



**Comments on the Duke Cancer Center Green
Level Radiation Oncology Linear Accelerator
Certificate of Need Application,
Project ID # J-12000-20**

December 31, 2020

In accordance with N.C. GEN. STAT. § 131E-185(a1)(1), University of North Carolina Hospitals at Chapel Hill (“UNC Hospitals”) and Rex Hospital, Inc. d/b/a UNC REX Healthcare (collectively, “UNC Health”) submit the following comments related to Duke University Health System, Inc.’s (“Duke’s”) application to acquire, replace, and relocate a linear accelerator (“linac”) from Precision Radiation Oncology Services and acquire a simulator in Wake County. UNC Health’s comments on this application include “*discussion and argument regarding whether, in light of the material contained in the application and other relevant factual material, the application complies with the relevant review criteria, plans and standards.*” See N.C. GEN. STAT. § 131E-185(a1)(1)(c). To facilitate the Agency’s review of these comments, UNC Health has organized its discussion by issue, noting some of the general Certificate of Need statutory review criteria and specific regulatory criteria creating the non-conformity on the application.

General Comments

UNC Health believes the background and history of the linac Duke proposes to acquire is important to this review. As noted in the application, the linac was originally acquired in 2005, before linacs were added to the CON Statute as per se reviewable. The owner of the equipment contended that it had properly acquired the linac for less than the capital threshold at the time, and that a CON was not required. After many years of discussions with the Agency, a no review determination was issued in 2011, and as noted in Table 9E in the *2012 SMFP*, the linac was finally included in the inventory seven years after its acquisition. Thus, the linac in question has never been subject to a need determination or a CON review, and its historical utilization has only ever reported performing more than 200 ESTVs in a single year, in the *2013 SMFP*. Since that time, the linac has performed few, if any, procedures. The linac has never been needed in the service area, and as explained in detail below, is still not needed given the available capacity of existing linacs—including Duke’s—in the service area.

Specific to this application, the proposed linac is not needed in ZIP code 27519, as UNC Health is currently developing its approved linac in the same ZIP code, less than five miles from Duke’s proposed location¹. Duke fails to provide any analysis or otherwise attempt to demonstrate why it needs to acquire an outdated linac, replace it and relocate it to the same area as UNC Health’s approved linac, particularly in a multi-county service area with many other large and growing ZIP codes that do not already have existing or approved linacs. This unnecessary duplication is magnified by the expense of the proposed project, well over \$10 million, and ongoing operational losses projected in all three project years. The proposed project is simply not needed, will not improve access for patients, and will increase costs through ongoing negative net income.

In summary, while the comments below address the specific issues in the application, the following reasons demonstrate why UNC Health believes the proposed project should be denied:

- Duke has sufficient capacity through its existing linacs in Wake County to accommodate the projected utilization.

¹ UNC Health’s approved location is its Panther Creek campus, located at 6715 McCrimmon Parkway, Cary, NC 27519. According to Google Maps, this location is 4.4 miles from Duke’s proposed location at 3208 Green Level West Road, Cary, NC 27519.

- Service Area 20 has the highest surplus of linacs in the state, with sufficient capacity to accommodate significant growth in utilization, far beyond what is projected in the application.
- UNC Health is already approved to develop a linac in the same ZIP code as Duke's proposed facility, less than five miles away.
- Duke's proposal would eliminate the only linac in Franklin County and relocate the equipment to an area already well-served by existing and approved linacs.
- Duke's projected utilization depends heavily on patients from other counties, chiefly Durham, traveling out of their home county and a farther distance for care.
- Duke proposes a freestanding radiation oncology facility, which, unlike other freestanding services, will be more costly for many patients and payors.
- The financial projections are missing numerous necessary expenses, including the staff and services listed in Section I as necessary for the proposed project.
- Even with the understated expenses, the proposal, a freestanding, non-hospital-based service, is projected to have negative income in all three project years, with no demonstration that it will ever be financially feasible.

Given these numerous substantial issues, UNC Health believes the proposed project should be denied.

Issue-Specific Comments

1. Duke fails to demonstrate the need of patients for the proposed project.

In Section C.4, Duke presents the reasons it believes the proposed project is needed, including to replace outdated equipment, to expand access at an alternative site in the service area, to meet the need of the growing/aging population, and to develop an off-campus site with non-hospital charges. While all of these may be factors that led Duke to propose the project, they do not indicate patient need for the project, for several reasons.

First, regarding the outdated equipment, while the equipment may be outdated and need replacing if it is to be used, that does not mean that it is needed by the patients served in Service Area 20. Duke acknowledges in the application that the equipment is not serving patients today and has not served any patients since 2018. As discussed below, there is no need in the service area for the capacity of the linac. Moreover, the linac can be replaced without Duke's acquisition and relocation of it. Thus, the age of the unused equipment does not demonstrate that patients need it to be replaced.

Next, Duke cites the population size and growth at the proposed location, ZIP code 27519 in Cary, Wake County. While UNC Health agrees that this ZIP code is a large and growing one, the need for a linac in this area has already been met, through UNC Health's approved project (J-10318-14) to develop a new linac in the same ZIP code at its Panther Creek campus. This location will allow coordination with other services located on the same campus, including physician services, urgent care, ambulatory surgery and diagnostic imaging. Duke fails to address or even note in its application why it needs to relocate the linac approximately 50 miles and one hour away from its existing location, in a service area spanning two counties with dozens of ZIP codes, to a location only a few blocks from UNC Health's approved linac at Panther Creek. While ZIP code 27519 may be nearly as large as all of Franklin County, as noted in the application, the proposed project would locate a second linac in this area, while depriving Franklin County of any access to radiation oncology services. Clearly this creates more geographic disparity, not less. Of note, Duke has existing and approved health services in Franklin County with which it could coordinate and co-locate the linac, including an approved ASF in Youngsville² and, through its joint venture with LifePoint (Duke LifePoint Healthcare), which owns the hospital in Louisburg, Maria Parham Franklin³. Moreover, Franklin County's population is projected to grow significantly in the next decade, 15.7 percent, which is faster than the state as a whole⁴. Clearly other options exist that meet Duke's criteria, while also not requiring Franklin County residents to be permanently without radiation therapy services, forcing them to drive a significant distance for several weeks for daily radiation treatment.

UNC Health also recognizes the growth and aging of the service area population. However, there is also significant underutilized linac capacity in the service area, including at Duke facilities. The existing and approved capacity will be sufficient to meet the need of the growing population for the foreseeable future—without the development of the

² https://info.ncdhhs.gov/dhsr/coneed/reviews/2016/nov/1231_franklin_sdsf.pdf

³ <https://www.mariaparhamfranklin.com/>

⁴ https://files.nc.gov/ncosbm/demog/countygrowth_2030.html

proposed project to use a linac that has never been needed in the service area. Please see the analysis below regarding the abundant linac capacity in the service area, which has the highest surplus of linacs in the state.

Finally, Duke uses carefully chosen words to describe the difference between freestanding and hospital-based reimbursement for the proposed project. As the Agency is aware, many services are currently reimbursed at a lesser rate for freestanding locations compared to hospitals, such as diagnostic imaging and ambulatory surgery. Radiation oncology treatment does not have the same difference, as UNC Health can attest as it operates both hospital-based and freestanding radiation oncology centers. While the difference varies based on the type of treatment being given and the corresponding billing codes, Medicare payments are virtually the same for both settings. However, commercial payors often reimburse at a higher rate for a freestanding setting compared to a hospital rate. Since Duke projects to provide a significant percentage of its care to commercial payors (43 percent per page 74), and given the minor differences for Medicare, it serves to benefit financially by proposing a freestanding setting, compared to a hospital-based setting. Duke hedged this point by saying that the freestanding center “may” cost significantly less for patients, but certainly it knows that this is likely not the case for the majority of patients.

Based on these issues, the application should be found non-conforming with Criteria 1, 3, 3a, 4, 5, 6, and 18a, as well as the performance standards at 10A NCAC 14C .1903.

2. Duke fails to demonstrate that its projections of patients it proposes to serve are based on reasonable assumptions and that those patients are in need of the proposed project.

In Section Q, starting on page 87, Duke presents its utilization methodology for the proposed project. Duke states that it believes most of the patients it proposes to serve will come from ZIP codes within a 20-minute drive time. While the application states that this is consistent with the majority of its radiation oncology services, no data or analysis is presented to demonstrate the reasonableness of this assumption. Duke then provides the annualized FY 2020 patient volume from those ZIP codes treated at a Duke facility in Durham and Wake counties, and then projects to shift a portion of this volume to the proposed facility.

When the ZIP codes are examined in more detail, it is apparent that many of these ZIP codes are located much closer to other existing Duke facilities. In Step 6, Duke presents the projected shift percentages by ZIP code, and even states on page 90 that geographic proximity may not be the only factor in patient’s choosing a particular facility. While that may be so, it is inconsistent with Section C.4, in which Duke states that the proposed project would expand geographic access for patients. This blatant inconsistency provides further evidence of the lack of the need for the project. Many patients within a 20-minute drive time of the facility already have access to a closer facility, including a Duke facility. The application provides no rationale or evidence that patients living closer to another facility would choose the proposed location. As an example of this issue, the table in Step 6, pages 91 and 92, projects that 117 of the 369 patients in Year 3 will come from Durham County (the first five ZIP codes in the table are in Durham County). Duke is the sole provider of radiation oncology in Durham County with nine linacs and significant available

capacity, as discussed below. There is simply no reason to believe that patients in downtown Durham, for example, which includes ZIP codes 27701 and 27707 and are adjacent to the ZIP code with Duke University Hospital and its eight linacs, would travel a greater distance to the proposed facility. Similarly, Duke projects that patients in Wakefield and other areas of northern Wake County, which are much closer to Duke Raleigh Hospital, will choose to travel to the proposed facility a much greater distance away. Duke has an existing radiation treatment center in Cary, yet it also projects patients in parts of Wake County that are closer to that facility to instead choose the proposed facility. This issue is highlighted by the analysis on page 94, where the application shows that the majority of patients are to be “shifted” to the proposed facility from Duke’s Durham County locations: 197 of the 336 patients in Year 3, or 58.6 percent. Given the proximity of so many patients to the existing Durham facilities, and the comparatively lower utilization of Duke’s Durham County linacs, it is unreasonable to believe that the projected shifts will occur.

The application simply provides no justification for the duplicity it presents: an argument for improved geographic access while expecting a significant portion of its patients to travel farther for the proposed service. Of particular note, radiation treatment is uniquely impactful on patients, given that they are required to travel daily for multiple weeks for treatments. As such, most patients would choose a facility closer to home rather than travel a greater distance for care. Duke acknowledges this fact in the first bullet on page 90 of the application, yet inexplicably ignores it when projecting its utilization.

The other factors presented on page 90 are equally unconvincing. Duke’s other radiation oncology facilities are also located in proximity to other Duke services, so there is no particular difference for the proposed location. Duke also refers to the “potentially” lower cost option, but provides no data to support this claim, because the data would not support this statement. As explained previously, the differences between hospital-based and freestanding reimbursement for radiation therapy is not comparable to that of other services; there is little difference for Medicare and costs are generally higher for commercial payors in a freestanding setting. Duke also claims that capacity constraints will drive patients to the proposed location; however, as explained below, Duke has no capacity constraints on its existing linacs and is unlikely to in the foreseeable future as well.

Based on these factors, the application should be found non-conforming with Criteria 1, 3, 5, 6 and 18a, as well as the performance standards at 10A NCAC 14C .1903.

3. The application fails to demonstrate that the linac is needed in Service Area 20.

Duke’s Available Capacity

In its utilization methodology, Duke focuses on the projected number of patients in order to attempt to demonstrate conformity with the performance standards for linacs, which allow applicants to use either ESTVs or patients. In the last few years, the number of treatments patients receive has generally declined as technology has improved. When the performance standards were developed the utilization of 250 patients or 6,750 ESTVs were usually equivalent, as an average of 27 ESTVs per patient was common ($6,750 \div 250$

= 27). Given current technology, the average number of ESTVs per patient is lower. For example, the 2020 SMFP reports 19,929 ESTVs for Duke Raleigh Hospital in Table 17C-1. Duke Raleigh’s Hospital License Renewal Application for the same year (2019 HLRA with 2018 data) reports 1,063 patients, which equates to 18.7 ESTVs per patient. In Section Q, Duke projects this ratio to decrease, as it has been, by projecting a ratio of 15.5 ESTVs per patient in year 3, based on 5,732 ESTVs (page 94) performed on 369 patients (page 92). Since an ESTV is a measurement of the utilization of the linac, fewer ESTVs per patient mean fewer treatments per patients, with capacity to treat a higher number of patients. Thus, while Duke may use patients in its analysis under the performance standards, an assessment of the ESTVs is helpful in determining whether the linacs are being efficiently used, as described in the first assumption in the SMFP methodology for linacs. Duke also agrees with this definition of capacity, as noted in its response to Section C.6 on page 29. Of note, however, neither the SMFP nor the administrative rules indicate that 6,750 is the maximum capacity of a linac; in fact, the SMFP methodology only triggers a need if the average utilization reaches that point, among other factors, indicating that additional volume can be accommodated, and the SMFP data show that many providers greatly exceed this number of ESTVs.

Today Duke operates four linacs in Wake County and nine in Durham County, the latter of which are relevant because Duke projects to shift a significant portion of volume from its Durham County facilities to the proposed linac. Using an ESTV threshold of 6,750 to demonstrate efficient use, the following table demonstrates the capacity and utilization of Duke’s existing linacs.

Duke Raleigh Hospital	2020 SMFP	2021 SMFP
Capacity (ESTVs)	27,000	27,000
Utilization (ESTVs)	19,929	21,286
<i>ESTVs under threshold (available capacity)</i>	7,071	5,714

Duke University Hospital and Duke Regional Hospital	2020 SMFP	2021 SMFP
Capacity (ESTVs)	60,750	60,750
Utilization (ESTVs)	43,262	42,677
<i>ESTVs under threshold (available capacity)</i>	17,488	18,073

As shown, Duke has considerable additional ESTV capacity on its existing linacs, both in Wake and Durham counties. Of note, Duke’s Durham County facilities experienced a decline in volume from the 2020 to 2021 SMFP, indicating that there may be less volume to shift in the future, and certainly even less need to do so since there are no capacity constraints on Duke’s existing equipment.

Even considering just Duke Raleigh’s existing capacity with four linacs, it has sufficient capacity to serve the projected patients. In Section Q, Duke projects the growth in its

service area based on population growth, 2.1 percent. Applying this percentage growth to Duke’s historical FY 2019 ESTVs through the third project year results in the following projected utilization.

	2019	2020	2021	2022	2023	2024	2025	2026
Utilization (ESTVs)	21,286	21,733	22,189	22,655	23,131	23,617	24,113	24,619
Capacity (ESTVs)	27,000	27,000	27,000	27,000	27,000	27,000	27,000	27,000
ESTVs under threshold	5,714	5,267	4,811	4,345	3,869	3,383	2,887	2,381

Measured on a per linac basis, the projected 24,619 equates to 6,155, clearly less than the efficient utilization standard of 6,750 ESTVs. In other words, if Duke were the only provider in Service Area 20 and it achieved this projected volume, the SMFP methodology would indicate no need for an additional linac. Duke has sufficient capacity on its four existing linacs to accommodate the growth projected in the application. If it wants to expand the number of locations at which it provides care, it can do so by relocating an existing linac.

An alternate analysis, using the projected shifts of patients, demonstrates that Duke still has sufficient capacity on its four existing linacs to accommodate these patients. Page 94 shows that Duke served a total of 1,187 patients (315 + 260 + 612 = 1,187) across its three Wake County sites in 2020. Page 95 projects that these same sites will serve a total of 1,184 patients in 2026. It should be noted here that Duke projects that its existing four linacs, which have significant capacity today, will have even lower utilization following the development of the proposed project, a fact that demonstrates the lack of need for the project. However, considering this projected volume and adding the volume projected for the new linac at Green Level, 369 patients (page 92), Duke projects to serve a total of 1,553 patients on five linacs in 2026 (1,184 + 369 = 1,553). For the proposed new site, Duke projects a total of 5,732 ESTVs (pages 93 and 94), which equates to a total of 15.5 ESTVs per patient (5,732 ÷ 369 = 15.53). Applying this ratio to the total projected number of patients in 2026, 1,553 results in a total ESTV projection of 24,124, fewer ESTVs than projected using the previous analysis. In either case, Duke has sufficient capacity to achieve its projected utilization without the proposed new linac.

Impact on Durham Facilities

While the analyses above demonstrate that the proposed new linac is not needed, even assuming Duke’s utilization projections are reasonable, as discussed previously, Duke’s projected utilization depends on massive shifts of volume from other facilities that are closer to many of the patients currently being served. As also noted above, 197 or 58.6 percent of the projected patients are shifted from Duke’s Durham County facilities. These facilities, however, are utilized at a lower rate than Duke’s Wake County facilities. According to the 2021 SMFP, the two Duke facilities in Durham County provided a total of 42,677 ESTVs in 2019 across nine linacs, or an average of 4,742 per linac. The current efficiency threshold for the nine machines is 60,750 (6,750 x 9 = 60,750), meaning that Duke has more than 18,000 ESTVs of capacity available in Durham County. The application fails to provide these data or conduct any analysis for Duke’s Durham facilities, but it is

clear that Duke is attempting to bolster its Wake County linac volume by projecting to shift volume from Durham, which is part of another service area. By projecting the unreasonable shift of patients that are closer to Duke’s Durham facilities, the application proposes to decrease geographic access for these patients while further increasing the underutilization and available capacity on Duke’s linacs in Durham County. These assumptions once again demonstrate the unreasonableness of Duke’s proposal, the lack of need for the proposed project, and that it would unnecessarily duplicate existing resources with the capacity to accommodate the projected patient volume.

Service Area 20’s Available Capacity

The application also fails to demonstrate the need for the proposed new linac in Service Area 20. According to the most recent data available in the *2021 SMFP*, excluding the unused Franklin County linac, Service Area 20 has the following utilization and capacity:

	Capacity (ESTVs)	2019 ESTVs	Available Capacity (ESTVs)
Duke (4 linacs)	27,000	21,286	5,714
UNC REX (5 linacs)	33,750	26,257	7,493
UNC Panther Creek (1 linac), approved	6,750	0	6,750
Total	67,500	47,543	19,957

As shown, without the linac Duke is proposing to acquire, Service Area 20 has more than sufficient capacity to allow for continued growth for the foreseeable future. Moreover, the approved development of UNC Health’s linac at Panther Creek will provide sufficient capacity in ZIP code 27519 and in western Wake County.

This abundance of capacity is noted in the *2021 SMFP*, which calculates the deficit or surplus in each service area using ESTVs. Table 17C-5 shows that Service Area 20 has a surplus of 3.96 linacs, the highest surplus in the state. Put another way, Service Area 20 accounts for 13 percent of the entire statewide surplus of linacs. All of the existing providers—UNC REX, UNC Hospitals and Duke—have capacity to meet the need of patients seeking care in the service area without the proposed linac. The fact that the linac in question was acquired under the capital threshold in 2005 and scarcely used in the last 15 years does not mean that its capacity is needed in the service area, as shown in the *SMFP*.

Previous Agency Findings

The Agency has previously reviewed applications for linear accelerators without a need determination in the *SMFP*. In 2005, two applications were filed and reviewed together, each for a linac in Service Area 17, which then included Wake, Franklin, Harnett and Johnston counties. In that review, the Agency carefully scrutinized the applications under Criteria 3 and 6, analyzing the need for the projects given existing excess capacity and the

potential impact on existing providers. The relevant excerpts from this review are provided below.

- Project ID # J-7438-05 – Raleigh Hematology Oncology Associates, PC d/b/a Cancer Centers of North Carolina (CCNC)– proposal to acquire a second linac.
- Project ID # J-7451-05 – Johnston Memorial Hospital – proposal to acquire a linac.

Regarding Criterion 3, the Agency found for CCNC: *“Moreover, the applicant did not adequately demonstrate that the eight existing linear accelerators in the service area are adequately utilized and that the addition of a second linear accelerator at the Macon Pond Road facility, for a total of nine linear accelerators in the service area, will not negatively impact the utilization of the existing linear accelerators. Consequently, the applicant did not adequately demonstrate the need for two linear accelerators at the Macon Pond Road facility.”* See Findings, pages 10-11.

For JMH, the Agency found the following for Criterion 3: *“As indicated in the table above, the 8 linear accelerators in the radiation oncology service area would have been utilized at only 72 percent of the minimum performance standard $[38,708/(6,750 \times 8) = 0.72]$ based on the number of procedures performed in FY2005. Also, in the applicant’s proposed service area the existing linear accelerator in Johnston County operated at only 16 percent of the minimum performance standard $[1,093/6,750 = 0.16]$ based on the number of procedures performed in FY2005.... However, the applicant did not adequately demonstrate that the existing linear accelerators in the service area are adequately utilized and that the addition of a linear accelerator at JMH will not negatively impact the utilization of the existing linear accelerators. Also, that applicant did not provide adequate documentation demonstrating that it is reasonable to project 70 percent of all radiation therapy patients in the service area will receive services at the proposed linear accelerator. Consequently, the applicant did not adequately demonstrate the need for a linear accelerator at JMH. In summary, the applicant did not adequately demonstrate the need the population proposed to be served has for an additional linear accelerator, and is not conforming with this criterion.”* See Findings, pages 21-22.

Under Criterion 6 for CCNC, the Agency found: *“As indicated in the table above, based on a minimum performance standard of 6,750 ESTVs, the 8 existing linear accelerators in the applicant’s proposed service area performed only 72 percent of the minimum performance standard $[38,708/(6,750 \times 8) = 0.72]$ based on the number of procedures performed in FY2005. Further, the volume of radiation therapy treatments performed on linear accelerators in the service area has not increased significantly over the most recent four years. Therefore, there is currently adequate linear accelerator capacity to meet the needs of the proposed service area. See Criterion (3) for additional discussion of historical utilization of linear accelerators in Wake and Johnston Counties. Consequently, the applicant failed to adequately demonstrate that acquiring a second linear accelerator will not result in unnecessary duplication of existing health service capabilities.”* See Findings, page 27.

For JMH, the Agency similarly found: *“As indicated in the table above, the existing 8 linear accelerators in the service area would have been utilized at only 72 percent of the minimum performance standard $[38,708/(6,750 \times 8) = 0.72]$ based on the number*

of procedures performed in FY2005. Also, the existing linear accelerator in Johnston County operated at only 16 percent of the minimum performance standard [1,093/6,750 = 0.16] based on the number of procedures performed in FY2005. Further, the volume of radiation therapy treatments performed on linear accelerators in the service area has not increased significantly over the most recent four years. Therefore, there is currently adequate linear accelerator capacity to meet the needs of the proposed service area. See Criterion (3) for additional discussion of historical utilization of linear accelerators in Wake and Johnston Counties. Consequently, the applicant failed to adequately demonstrate the need for an additional linear accelerator to serve the proposed population.” See Findings, page 29.

UNC Health believes that this situation, in which Duke is applying to acquire a linac, replace it and relocate it to Wake County, which has a surplus of linacs, from Franklin County, which will have no linacs, requires a similar analysis of the need to develop the project.

Based on these issues, the application should be found non-conforming with Criteria 1, 3, 3a, 4, 5, 6, and 18a, as well as the performance standards at 10A NCAC 14C .1903.

4. Duke fails to demonstrate the immediate and long-term financial feasibility of its proposal based on reasonable costs and charges.

Missing expenses

Duke projects its expenses on Form F.3 Operating Costs in Section Q, with assumptions on pages to follow. Several of the line items contain no costs, however, though expenses in those categories are likely to be incurred for the proposed service. For example, no expenses are provided for other supplies or utilities; the assumptions refer to costs for drugs and other expenses, but the costs for these items have been left off the pro forma. No costs are provided for dietary, yet the line drawings in Exhibit K.2 indicate space for a nourishment room. Moreover, the costs for medical supplies appear to be understated, particularly if they include any other costs. The assumptions state they are calculated on a per procedure basis, but Duke fails to explain what that per procedure cost is based on. It would appear to be less than \$3 per procedure, based on the projected procedure volume. The maintenance costs are also understated, based on the assumptions, which state that the first year’s expenses include an extremity CT scanner (presumably the simulator, although that is not specified), and that subsequent years will add maintenance for the other equipment plus an inflation factor. However, the only addition in years two and three is the 2% inflation factor. Thus, costs for the additional maintenance for the linac and perhaps other equipment are missing.

The pro forma is also missing expenses for staff (either as direct FTEs or an allocation of overhead costs) noted in Section I, which states on page 61 that the following services will be provided by Duke-employed staff:

- Business office/registration
- Medical records
- Administration

- Materials management
- Quality control
- Clinical engineering

Neither the staffing table in Form H nor any of the expense line items on Form F.3 contain any costs for these staff. The application also states that laundry/housekeeping will be provided through a contract with a third party, and that physics support will be provided through a contract with the School of Medicine. While the financial assumptions do indicate that the costs for the physicist is included in professional fees, no other expenses for these necessary services are included. Of note, while the assumptions do refer to housekeeping/maintenance being included in the building costs, that is the allocation for the building housekeeping and maintenance, not the internal costs for the radiation oncology facility.

While some of these services may be provided by Duke (as a corporate entity) and not by direct staff, Form F.3 contains no line items for indirect costs or any overhead allocation, so the costs for these services are not included. Further, no costs for the contract for housekeeping/laundry services are included, nor is any indication that these services are available or what they would cost (such as a letter from the prospective vendor).

Most critically, as a freestanding radiation oncology center, certified by CMS as a separate provider than any of Duke's existing facilities, the pro formas fail to include staff that are needed to maintain that certification and separation from other providers. No staff are listed on Form H or Form F.3 for reception/registration, yet the line drawings clearly show space for this staff to work to greet and register patients. Page 61 cites to "financial counseling staff" on site, but no FTEs or costs for these staff members are provided. No business office or accounting personnel are provided, either direct or indirect, to accommodate the coding and billing for a freestanding radiation center. No records office staff, either direct or indirect, are provided to separately maintain the patient records for the freestanding radiation oncology center. No staff are provided to negotiate and establish separate contracts for managed care payors for the freestanding radiation oncology center. The application simply fails to demonstrate how it can develop and offer the proposed services, in a separately certified freestanding radiation oncology center, without either the direct staff or expenses that will be paid to Duke (as a corporate entity/separate provider) or another party to provide the services.

Lack of Financial Feasibility

Despite the missing expenses described above, which likely total well into six figures, the proposal is projected to have a net loss in all three project years. In Section F, page 53, the application states that the health system will cover any initial development costs and ongoing operating costs. This statement does not demonstrate the financial feasibility of the proposal, however, for multiple reasons. First, the proposal is for a freestanding radiation oncology center, which may be owned by the health system, but will bill and be reimbursed apart from the existing hospitals. Second, the funding letter in Exhibit F.2 does not indicate that Duke will devote unlimited resources to the project; rather, it limits it to \$15,000,000, of which nearly \$11,000,000 is the capital cost for the project. Given the substantial operating losses projected in all three years, the application certainly does not

establish that sufficient funds are available to offset these losses. Further, the fact that the health system may continue to have positive net income despite these losses does not demonstrate the long-term feasibility of this proposal, which is stated repeatedly as the development of a freestanding, non-hospital-based radiation oncology center. The proposed project is not located on a hospital campus, is not operated as part of a hospital and will bill separately from any existing hospital. While UNC Health recognizes that the Agency has, in the past, allowed applicants for projects that were part of a larger facility to show operating losses in all three project years, such as for a hospital emergency department, when that service was part of and supported a larger facility that did have positive net income. In this case, Duke has chosen to propose a separately certified, freestanding facility, and it must demonstrate the financial feasibility of that proposal, which it has failed to do.

For these reasons, the application should be found non-conforming with Criteria 1, 5, 7, 8 and 18a.