Center are located at the same site as the MRI services. The applicants expect to obligate the capital expenditure within 30 days after approval and anticipate that it will be complete within one year of CON approval.

## **II. TYPE OF REVIEW REQUIRED**

Projects which propose the provision of radiation therapy services are reviewed in accordance with Section 41-7-191, subparagraphs (1) (d)(vi), and (f) Mississippi Code 1972 Annotated, as amended, and duly adopted rules, procedures, plans, criteria, and standards of the Mississippi State Department of Health.

In addition, this project is reviewed under Section 41-7-191(16) Mississippi Code 1972 Annotated, as amended. Specifically, 41-7-191(16):

The Mississippi State Department of Health shall issue any certificates of need necessary for Mississippi State University and a public or private health care provider to jointly acquire and operate a linear accelerator and a magnetic resonance imaging unit. Those certificates of need shall cover all capital expenditures related to the project between Mississippi State University and the health care provider, including, but not limited to, the acquisition of the linear accelerator, the magnetic resonance imaging unit and other radiological modalities; the offering of linear accelerator and magnetic resonance imaging services; and the cost of the construction of facilities in which to locate these services. The linear accelerator and the magnetic resonance imaging unit shall be (a) located in the

magnetic resonance imaging unit shall be (a) located in the City of Starkville, Oktibbeha County, Mississippi; (b) operated jointly by Mississippi State University and the public or private health care provider selected by the Mississippi State University through a request for proposals (RFP) process in which Mississippi State University selects, and the Board of Trustees of State Institutions of Higher Learning approves, the health care provider that makes the best overall proposal; (c) available to Mississippi State University for research purposes two-thirds (2/3) of the time that the linear accelerator and magnetic resonance imaging unit are operational; and (d) available to the public or private health care provider selected by Mississippi State University and approved by the Board of Trustees of State Institutions of Higher Learning one-third (1/3) of the time for clinical, diagnostic and treatment purposes. For purposes of this subsection, the provisions of Section 41-7-193(1) requiring substantial compliance with the projection of need as reported in the current *State Health Plan* are waived.

Pursuant to ruling of the Mississippi Supreme Court in Oktibbeha County Hospital vs. Mississippi State Department of Health and Premier Radiology, P.A., 956 So. 2d 2007 (Miss. 2007), in 41-7-191(16) the Mississippi Legislature effectively waived all CON requirements including any affected party to request a hearing during the course of review.

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

#### Conformance with House Bill 1345, 2004

- a. **Affirm to be located in the city of Starkville:** The applicants state that the proposed therapeutic radiation equipment and offering of therapeutic radiation services will be located at The Cancer Center, 500 Mallory Lane, Starkville, Oktibbeha County, Mississippi.
- b. **Request for Proposals (RFP) process:** According to the applicants, Premier was the sole responder to a Request for Proposals (RFP) issued by MSU in May 2004, pursuant to House Bill 1345, seeking collaboration with MSU by a radiological health care provider. A technical review committee including area physicians reviewed Premier's proposal and recommended that MSU move forward with agreement with Premier on the basis of the private investment proposed, MSU's access to equipment to be provided by Premier, the design of the facility to be constructed, and other benefits to be provided to MSU, such as technical support, clinical support, opportunities for research collaboration, the level of continuing support for facility, and equipment maintenance.

The application contains two separate Resolutions of the Board of Directors and Officers of Premier Radiology, P.A. and Board of Trustees of State Institutions of Higher Learning for the proposed project.

- c. **Available to Mississippi State University two-thirds (2/3) of the time:** Pursuant to House Bill 1345, 2004, the applicants state that the LINAC will be utilized for research two-thirds (2/3) of the time it is in operation.

- d. **One-third (1/3) of the time:** Pursuant to House Bill 1345, 2004, the applicants state that the LINAC will be available to the medical professionals for clinical use one-third (1/3) of the time it is in operation.

**A. State Health Plan (SHP)**

The *FY 2009 State Health Plan* contains policy statements, criteria, and standards which an applicant is required to meet before receiving CON authority for the acquisition or otherwise control of therapeutic radiation equipment and/or the offering of therapeutic radiation services.

**Acquisition or Otherwise Control of Therapeutic Radiation Equipment**

**SHP Criterion 1 - Need**

As previously stated, House Bill 1345, 2004 Mississippi Legislature, stipulates that the Department shall issue a CON to MSU and a public or private health care provider to jointly acquire and operate a linear accelerator unit and waives the need as stated in the *State Health Plan*.

The applicants propose to purchase a Clinac iX with OBI, PV, 120MLC, Eclipse, ARIA, Rapid Arc et al. MSU and Premier Radiology project that the center will perform 3,234 procedures the first year, 3,892 the second and 4,680 in the third year.

**SHP Criterion 2 – Access to Diagnostic Services**

According to the applicants, diagnostic X-ray, CT scan, and ultra sound services are available on-site.

**SHP Criterion 3 – Staffing of Services**

The applicants assert that it will have the required staff available for this criterion.

**SHP Criterion 4 – Access to Brachytherapy Staff, Treatment Aides, Social Workers, Dietitians, and Physical Therapies**

The applicants affirm that access will be available as needed to brachytherapy staff, treatment aides, social workers, dietitians, and physical therapists.

**SHP Criterion 5 – Medical Staff's Residence Within 60 Minutes of the Facility**

According to MSU and Premier Radiology, all physicians who are responsible for therapeutic radiation service at the facility, including the radiation oncologist-in-chief, will reside within 60 minutes normal driving time of the facility.

#### **SHP Criterion 6a and b – Access to a Capable Simulator**

The applicants affirm that the facility will have access to a modern simulator capable of precisely producing the geometric relationships of the treatment equipment to a patient and which produces high quality diagnostic radiographs.

MSU and Premier Radiology propose that the simulator will be located onsite; however, if it is at a different site, 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 of the patient.

The applicants affirm that, if the linear accelerator (LINAC) 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.

#### **SHP Criterion 7 – Access to a Computerized Treatment Planning System**

The applicants affirm that all treatments will be under the control of a board certified or board eligible radiation oncologist. The application contains the curriculum vitae of Elbert Alan Duncan of Tupelo, Mississippi, for the proposed project.

#### **SHP Criterion 8 – Staffing of a Board Certified/Board Eligible Radiation Oncologist**

The applicants affirm that all treatments will be under the control of a board certified or board eligible radiation oncologist. As stated above, the application contains the curriculum vitae on Elbert Alan Duncan of Tupelo, Mississippi, for the proposed project.

#### **SHP Criterion 9 – Site, Plan and Equipment Approval by the Division of Radiological Health**

According to the Mississippi State Department of Health's Division of Radiological Health, the X-Ray branch staff has reviewed the shielding design for the propose linear accelerator at Premier Radiology Cancer Center at Starkville. The plans appear to meet the requirements of the Regulations for the Control of Radiation in Mississippi and NCRP Report 51.

#### **SHP Criterion 10 – Quality Assurance Programs**

The applicants affirm that the therapeutic radiation program shall meet, at a minimum, the physical aspects of quality assurance guidelines established by the American College of Radiology.

#### **SHP Criterion 11 – Compliance with Criterion 10a and b**

MSU and Premier Radiology affirm their understanding and agreement that failure to comply with criterion 10a and b will result in revocation of the CON.

### **State Health Plan Therapeutic Radiation Equipment/Service Need Methodology**

The applicants acknowledge that the above need methodology, pursuant to House Bill 1345, the therapeutic radiation equipment/service need methodology is waived for the proposed project.

#### **B. General Review (GR) Criteria**

Chapter 8 of the *Mississippi Certificate of Need Review Manual*, 2008 Revision, addresses general criteria by which all CON applications are reviewed. The applicable criteria are as follows:

##### **GR Criterion 2 - Long Range Plan**

House Bill 1345 contemplates MSU and a private healthcare provider, Premier Radiology, LLC, working together to provide research and clinical opportunities for the entire state. According to the applicants, the acquisition and provision of LINAC services is another way in which House Bill 1345, MSU and Premier Radiology plan to accomplish that goal.

##### **GR Criterion 3 - Availability of Alternatives**

MSU and Premier Radiology state that no other alternative approaches were considered as House Bill 1345 clearly mandates that MSU and the healthcare provider jointly acquire and operated a LINAC.

##### **GR Criterion 4 - Economic Viability**

**Proposed charges:** The applicants state that the proposed charge per procedure is \$1,055 for years one, two and three and the cost per procedure is \$265 for year one, \$266 for year two and \$236 for year three for the proposed project.

**Projected levels of utilization:** MSU and Premier Radiology project that the unit will perform 3,136 procedures in year one, 3,892 in year two, and 4,680 in year three. The applicants believe that the projected utilization is reasonably consistent with other LINAC providers within the state, especially given that the LINAC will only be utilized 1/3 of the time it is in operation for clinical purposes.

**Feasibility study:** The proposed project requires no feasibility study because the capital expenditure for the proposed project is \$481,560, which falls below \$2,000,000.

##### **GR Criterion 5 - Need for Service**

a. **The need that the population served or to be served has for the services:** As previously mentioned, House Bill 1345, 2004 Mississippi Legislature, waives the need for the proposed

need for the proposed project. However, the applicants intend to offer LINAC services regardless of patients' ability to pay and state that they will not discriminate against low income persons, racial or ethnic minorities, elderly, women, handicapped persons, or any other underserved groups.

- b. **Relocation:** The project is not for relocation of services. Therefore, this item is not applicable.
- c. **The current and projected utilization of like facilities:** The applicants submit that the project meets the requirements of House Bill 1345 in which the need criterion in the current *State Health Plan* was waived. The unit is proposed to be used solely for clinical purposes by MSU one third (1/3) of the time it is in operation. Therefore, applicants expect that any effect on other providers in Service Area 1 should be minimal.

According to the *FY 2009 Mississippi State Health Plan*, General Hospital Service Area 1, wherein the proposed facility will be located, has a total of five (5) linear accelerator units, and performed a total of 52,099 therapeutic radiation procedures during FY 2007, for an average of 10,419 procedures per unit.

- d. **The probable effect of the proposed facility or service on existing facilities or services providing similar services:** The applicants assert that because of House Bill 1345, this criterion does not apply to the project.
- e. The application contains 20 letters of support and the project has received no letters of opposition.

#### **GR Criterion 6 – Accessibility**

MSU and Premier Radiology assert that they intend to offer LINAC services regardless of patients' ability to pay and will not discriminate against low-income persons, racial or ethnic minorities, women, handicapped persons, other underserved groups or the elderly. The applicants state that since it began offering MRI services, approximately two percent of its patients could be classified as medically underserved. MSU and Premier Radiology project that two percent care will be provided to medically indigent patients and three percent will be provided to charity patients for year one and two for the proposed project.

The applicants propose that the proposed project would be available to all patients regardless of their payor source (Medicaid/Medicare programs) or inability to pay.

#### **GR Criterion 7 - Information Requirement**

The applicants affirm that they will maintain required records regarding charity care, care to the medically indigent, and Medicaid/Medicare populations, and make items available to the Mississippi State Department of Health within 15 days of request for this criterion.

#### **GR Criterion 8 - Relationship to Existing Health Care System**

According to the *FY 2009 Mississippi State Health Plan*, General Hospital Service Area 1, wherein the proposed facility will be located, has a total of five (5) linear accelerator units, and performed a total of 52,099 therapeutic radiation procedures during FY 2007, for an average of 10,419 procedures per unit. The applicants state that House Bill 1345 shows that the general population will only utilize the LINAC services 1/3 of the time the equipment is in operation; the other portion of the time will be used to conduct research, thus the applicants believe that there should be no adverse impact on other providers within the service area. According to the applicants, should the need arise, the applicants will transfer patients to Oktibbeha County Hospital, Baptist-Columbus and North Mississippi Medical Center for the proposed project. The applicants assert that the quality of the LINAC equipment and the services of highly qualified physicians will provide exceptional LINAC services to the patients of the area and state.

**GR Criterion 9 - Availability of Resources**

The applicants project 2.5 full-time equivalent (FTE) staff to accommodate the new therapeutic radiation service. The projected annual cost of the FTE staff is \$159,246.

**GR Criterion 10 – Relationship to Ancillary or Support Services**

According to the applicants, MSU and Premier Radiology will have all necessary ancillary and support services needed to establish and sustain the proposed therapeutic radiation service. The applicants state that if additional services are needed, they do not anticipate any difficulties in obtaining ancillary and support services.

**GR Criterion 11 - Health Professional Training Programs**

MSU and Premier Radiology state that they will work with local and regional health professional training programs to meet the clinical needs of its students.

**GR Criterion 12 – Access by Health Professional Schools**

As previously mentioned, the applicants state that they will work with local and regional health professional training programs to meet the clinical needs of students.

**GR Criterion 16 – Quality of Care**

MSU and Premier Radiology state that they have successfully operated the Institute for Neuro-Cognitive Science and Technology for two years and have served both the public's clinical needs, as well as the purpose of House Bill 1345 by promoting research at MSU.

The applicants assert that the primary purpose of the proposed project is for conducting research. The applicants believe that the quality of the LINAC equipment and the services of highly qualified physicians will provide exceptional LINAC services to the patients of the area and state. MSU and Premier assert that currently the Institute for Neuro-Cognitive Science and Technology and Imaging Centers for Excellence, LLC are providers within the following networks: Blue Cross Blue Shield

networks: Blue Cross Blue Shield Association, Health Link, United HealthCare, and Humana. The Imaging Centers for Excellence, LLC is also a participating provider in Medicare, Medicaid and Champus. The applicants anticipate that the services provided in The Cancer Center will have the participation status.

**IV. FINANCIAL FEASIBILITY**

A. Capital Expenditure Summary

Construction Cost - Renovation Capital Improvements Total Fixed Equipment Cost Total Non-Fixed Equipment Cost Fees Contingency Reserve Capitalized Interest	
<b>Total Proposed Capital Expenditure</b>	<b>\$</b>

The above proposed capital expenditure is for the acquisition of therapeutic radiation equipment. The applicants propose to purchase a Clinac iX with OBI, PV, 120MLC, Eclipse, ARIA, Rapid Arc et al.

B. Method of Financing

The applicants propose that the project will be funded by a line of credit from Renasant Bank, Tupelo. The application contains a letter from Renasant Bank confirming that it has extended a revolving line of credit in the amount of \$1,000,000 to the applicants for the purpose of providing short term working capital for operations.

C. Effect on Operating Cost

The applicants' three-year projections of revenues and expenses for the first three years of operation are attached as Attachment 1.

D. Cost to Medicare/Medicaid

The applicants project the following costs to third party payors:

Patient Mix	Utilization Percent	First Year Cost
Medicaid	7	\$231,594
Medicare	60	1,985,088
Other Payors	<u>33</u>	<u>1,091,799</u>

<b>Total</b>	<b>100</b>	<b><u>\$3,308,481</u></b>
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The applicants project that approximately 3 percent care will be provided to charity care patients and 2 percent to medically indigent patients for year one and two for the proposed project.

**V. RECOMMENDATIONS OF OTHER AFFECTED AGENCIES**

The Division of Medicaid was provided an opportunity to review and comment on this project.

**VI. CONCLUSION AND RECOMMENDATION**

This project is in substantial compliance with the criteria and standards for the acquisition or otherwise control of therapeutic radiation equipment and/or the offering of therapeutic radiation services, as contained in the *FY 2009 State Health Plan*; the *Mississippi Certificate of Need Review Manual*, 2008 Revisions; and all adopted rules, procedures, and plans of the Mississippi State Department of Health.

The project also complies with House Bill 1345 of the 2004 Mississippi Legislative Session, which states that the Mississippi State Department of Health shall issue any certificates of need necessary for Mississippi State University and a public or private health care provider to jointly acquire and operate a linear accelerator and a magnetic resonance imaging unit. Those certificates of need shall cover all capital expenditures related to the project between Mississippi State University and the health care provider, including, but not limited to, the acquisition of the linear accelerator, the magnetic resonance imaging unit and other radiological modalities; the offering of linear accelerator and magnetic resonance imaging services; and the cost of the construction of facilities in which to locate these services. The linear accelerator and the magnetic resonance imaging unit shall be (a) located in the City of Starkville, Oktibbeha County, Mississippi; (b) operated jointly by Mississippi State University and the public or private health care provider selected by Mississippi State University through a request for proposals (RFP) process in which Mississippi State University selects, and the Board of Trustees of State Institutions of Higher Learning approves, the health care provider that makes the best overall proposal; (c) available to Mississippi State University for research purposes two-thirds (2/3) of the time that the linear accelerator and magnetic resonance imaging unit are operational; and (d) available to the public or private health care provider selected by Mississippi State University and approved by the Board of Trustees of State Institutions of Higher Learning one-third (1/3) of the time for clinical, diagnostic and treatment purposes. For purposes of this subsection, the provisions of Section 41-7-193(1) requiring substantial compliance with the projection of need as reported in the current *State Health Plan* are waived.

Therefore, the Division of Health Planning and Resource Development respectfully recommends approval of this application submitted by Mississippi State University and Premier Radiology, P.A.

Attachment 1

MSU and Premier Radiology, LLC Three-Year Operating Statement (Project Only)			
	Year 1	Year 2	Year 3
<b>Revenue</b>			
Patient Revenue:			
Inpatient			
Outpatient	\$3,	\$4,	\$4,
<b>Gross Patient Revenue</b>	<b>\$3,</b>	<b>\$4,</b>	<b>\$4,</b>
Charity Care		205,303	
Deductions from R	1,	2,	2,
<b>Net Patient Revenue</b>	<b>\$1,</b>	<b>\$1,</b>	<b>\$1,</b>
<b>Expenses</b>			
Operating Expenses:			
Salaries	\$	\$153,821	\$
Benefits			
Supplies			
Services			
Lease			
Depreciation			
Interest			
Other			
<b>Total Expenses</b>	<b>\$</b>	<b>\$ 1,</b>	<b>\$ 1,</b>
<b>Net Income (Loss)</b>	<b>\$</b>	<b>\$607,76</b>	<b>\$</b>
<b>Assumptions</b>			
Inpatient days			
Outpatient days			
Procedures			
Charge per outpatient			
Charge per inpatient day			
Charge per procedure			
Cost per inpatient day			
Cost per outpatient day			
Cost per procedure			