

ATTACHMENT – REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA – Conditional

NC – Nonconforming

NA = Not Applicable

Decision Date: February 23, 2015

Findings Date: February 23, 2015

Project Analyst: Michael J. McKillip

Assistant Chief: Martha J. Frisone

Project ID #: J-10364-14

Facility: Clayton Radiation Oncology (CRO)

FID #: 080619

County: Johnston

Applicant(s): Johnston Radiation Oncology, LLC (JRO)

Project: Acquire a CT simulator

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

G.S. 131E-183(a) The Department shall review all applications utilizing the criteria outlined in this subsection and shall determine that an application is either consistent with or not in conflict with these criteria before a certificate of need for the proposed project shall be issued.

- (1) The proposed project shall be consistent with applicable policies and need determinations in the State Medical Facilities Plan, the need determination of which constitutes a determinative limitation on the provision of any health service, health service facility, health service facility beds, dialysis stations, operating rooms, or home health offices that may be approved.

NA

The applicant, JRO d/b/a CRO, proposes to acquire a CT simulator to be installed on the second floor of a medical office building, Johnston Professional Plaza, which is located at 2076 Highway 42 West in Clayton.

The applicant does not propose to increase the number of licensed beds in any category, add any new health services or acquire equipment for which there is a need determination in the 2014 State Medical Facilities Plan (SMFP). Therefore, there are no need determinations in the 2014 SMFP that are applicable to this review. Also, there are no policies in the 2014 SMFP applicable to this review. Therefore, this criterion is not applicable.

- (2) Repealed effective July 1, 1987.

- (3) The applicant shall identify the population to be served by the proposed project, and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and, in particular, low income persons, racial and ethnic minorities, women, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.

C

The applicant, JRO, proposes to acquire a CT simulator to be located on the second floor of a medical office building at 2076 Highway 42 West in Clayton. In Section I.11, page 10, the applicant states, “*The sole member of JRO is JRH Ventures, LLC*” and “*JRH Ventures, LLC is owned 50 percent by Johnston Memorial Hospital Authority (JMHA) d/b/a Johnston Health and 50 percent by Rex Hospital, Inc.*” JRO currently operates a linear accelerator on the first floor of the same medical office building in Clayton. In Section I.6, page 6, the applicant identifies Rex Hospital, Inc. as the management company for the facility. In Section II.1, pages 18-23, the applicant describes the project as follows:

“JRO proposes to acquire and relocate an 8-slice CT simulator to be used as part of the radiation therapy services provided at CRO. JRO will acquire the 8-slice CT simulator from Johnston Health Services Corporation. As part of a separate exemption request, Johnston Health Services Corporation will replace the CT unit that will be acquired by JRO....

The proposed simulator will be located at Johnston Professional Plaza in 872 square feet of leased space on the second floor of an existing medical office building. ... JRO provides radiation oncology services at CRO, which is located on the first floor of the Johnston Professional Plaza medical office building in Clayton. Through a partnership with Rex/UNC Healthcare, UNC Hospital’s radiation oncologists have provided radiation therapy services at CRO for five years. ... Although CRO currently provides radiation therapy treatments, it does not have the capabilities to provide simulation services to its patients prior to beginning their radiation therapy. ... Patients needing simulation related to their radiation therapy treatments must currently travel to Smithfield or to facilities located outside of Johnston County, such as Rex Hospital in Wake County, to receive simulation. ... The proposed project will allow patients to receive simulation and treatment planning in a familiar, convenient location, thus reducing the burden of traveling for these patients and enabling them to receive care closer to home....

In addition to the scan room where the proposed simulator will be located, the simulator suite will also house a reception/waiting area, restroom/dressing area, and a control room, as shown in the proposed line drawings in Exhibit 4.”

Population to be Served

In Sections III.4 and III.5, pages 75-77, the applicant provides the current and projected patient origin for radiation therapy services at JRO, as shown in the table below.

**Johnston Radiation Oncology
Radiation Therapy Patient Origin**

County	Current (FY2014) Percent of Total Patients	FY2016 Percent of Total Patients	FY2017 Percent of Total Patients
Johnston	46.6%	46.6%	46.6%
Wake	38.7%	38.7%	38.7%
Harnett	9.8%	9.8%	9.8%
Nash	1.8%	1.8%	1.8%
Sampson	1.8%	1.8%	1.8%
Wilson	1.2%	1.2%	1.2%
TOTAL	100.0%	100.0%	100.0%

In Section III.6(d), page 77, the applicant states, “*JRO does not expect any change in its patient origin as a result of the proposed project.*” The applicant adequately identified the population proposed to be served.

Analysis of Need

In Section III.1(a) and (b) of the application, the applicant describes the factors which it states support the need for the proposed project, including:

- The advantages to patient convenience and improved care coordination by providers that will result from the availability of on-site simulation for the existing radiation oncology service (pages 49-52).
- The projected population growth and aging in the proposed service area (pages 52-56).

In Section IV.1, page 81, the applicant provides historical and projected utilization for the existing linear accelerator and the proposed simulator at JRO through the first three years of operation following completion of the project (FY2013-FY2019), which is summarized below.

**Johnston Radiation Oncology
 Linear Accelerator and Simulator Utilization, FY2013-FY2019**

Fiscal Year (July 1 – June 30)	Patients	Simulations	ESTV Treatments*	Percent Change
2013	141	112	3,246	---
2014	166	143	4,018	23.8%
2015	168	131	4,075	1.4%
2016	171	159	4,133	1.4%
2017	173	170	4,192	1.4%
2018	176	172	4,251	1.4%
2019	178	175	4,312	1.4%

*ESTVs = equivalent simple treatment visits.

As indicated in the table above, the applicant projects utilization of the existing linear accelerator and proposed simulator will increase by 1.4 percent per year from FY2014 through the third year of the project (FY2019).

In Section III.1(b), pages 56-70, the applicant describes its assumptions and methodology for projecting utilization of the existing linear accelerator and proposed simulator at JRO. On pages 58-60, the applicant identified the ZIP Code areas in its primary service area, which includes Clayton and Garner, and its secondary service area, which includes Benson, Smithfield, and Willow Springs (See table on page 59 of the application). Based on the North Carolina Office of State Budget and Management (NCOSBM) population projections for Johnston County from 2014 to 2019, which project an average annual population growth rate of 1.4 percent, the applicant projects the number of patients to be treated with JRO’s existing linear accelerator and proposed simulator will increase by 1.4 percent each year from FY2014 through FY2019, which is shown in the table on page 61, and summarized below:

JRO Projected Patient Volume

Fiscal Year	Number of Patients
2015	168
2016	171
2017	173
2018	176
2019	178
CAGR*	1.4%

Source: Table on page 61.

*CAGR = Compound annual growth rate.

On pages 62-63, the applicant describes the basis of its projections for simulations as follows:

“Due the current circumstances of patients receiving simulation services at other facilities, JRO is not capturing all simulation patients within its record system. As stated previously, JRO captures patients receiving simulation by Johnston Health in Smithfield within its internal record system but does not capture patients that

receive these services at Rex in its records. In order to more accurately project the ratio of simulations to patients, JRO analyzed the ratio experienced by freestanding radiation oncology providers who own a simulator onsite similarly to how services will be provided at CRO upon completion of the proposed project. ... As shown in the [table on page 63], the statewide ratio of simulation to linear accelerator patients is approximately 1:1. JRO has projected the number of simulations to be performed at CRO upon completion of the project based on the assumption that it will experience a ratio equal to 0.98, as shown [in the table on page 63], beginning in the second quarter of FY 2016. JRO believes this assumption is conservative as it is projecting to perform less than one simulation per patient which accounts for patients that may choose to receive simulation elsewhere.”

As discussed above, the applicant projects the number of patients to be served by the existing linear accelerator and proposed simulator will increase from FY2014 to FY2019 at the same rate of increase as projected for the Johnston County population (1.4 percent per year) estimated by the NCOSMB for the time period from 2014 to 2019. Based on data from existing freestanding radiation oncology providers in North Carolina, the applicant estimated the ratio of patients to simulations performed to be approximately one to one. Based on these assumptions, the applicant projects the total number of simulations to be provided through the third year of operation of the project. Exhibit 29 contains letters from the physicians and surgeons in the proposed service area expressing support for the proposed project and their intention to refer patients to JRO. The projected utilization of the existing linear accelerator and proposed simulator at JRO is based on reasonable and adequately supported assumptions. JRO adequately demonstrates the need for the proposed simulator.

Access

The applicant projects 53.5% of the patients will be covered by Medicare (44.2%) and Medicaid (9.3%). The discussion regarding access found in Criterion (13c) is incorporated herein by reference. The applicant adequately demonstrates the extent to which all residents of the area, including medically underserved groups, are likely to have access to the proposed services.

Conclusion

In summary, the applicant adequately identified the population to be served, adequately demonstrated the need the population projected to be served has for the proposed project, and demonstrated the extent to which all residents of the area, including medically underserved groups, are likely to have access to the proposed services. Therefore, the application is conforming to this criterion.

- (3a) In the case of a reduction or elimination of a service, including the relocation of a facility or a service, the applicant shall demonstrate that the needs of the population presently served will be met adequately by the proposed relocation or by alternative arrangements, and the effect of the reduction, elimination or relocation of the service on the ability of low income persons,

racial and ethnic minorities, women, handicapped persons, and other underserved groups and the elderly to obtain needed health care.

NA

- (4) Where alternative methods of meeting the needs for the proposed project exist, the applicant shall demonstrate that the least costly or most effective alternative has been proposed.

CA

In Section III.3, pages 73-74, the applicant discusses the alternatives it considered prior to submitting this application, which include:

1. Maintaining the status quo, which the applicant states was rejected because it does not address the lack of availability of onsite simulation and treatment planning capability at JRO, and would continue to burden and inconvenience patients who must travel to other locations for that service.
2. Purchasing a new simulator, rather than acquiring and relocating an existing simulator, which the applicant states was rejected because of the larger financial expenditure that would be required.

After considering those alternatives, the applicant states the alternative represented in the application is the most effective alternative to meet the identified need.

Furthermore, the application is conforming to all other statutory and regulatory review criteria, and thus, is approvable. A project that cannot be approved cannot be an effective alternative.

In summary, the applicant adequately demonstrates that the proposal is the least costly or most effective alternative to meet the identified need. Therefore, the application is conforming to this criterion and approved subject to the following conditions.

- 1. Johnston Radiation Oncology, LLC shall materially comply with all representations made in the certificate of need application.**
- 2. Johnston Radiation Oncology, LLC shall not acquire, as part of this project, any equipment that is not included in the project's proposed capital expenditures in Section VII of the application and that would otherwise require a certificate of need.**
- 3. Johnston Radiation Oncology, LLC shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.**

- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

In Section VIII.1, page 107, the applicant projects the capital cost for the project will be \$336,259. In Section VIII.3, the applicant states it will finance the capital costs with \$111,000 in accumulated reserves from JRH Ventures, LLC (on behalf of JRO) and \$225,259 in accumulated reserves from Johnston Health Enterprises, Inc. (JHE), which is a wholly owned subsidiary of Johnston Health Services Corporation. In Section I.11, page 10, the applicant states, “*The sole member of JRO is JRH Ventures, LLC*” and “*JRH Ventures, LLC is owned 50 percent by Johnston Memorial Hospital Authority (JMHA) d/b/a Johnston Health and 50 percent by Rex Hospital, Inc.*” In Section IX.1, the applicant projects no start-up expenses or initial operating expenses, as the facility is already providing radiation therapy services. In Exhibit 25, the applicant provides a letter dated November 17, 2014 from the Manager of JRH Ventures, LLC, which states

“As a manager of JRH Ventures, LLC, I am responsible for the financial operations of the organization. As such, I am very familiar with the organization’s financial position. JRH Ventures, the sole member of Johnston Radiation Oncology, is committed to providing \$111,000 to Johnston Radiation Oncology for its proposed project to acquire a CT simulator.”

JRH Ventures, LLC will fund the capital costs from existing accumulated cash reserves. This expenditure will not impact any other capital projects currently underway or planned for at this time. For verification of the availability of these funds and our ability to finance these projects internally, please refer to the ‘Cash and Cash Equivalents’ line item in the audited financial statements included with this Certificate of Need application.”

Exhibit 26 contains a copy of the audited financial statements for JRH Ventures, LLC for the years ended June 30, 2013 and 2014 which indicate that JRH Ventures, LLC had \$1.2 million in cash and cash equivalents as of June 30, 2014. Also in Exhibit 25, the applicant provides a letter dated November 17, 2014 from the Vice President and Treasurer for JHE, which states

“As Vice President and Treasurer, I am responsible for the financial operations of Johnston Health Enterprises. As such, I am very familiar with the organization’s financial position. Johnston Health Enterprises is committed to funding \$225,259 for the up-fit of space on the second floor of the Johnston Professional Plaza medical building. The space will be leased to Johnston Radiation Oncology.”

Johnston Health Enterprises will fund the capital cost from existing accumulated cash reserves. This expenditure will not impact any other capital projects currently

underway or planned for at this time. For verification of the availability of these funds and our ability to finance these projects internally, please refer to the 'Cash and Cash Equivalents' line item in the audited financial statements for Johnston Health, which includes Johnston Health Enterprises, submitted with this Certificate of Need application."

Exhibit 26 contains a copy of the audited financial statements for Johnston Health for the years ended September 30, 2012 and 2013 which indicate that Johnston Health had \$4.9 million in cash and cash equivalents as of September 30, 2013.

The applicant adequately demonstrated the availability of sufficient funds for the capital needs of the proposal.

In the pro forma financial statements for JRO (Form B), the applicant projects revenues will exceed expenses in the first three operating years, as shown below:

Johnston Radiation Oncology			
	FY2017 Year 1	FY2018 Year 2	FY2019 Year 3
Total Revenue	\$2,174,397	\$2,243,342	\$2,314,108
Total Expenses	\$1,373,941	\$1,415,535	\$1,456,944
Net Income (Loss)	\$800,456	\$827,807	\$857,164

Operating costs and revenues are based on reasonable assumptions including projected utilization. See the pro forma financial statements in the application for the assumptions. The discussion regarding analysis of need found in Criterion (3) is incorporated herein by reference. The applicant adequately demonstrated that the financial feasibility of the proposal is based upon reasonable projections of operating costs and revenues, and the application is conforming with this criterion.

- (6) The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

C

The applicant, JRO, proposes to acquire a CT simulator to be located on the second floor of a medical office building at 2076 Highway 42 West in Clayton. The applicant currently operates a linear accelerator on the first floor of the same medical office building in Clayton. On pages 18-23, the applicant states,

"JRO provides radiation oncology services at CRO, which is located on the first floor of the Johnston Professional Plaza medical office building in Clayton. Through a partnership with Rex/UNC Healthcare, UNC Hospital's radiation oncologists have provided radiation therapy services at CRO for five years. ...

Although CRO currently provides radiation therapy treatments, it does not have the capabilities to provide simulation services to its patients prior to beginning their radiation therapy. ... Patients needing simulation related to their radiation therapy treatments must currently travel to Smithfield or to facilities located outside of Johnston County, such as Rex Hospital in Wake County, to receive simulation. ... The proposed project will allow patients to receive simulation and treatment planning in a familiar, convenient location, thus reducing the burden of traveling for these patients and enabling them to receive care closer to home.....”

In Section IV.1, page 81, the applicant provides historical and projected utilization for the existing linear accelerator and the proposed simulator at JRO through the first three years of operation following completion of the project (FY2013-FY2019), which is summarized below.

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2018	176	172	4,251	1.4%
2019	178	175	4,312	1.4%

*ESTVs = equivalent simple treatment visits.

As indicated in the table above, the applicant projects utilization of the existing linear accelerator and proposed simulator will increase by 1.4 percent per year from FY2014 through the third year of the project (FY2019). JRO adequately demonstrated the need to acquire a CT simulator to support its existing radiation oncology service. The discussion regarding analysis of need found in Criterion (3) is incorporated herein by reference. Consequently, the applicant adequately demonstrates the proposed project would not result in the unnecessary duplication of existing or approved health service capabilities or facilities in the applicant’s service area. Therefore, the application is conforming with this criterion.

- (7) The applicant shall show evidence of the availability of resources, including health manpower and management personnel, for the provision of the services proposed to be provided.

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In Section VII.1, pages 98-99, the applicant provides the current (2014) and proposed Year 2 (FY2018) staffing for JRO, as shown below in the table.

Position	Current Staffing	Proposed Staffing Year 2
Nurse	0.50	0.50
Front Desk	0.50	0.50
Therapist	0.50	0.50
Coordinator Therapist	0.50	0.50
Manager	0.50	0.50
Billing	0.50	0.50
Dosimetrist	0.50	0.50
Physicist	0.50	0.50
Transcriptionist	0.25	0.25
TOTAL	4.25	4.25

Source: Tables VII.1 and VII.2, pages 98-99.

In Section VII.3, page 100, the applicant states it does not propose to add any additional staff as part of the proposed project. In Section VII.8, page 102, the applicant identifies Charles W. Scarantino, M.D. as the Medical Director for JRO. Exhibit 21 contains a copy of a letter from Dr. Scarantino expressing his support for the project and willingness to continue to serve as Medical Director for JRO. Exhibit 29 of the application contains copies of letters from area physicians and surgeons expressing support for the proposed project. The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services. Therefore, the application is conforming to this criterion.

- (8) The applicant shall demonstrate that the provider of the proposed services will make available, or otherwise make arrangements for, the provision of the necessary ancillary and support services. The applicant shall also demonstrate that the proposed service will be coordinated with the existing health care system.

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In Section II.2, page 24, and Exhibits 2, 6 and 7, the applicant documents that all of the necessary ancillary and support services for the proposed services will be provided by the applicant or through arrangements with Rex Healthcare or Johnston Health. In Section V.2, page 84, the applicant states that JRO does not have formal transfer agreements, but that, in the event of an emergency, patients will be sent to Johnston Health Clayton, which operates an emergency department, operating rooms, and inpatient acute care services. Exhibit 29 contains copies of letters from physicians and surgeons expressing support for the proposed project. The applicant adequately demonstrates that necessary ancillary and support services will be available and that the proposed project will be coordinated with the existing health care system. Therefore, the application is conforming with this criterion.

- (9) An applicant proposing to provide a substantial portion of the project's services to individuals not residing in the health service area in which the project is located, or in adjacent health

service areas, shall document the special needs and circumstances that warrant service to these individuals.

NA

- (10) When applicable, the applicant shall show that the special needs of health maintenance organizations will be fulfilled by the project. Specifically, the applicant shall show that the project accommodates: (a) The needs of enrolled members and reasonably anticipated new members of the HMO for the health service to be provided by the organization; and (b) The availability of new health services from non-HMO providers or other HMOs in a reasonable and cost-effective manner which is consistent with the basic method of operation of the HMO. In assessing the availability of these health services from these providers, the applicant shall consider only whether the services from these providers:
- (i) would be available under a contract of at least 5 years duration;
 - (ii) would be available and conveniently accessible through physicians and other health professionals associated with the HMO;
 - (iii) would cost no more than if the services were provided by the HMO; and
 - (iv) would be available in a manner which is administratively feasible to the HMO.

NA

- (11) Repealed effective July 1, 1987.
- (12) Applications involving construction shall demonstrate that the cost, design, and means of construction proposed represent the most reasonable alternative, and that the construction project will not unduly increase the costs of providing health services by the person proposing the construction project or the costs and charges to the public of providing health services by other persons, and that applicable energy saving features have been incorporated into the construction plans.

NA

- (13) The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and of members of medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and handicapped persons, which have traditionally experienced difficulties in obtaining equal access to the proposed services, particularly those needs identified in the State Health Plan as deserving of priority. For the purpose of determining the extent to which the proposed service will be accessible, the applicant shall show:
- (a) The extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved;

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In Section VI.13, page 96 the applicant reports the payer mix for JRO for the last year (FY2014), which is summarized in the following table:

JRO Payer Category	FY2014 Procedures as % of Total
Self Pay/Indigent/Charity	1.8%
Medicare/Medicare Managed Care	44.2%
Medicaid	9.3%
Commercial Insurance/Managed Care	44.7%
Total	100.0%

The Division of Medical Assistance (DMA) maintains a website which offers information regarding the number of persons eligible for Medicaid assistance and estimates of the percentage of uninsured for each county in North Carolina. More current data, particularly with regard to the estimated uninsured percentages, was not available.

County	Total # of Medicaid Eligibles as % of Total Population June 2010	Total # of Medicaid Eligibles Age 21 and older as % of Total Population June 2010	% Uninsured CY 2008-2009 (Estimate by Cecil G. Sheps Center)
Johnston	17%	6.7%	20.0%
Statewide	17%	6.7%	19.7%

The majority of Medicaid eligibles are children under the age of 21. This age group does not utilize the same health services at the same rate as older segments of the population, particularly the radiation therapy simulation services proposed in this application.

Moreover, the number of persons eligible for Medicaid assistance may be greater than the number of Medicaid eligibles who actually utilize health services. The DMA website includes information regarding dental services which illustrates this point. For dental services only, DMA provides a comparison of the number of persons eligible for dental services with the number actually receiving services. The statewide percentage of persons eligible to receive dental services who actually received dental services was 48.6% for those age 20 and younger and 31.6% for those age 21 and older. Similar information is not provided on the website for other types of services covered by Medicaid. However, it is reasonable to assume that the percentage of those actually receiving other types of health services covered by Medicaid is less than the percentage that is eligible for those services.

The Office of State Budget & Management (OSBM) maintains a website which provides historical and projected population data for each county in North Carolina. In addition, data is available by age, race or gender. However, a direct comparison to the applicants' current payer mix would be of little value. The population data by age, race or gender does not include information on the number of elderly, minorities, women or handicapped persons utilizing health services.

The applicant demonstrates that medically underserved populations currently have adequate access to the applicant's existing services and is conforming to this criterion.

- (b) Its past performance in meeting its obligation, if any, under any applicable regulations requiring provision of uncompensated care, community service, or access by minorities and handicapped persons to programs receiving federal assistance, including the existence of any civil rights access complaints against the applicant;

C

Recipients of Hill-Burton funds were required to provide uncompensated care, community service and access by minorities and handicapped persons. In Section VI.11, page 95, the applicant states:

"JRO has no obligation under federal regulations to provide uncompensated care. Nonetheless, it provides, without obligation, a considerable amount of bad debt and charity care. As stated previously, JRO does not discriminate based on age, gender, geographic location, cultural background, physical mobility, or ability to pay for services. JRO also complies with applicable regulations regarding access by handicapped persons."

In Section VI.10 (a), page 94, the applicant states that no Office of Civil Rights complaints have been filed against it in last five years. The application is conforming to this criterion.

- (c) That the elderly and the medically underserved groups identified in this subdivision will be served by the applicant's proposed services and the extent to which each of these groups is expected to utilize the proposed services; and

C

In Section VI.14, page 96, the applicant provides the projected payer mix for the second full fiscal year of operation (FY2018) for JRO, as shown in the table below.

JRO Payer Category	FY2014 Procedures as % of Total
Self Pay/Indigent/Charity	1.8%

Medicare/Medicare Managed Care	44.2%
Medicaid	9.3%
Commercial Insurance/Managed Care	44.7%
Total	100.0%

On page 96, the applicant states, “*JRO does not expect any change in its payor mix as a result of the proposed project.*” The applicant demonstrates that medically underserved populations will have adequate access to the proposed services. Therefore, the application is conforming to this criterion.

- (d) That the applicant offers a range of means by which a person will have access to its services. Examples of a range of means are outpatient services, admission by house staff, and admission by personal physicians.

C

In Section VI.9(a), page 93, the applicant describes the range of means by which a person will have access to the proposed services. The information provided is reasonable and supports a finding of conformity to this criterion.

- (14) The applicant shall demonstrate that the proposed health services accommodate the clinical needs of health professional training programs in the area, as applicable.

C

In Section V.1 of the application, the applicant states, “*As an existing provider of radiation therapy services, JRO has established relationships with health professional training programs in the area, specifically with Johnston Community College radiography students.*” The information provided in Section V.1 is reasonable and supports a finding of conformity to this criterion.

- (15) Repealed effective July 1, 1987.
- (16) Repealed effective July 1, 1987.
- (17) Repealed effective July 1, 1987.
- (18) Repealed effective July 1, 1987.
- (18a) The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact upon the cost effectiveness, quality, and access to the services proposed; and in the case of applications for services where competition between providers will not have a favorable impact on cost-effectiveness, quality, and access to the services proposed, the applicant shall demonstrate that its application is for a service on which competition will not have a favorable impact.

C

The applicant, JRO, proposes to acquire a CT simulator to be located on the second floor of a medical office building at 2076 Highway 42 West in Clayton. JRO currently operates a linear accelerator on the first floor of the same medical office building in Clayton.

In Section V.7, pages 87-88, the applicant discusses how any enhanced competition in the service area will promote the cost-effectiveness, quality and access to the proposed services. The applicant states,

“The proposed project will foster competition by promoting cost-effectiveness, quality, and access to services in the proposed service area and will thus be in compliance with the spirit and legislative intent of the Certificate of Need Law.

The proposed project is indicative of JRO’s commitment to containing healthcare costs. The proposed project involves the acquisition of an existing CT simulator to be placed in an existing medical office building. The only construction costs associated with the proposed project are related to the up-fitting of existing space, as shown in Section VIII. Additionally, patients also benefit from the proposed project in terms of reduced out-of-pocket expenses related to traveling, such as gas and parking fees that may be incurred elsewhere.

JRO also believes that the proposed project will promote the provision of quality healthcare services to patients in the service area. The colocation of medical oncology, radiation oncology, and simulation and radiation treatment planning services within the medical office building in Clayton will allow for more open and direct communication among members of the comprehensive treatment team which results in better patient care....

The proposed project will also promote access to healthcare services in the proposed service area. Given the nature of radiation oncology services, it is of the utmost importance that patients have access to a convenient location where they can receive reliable, continuous care. JRO currently owns and operates a linear accelerator in the medical office building on the Johnston Health campus in Clayton. However, radiation therapy patients needing simulation relating to their treatments must currently travel to Smithfield in Johnston County or Rex in Wake County for simulation and treatment planning. The proposed project will allow patients to receive simulation and treatment planning in a familiar, convenient location, thus reducing the burden of traveling for these patients and enabling them to receive care closer to home.”

See also Sections II, III, V, VI and VII where the applicant discusses the impact of the project on cost-effectiveness, quality and access.

The information in the application is reasonable and credible and adequately demonstrates that any enhanced competition in the service area includes a positive impact on cost-effectiveness, quality and access to the proposed services. This determination is based on the information in the application and the following analysis:

- The applicant adequately demonstrates the need for the proposed project and that it is a cost-effective alternative. The discussions regarding the analysis of need and alternatives found in Criteria (3) and (4), respectively, are incorporated herein by reference.
- The applicant adequately demonstrates it would continue to provide quality services. The discussions regarding quality found in Criteria (1) and (20) are incorporated herein by reference.
- The applicant demonstrates it will continue to provide adequate access to medically underserved populations. The discussions regarding access found in Criteria (1) and (13) are incorporated herein by reference.

The application is conforming to this criterion.

- (19) Repealed effective July 1, 1987.
- (20) An applicant already involved in the provision of health services shall provide evidence that quality care has been provided in the past.

C

According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, no incidents occurred within the eighteen months immediately preceding the date of this decision, for which any sanctions or penalties related to quality of care were imposed by the State on Johnston Health. Therefore, the application is conforming with this criterion.

- (21) Repealed effective July 1, 1987.
- (b) The Department is authorized to adopt rules for the review of particular types of applications that will be used in addition to those criteria outlined in subsection (a) of this section and may vary according to the purpose for which a particular review is being conducted or the type of health service reviewed. No such rule adopted by the Department shall require an academic medical center teaching hospital, as defined by the State Medical Facilities Plan, to demonstrate that any facility or service at another hospital is being appropriately utilized in order for that academic medical center teaching hospital to be approved for the issuance of a certificate of need to develop any similar facility or service.

C

SECTION .1900 – CRITERIA AND STANDARDS FOR RADIATION THERAPY EQUIPMENT

10A NCAC 14C .1902 INFORMATION REQUIRED OF APPLICANT

(a) An applicant proposing to acquire radiation therapy equipment shall use the Acute Care Facility/Medical Equipment application form.

-C- The applicant used the Acute Care Facility/Medical Equipment application form.

(b) An applicant proposing to acquire radiation therapy equipment shall provide the following information:

(1) a list of all the radiation therapy equipment to be acquired and documentation of the capabilities and capacities of each item of equipment;

-C- The applicant identified the CT simulator to be acquired and documented its capabilities in Section II.8, pages 31-32 of the application. In Section IV.2, page 32, the applicant states, *“The proposed CT simulator can perform a maximum of 5,100 HECT units per 10A NCAC 14C .2303. However, please note that JRO proposes to only use the CT simulator for simulation for its radiation therapy service, which does not have a corresponding HECT unit value.”*

(2) documentation of the purchase price and fair market value of each piece of radiation therapy equipment, each simulator, and any other related equipment proposed to be acquired;

-C- The applicant documented the purchase price of the equipment in Exhibit 5 of the application.

(3) the projected number of patient treatments by intensity modulated radiation treatment (IMRT); stereotactic radiosurgery; simple, intermediate and complex radiation treatments to be performed on each piece of radiation therapy equipment for each of the first three years of operation following the completion of the proposed project and documentation of all assumptions by which utilization is projected;

-NA- The applicant proposes to acquire a CT simulator.

(4) documentation that the proposed radiation therapy equipment shall be operational at least seven hours per day, five days a week;

-C- In Section II.8, page 33, the applicant states JRO operates from 8:00 a.m. to 5:00 p.m., Monday through Friday.

(5) documentation that no more than one simulator is available for every two linear accelerators in the applicant's facility, except that an applicant that has only one linear accelerator may have one simulator;

- C- In Section II.8, page 33, the applicant states JRO does not currently operate a simulator. Following completion of the proposed project, JRO would operate one simulator and one linear accelerator. Therefore, the applicant is conforming with this Rule.
- (6) *documentation that the services shall be offered in a physical environment that conforms to the requirements of federal, state, and local regulatory bodies;*
- C- In Section II.8, page 34, and Exhibit 9, the applicant provides documentation that the existing facility and proposed renovations will conform to the requirements of federal, state and local regulatory bodies.
- (7) *the projected total number of radiation treatment patients by county that will be treated in the facility in each of the first three years of operation following completion of the proposed project;*
- C- In Section II.8, page 35, the applicant provides a table showing the projected total number of radiation treatment patients by county to be treated at the facility in each of the first three years of operation.
- (8) *the projected number of radiation treatment patients that will be treated for palliation in each of the first three years of operation following completion of the proposed project; and*
- C- In Section II.8, page 35, the applicant provides a table showing the projected total number of radiation treatment patients that will be treated for palliation at the facility in each of the first three years of operation.
- (9) *the projected number of radiation treatment patients that will be treated for cure in each of the first three years of operation following completion of the proposed project.*
- C- In Section II.8, page 36, the applicant provides a table showing the projected total number of radiation treatment patients that will be treated for cure at the facility in each of the first three years of operation.
- (c) *An applicant proposing to acquire a linear accelerator for development of a multidisciplinary prostate health center pursuant to a need determination for a demonstration project in the State Medical Facilities Plan shall provide the following information:*
- (1) *description of all services to be provided by the proposed multidisciplinary prostate health center, including a description of each of the following services:*
- (A) *urology services,*
- (B) *medical oncology services,*
- (C) *biofeedback therapy,*
- (D) *chemotherapy,*

- (E) *brachytherapy, and*
- (F) *living skills counseling and therapy;*
- (2) *documentation that urology services, medical and radiation oncology services, biofeedback therapy, brachytherapy and post-treatment living skills counseling and therapy will be provided in the same building;*
- (3) *description of any services that will be provided by other facilities or in different buildings;*
- (4) *demographics of the population in the county in which the proposed multidisciplinary prostate health center will be located, including:*
 - (A) *percentage of the population in the county that is African American,*
 - (B) *the percentage of the population in the county that is male,*
 - (C) *the percentage of the population in the county that is African American male,*
 - (D) *the incidence of prostate cancer for the African American male population in the county, and*
 - (E) *the mortality rate from prostate cancer for the African American male population in the county;*
- (5) *documentation that the proposed center is located within walking distance of an established bus route and within five miles of a minority community;*
- (6) *documentation that the multiple medical disciplines in the center will collaborate to create and maintain a single or common medical record for each patient and conduct multidisciplinary conferences regarding each patient's treatment and follow-up care;*
- (7) *documentation that the center will establish its own prostate/urological cancer tumor board for review of cases;*
- (8) *copy of the center's written policies that prohibit the exclusion of services to any patient on the basis of age, race, religion, disability or the patient's ability to pay;*
- (9) *copy of written strategies and activities the center will follow to assure its services will be accessible by patients without regard to their ability to pay;*
- (10) *description of the center's outreach activities and the manner in which they complement existing outreach initiatives;*
- (11) *documentation of number and type of clinics to be conducted to screen patients at risk for prostate cancer;*
- (12) *written description of patient selection criteria, including referral arrangements for high-risk patients;*
- (13) *commitment to prepare an annual report at the end of each of the first three operating years, to be submitted to the Medical Facilities Planning Section and the Certificate of Need Section, that shall include:*
 - (A) *the total number of patients treated;*
 - (B) *the number of African American persons treated;*
 - (C) *the number of persons in other minority populations treated; and*
 - (D) *the number of insured, underinsured and uninsured patients served by type of payment category;*
- (14) *documentation of arrangements made with a third party researcher to evaluate, during the fourth operating year of the center, the efficacy of the clinical and*

outreach initiatives on prostate and urological cancer treatment, and develop recommendations regarding the advantages and disadvantages of replicating the project in other areas of the State. The results of the evaluation and recommendations shall be submitted in a report to the Medical Facilities Planning Section and Certificate of Need Section in the first quarter of the fifth operating year of the demonstration project; and

(15) *if the third party researcher is not a historically black university, document the reasons for using a different researcher for the project.*

-NA- The applicant is not proposing to acquire a linear accelerator for development of a multidisciplinary prostate health center pursuant to a need determination for a demonstration project in the State Medical Facilities Plan.

10A NCAC 14C .1903 PERFORMANCE STANDARDS

(a) *An applicant proposing to acquire a linear accelerator shall demonstrate that each of the following standards will be met:*

(1) *an applicant's existing linear accelerators located in the proposed radiation therapy service area performed at least 6,750 ESTV treatments per machine or served at least 250 patients per machine in the twelve months prior to the date the application was submitted;*

(2) *each proposed new linear accelerator will be utilized at an annual rate of 250 patients or 6,750 ESTV treatments during the third year of operation of the new equipment; and*

(3) *an applicant's existing linear accelerators located in the proposed radiation therapy service area are projected to be utilized at an annual rate of 6,750 ESTV treatments or 250 patients per machine during the third year of operation of the new equipment.*

-NA- The applicant is not proposing to acquire a linear accelerator.

(b) *A linear accelerator shall not be held to the standards in Paragraph (a) of this Rule if the applicant provides documentation that the linear accelerator has been or will be used exclusively for clinical research and teaching.*

-NA- The applicant is not proposing to acquire a linear accelerator.

(c) *An applicant proposing to acquire radiation therapy equipment other than a linear accelerator shall provide the following information:*

(1) *the number of patients that are projected to receive treatment from the proposed radiation therapy equipment, classified by type of equipment, diagnosis, treatment procedure, and county of residence; and*

-NA- The applicant is proposing to acquire a CT simulator.

(2) *the maximum number and type of procedures that the proposed equipment is capable of performing.*

-NA- The applicant is proposing to acquire a CT simulator. In Section II.8, page 42, the applicant states, *“The proposed CT simulator can perform a maximum of 5,100 HECT units per 10A NCAC 14C .2303. However, please note that JRO proposes to only use the CT simulator for simulation for its radiation therapy service, which does not have a corresponding HECT unit value. The simulator will not be used for diagnostic scans.”*

(d) *The applicant shall document all assumptions and provide data supporting the methodology used to determine projected utilization as required in this Rule.*

-NA- The applicant is proposing to acquire a CT simulator.

10A NCAC 14C .1904 SUPPORT SERVICES

(a) *An applicant proposing to acquire radiation therapy equipment shall document that the following items shall be available; and if any item shall not be available, the applicant shall provide substantive information obviating the need for that item:*

(1) *an organized program of radiation therapy continuing education for radiation therapists, technologists and medical staff;*

-C- In Section II.8, page 43, the applicant states that JRO currently provides an organized program of continuing education for radiation therapy staff.

(2) *a program for the collection of utilization data relative to the applicant's provision of radiation therapy services;*

-C- In Section II.8, pages 43-44, the applicant states that it has a program for the collection of utilization data.

(3) *medical laboratory services;*

-C- In Section II.8, page 44, the applicant states that Johnston Health Smithfield and Johnston Health Clayton provide medical laboratory services to the patients of JRO. Exhibit 7 contains a copy of a letter from the President and CEO of Johnston Health which states these services are available to the radiation therapy patients served by JRO.

(4) *pathology services; and*

-C- In Section II.8, page 44, the applicant states that Johnston Health Smithfield and Johnston Health Clayton provide pathology services to the patients of JRO. Exhibit 7 contains a copy of a letter from the President and CEO of Johnston Health which states these services are available to the radiation therapy patients served by JRO.

(5) *pharmaceutical support services.*

-C- In Section II.8, page 44, the applicant states that Johnston Health Smithfield and Johnston Health Clayton provide pharmaceutical support services to the patients of JRO. Exhibit 7 contains a copy of a letter from the President and CEO of Johnston Health which states these services are available to the radiation therapy patients served by JRO.

(b) An applicant proposing to acquire a linear accelerator for development of a multidisciplinary prostate health center pursuant to a need determination for a demonstration project in the State Medical Facilities Plan shall provide a written description of the center's plans and strategies to establish:

- (1) an African American Prostate Cancer Education/Outreach Program that will partner with and complement existing support groups, such as the N.C. Minority Prostate Cancer Awareness Action Team; and*
- (2) an Advisory Board composed of representatives of prostate cancer advocacy groups, prostate cancer patients and survivors that will meet regularly to provide feedback to the center regarding outreach practices which are effective or which need to be changed.*

-NA- The applicant is not proposing to acquire a linear accelerator for development of a multidisciplinary prostate health center pursuant to a need determination for a demonstration project in the State Medical Facilities Plan.

10A NCAC 14C .1905 STAFFING AND STAFF TRAINING

(a) An applicant proposing to acquire radiation therapy equipment shall document the number and availability of staff or provide evidence that obviates the need for staff in the following areas:

- (1) Radiation Oncologist;*

-C- In Section II.8, page 45, the applicant states that currently eight radiation oncologists from the Department of Radiation Oncology at UNC Hospitals are assigned to Wake and Johnston counties. The applicant states one radiation oncologist, Douglas Fein, M.D., is staffed at JRO full-time. Exhibit 12 contains a copy of a letter from Dr. Fein expressing his willingness to provide services to JRO.

- (2) Radiation Physicist;*

-C- In Section II.8, page 45, the applicant identifies Rex Healthcare as the provider of radiation physicist services to JRO. Exhibit 2 contains a copy of the management agreement between JRO and Rex Healthcare which includes the provision of these services.

- (3) Dosimetrist or Physics Assistant;*

-C- In Section II.8, pages 45-46, the applicant identifies Rex Healthcare as the provider of dosimetry services to JRO. Exhibit 2 contains a copy of the management agreement between JRO and Rex Healthcare which includes the provision of these services.

(4) *Radiation Therapist;*

- C- In Section II.8, page 46, the applicant identifies Rex Healthcare as the provider of radiation therapist services to JRO. Exhibit 2 contains a copy of the management agreement between JRO and Rex Healthcare which includes the provision of these services.

(5) *Radiation-Oncology Administrator;*

- C- In Section II.8, page 46, the applicant identifies Rex Healthcare as the provider of radiation oncology managerial services to JRO. Exhibit 2 contains a copy of the management agreement between JRO and Rex Healthcare which includes the provision of these services.

(6) *Registered Nurse or LPN;*

- C- In Section II.8, page 46, the applicant identifies Rex Healthcare as the provider of nursing services to JRO. Exhibit 2 contains a copy of the management agreement between JRO and Rex Healthcare which includes the provision of these services.

(7) *Physical Therapist;*

- C- In Section II.8, page 46, the applicant states that physical therapy services will be provided by Johnston Health. Exhibit 7 contains a copy of a letter from the President and CEO of Johnston Health which states these services are available to the radiation therapy patients served by JRO.

(8) *Dietician;*

- C- In Section II.8, page 47, the applicant states that dietician services will be provided by Johnston Health. Exhibit 7 contains a copy of a letter from the President and CEO of Johnston Health which states these services are available to the radiation therapy patients served by JRO.

(9) *Pharmacist;*

- C- In Section II.8, page 47, the applicant states that pharmacist services will be provided by Johnston Health. Exhibit 7 contains a copy of a letter from the President and CEO of Johnston Health which states these services are available to the radiation therapy patients served by JRO.

(10) *Social Worker; and*

- C- In Section II.8, page 47, the applicant states that social work services will be provided by Johnston Health as needed.

(11) *Maintenance Engineer.*

- C- In Section II.8, page 47, the applicant states that maintenance engineers will be provided by Johnston Health as needed.
- (b) *An applicant proposing to acquire a linear accelerator for development of a multidisciplinary prostate health center pursuant to a need determination for a demonstration project in the State Medical Facilities Plan shall document that the center will have:*
- (1) *a medical director who is either a urologist certified by the American Board of Urology, a medical oncologist certified by the American Board of Internal Medicine, or a radiation oncologist certified by the American Board of Radiology; and*
 - (2) *a multidisciplinary team consisting of medical oncologists, radiation oncologists, urologists, urologic pharmacologists, pathologists and therapy specialists.*
- NA- The applicant is not proposing to acquire a linear accelerator for development of a multidisciplinary prostate health center pursuant to a need determination for a demonstration project in the State Medical Facilities Plan.