

## ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: November 30, 2017

Findings Date: November 30, 2017

Project Analyst: Mike McKillip

Team Leader: Lisa Pittman

Project ID #: J-11382-17

Facility: Duke Proton Therapy Center

FID #: 170365

County: Durham

Applicants: Duke-Provision Proton Therapy Center, LLC  
Duke University Health System, Inc.  
Provision Trust, Inc.

Project: Develop a two-room proton therapy center

### REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

N.C. Gen. Stat. §131E-183(a) The Agency 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.

C

Duke-Provision Proton Therapy Center, LLC, Duke University Health System, Inc. (DUHS) and Provision Trust, Inc. [**Duke Proton Therapy Center**] propose to acquire a two-room proton therapy system to be developed in a new facility to be constructed on the campus of Duke's Lenox Baker Children's Hospital in Durham.

#### **Need Determination and Policies**

There are no need determinations in the 2017 State Medical Facilities Plan (SMFP) applicable to the acquisition of proton therapy equipment. However, Policy GEN-4 is applicable.

## **Policy GEN-4**

Policy GEN-4 states:

*“Any person proposing a capital expenditure greater than \$2 million to develop, replace, renovate or add to a health service facility pursuant to G.S. 131E-178 shall include in its certificate of need application a written statement describing the project’s plan to assure improved energy efficiency and water conservation.*

*In approving a certificate of need proposing an expenditure greater than \$5 million to develop, replace, renovate or add to a health service facility pursuant to G.S. 131E-178, Certificate of Need shall impose a condition requiring the applicant to develop and implement an Energy Efficiency and Sustainability Plan for the project that conforms to or exceeds energy efficiency and water conservation standards incorporated in the latest editions of the North Carolina State Building Codes. The plan must be consistent with the applicant’s representation in the written statement as described in paragraph one of Policy GEN-4.*

*Any person awarded a certificate of need for a project or an exemption from review pursuant to G.S. 131E-184 are required to submit a plan of energy efficiency and water conservation that conforms to the rules, codes and standards implemented by the Construction Section of the Division of Health Service Regulation. The plan must be consistent with the applicant’s representation in the written statement as described in paragraph one of Policy GEN-4. The plan shall not adversely affect patient or resident health, safety or infection control.”*

The proposed capital expenditure for this project is greater than \$5 million. In Section B.11, pages 30-31, the applicants state:

*“DPTC [Duke Proton Therapy Center] has designed the proposed facility to be in compliance with all applicable federal, state, and local building codes, and requirements for energy efficiency and consumption, including Policy GEN-4. The project will be designed to be energy efficient and to conserve water.”*

The applicants adequately demonstrate that the application includes a written statement describing the project’s plan to assure improved energy efficiency and water conservation. Therefore, the application is consistent with Policy GEN-4.

## **Conclusion**

In summary, the applicants adequately demonstrate that the proposal is consistent with Policy GEN-4. Therefore, the application is conforming to this criterion.

- (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 applicants, Duke Proton Therapy Center (DPTC), propose to acquire a two-room proton therapy system to be developed in a new facility to be constructed on the campus of Duke's Lenox Baker Children's Hospital in Durham. In Section C.1, pages 33-35, the applicants describe the proposed project as follows:

*"DPTC is proposing to construct a proton therapy center with two-rooms at 3000 Erwin Road on the Duke University campus. ... Development of the proposed proton therapy center represents a cooperative arrangement between DUHS and Provision Trust, Inc. Provision Trust, Inc. and DUHS are the members of Duke-Provision Proton Therapy Center, LLC and will leverage their knowledge and experience in the development and operation of this facility...."*

*The proton therapy center will occupy a dedicated new building of approximately 30,500 square feet. New construction is necessary because the shielding and weight-bearing requirements of proton treatment facilities exceed normal building requirements. ... The proton treatment system is housed in three shielded rooms or 'vaults,' accessible through heavily shielded doors and supported by control rooms. Each of the treatment vaults includes a proton control room. One vault houses an accelerator that accelerates the protons and generates the beam. The beam passes through a fixed beamline and is directed into the two adjoining vaults. The treatment vaults are 'gantry treatment rooms' (a gantry rotates the beam delivery mechanism around the patient table to treat from multiple angles).*

*The first floor has a specialized CT area with simulation, control, and workrooms that send patient data to the proton treatment planning areas. The floor also contains several offices, utility and storage areas. The second floor of the building contains research, physics, conference rooms, a meeting space, medical and facility staff offices and support rooms, an IT room, storage rooms, and mechanical/electrical rooms."*

### **Patient Origin**

The 2017 SMFP does not define a service area for proton therapy equipment. In Section C.3, page 40, the applicants provide the projected patient origin for the first three operating years (FY2021-FY2023), as shown in the table below.

**Projected Patient Origin for Proton Therapy Services at DPTC**

County	Percent of Total Patients	PY 1 FY2021 Patients	PY 2 FY2022 Patients	PY 3 FY2023 Patients
Wake	29.5%	116	157	182
Durham	16.9%	67	90	104
Person	4.0%	16	21	25
Orange	3.8%	15	20	23
Granville	2.6%	10	14	16
Johnston	2.6%	10	14	16
Alamance	2.2%	8	11	13
Guilford	1.7%	7	9	10
Vance	1.1%	4	6	7
Other NC*	24.0%	95	128	148
Other States	11.7%	46	62	72
<b>TOTAL</b>	<b>100.0%</b>	<b>395</b>	<b>532</b>	<b>616</b>

Source: Table on page 40 of the application.

\*The applicant states the counties included in the "Other NC" category represent counties from which one percent or less of total patients are expected to originate.

In Section C.3, page 41, the applicants state, "The projected patient origin is consistent with DUHS's historical experience providing radiation therapy services." The applicants adequately identified the population proposed to be served.

**Analysis of Need**

In Section C.4 of the application, the applicants describe the factors which they state supports the need for the proposed project, including:

- The treatment advantages of proton therapy over conventional radiation therapy (p. 42-51).
- The current lack of access to proton therapy services in North Carolina (p. 51-57).
- The need to provide educational and research opportunities in the field of proton therapy (p. 57-60).
- Recent expansions in reimbursement and coverage by payors for proton therapy (p. 61).
- The historical and projected growth in cancer cases in North Carolina (p. 64-65).
- The historical and projected growth in utilization of proton therapy to treat cancer (p. 66-71).
- The projected growth and aging of the service area population, and the projected growth of the pediatric population in the service area (p. 72-76).
- Projected increases in cancer incidence in the service area population (p.76-79).
- Historical and projected utilization of radiation therapy services at Duke University Health System hospitals, and the projected number of patients that would be appropriate candidates for proton therapy (p.79-84).

The information provided by the applicants in the pages referenced above is reasonable and adequately supported.

Projected Utilization

In Section Q, page 173, the applicants provide projected utilization for the proposed proton therapy equipment through the first three years of operation following completion of the project, which is summarized below.

**Projected Utilization of Proton Therapy Services at Duke Proton Therapy Center**

	<b>PY 1 FY2021</b>	<b>PY 2 FY2022</b>	<b>PY 3 FY2023</b>
Number of units*	2	2	2
Patients	395	532	616
Total Treatments	10,867	14,644	16,964

\*The applicants state, "DPTC proposes to develop a two-room proton therapy center. The center will house one cyclotron and two gantry treatment rooms."

As shown in the above table, the applicants project they will provide 10,867 treatments with the proposed proton therapy equipment in the first year of operation, and 16,964 treatments in the third operating year of the project. In Section C.11, page 97, the applicants project the proposed proton therapy equipment will have a maximum capacity of 9,193 treatments per year per room, with a maximum annual capacity of 18,386 for both rooms, based on the assumption the equipment is operational 16 hours per day, five days per week.

In Section Q, pages 161-173, the applicants describe their assumptions and methodology for projecting utilization of the proton therapy equipment at DPTC, as summarized below.

**Step 1: Identify Historical Utilization of DUHS Radiation Services**

The applicants reviewed the historical utilization of radiation therapy services at DUHS hospitals and determined that DUHS radiation therapy patient volume increased at an average annual growth rate of 9.8 percent over the past four years, from 2,621 patients in FY2014 to 3,466 patients in FY2017. See the table on page 161 of the application.

**Step 2: Identify Potential Proton Therapy Patient Base**

The applicants identified the cancer programs that are appropriate for proton therapy, and reviewed the historical utilization of those programs to estimate the number of patients by program that would have been appropriate for proton therapy services, as shown in the following table:

**Combined DUHS Adult Radiation Therapy Patients  
 By Cancer Program Appropriate for Proton Therapy**

<i>Program</i>	<i>% Appropriate for Proton Therapy</i>	<i>FY2014</i>	<i>FY2015</i>	<i>FY2016</i>	<i>FY2017</i>
<i>Brain Tumor</i>	<i>30%</i>	<i>89</i>	<i>96</i>	<i>107</i>	<i>125</i>
<i>Breast Oncology</i>	<i>10%</i>	<i>43</i>	<i>58</i>	<i>61</i>	<i>63</i>
<i>GI Oncology</i>	<i>40%</i>	<i>109</i>	<i>107</i>	<i>136</i>	<i>156</i>
<i>GU Oncology</i>	<i>60%</i>	<i>105</i>	<i>120</i>	<i>149</i>	<i>144</i>
<i>GYN Oncology</i>	<i>15%</i>	<i>14</i>	<i>16</i>	<i>18</i>	<i>18</i>
<i>Head and Neck Oncology</i>	<i>30%</i>	<i>35</i>	<i>47</i>	<i>44</i>	<i>65</i>
<i>Hematology-Oncology</i>	<i>20%</i>	<i>30</i>	<i>33</i>	<i>31</i>	<i>38</i>
<i>Sarcoma</i>	<i>20%</i>	<i>20</i>	<i>19</i>	<i>17</i>	<i>14</i>
<i>Thoracic Oncology</i>	<i>25%</i>	<i>86</i>	<i>98</i>	<i>95</i>	<i>100</i>
<b><i>Total Unique Patients</i></b>		<b><i>531</i></b>	<b><i>594</i></b>	<b><i>658</i></b>	<b><i>723</i></b>

Source: Table on page 163 in Section Q of the application.

On page 163, the applicants state,

*“As described previously, based on the historical experience of existing proton therapy providers, there is a generally accepted range of radiation therapy candidates by tumor type that are clinically eligible and will benefit from proton therapy compared to traditional radiation treatment. ... From FY2014 to FY2017, the number of DUHS radiation therapy patients that would have been appropriate candidates for proton therapy grew by a compound annual growth rate (CAGR) of 10.9 percent. Based on the expert clinical judgment of Duke radiation oncology leadership, and the historical patient base of DUHS radiation therapy patients, an historical patient base of over 700 adults is appropriate for proton therapy.”*

**Step 3: Project Potential DUHS Proton Therapy Patients**

The applicants projected the potential patients by program that would be appropriate for proton therapy through the first three years of the proposed project, based on a projected average annual growth rate of 3.6 percent, which is one-third the applicants’ historical growth rate from FY2014 to FY2017, as identified in the previous step.

***DUHS Potential Proton Therapy Patient Base***

<b><i>Program</i></b>	<b><i>FY2018</i></b>	<b><i>FY2019</i></b>	<b><i>FY2020</i></b>	<b><i>FY2021</i></b>	<b><i>FY2022</i></b>	<b><i>FY2023</i></b>
<i>Brain Tumor</i>	130	134	139	144	149	155
<i>Breast Oncology</i>	66	68	71	73	76	79
<i>GI Oncology</i>	162	168	174	180	187	193
<i>GU Oncology</i>	149	155	160	166	172	178
<i>GYN Oncology</i>	19	20	21	21	22	23
<i>Head and Neck Oncology</i>	67	70	72	75	77	80
<i>Hematology-Oncology</i>	39	41	42	44	45	47
<i>Sarcoma</i>	14	15	15	16	16	17
<i>Thoracic Oncology</i>	103	107	111	115	119	123
<b><i>Total Unique Patients</i></b>	<b>749</b>	<b>776</b>	<b>805</b>	<b>834</b>	<b>864</b>	<b>895</b>

Source: Table on page 164 in Section Q of the application.

**Step 4: Estimate Proton Therapy Market Share**

In Section C.1, page 70, the applicants project that 11.6% of all statewide cancer cases would be appropriate candidates for proton therapy. Based on those projections, the applicants project their statewide market share of proton therapy patients through the first three operating years, as shown in the following table:

***DUHS Estimated Projected Market Share of Potential Proton Therapy Patients***

	<b><i>FY2017</i></b>	<b><i>FY2018</i></b>	<b><i>FY2019</i></b>	<b><i>FY2020</i></b>	<b><i>FY2021</i></b>	<b><i>FY2022</i></b>	<b><i>FY2023</i></b>
<i>Statewide Cancer Cases projected by State Center for Health Statistics</i>	59,349	60,173	61,009	61,856	62,715	63,585	64,468
<i>Proton-Appropriate Cases (11.6%)</i>	6,870	6,966	7,062	7,160	7,260	7,361	7,463
<i>DUHS Potential Proton Therapy Patients (Step 3)</i>	723	749	776	805	834	864	895
<b><i>DUHS Market Share of Potential Proton Therapy Patients</i></b>	<b>10.5%</b>	<b>10.8%</b>	<b>11.0%</b>	<b>11.2%</b>	<b>11.5%</b>	<b>11.7%</b>	<b>12.0%</b>

Source: Table on page 166 in Section Q of the application.

**Step 5: Determine Project Years**

The applicants assume the project will become operational on July 1, 2020. Therefore, the project years are based on July-June fiscal years, which is consistent with the historical utilization reported above.

**Step 6: Project DUHS Proton Therapy Patients**

Due to limitations of insurance coverage for this service that will be new to North Carolina, the applicants project that only 45 to 55 percent of DUHS patients that are appropriate for proton therapy will receive proton therapy services in the first three project years, as summarized in the following table:

**Duke Proton Therapy Center  
 Projected Proton Therapy Patients**

	<b>PY 1 FY2021</b>	<b>PY 2 FY2022</b>	<b>PY 3 FY2023</b>
% of Potential Proton Therapy Patients	45%	50%	55%
Proton Therapy Patients (Adult)	375	432	492

Source: Table on page 168 of Section Q.

**Step 7: Project DPTC Market Share**

Based on the number of proton therapy-appropriate patients the applicants expect to be referred to the DPTC, the applicants calculate the projected statewide market share, as summarized in the table below:

**Duke Proton Therapy Center  
 Projected Proton Therapy Patients and Market Share Estimates**

	<b>PY 1 FY2021</b>	<b>PY 2 FY2022</b>	<b>PY 3 FY2023</b>
DPTC Patients	375	432	492
Statewide Market Share*	5.2%	5.9%	6.6%

Source: Table on page 169 of Section Q.

\*Based on percentage of total market calculated in Step 4 above.

**Step 8: Project Incremental Market Share (External Referrals)**

In addition to patients referred from within DUHS, the applicants project some additional (“*incremental*”) percentage of patients will be referred to DPTC from other providers, as summarized in the table below:

**Duke Proton Therapy Center  
 Projected Proton Therapy Patients Referred From Other Providers**

	<b>PY 1 FY2021</b>	<b>PY 2 FY2022</b>	<b>PY 3 FY2023</b>
Referrals from Other Providers	0.0%	1.00%	1.25%
Proton Therapy Patients	0	74	93

Source: Table on page 170 of Section Q.

**Step 9: Project Total Adult DPTC Patients**

The applicants then combine their projections of internal and external referrals to the DPTC and re-calculate total projected market share, as summarized in the following table:



**Duke Proton Therapy Center  
 Projected Adult Proton Therapy Patients**

	<b>PY 1 FY2021</b>	<b>PY 2 FY2022</b>	<b>PY 3 FY2023</b>
Statewide Proton Appropriate Cases	7,260	7,361	7,463
Patients Referred from DUHS	375	432	492
Patients Referred from Other Providers	0	74	93
Total Adult DPTC Patients	375	506	586
DPTC Market Share	5.2%	6.9%	7.8%

Source: Table on page 170 of Section Q.

**Step 10: Project Pediatric Patients**

Based on the applicants' experience, they project pediatric patients will represent an additional five percent of total patients. The applicants combine their projections of pediatric patients to be referred to DPTC and combine those projections with their projections of adult patients, as summarized in the following table:

**Duke Proton Therapy Center  
 Projected Total Proton Therapy Patients**

	<b>PY 1 FY2021</b>	<b>PY 2 FY2022</b>	<b>PY 3 FY2023</b>
Adult Proton Therapy Patients	375	506	586
Pediatric Proton Therapy Patients	20	27	31
Total Proton Therapy Patients	395	532	616

Source: Table on page 171 of Section Q.

**Step 11: Project Proton Therapy Treatments**

Based on the applicants' experience, and the experience and opinions of experts in the field, the applicants estimate that proton therapy patients will receive an average of 27.5 treatments per patient. See table on page 172 of the application. Based on the projected number of patients and the projected number of treatments per patient, the applicants project the total number of treatments in the first three operating years, as summarized in the table below:

**Duke Proton Therapy Center  
 Projected Proton Therapy Patients and Treatments**

	<b>PY 1 FY2021</b>	<b>PY 2 FY2022</b>	<b>PY 3 FY2023</b>
Average Treatments Per Patient	27.5	27.5	27.5
Proton Therapy Patients	395	532	616
Proton Therapy Treatments	10,867	14,644	16,964

Source: Table on page 173 of Section Q.

As discussed above, the applicants project utilization of the proposed proton therapy equipment based on statewide cancer incidence data and the historical utilization of DUHS radiation therapy services, as well as the clinical expertise and operational experience of the applicants. Exhibit 14 contains letters from physicians expressing support for the proposed project.

Projected utilization of the proton therapy equipment at DPTC is based on reasonable and adequately supported assumptions. Therefore, the applicant adequately demonstrates the need to acquire the proton therapy equipment at DPTC.

### **Access**

In Section C.10, page 88, the applicants state their commitment to provide services to all patients who need the services regardless of their ability to pay, racial/ethnic origin, age, gender, physical or mental conditions or other conditions that would classify them as underserved. In Section L.3, page 144, the applicants project that 35.9 percent of pediatric proton therapy services will be provided to Medicaid recipients and 50.4 percent of adult proton therapy services will be provided to Medicare and Medicaid recipients at DPTC in the second year of operation following completion of the project. The applicants adequately demonstrate the extent to which all residents, including underserved groups, will have access to the proposed services.

### **Conclusion**

In summary, the applicants adequately identified the population to be served, demonstrate the need the population has for the project and adequately demonstrates the extent to which all residents, including underserved groups, will 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

The applicants do not propose to reduce or eliminate a service or relocate a facility or service. Therefore, Criterion (3a) is not applicable to this review.

- (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.

C

In Section E.2, pages 104-107, the applicants describe the following alternatives:

- Acquire another type of equipment – The applicants state this was not an effective alternative due to the innovations in technology of the selected equipment with regard to cost and clinical capabilities in comparison to other types of equipment.

- Develop a single-room facility – The applicants determined that two rooms would be needed to meet the expected demand for proton therapy services.
- Develop the project at another location – The applicants determined this was not an effective alternative due to the fact that locating the facility on the Durham hospital campus ensures the greatest coordination of care for cancer patients and maximizes the research and training opportunities.
- Develop the project as a joint venture – The applicants state this was not an effective alternative because of the difficulty of identifying a suitable joint venture arrangement.

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 applicable statutory review criteria, and thus, the application is approvable. An application that cannot be approved is not an effective alternative.

In summary, the applicants adequately demonstrate that this 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. Duke-Provision Proton Therapy Center, LLC, Duke University Health System, Inc. and Provision Trust, Inc. shall materially comply with all representations made in the certificate of need application.**
- 2. Duke-Provision Proton Therapy Center, LLC, Duke University Health System, Inc. and Provision Trust, Inc. shall develop no more than one two-room proton therapy center, with one cyclotron and two gantry treatment rooms.**
- 3. Duke-Provision Proton Therapy Center, LLC, Duke University Health System, Inc. and Provision Trust, Inc. shall not acquire as part of this project any equipment that is not included in the project's proposed capital expenditures in Section Q of the application and that would otherwise require a certificate of need.**
- 4. Duke-Provision Proton Therapy Center, LLC, Duke University Health System, Inc. and Provision Trust, Inc. shall develop and implement an energy efficiency and sustainability plan for the project that conforms to or exceeds energy efficiency and water conservation standards incorporated in the latest editions of the North Carolina State Building Codes.**
- 5. No later than three months after the last day of each of the first three full years of operation following initiation of the services authorized by this certificate of need, Duke-Provision Proton Therapy Center, LLC, Duke University Health System, Inc. and Provision Trust, Inc. shall submit, on the form provided by the Healthcare Planning and Certificate of Need Section, an annual report containing the:**

- a. Payor mix for the services authorized in this certificate of need.
  - b. Utilization of the services authorized in this certificate of need.
  - c. Revenues and operating costs for the services authorized in this certificate of need.
  - d. Average gross revenue per unit of service.
  - e. Average net revenue per unit of service.
  - f. Average operating cost per unit of service.
6. **Duke-Provision Proton Therapy Center, LLC, Duke University Health System, Inc. and Provision Trust, Inc. 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

The applicants, DPTC, propose to acquire a two-room proton therapy system to be developed in a new facility to be constructed on the campus of Duke's Lenox Baker Children's Hospital in Durham.

**Capital and Working Capital Costs**

In Section Q, Form F.1a, the applicants state the total capital cost for the proposed project is projected to be as follows:

**Duke Proton Therapy Center Capital Cost**

<b>Cost Category</b>	<b>Projected Capital Cost</b>
Closing Costs	\$1,000,000
Site Preparation	\$762,000
Construction/Renovation	\$14,759,548
Landscaping	\$213,500
Architect/Engineering Fees	\$1,090,000
Medical Equipment	\$41,100,000
Non-Medical Equipment	\$1,000,000
Furniture	\$468,500
Consultant Fees	\$5,500,000
Financing Costs	\$8,000,000
Interest during construction	\$13,500,000
Other (Contingency)	\$1,000,000
<b>TOTAL CAPITAL COST</b>	<b>\$88,394,048</b>

Source: Section Q, Form F.1a of the application.

In Section F.3, pages 110-111, the applicants state that start-up are expected to be \$1,460,000 and initial operating expenses are estimated to be \$2 million, for total working capital required of \$3,460,000.

**Availability of Funds**

In Section F.2, page 109, the applicants state that the \$88,394,048 in project capital costs for the proposed proton therapy facility will be funded by tax-exempt revenue bonds. In Section F.3, page 111, the applicants state that the \$3,460,000 in working capital costs for the proposed proton therapy facility will also be funded by tax-exempt revenue bonds. In Exhibit 12, the applicants provide a letter dated August 1, 2017, from the Managing Director for the Healthcare Finance Group for BB&T Capital Markets documenting its intention to provide tax-exempt bond financing in the amount of \$92 million to finance the proposed project. The applicants adequately demonstrate that sufficient funds will be available for the capital and working capital needs of the project.

**Financial Feasibility**

The applicants provided pro forma financial statements for the first three full fiscal years of operation following completion of the project. In the pro forma financial statements (Form F.4), the applicants project that operating expenses will exceed revenues in the first three full fiscal years of operation of the project, but that the net cash flows for the project will be positive in each of the first three operating years, as shown in the table below.

**Projected Revenue and Expenses for Radiation Oncology Services at UNC Hospitals**

	<b>PY1 FY2021</b>	<b>PY2 FY2022</b>	<b>PY3 FY2023</b>
Total Treatments	10,867	14,644	16,964
Total Gross Revenue (Charges)	\$57,741,540	\$77,810,485	\$90,136,489
Total Net Revenue	\$16,610,953	\$22,384,341	\$25,930,258
Average Net Revenue/Treatment	\$1,529	\$1,529	\$1,529
Total Operating Expenses	\$19,802,624	\$25,083,580	\$26,549,488
Average Operating Expense/Treatment	\$1,822	\$1,713	\$1,565
Net Income (Loss)	(\$3,191,671)	(\$2,699,239)	(\$619,230)
<b>Net Cash Income</b>	<b>\$74,530</b>	<b>\$566,962</b>	<b>\$379,387</b>

The assumptions used by the applicants in preparation of the pro forma financial statements are reasonable, including projected utilization, costs and charges. See Section Q of the application for the assumptions used regarding costs and charges. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference. The applicants adequately demonstrate sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.

**Conclusion**

In summary, the applicants adequately demonstrate the financial feasibility of the project is based upon reasonable and adequately supported assumptions regarding projected utilization, revenues (charges) and operating costs. Therefore, the application is conforming to 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 applicants, DPTC, propose to acquire a two-room proton therapy system to be developed in a new facility to be constructed on the campus of Duke's Lenox Baker Children's Hospital in Durham. The 2017 SMFP does not define a service area for proton therapy equipment. There is currently no proton therapy equipment or centers operating in North Carolina. However, on October 31, 2017, the Agency issued a Certificate of Need to UNC Hospitals (Project I.D. # J-11365-11) to acquire one unit of proton therapy equipment to be located in Chapel Hill (Orange County). In Section G.3, page 116, the applicants state,

*“There is currently no proton therapy provider in the state, and none proposed for Durham County. While UNC Hospitals have proposed a new proton therapy center for Orange County, the proposed projects to serve only 197 patients during its third project year (2024), which is also the equivalent of UNC's proposed equipment capacity (see page 3 of Section Q: Form C Assumptions and Methodology). Therefore, UNC's proposal is insufficient to meet the potential demand based solely on DUHS historical patient volumes (described previously in Section C). The UNC application accordingly recognizes that the need for proton therapy services in the state far exceeds its projected capacity.”*

The applicants adequately demonstrate the need to acquire the proton therapy equipment. The discussion regarding analysis of need found in Criterion (3) is incorporated herein by reference. Therefore, the applicants adequately demonstrate that the proposal would not result in unnecessary duplication of existing or approved services or facilities. Consequently, the application is conforming to 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.

C

In Section Q, Form H, the applicant provides the projected full-time equivalent (FTE) staffing for the proposed proton therapy services at DPTC for each of the first three operating years, as summarized in the table below.

<b>Position</b>	<b>FY2021 FTE</b>	<b>FY2022 FTE</b>	<b>FY2023 FTE</b>
Business Development Manager	1.0	1.0	1.0
Clerical Lead	1.0	1.0	1.0
Clerical (FCC)	1.5	3.0	3.0
Director Medical Physicist	1.0	1.0	1.0
Senior Medical Physicist	2.0	2.5	3.0
Staff Medical Physicist	1.0	1.5	2.0
Dosimetrist	4.0	5.0	6.0
Chief Radiation Therapist	1.0	1.0	1.0
Simulation Radiation Therapist	1.8	2.0	2.0
Radiation Therapist	6.5	10.5	12.0
Research Manager	1.0	1.0	1.0
<b>TOTAL</b>	<b>35.2</b>	<b>51.0</b>	<b>55.0</b>

Source: Form H in Section Q of the application.

In Section H.2, page 121, the applicants describe their experience and process for recruiting and retaining staff. In Section H.4, page 123, the applicants identify Christopher Willett, M.D., as the Medical Director for the DPTC. The applicants adequately demonstrate 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.

C

In Section I.1, page 125, the applicants identify and describe the manner in which they will provide the necessary ancillary and support services. Exhibit 14 of the application contains copies of letters from physicians expressing support for the proposed project. The applicants adequately demonstrate that necessary ancillary and support services are available and that the proposed services will be coordinated with the existing health care system. Therefore, the application is conforming to 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

The applicants do not project to provide the proposed services to a substantial number of persons residing in Health Service Areas (HSAs) that are not adjacent to the HSA in which the services will be offered. Furthermore, the applicants do not project to provide the proposed

services to a substantial number of persons residing in other states that are not adjacent to the North Carolina county in which the services will be offered.

- (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

The applicants are not HMO's. In addition, in Section L.3, page 144, the applicants do not project a payer mix to include HMO's. Therefore Criterion (10) is not applicable.

- (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.

C

The applicants, DPTC, propose to acquire a two-room proton therapy system to be developed in a new facility to be constructed on the campus of Duke's Lenox Baker Children's Hospital in Durham. The proposed two-story facility will be 30,500 square feet. Exhibit 7 contains a certified cost estimate from an architect that estimates construction costs that are consistent with the project capital cost projections provided by the applicants in Section Q, Form F.1a of the application. In Section K.4, pages 131-132, the applicants describe the methods that will be used by the facility to maintain efficient energy operations and contain the costs of utilities. The discussion regarding costs and charges found in Criterion (5) is incorporated herein by reference. The applicants adequately demonstrate that the cost, design and means of construction represent the most reasonable alternative for the proposed addition and renovations, and that the construction cost will not unduly increase costs and charges for health services. Therefore, the application is conforming to this criterion.



(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;

NA

(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 L.2, page 142, the applicants state,

*“DPTC is a new facility, with no federal obligations regarding care, service or access. ... For information purposes, Duke University Health System hospitals have satisfied the requirements of applicable federal regulations to provide, on an annual basis, a certain amount of uncompensated care in return for Hill Burton funds previously received. Further, they comply with the provision of section 501® of the Internal Revenue Code including provisions requiring a published financial assistance policy, limiting charges to self-pay patients, and periodically conducting a Community Health Needs Assessment.”*

In Section L.2, pages 143-144, the applicants state that no civil rights access complaints have been filed against DUHS or the other applicants in the 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 L.3, page 144, the applicants project the following payer mix for proton therapy services during the second operating year (FY2022):

<b>Payor Category</b>	<b>Proton Therapy Services as Percent of Total</b>
Self-Pay/Charity	1.6%
Medicare	44.84%
Medicaid	5.26%
Commercial/Managed Care	45.77%
Other	2.53%
<b>Total</b>	<b>100.0%</b>

Source: Table on page 144 of the application.

On page 144, the applicants state projected payer mix is based on the historical payer mix for radiation therapy services at Duke University Hospital. The applicants adequately demonstrate that medically underserved populations will have 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 L.5, page 145, the applicants describe the range of means by which a person will have access to DPTC's proton therapy services. The applicants adequately demonstrate that the facility will offer a range of means by which patients will have access to the proposed services. Therefore, the application is conforming 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 M.1, page 147, the applicants state that Duke University Hospital serves a clinical training site for a broad range of health professional training programs. Exhibit 13 of the application contains a letter from the Dean of the Duke University School of Medicine expressing their intention to utilize the DPTC as a training site for health professional training programs. The information provided is reasonable and adequately supports a determination that the application is conforming 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 applicants, DPTC, propose to acquire a two-room proton therapy system to be developed in a new facility to be constructed on the campus of Duke's Lenox Baker Children's Hospital in Durham. The 2017 SMFP does not define a service area for proton therapy equipment. There is currently no proton therapy equipment or centers operating in North Carolina. However, on October 31, 2017, the Agency issued a Certificate of Need to UNC Hospitals (Project I.D. # J-11365-11) to acquire one unit of proton therapy equipment to be located in Chapel Hill (Orange County).

In Sections N.1 and N.2, pages 148-154, the applicants discuss how any enhanced competition will have a positive impact on the cost-effectiveness, quality and access to the proposed services. On page 154, the applicants state:

*“As described in Section N.2, this proposed project will have a positive impact on cost effectiveness, quality and access to services for radiation oncology patients in North Carolina. To the extent that DHSR approves both the UNC Hospitals and DPTC CON applications to develop proton therapy centers, and given the overwhelming need for proton therapy capacity in North Carolina, state citizens will benefit from having two experienced and capable providers offering proton therapy services in HSA IV, with both competing, as they do in many other clinical services, to offer cost effective and high-quality services to a broad range of patients.”*

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

One of the applicants, Duke University Health System (DUHS), owns or manages three hospitals in North Carolina. The other two applicants, Duke-Provision Proton Therapy Center, LLC and Provision Trust, Inc., do not own or manage any licensed healthcare facilities in North Carolina. According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, none of the DUHS facilities is currently out of compliance with a CMS Condition of Participation, nor have any other incidents occurred within the eighteen months immediately preceding submission of the application through the date of this decision, for which any sanctions or penalties related to quality of care were imposed by the State on any facility owned and operated by the Duke University Health System. After reviewing and considering information provided by the applicants and by the Acute and Home Care Licensure and Certification Section and considering the quality of care provided at DUHS facilities, the applicants provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to 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

The application is conforming with all applicable Criteria and Standards for Radiation Therapy Equipment. The specific criteria are discussed below.

**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 applicants are 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 applicants are 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 who are projected to receive treatment from the proposed radiation therapy equipment, classified by type of equipment, diagnosis, treatment procedure, and county of residence; and*

**-C-** In Section C.11, page 95, the applicants provide the number of patients who are projected to receive treatment with the proposed proton therapy equipment by diagnosis and treatment procedure. The applicants provide number of patients who are projected to receive treatment with the proposed proton therapy equipment by county of residence in Section C.11, page 96.

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

**-C-** The applicant provides the projected maximum number and types of procedures that the proton therapy equipment is capable of performing in Section C.11, page 97.

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

**-C-** The applicants documented the assumptions and methodology supporting utilization of the proton therapy equipment in Section Q, Form C.