UNC HEALTH CARE

THE UNC HEALTH CARE SYSTEM

4030 BONDURANT HALL
CAMPUS BOX 7000
CHAPEL HILL, NC 27599-7000

T 919.966.4161
F 919.966.8623
roper@med.unc.edu

WILLIAM L. ROPER, MD, MPH
Chief Executive Officer

March 22, 2011

VIA HAND DELIVERY

Ms. Carol Potter
North Carolina Division of Health Service Regulation
Medical Facilities Planning Section
Council Building
701 Barbour Drive
Raleigh, North Carlina 27603

RE: Response by UNC to Novant's Petition to Repeal or Amend Policy AC-3 in the Draft 2012 State Medical Facilities Plan

Dear Ms. Potter:

On behalf of University of North Carolina Hospitals at Chapel Hill ("UNC" or "UNC Hospitals"), please find enclosed for filing its written Response to the Petition filed by Novant Health, Inc. ("Novant") with the State Health Coordinating Council ("SHCC") on March 2, 2011.

Should you have any questions or concerns, please do not hesitate to contact me.

Sincerely,

William L. Roper

WLR:mem

Enclosure

Response By UNC to Novant's Petition To Repeal or Amend Policy AC-3 in the Draft 2012 State Medical Facilities Plan

This Response is filed by the University of North Carolina Hospitals at Chapel Hill ("UNC" or "UNC Hospitals") related to the Petition filed by Novant Health, Inc. ("Novant") with the State Health Coordinating Council ("SHCC") on March 2, 2011 to repeal or amend Policy AC-3 relating to Academic Medical Teaching Center Hospitals ("AMCs") in the draft 2012 State Medical Facilities Plan (the "Draft Plan").

Because Novant's Petition primarily re-states the substance of its prior Petition filed on August 2, 2010, UNC is attaching its Response to that prior Petition as Exhibit A ("2010 Response"). The exhibits that UNC included with its 2010 Response also are included in the attached Exhibit A – see Exhibits A1 and A2 therein. Exhibit A1 to UNC's 2010 Response contains excerpts from UNC's Hillsborough Hospital CON application (Project I.D. No. J-8330-09), which, although not a Policy AC-3 application, discusses at length UNC's AMC teaching and research activities as of 2009 from a broad hospital perspective. As shown in Exhibit A1, UNC is accredited by the Accreditation Council for Graduate Medical Education ("ACGME") for residency and fellowship programs in areas ranging from critical front-line practice areas (such as Emergency Medicine and Family Medicine) to highly specialized fields such as Medical Genetics. Exhibit A2 to UNC's 2010 Response contains excerpts from UNC's Policy AC-3 CON application for a linear accelerator (Project I.D. No. J-8500-10), which discusses UNC's AMC teaching and research activities related to radiation oncology.

It is noteworthy that Novant's Petition fails to refute the contentions raised in UNC's 2010 Response. In particular, UNC notes that pages 4 through 7 of its 2010 Response addresses many of Novant's repeated arguments, including those stating that healthcare has changed since 1983, the AMCs do not need Policy AC-3, Policy AC-3 gives AMCs an unfair advantage, and Policy AC-3 is inconsistent with North Carolina's health planning process. Similar to its 2010 Petition, Novant's 2011 Petition fails to provide any compelling reason for eliminating the long-standing SMFP policy set forth in Policy AC-3. Novant continues to ignore the unique role performed by AMCs in their teaching and research missions. Novant also continues to ignore that Policy AC-3 is a reflection that the Governor and the SHCC have recognized for decades that the hands-on training of our future medical professionals requires the use of certain medical resources at levels not needed outside of the AMC context.

In addition to relying upon its 2010 Response, UNC also cross-references herein its Petition filed on March 2, 2011, to modify Policy AC-3. UNC filed the Petition along with Duke, Baptist and Pitt. UNC will refer to that Petition as the "AMC's Petition." The AMC's Petition discusses the legitimacy of Policy AC-3, the Policy's consistency with the CON Law, and the Policy's recognition of the uniqueness of AMCs.

Because so many of Novant's erroneous contentions were dispelled by UNC's 2010 Response attached as Exhibit A and the AMC's Petition, UNC presents the following abbreviated reasons supporting the denial of Novant's Petition.

I. Policy AC-3 is Consistent with the CON Law and the Health Planning Process

At the outset of its Petition, Novant recognizes that "AMCs may have some unique needs that merit special consideration in the health planning process." (Novant's Petition, p. 1) However, Novant then ignores those unique characteristics and proceeds to paint a false picture of the Certificate of Need ("CON Law") and North Carolina's health planning policy. As shown below, Policy AC-3 is consistent with the CON Law and the health planning process:

- Policy AC-3 furthers the intent of the CON Law by assuring equitable distribution of resources to be used for education and research. Policy AC-3 requires a proposed project to be offered for one of three distinct academic purposes: (1) an expansion of students, residents, or faculty; (2) an expansion of research activities; or (3) to accommodate changes in the requirements of specialty education accrediting bodies. These purposes coincide with the uniqueness of AMCs as presented in their intense devotion to teaching and training in myriad medical practice areas. Without Policy AC-3, the equitable distribution purpose underlying the CON Law would be thwarted as AMCs would be faced with the decision of whether to focus on providing hospital services to patients **or** training medical professionals, instead of focusing on their fundamental purpose of providing both simultaneously. See Exhibit A, p. 6; see also AMC's Petition, pp. 6-8.

- Policy AC-3 furthers the intent of the CON Law by increasing accessibility of health services so that AMCs can achieve their teaching and research missions. The methodologies in the SMFP do not factor in the additional teaching and research requirements of the AMCs, or their need to satisfy requirements of education accrediting bodies.

- For instance, the unique teaching and research missions of AMCs generally result in longer procedure times than in non-AMC settings. See AMC's Petition, pp. 9-10; see also Exhibit A, pp. 5-6. However, the SMFP makes no such distinction for AMCs. In addition, the AMCs have a different patient base than non-AMCs in that the AMCs generally serve much wider service areas than non-AMCs. However, the SMFP need determinations are based on smaller defined service areas, which for most services is a single county. See AMC's Petition, pp. 11-12.

- Because the need methodologies were neither designed, nor could they reasonably be expected to account, for the AMC's teaching and research components, it is logical for the SMFP to contain a policy that allows the AMCs to maintain their academic capabilities by allowing projects to be applied for outside of the SMFP need determinations.

- Policy AC-3 also dovetails with the CON Law by acting as a safety valve on the health planning system to account for the special demands of AMCs, which, as noted above, are not otherwise accounted for in the SMFP health planning methodologies. Policy AC-3 recognizes that AMCs endeavoring to carry out their

teaching and research functions need not tie up every SMFP need allocation to meet their AMC-related demands. This process works because it allows non-AMCs to file for SMFP allocations without being concerned that they must compete in every competitive review cycle against an AMC citing its teaching and research functions as a basis for comparative superiority. With Policy AC-3, more SMFP allocations are thereby freed up for non-AMC applicants like Novant to compete for the reviewable assets.

- The CON Law recognizes the unique place of AMCs within the greater CON structure. In N.C. Gen. Stat. § 131E-183(b), the General Assembly forbade the North Carolina Department of Health and Human Services from requiring AMCs to address utilization-based performance standards in CON applications. By enacting N.C. Gen. Stat. § 131E-183(b), the General Assembly legislatively concluded that the AMCs are not unnecessarily duplicating other CON-regulated services. N.C. Gen. Stat. § 131E-183(b) supports Policy AC-3, and shows that the General Assembly determined that the needs of AMCs are different than non-AMCs. Clearly, if utilization issues do not apply to any CON application filed by an AMC, it is reasonable for the SMFP to have a policy that allows AMCs to file CON applications in narrow situations outside the SMFP need determination process.

- One of the purposes of the CON Law is to foster competition, which is favored because it helps to lower prices and improve quality. See N.C. Gen. Stat. § 131E-183(a)(18a). Policy AC-3 effectuates this purpose by allowing AMCs to utilize Policy AC-3 to satisfy their teaching and research needs, and not interposing those unique teaching and research needs in competitive CON reviews against non-AMCs. A fundamental misconception in Novant's Petition is that the CON Law provides Novant with a right to be free from competition, or that it somehow has a protectable interest in the patients it treats. This is clearly reflected in Novant's proposed modifications to Policy AC-3 to allow a competitor to have veto power on a Policy AC-3 proposal. See Novant's Petition, p. 7. Nothing could be further from the truth. See Bio-Medical Applications v. N.C. Dep't of Health and Human Servs., 179 N.C. App. 483, 491-92, 634 S.E.2d 572, 578 (2006) (no right to be protected against competition). Moreover, there is no language in the CON Law that speaks in terms of a population being aligned with a certain provider.

- There is nothing in the CON Law that restricts or discourages the State of North Carolina from having AMCs or a policy such as Policy AC-3 to address the uniqueness of the AMCs. Indeed, the CON Law contemplates that the SMFP will contain policies such as Policy AC-3 that will be applied in CON reviews. The first statutory review criterion – N.C. Gen. Stat. § 131E-183(a)(1) ("Criterion 1") – requires a project to be consistent with "all applicable policies and need determinations" in the SMFP. Thus, the General Assembly treated "policies and need determinations" equally, and does not permit the CON Section to ignore applicable policies.

- As in its 2010 Petition, Novant continues to assert that the research exemption in N.C. Gen. Stat. § 131E-179(c) obviates the need for Policy AC-3. Novant's contention is without merit. First, the Section 179 exemption is extremely narrow, and only allows exemptions for equipment or services for which there is never a patient charge. In other words, Section 179 is unavailable for clinical research done in conjunction with reimbursed care. Such a narrow use of CON regulated items is so rare that Section 179 has seldom been invoked. Large capital investments in clinical equipment that cannot provide reimbursable services are frequently financially infeasible. Second, that narrow exemption also does not address CON assets needed for the AMC teaching function or to maintain accreditation standards, which constitute two of the three AC-3 elements. See Exhibit A, p. 6; see also AMC's Petition, p. 12.

II. The Uniqueness of the AMCs is Reflected in Policy AC-3

Novant largely ignores the benefits of the AMCs and the unique role they play in North Carolina's health system, and how that role is reasonably advanced by Policy AC-3. The following exemplifies the unique roles of AMCs:

- The depth, quality, and volume of health care services that exist in North Carolina at the local level would be depleted without the AMCs. The AMCs train the overwhelming majority of North Carolina's medical professionals. See AMC's Petition, pp. 6-8. Without the training and educational opportunities afforded by the AMCs, trained providers would not – and in fact could not – enter the non-AMC environment. As a result, without Policy AC-3, equitable geographic access to cost efficient, high quality healthcare services throughout North Carolina would not be realized. This would be contrary to the CON Law, as noted above.

- Furthermore, as described in detail in UNC's 2010 Response attached as Exhibit A, UNC educates more than just medical students. UNC educates a wide array of students being trained to provide health care services, including, but not limited to, the fields of: nursing, pharmacy, laboratory, radiology technologist, radiation oncology technologists, dosimetry, pastoral care, and allied health (physical therapy/occupational therapy). See Exhibit A, p. 5; see also AMC's Petition, p. 6 (showing UNC has 640 medical students plus 738 additional interns, residents and fellows, as well as learners in pharmacy, dentistry, nursing, laboratory, radiology, physical therapy, occupational therapy, and many other allied health programs).

- It also is important to remember the pivotal role of AMCs in the development of modern medicine. AMCs are typically at the forefront of new techniques and technologies. While certain techniques and technologies eventually are performed and available at other facilities, most were developed through the teaching and research functions at AMCs. UNC listed numerous examples in its 2010 Response. See Exhibit A, p. 5; see also AMC's Petition pp. 9-10.

- Unlike non-AMC hospitals like Novant, the AMCs are driven in part by their educational and research missions. It is not just about treating patients or the technology being offered, but the unique needs to educate and perform research. Policy AC-3 addresses this unique component of AMCs.

- Without Policy AC-3, an important avenue to invest in academic resources would be extinguished. Novant makes the bald, self-serving conclusion that Policy AC-3 has not benefited the AMCs. See Novant's Petition, p. 19. The AMC's Petition lists numerous benefits arising from Policy AC-3. See AMC's Petition, p. 10.

III. Novant Shows No Abuse of Policy AC-3

The fallacy in Novant's Petition is further reflected in its failure to show any abuse of Policy AC-3, and its focus upon a single CON case pending between it and Baptist, as shown below:

- Novant is unable to allege any problems it has with Policy AC-3 other than a pending case with Baptist. As UNC contented in its 2010 Response, Novant's attempts to litigate the Baptist appeal in this forum is an abuse of the SHCC process. The CON Section approved the Baptist application. Novant appealed that approval and the issues of Policy AC-3 as applied in that case are now before the Administrative Law Judge ("ALJ"). The judicial process is perfectly capable of resolving Novant's disputes about Baptist. It is simply disingenuous for Novant to preempt that process by complaining about Baptist in this forum. Quite frankly, Novant's continued complaints about Baptist in this forum reflects Novant's lack of confidence about its arguments before the ALJ, and also reflects Novant's attempts to undercut the authority of the ALJ and the Final Agency Decision-maker at the Division of Health Service Regulation.

- Continuing Novant's misrepresentations, Novant's Petition cites UNC as recently being approved for a new imaging center in Orange County and a new community hospital in Orange County. See Novant's Petition, p. 16. Neither were Policy AC-3 applications. Further, there is no "new community hospital" as represented by Novant. UNC assumes that Novant is referring to UNC's Hillsborough campus which will be part of UNC's AMC. UNC's Hillsborough campus will operate as an extension of UNC's AMC with AMC teaching and research functions being performed at that location and will not operate as a community hospital.

- Identical to its 2010 Petition, Novant's 2011 Petition is internally inconsistent in stating that Policy AC-3 is abused while also stating Policy AC-3 is rarely invoked. As UNC detailed in its 2010 Response attached as Exhibit A, Novant's argument that Policy AC-3 is sparingly used undermines Novant's request. If AMCs are seldom and conservatively invoking Policy AC-3, then there is obviously little need for the SHCC to turn its attention to the Policy which, by Novant's own admission, is not being overused. Indeed, the AMCs have used Policy AC-3 only when it is applicable, thereby adhering to the Policy's narrow

focus and respecting its proper place in the health planning process. This is exemplified in Novant's Petition when Novant complains about two UNC's projects and one Pitt project, none of which were Policy AC-3 projects. See Novant's Petition, pp. 6, 16.

- Policy AC-3 projects require the filing of a CON application that undergoes CON review under N.C. Gen. Stat. § 131E-183(a). The CON Section can deny an AC-3 application when it deems it nonconforming with the CON review criteria, which includes nonconformance with Policy AC-3 under Criterion 1. Invocation of Policy AC-3 in no way guarantees an application's approval. Further, as with any other CON application, the public has the right and opportunity to comment on any Policy AC-3 application, and affected persons have the right to commence contested cases to challenge any approval. Thus, Policy AC-3 projects undergo review, just like any other CON application, which thereby provides a safeguard against any abuse. In fact, Novant availed itself of this framework in commenting against the Baptist application and commencing its contested case against Baptist.

IV. Policy AC-3 Continues to Be Necessary

As shown by the data in UNC's 2010 Response to Novant's 2010 Petition and in the AMC's Petition, there is a continuing need to have a flexible health planning policy for the AMCs in North Carolina:

- From 1989 to 2010, the number of interns, residents and fellows training at UNC has increased by 57%. During that same timeframe, the number of specialty areas in which such interns, residents and fellows are trained at UNC increased by 30%. See Exhibit A, p. 4.

- The United States faces a pending shortage of physicians and other health care providers. To address the estimated potential shortage of physicians, the American Association of Medical Colleges has proposed increasing enrollment in medical schools by 30% by 2015.[1] Policy AC-3 is the type of flexible policy that enables AMCs to address physician shortages. In this health care environment, it simply does not make sense to eliminate a flexible health planning tool such as Policy AC-3.

- Reflecting the expansion of medical education, the UNC Board of Governors has already approved the development of UNC-Chapel Hill based medical campuses in Charlotte and Asheville as a first step to address physician shortages.

[1] See AMC's Petition, p. 17 (referencing June 2006 AAMC Statement on the Physician Workforce that can be found at http://www.aamc.org/download/55458/data/workforceposition.pdf).

V. No Need to Repeal or Modify Policy AC-3 as Sought by Novant

As the arguments above underscore, Novant's Petition fails to provide compelling reasons to overturn long-standing SMFP and CON statutory policy. Novant is merely re-hashing the arguments in its previously denied Petition. As this Response and UNC's 2010 Response show, there is no basis to eliminate Policy AC-3 and numerous reasons to support its continuation. Novant's Petition should therefore be denied in all respects, including the proposed adjustments, which Novant proposes as an alternative to abolishing Policy AC-3.

Novant's proposed "modifications" to Policy AC-3 are nothing more than a backhanded way to abolish Policy AC-3 and are contrary to the CON Law and North Carolina's health planning process, as shown below:

- Novant's Proposed Modification #1[2] would require AMCs to file a special needs petition with the SHCC. An AMC could currently file a special needs petition regardless of Policy AC-3, which begs the question of why have Policy AC-3 at all under such a requirement. This is just another way of abolishing Policy AC-3. Furthermore, Novant's suggested analysis of such a petition is so onerous that an AMC would not avail itself of a Policy AC-3 special needs petition over a standard special needs petition.

- Novant's Proposed Modification #2[3] continues the onerous special needs petition requirement by imposing a "clear and convincing" legal standard of proof for when a surplus exists. Such a standard is a legal term of art that imposes a high burden to satisfy. It is just another layer added by Novant to thwart Policy AC-3. This "clear and convincing" standard is not applicable to any other type of special needs petition, which again begs the question of why have the avenue at all when less onerous options are available.

- Novant's Proposed Modification #3[4] would permit anyone, not just the AMC, to apply for the Policy AC-3 need. This requirement undermines the whole reason for Policy AC-3 to exist. The purpose of Policy AC-3 is to assist the AMCs in meeting their teaching and research functions, which cannot be done at non-AMC facilities. To allow a non-AMC to apply for a Policy AC-3 project would be futile because the non-AMC cannot perform the teaching and research functions of the AMC. In other words, the fact that anyone may apply to meet the need eliminates any acknowledgement of the special needs of AMCs, and essentially eliminates Policy AC-3.

- To adopt Novant's modification of opening up a Policy AC-3 review to non-AMCs would almost invariably result in AMCs forgoing the Policy AC-3 option altogether and instead filing in competitive SMFP review cycles when an AC-3

[2] See Novant's Petition, pp. 5-6.

[3] See Novant's Petition, p. 6.

[4] See Novant's Petition, p. 6.

application would have been more appropriate. As pointed out in Part I above, this Novant modification would vitiate the laudable safety valve function of Policy AC-3.

- The reporting requirements (Proposed Modifications #4 and #6)[5] suggested by Novant are unnecessary and onerous. Hospitals do not typically track utilization and patient origin by bed or specific piece of equipment. Rather, those items are typically tracked by unit, department, or service line. Moreover, unless all CON recipients are now going to be required to track similar data for each CON asset in exchange for the right to receive a CON, it makes little policy sense to require each Policy AC-3-acquired asset to be subjected to these onerous requirements. Policy AC-3 applications are not demonstration projects.

- Further, under Novant's approach, an AMC-approved applicant would have reporting obligations that a non-AMC-approved applicant would not have, even though both would be competitive in a CON review. Not only is this patently unfair, this undoubtedly would be used by each non-AMC applicant to argue that their project is comparatively superior to the AMC project.

- Novant also suggests a modification (Proposed Modification #5),[6] which essentially would give an AMC's competitor veto power over an AC-3 application and defeat the entire purpose of Policy AC-3. A CON applicant under Policy AC-3 is already required to show that competitors within a 20-mile radius cannot meet the need proposed in the AC-3 application. See text of Policy AC-3. The current Policy is sound, which requires the CON Section to make that determination. Novant's proposal would allow a competitor to veto an AC-3 application any time that competitor either: (a) asserts that it was meeting the need; or (b) simply refuses to provide a letter of support asserting that the competitor does not meet the need. Novant's Proposed Modification #5 should be rejected for the same reasons that the CON statute and rules do not now require a letter of support from all competitors for any CON application to be approved.

- Furthermore, Proposed Modification #5 is anti-competitive because it would allow the CON process to be used by a competitor to bar projects. This is contrary to the competition purpose underlying the CON Law. See Part I above.

- Finally, Novant suggests rulemaking in Proposed Modification #7, which is outside the purview of the SHCC and Planning Section to consider.

It is clear that Novant's proposed adjustments are simply a thinly veiled attempt to totally abolish Policy AC-3 by thwarting its purpose. Novant completely misses the point of the need to have a flexible health planning policy such as Policy AC-3.

---

[5] See Novant's Petition, pp. 6-8.

[6] See Novant's Petition, p. 7.

Conclusion

UNC requests that the SHCC deny Novant's Petition to repeal or modify Policy AC-3 in the Draft Plan because:

1. Novant's Petition requests repeal of, or substantial modifications to, a long-standing SMFP policy without compelling reasons; and

2. Novant is improperly seeking to litigate its contested case against the CON Section and Baptist through this SHCC Petition. This is not the appropriate forum for such a dispute.

Exhibits

A. UNC's Response to Novant's August 2, 2010 SHCC Petition

A1. Excerpts from UNC's Hillsborough Hospital CON application.
(p. 1, pp. 238-251)

A2. Excerpts from UNC's Policy AC-3 CON application for a linear accelerator.
(p. 1, pp. 33-41, pp. 65-75)

UNC HEALTH CARE

THE UNC HEALTH CARE SYSTEM

4030 BONDURANT HALL
CAMPUS BOX 7000
CHAPEL HILL, NC 27599-7000

T 919.966.4161
F 919.966.8613
roper@med.unc.edu

WILLIAM L. ROPER, MD, MPH
Chief Executive Officer

Received and accepted by Carol S. Potter DHSR Planning 8/20/2010 at 1:10 pm.

August 20, 2010

VIA HAND DELIVERY
Ms. Carol Potter
North Carolina Division of Health Service Regulation
Medical Facilities Planning Section
2714 Mail Service Center
Raleigh, North Carolina 27699-2714

RE: Response By UNC to Novant's Petition To Repeal or Amend Policy AC-3 in the Draft 2011 State Medical Facilities Plan

Dear Ms. Potter:

On behalf of University of North Carolina Hospitals at Chapel Hill ("UNC" or "UNC Hospitals"), please find enclosed for filing its written Response to the untimely request filed by Novant Health, Inc. ("Novant") with the State Health Coordinating Council ("SHCC") on August 2, 2010.

Should you have any questions or concerns, please do not hesitate to contact me.

Sincerely,

William L. Roper

WLR:mm

Enclosure

EXHIBIT
tabbies
A

Response By UNC to Novant's Petition To Repeal or Amend Policy AC-3 in the Draft 2011 State Medical Facilities Plan

This Response is filed by the University of North Carolina Hospitals at Chapel Hill ("UNC" or "UNC Hospitals") related to the untimely request filed by Novant Health, Inc. ("Novant") with the State Health Coordinating Council ("SHCC") on August 2, 2010 to repeal or amend Policy AC-3 relating to Academic Medical Centers ("AMCs") in the draft 2011 State Medical Facilities Plan (the "Draft Plan").

Background

UNC is the only State-owned teaching hospital in North Carolina. UNC Hospitals, as an entity, consists of the North Carolina Memorial Hospital, the North Carolina Children's Hospital, the North Carolina Neurosciences Hospital, the North Carolina Women's Hospital and the North Carolina Cancer Hospital. It is governed and administered as an affiliated enterprise of the University of North Carolina System.

UNC Hospitals is a public, academic medical center operated by and for the people of North Carolina. UNC's mission is to provide high quality patient care, to educate health care professionals, to advance research, and to provide community service. UNC Hospitals serves as a clinical teaching site for a broad range of health care disciplines, including residency and fellow training programs operated by UNC Hospitals and the School of Medicine at UNC-Chapel Hill. We have included, as Exhibit 1 to this Response, excerpts from UNC's recent Hillsborough Hospital CON application (Project I.D. No. J-8330-09) which, although not a Policy AC-3 application, discuss at length UNC's AMC teaching and research activities as of 2009 from a broad hospital perspective. We have also included, as Exhibit 2 to this Response, excerpts from UNC's recent Policy AC-3 CON application for a linear accelerator (Project I.D. No. J-8500-10), which discuss UNC's AMC teaching and research activities related to radiation oncology. As of 2010, UNC was training 738 fellows and residents at UNC Hospitals, in numerous fields. See Exhibit 2.

Novant's Request for Statewide Draft Plan Change

On August 2, 2010, Novant filed its request with the SHCC to amend the Draft Plan by seeking to repeal or substantially modify Policy AC-3, a statewide policy. UNC adamantly opposes Novant's proposed amendment to the Draft Plan. Summarized (and then more fully described) below are multiple, independent reasons to deny Novant's request. Any one of these reasons, by itself, justifies denial. The reasons are as follows:

1. The request is not timely and should be denied on that basis alone. Novant requests a change in a basic policy, Policy AC-3, in the Draft Plan, which has a statewide impact. Thus, per the SMFP's filing deadlines, Novant's Petition was required to be filed on or before March 3, 2010. See 2010 SMFP, pp. 9-10.
2. Novant's request, even were it timely filed, requests repeal of, or substantial modifications to, a long-standing SMFP policy without any compelling reasons. In the discussion below, UNC refutes each point raised by Novant as a purported reason to repeal or modify Policy AC-3.

3. Novant spends quite a number of pages in its Petition on specific arguments about a specific CON application which Novant opposes. That appears to be the real reason that Novant filed this SHCC Petition, and filed it untimely – to seek some leverage in that private dispute. Novant has filed a contested case in the Office of Administrative Hearings ("OAH") challenging the CON Section's approval of a Policy AC-3 CON application filed by N.C. Baptist Hospitals ("Baptist"). In that case, Novant is alleging that Baptist misused Policy AC-3. Novant is improperly seeking to litigate its contested case against the CON Section and Baptist through this SHCC petition. This is not the appropriate forum for such a dispute.

Each of these comments is more fully described in the discussion set forth below.

1. Novant's Request Is Not Timely

Novant's request is untimely. As explained below, Novant's request proposes a change in one of the Draft Plan's basic policies, which has a statewide impact. Thus, Novant's Petition was required to be filed on or before March 3, 2010. See 2010 SMFP, pp. 9-10.

As a result of the statewide impact of Novant's proposed change, Novant was required to submit its proposed changes to the Draft Plan over five months ago. The 2010 SMFP clearly states *"People who wish to recommend changes that may have a statewide effect are asked to contact the Medical Facilities Planning staff as early in the year as possible, and to submit petitions no later than March 3, 2010. These types of changes will need to be considered in the first four months of the calendar year as the 'Proposed N.C. State Medical Facilities Plan' . . . is being developed."* See 2010 SMFP, p. 9.

Adjustment to Need Determination Petitions, as opposed to Petitions for Changes in Basic Policies and Methodologies, may be submitted later in the planning process. However, Novant's request is clearly not seeking an Adjustment to Need Determinations. On page 11 of the 2010 SMFP, Adjustment to Need Determinations are described as appropriate for *"People who believe that unique or special attributes of a particular geographic area or institution give rise to resource requirements that differ from those provided by application of the standard planning procedures and polices..."* See also 2010 SMFP, p. 11. Novant's request does not address the unique attributes of a geographic area or institution, and thus Novant's Petition is not an appropriate request at this stage of the planning process.

Petitions proposing a statewide impact and changes to existing SMFP policies require careful consideration. That is why the SMFP, each year, requires that such substantial modifications be filed early in the year's planning process. Novant's efforts to force a statewide policy change into the Fall SMFP schedule – toward the end of the process, which is reserved for special needs petitions – contravenes the very thoughtful timetable which the SHCC and the Planning Section have established for consideration of "statewide impact" petitions.

2. **In Any Event, Novant's Request Should be Denied.**

Even if the request were specific to the unique circumstances of an institution or geographic area (which it is not), Novant does not make a persuasive argument to change a long-standing SHCC policy. Novant has the burden of demonstrating compelling reasons why such a long-standing policy should be abandoned or substantially altered.

For reference purposes, we have set forth below Policy AC-3:

> POLICY AC-3: EXEMPTION FROM PLAN PROVISIONS FOR CERTAIN ACADEMIC MEDICAL CENTER TEACHING HOSPITAL PROJECTS[1]
>
> Projects for which certificates of need are sought by academic medical center teaching hospitals may qualify for exemption from the need determinations of this document. The Medical Facilities Planning Section shall designate as an Academic Medical Center Teaching Hospital any facility whose application for such designation demonstrates the following characteristics of the hospital:
>
> 1. Serves as a primary teaching site for a school of medicine and at least one other health professional school, providing undergraduate, graduate and postgraduate education.
>
> 2. Houses extensive basic medical science and clinical research programs, patients and equipment.
>
> 3. Serves the treatment needs for patients from a broad geographic area through multiple medical specialties.
>
> Exemption from the provisions of need determination of the North Carolina State Medical Facilities Plan shall be granted to projects submitted by Academic Medical Center Teaching Hospitals designated prior to January 1, 1990 provided the projects comply with one of the following conditions:
>
> 1. Necessary to complement a specified and approved expansion of the number or types of students, residents or faculty, as certified by the head of the relevant associated professional school; or
>
> 2. Necessary to accommodate patients, staff or equipment for a specified and approved expansion of research activities, as certified by the head of the entity sponsoring the research; or

[1] *See* 2010 SMFP, Chapter 4, at pages 23-24.

3. Necessary to accommodate changes in requirements of specialty education accrediting bodies, as evidenced by copies of documents issued by such bodies.

A project submitted by an Academic Medical Center Teaching Hospital under this Policy that meets one of the above conditions shall also demonstrate that the Academic Medical Center Teaching Hospital's teaching or research need for the proposed project cannot be achieved effectively at any non-Academic Medical Center Teaching Hospital provider which currently offers the service for which the exemption is requested and which is within 20 miles of the Academic Center Teaching Hospital.

Any health service facility or health service facility bed that results from a project submitted under this Policy after January 1, 1999 shall be excluded from the inventory of that health service facility or health service facility beds in the North Carolina State Medical Facilities Plan.

Discussion of Novant's Purported Reasons for Proposed Adjustment

The discussion below addresses each of Novant's points, using the same numbering and lettering for headings as Novant's SHCC Petition.

I. Novant Argues That Policy AC-3 is No Longer Necessary.

A. Novant Argues that Healthcare has changed dramatically since 1983.

Novant first argues that, because the healthcare environment has changed since Policy AC-3's (or its predecessor provision's) inception in 1983, the policy is no longer needed. In that context, Novant focuses on some transitions, since 1983, to outpatient services and argues that there is now more parity among hospitals (AMCs and non-AMCs) in terms of technology and the sophistication of services offered.

However, these arguments miss the point of Policy AC-3. As the above-quoted language shows, the focus of Policy AC-3 is on AMC teaching and research functions, and the need to have flexible health planning policies when AMC projects are needed to complement and accommodate such functions. In fact, the converse of Novant's argument is true. Since 1983, the clinical resource demands associated with AMC teaching and research have only increased. UNC's data shows that, since 1989, the number of interns, residents and fellows training at UNC has increased by 57%.[2] Moreover, during that same timeframe, the number of specialty areas in which such interns, residents and fellows are trained at UNC increased by 30%.[3] Thus, not only

[2] Between 1989 and 2010, the number of interns, residents and fellows training at UNC has increased from 469 to 738. Similar data was not available from 1983, when Policy AC-3's predecessor provision was first adopted, but the 1989 comparison should be a more conservative number than if 2010 data were compared with 1983 data.

[3] Between 1989 and 2010, the number of specialty areas in which interns, residents and fellows train at UNC has increased from 50 to 65.

has UNC experienced increased demands on its medical assets with respect to the number of medical trainees, UNC has also seen increased demands as a result of the significant increase in the number of medical practice areas in which training now occurs.

Further, it is important to emphasize that UNC educates more than just medical students. UNC educates a wide array of students being trained to provide health care services, including, but not limited to, the fields of: nursing, pharmacy, laboratory, radiology technologist, radiation oncology technologists, dosimetry, pastoral care, and allied health (physical therapy/occupational therapy).

It is also important to remember the pivotal role of AMCs in the development of modern medicine. By way of example, among the many advances pioneered at America's medical schools and teaching hospitals are the following:

- First Live polio vaccine
- First successful pancreas transplant
- First successful bone marrow transplant
- First intensive care unit for newborns
- First human gene therapy for cystic fibrosis
- First adult human heart transplant in the United States
- First successful liver transplant
- First successful pediatric heart transplant
- First successful surgery on a fetus in utero
- First to discover that adult heart diseases begin in childhood
- First to discover the genetic markers that increase risk of multiple myeloma, a deadly cancer of the blood

See Association of American Medical Colleges Website, Article entitled "What Roles Do Teaching Hospitals Fulfill?"

Policy AC-3 is a long-standing recognition by the Governor and the SHCC of the unique role that AMCs play in the healthcare field. The role extends beyond comparing which hospitals have the newest technology or which specialty hospital might have a high acuity factor. The uniqueness of the AMCs lies, in part, in their intense devotion to teaching in myriad medical practice areas, and not just highly specialized practice areas. As Exhibit 1 illustrates, UNC has ACGME[4] accredited residency and fellowship programs in areas ranging from critical front-line practice areas (such as Emergency Medicine and Family Medicine) to highly specialized fields such as Medical Genetics.

When viewed in this broader context, it is quite irrelevant that Novant's Petition boasts of a high case mix index for its narrow scope of orthopaedic patients at Presbyterian Orthopaedic Hospital. See Novant Petition, p. 7. For decades now, the Governor and the SHCC have recognized – through Policy AC-3 – that the hands-on training of our future medical professionals requires the use of certain medical resources (e.g., operating rooms, linear accelerators) at levels not needed outside of the AMC context. As UNC's recent AC-3 application discusses, "resident involvement in treatment can make treatment delivery slower." See Exhibit 2, p. 33. This is one

[4] ACGME is the Accreditation Council for Graduate Medical Education.

example of additional medical resource capacity consumption that non-AMCs do not experience at the same levels as AMCs. Were it not for the Policy AC-3 option of applying for resources outside of the SMFP need determination process, AMCs would sometimes be faced with the decision of whether to focus on providing hospital services to patients or training medical professionals, instead of focusing on the AMCs fundamental purpose of providing both simultaneously. Thus, Policy AC-3 promotes the public good performed by AMCs such as UNC, by providing an essential option available to AMCs to facilitate that public good.

B. Novant Argues That The AMCs Do Not Need Policy AC-3.

Novant's Petition is internally inconsistent and proves the point that AC-3 should not be repealed or changed. First, Novant contends that the "the relative lack of activity under Policy AC-3 suggests that the AMCs do not rely heavily on Policy AC-3 to address their teaching and research needs or other healthcare activities." See Novant Petition, p. 8. But then Novant inconsistently expresses concern that Baptist is abusing the Policy AC-3 process by allegedly aggressive use. See Novant Petition, p. 10-14. Novant cannot have it both ways. Novant's Petition cannot make up its mind about whether AMCs are not using Policy AC-3 enough or using it too much.

Novant's argument that Policy AC-3 is sparingly used undermines Novant's request. If AMCs are seldom and conservatively invoking Policy AC-3, then there is obviously little need for the SHCC to turn its attention to a policy which, by Novant's own admission, is not being overused. Indeed, the AMCs have used Policy AC-3 only when it is applicable, respecting the policy's proper place in the health planning process. Also, Novant's Petition ignores the fact that the CON Section can deny an AC-3 application when the Section deems it nonconforming, either because it is inappropriate under Policy AC-3's terms or otherwise nonconforming with the review criteria. Invocation of Policy AC-3 in no way guarantees an application's approval. Moreover, as previously articulated, if Novant has a concern about Baptist's use of Policy AC-3 in Baptist's recent approval, Novant's recently initiated contested case is the forum in which to address that concern.

Novant also argues that the research exemption in N.C. Gen. Stat. §131E-179(c) of the CON statute obviates the need for Policy AC-3. First, the Section 179 exemption is extremely narrow, and only allows exemptions for equipment or services for which there is never a patient charge. Such a narrow use of CON regulated items is so rare that Section 179 has seldom been invoked. Second, that narrow exemption also does not address CON assets needed for the AMC teaching function, which constitutes two of the three AC-3 elements.

II. Novant's Assertion that Policy AC-3 Gives Academic Medical Centers an Unfair Advantage.

In asserting AMCs unfair advantage, Novant's Petition is internally inconsistent and proves the opposite point. First, Novant complains that Policy AC-3 sometimes allows AMCs to avoid filing for projects in competitive SMFP need determination review cycles. Indeed, the whole purpose of Policy AC-3 is to recognize that AMCs endeavoring to carry out their teaching and research functions need not tie up every SMFP need allocation to meet their AMC-related demands. This process works because it allows non-AMCs to file for SMFP allocations without being concerned that they must compete in every competitive review cycle against an AMC

citing its teaching and research functions as a basis for its comparative superiority. With Policy AC-3, more SMFP allocations are thereby freed up for non-AMC applicants like Novant to compete for the reviewable assets. In this sense, Policy AC-3 acts as a safety valve on the health planning system to account for the demands of AMCs, which are not otherwise accounted for in the SMFP health planning methodologies. See Part III below.

Novant spends a substantial portion of its Petition seeking to litigate – before the SHCC – its case against Baptist's most recent AC-3 application. This is an abuse of the SHCC process. Novant has a pending case before OAH wherein its grievances against the Baptist application, and the CON Section's approval thereof, will be heard and ruled upon. This section of the Novant Petition makes clear that Novant's SHCC Petition, belatedly filed, is just a means by which to seek some leverage in its current litigation against Baptist and the CON Section.

III. Novant's Assertion that Policy AC-3 Is Inconsistent with North Carolina's Health Planning Process.

Novant finally contends that Policy AC-3 is inconsistent with the SMFP planning process. To the contrary, the SHCC and Governor decided years ago that the SMFP's statistically-driven need methodologies do not factor in the idiosyncratic needs of each AMC based on its teaching and research demands, which can flex in response to the unique demands of each AMC. As mentioned in Part II above, this is where Policy AC-3 acts as a safety valve to allow projects to be applied for outside of the SMFP need determinations because the need methodologies were never designed to account for these AMC components. However, the increased needs of AMCs that result in Policy AC-3 CON applications are sufficiently frequent and imminently arising that the special needs petition process is inadequate to the task.

Moreover, the fallacy in Novant's argument that Policy AC-3 is inconsistent with North Carolina health planning policy is further supported when one realizes that the General Assembly, in the CON statute itself, recognized the unique place of AMCs within the greater CON structure. In N.C. Gen. Stat. §131E-183(b), the General Assembly forbade the Department of Health and Human Services from adopting CON rules which would require AMCs to address certain levels of unnecessary duplication in a CON application. N.C. Gen. Stat. § 131E-183(b) states:

> 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 conduced 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.

See N.C. Gen. Stat. § 131E-183(b) (emphasis added).

Novant's Proposed Adjustments to Policy AC-3

As the arguments above underscore, Novant's Petition is untimely and fails to provide compelling reasons to overturn long-standing SMFP and CON statutory policy. Novant's Petition should therefore be denied in all respects, including the proposed adjustments which Novant proposes as an alternative to abolishing Policy AC-3.

Novant offers suggested modifications, such as Proposed Modification #1,[5] which would forbid the use of Policy AC-3 when an SMFP surplus exists. This is just another way of abolishing Policy AC-3. Most assets subject to CON in North Carolina are also subject to SMFP need determinations. Need determinations only exist when there are SMFP asset deficits rather than surpluses. To adopt Novant's modifications would almost invariably require an AMC to file in a competitive SMFP review cycle when an AC-3 application would have been more appropriate. As pointed out in Part II above, this Novant modification would vitiate the laudable safety valve function of Policy AC-3.

The reporting requirements (Proposed Modifications #2 and #4)[6] suggested by Novant are unnecessary and onerous. Hospitals do not typically track utilization and patient origin by bed or specific piece of equipment. Rather, those items are typically tracked by unit, department, or service line. Moreover, unless all CON recipients are now going to be required to track similar data for each CON asset in exchange for the right to receive a CON, it makes little policy sense to require each Policy AC-3-acquired asset to be subjected to these onerous requirements. Policy AC-3 applications are not demonstration projects.

Novant also suggests a modification (Proposed Modification #3),[7] which essentially would give an AMC's competitor veto power over an AC-3 application and defeat the entire purpose of Policy AC-3. A CON applicant under Policy AC-3 is already required to show that competitors within a 20-mile radius cannot meet the need proposed in the AC-3 application. See page 4 above (text of Policy AC-3). The current policy is sound, which requires the CON Section to make that determination. Novant's proposal would allow a competitor to veto an AC-3 application any time that competitor either: (a) asserts that it was meeting the need; or (b) simply refuses to provide a letter of support asserting that the competitor does not meet the need. Novant's Proposed Modification #3 should be rejected for the same reasons that the CON statute and rules do not now require a letter of support from all competitors for any CON application to be approved.

Finally, Novant suggests rulemaking in Proposed Modification #5, which is outside the purview of the SHCC and Planning Section to consider.

It is clear that Novant's proposed adjustments are simply a thinly veiled attempt to totally abolish Policy AC-3 by thwarting its purpose.

---

[5] See Novant Petition, p. 17.

[6] See Novant Petition, p. 17-19.

[7] See Novant Petition, p. 18.

Conclusion

UNC requests that the SHCC deny Novant's request to repeal or modify Policy AC-3 in the Draft Plan because:

1. The request is not timely and should be denied on that basis alone. Novant requests a change in a basic policy, Policy AC-3, in the Draft Plan, which has a statewide impact, and thus was required to be filed on or before March 3, 2010, per the specific provisions of the SMFP. See 2010 SMFP, pp. 9-10.
2. Novant's request, even were it timely filed, requests repeal or substantial modifications to a long-standing SMFP policy without compelling reasons.
3. Novant is improperly seeking to litigate its contested case against the CON Section and Baptist through this SHCC petition. This is not the appropriate forum for such a dispute.

Exhibits

1. Excerpts from UNC's Hillsborough Hospital CON application. (p. 1, pp. 238-251)
2. Excerpts from UNC's Policy AC-3 CON application for a linear accelerator. (p. 1, pp. 33-41, pp. 65-75)

Certificate of Need Application
ACUTE CARE FACILITY/
MEDICAL EQUIPMENT PROJECT
State of North Carolina, Department of Health and Human Services

Received by the
CON Section
15 APR 2009 01 : 03

OFFICE USE ONLY
Project I. D. Number: J-8330-09
Proposal Type: _____
Batch Category: _____
Beginning of Review: _____

I. IDENTIFICATION

1. **Legal Name of the Applicant: The applicants are the legal entities (i.e., persons or organizations) that will own the facility and any other persons who will offer, develop or incur an obligation for a capital expenditure for the proposed new institutional health service.**

University of North Carolina Hospitals at Chapel Hill ("UNC Hospitals")
(Name of Applicant)

101 Manning Drive
(Street & Number)

Chapel Hill (City) NC (State) 27514 (Zip) Orange (County)

2. **Name of Parent Company (if applicable): Response:** Not Applicable

3. **Person to whom all correspondence and questions regarding this application should be directed:**

Dee Jay Zerman (Name) Associate Director of Planning (Title)

Herdick Office Building, Suite G050, 211 Firday Center Drive, Chapel Hill, NC 27517
(Street & Number) (City) (State) (Zip)

919-966-1129 (Telephone #, including area code and extension) 919-966-3815 Fax #

dzerman@unch.unc.edu
Email Address

EXHIBIT A1

4. **Name of Lessor (If applicable):** **Response:** Not Applicable

5. **Name of Lessee (If applicable):** **Response:** Not Applicable

6. **Name of Management Company (If applicable):** **Response:** Not Applicable

EXHIBIT 1

V. COORDINATION WITH EXISTING HEALTH CARE PROVIDERS

1. (a) **Describe how the proposed project relates to the clinical needs of health professional training programs in the area, including any anticipated relationships.**

   (b) **Indicate the extent to which the schools in the area will have access to the facility for health professional training purposes.**

Responses to (a) and (b): The clinical components of the project currently serve, and will continue to serve, as resources for undergraduate, graduate and post graduate medical and other health science education programs for the University of North Carolina - Chapel Hill. Health professional training requires opportunities to participate in realistic patient care encounters in a variety of clinical settings. UNC Hospitals serves as a clinical teaching site for a broad range of health care disciplines including medical, dental, public health, pharmacy and nursing students, as well as post-graduate residents and trainees and students in medical technology, physical therapy, radiologic technology, respiratory care, phlebotomy, occupational therapy, pastoral care, and many more. The University of North Carolina at Chapel Hill is the *only* Academic Medical Center in North Carolina that has all 5 of the health professional schools with students actively learning at their affiliated teaching hospital. In addition, they serve as major foci for the residency and fellow training programs operated by UNC Hospitals and the School of Medicine at UNC-CH. Some details of various educational components are discussed below.

Part of the primary mission of the medical / surgical units is to provide a quality educational experience for trainees and to provide an environment to foster academic activities and enhance the scientific foundations of the field. The faculty participates in a wide range of educational activities. These activities include patient rounds, medical student lectures, departmental morning conferences and grand rounds, resident-oriented conferences in other departments/schools, grand rounds in other departments, community educational programs, CME lectures at outside hospitals/institutions, lectures, and lectures at state and national meetings.

Many fellowship-training programs are sponsored through the clinical departments and various divisions. These programs provide comprehensive education in the management of all varieties of diseases and conditions unique to sub-specialty patients. Following is a listing of residencies and fellowships that are ACGME accredited:

Allergy & Immunology
Anesthesiology
Pediatric Anesthesiology
Anesthesiology/Critical Care
Anesthesiology/Pain Medicine
Dermatology
Emergency Medicine
Bloodbanking/Transfusion Med.
Cytopathology
Forensic Pathology
Hematology
Neuropathology
Pediatrics
Pediatrics/Critical Care

Family Medicine
Medical Genetics
Internal Medicine
Internal Medicine/Cardiovascular
Internal Medicine/Endocrinology
Internal Medicine/Gastroenterology
Internal Medicine/Infectious Disease
Internal Medicine/Nephrology
Internal Medicine/Rheumatology
Internal Medicine/Geriatric Medicine
Internal Medicine/Interventional Cardiology
IM/Clinical Cardiac Electrophysiology
IM/Hematology/Oncology
IM/Pulmonology/Critical Care
Surgery/Neurosurgery
Neurology
Neurology/Child
Molecular Genetic Pathology
Nuclear Medicine
Obstetrics & Gynecology
Ophthalmology
Orthopaedic Surgery
Otolaryngology
Pathology/Anatomic and Clinical
Pediatrics/Endocrinology
Peds/Hematology/Oncology
Pediatrics/Nephrology
Neonatal/Perinatal Medicine
Pediatrics/Pulmonology
Developmental/Behavioral Peds
Physical Medicine & Rehab
Surgery/Plastics
Preventive Medicine
Psychiatry
Psychiatry/Child/Adolescent
Psychiatry/Forensic
Radiology/Diagnostic
Radiology/Neuroadiology
Rad/Vascular and Interventional
Radiation Oncology
Surgery/General
Surgery/Critical Care
Surgery/Vascular
Surgery/Thoracic
Surgery/Urology
Sleep Medicine
Internal Medicine/Pediatrics

Other fellowships in the Department of Surgery include burn, plastics, cardiothoracic, gastrointestinal, and transplant. Fellows, residents, students, nurses, and pharmacists also participate in the clinical research programs relating to disease and illness. These projects are designed and supervised by faculty and findings from these studies are presented at international meetings and published in peer-reviewed journals. These studies have contributed significantly to the advancement of knowledge relating to the care of patients with complex illnesses.

UNC Hospitals' Department of Family Medicine also sponsors a Family Practice Residency Training Program, which is accredited by the ACGME, which follows the guidelines of the American Board of Family Practice.

In addition to physician training, the inpatient medical / surgical units work with the UNC School of Nursing through the Clinical Partners Program to provide a clinical rotation for nursing students. Every summer, each unit is assigned nurse externs, for the purpose of providing the nurse externs an opportunity to expand their knowledge base as well as receive academic credit. The services also work with the UNC School of Nursing to provide an opportunity for senior nurses and high school students to shadow a nurse to help recruit young people to UNC and/or the nursing profession. These services also provide clinical rotations to respiratory therapy students from Durham Technical College and

Rockingham Community College. The medicine units also provide clinical rotations for Durham Technical College nursing students.

Part of the primary mission of the surgical service is to provide a quality educational experience for trainees in surgical care and to provide an environment to foster academic activities and enhance the scientific foundation of the field. The faculty participates in a wide range of educational activities. The activities include patient rounds, medical student lectures, departmental morning conferences and grand rounds, resident-oriented conferences in other departments/ schools, grand rounds in other departments, community education programs, CME lectures at outside hospital/institutions, lectures, and courses at meetings. The post surgical and critical care services also provide required clinical rotations for residents. In addition, the several nursing units host outside visitors or trainees from other programs. Examples include: senior medical students on critical care rotations, pharmacy students and residents, nurse trainees, visiting clinicians from the community, or clinicians from other countries.

As an example of the types of teaching programs at UNC Hospitals, the inpatient unit is essential to the teaching mission of the Department of Neurology. Didactic bedside teaching is particularly important in this discipline, and actual patient presentations are vital. On a daily basis, the Attending staff conducts teaching rounds for residents from a number of different Departments, fellows, and medical students. Medical students from other Schools, both in and out of State, and Community Practitioners also attend teaching sessions in this setting. Multidisciplinary conferences are conducted weekly, and include PT, OT, Social Work, Speech Pathology, Nursing and a variety of medical disciplines. These combine teaching and patient care. Hands-on experience and didactic lectures are also provided for other health care professionals, including OT, PT, Speech and Language Pathologists. Electrophysiology technician students are trained in our inpatient monitoring unit.

Another example from Neurology reflects the fact that we provide opportunities for interested trainees from outside the University. These include Medical Students from other In-State and Out of State colleges or schools who request Neurology rotations. They also include Community Physicians and other allied health professionals who request opportunities to observe. Physical, Occupational and Speech Therapy students from other in- and out of state schools are frequent trainees on the unit

Other educational programs utilizing our facilities include programs within the UNC Eshelman School of Pharmacy, UNC Department of Allied Health Sciences (Clinical Laboratory Science, Cytotechnology, Occupational Science, Physical Therapy, Radiologic Science, Rehabilitation Counseling and Psychology, and Speech and Hearing Sciences).

(c) Describe the efforts made by the applicant to establish relationships with the training programs. In addition, provide any supporting documentation regarding these efforts.

Response: See response to questions 1(a) and 1(b) above. UNC Hospitals is a teaching institution with obligations to all of the Health Science Schools at UNC. The relationship between UNC Hospitals and the School of Medicine is evident in the organization and structure of UNC Hospitals.

2. (a) **Identify all facilities with which transfer agreements will be arranged.**

Response: The clinical services will serve as a site for clinical practice, training and research for the clinical staff at UNC Hospitals. As such, no transfer agreements are required since the facility is an integral part of the UNC-CH and UNC Hospitals program.

The total UNC Hospitals' medical staff consists of 1033 attending physicians and dentists, 208 other Health Professionals, and also 713 fellows, residents, and interns as of February 29, 2009. These 1,954 physicians and dentists are also complemented by 100 Independent Allied Health Professionals, for a total of 2,054 providers. Each of these providers has access to and will continue to utilize UNC Hospitals' services. These physicians, as well as all other referring physicians from the region and state, will have access to the services, as appropriate for their patients.

(b) **Provide copies of any correspondence to or from the hospital(s) or other local health care providers in the area that document your efforts to obtain commitments to establish transfer agreements.**

Response: Since UNC Hospitals is a tertiary and quaternary care hospital based program, no transfer agreements are required for UNC Hospitals' patients. UNC Hospitals has transfer or affiliation agreements with other hospitals, long term care and life care facilities in North Carolina for referrals to UNC Hospitals. In general, it is UNC Hospitals' operating policy to work actively with any agency, program, service, or provider that may want to refer patients to UNC Hospitals and its medical staff and programs. Written agreements are not required in order to develop these working arrangements, but rather we work closely through a person or small group of people to make these cooperative relationships work. Standard transfer agreements exist from a wide variety of hospitals and long-term care facilities in the state.

No new working agreements are currently planned, as they are not necessary for referring agencies to make referrals to UNC Hospitals. While informal and formal relationships exist that facilitate the continuity of care from a referring physician or agency, no additional contracts are planned other than those that may result from negotiations with managed care companies. No working agreements are necessary for physicians who make patient referrals to the UNC Hospitals. Informal working agreements have existed with the County Social Services Departments, County Child Support Enforcement Offices, County Public Health Departments, State Hospital Facilities, and Piedmont Health Services for a number of years. Referral relationships with no written working agreements have also existed with home health agencies and other patient care providers.

(c) List the local hospitals with which any transfer agreements have been established. Provide a sample copy of a transfer agreement with a hospital.

Response: UNC Hospitals is the only local hospital in hospital service area of Orange and Caswell Counties as defined in the SMFP. Written transfer agreements already exist with the following hospitals and facilities:

Alamance Regional Medical Center
Albemarle Hospital
Amisub of North Carolina, Inc d/b/a Central Carolina Hospital
Angel Medical Center
Annie Penn Memorial Hospital
Anson Community Hospital
Beaufort County Hospital
Bertie County Rural Health Association
Bertie Memorial Hospital
Betsy Johnson Memorial Hospital
Bladen County Hospital
Britthaven of Chapel Hill
Bryan Center
Cabarrus Memorial Hospital/Northeast Medical Center
Cape Fear Valley
Cape Fear Valley Health System
Carolina Medical Center - Union
Carteret General Hospital
Caswell Center
Catawba Valley Medical Center
Cedars of Chapel Hill Club, Inc
Central Carolina Hospital
Chapel Hill Rehabilitation and Health Care Center
Chatham Hospital Inc
Community General Health Partners, Inc d/b/a Thomasville Medical Center
Community Hospital of Rocky Mount
Craven Regional Medical Authority
Danville Urologic Clinic
Davis Community Hospital
Dorothea Dix Hospital
Dosher Memorial Hospital
Duke Raleigh Hospital
Duke University Health System
Duke University Health System Inc. d/b/a Duke Hospital
Durham Regional Hospital
East Carolina Health - Chowan, Inc d/b/a Chowan Hospital

First Health of the Carolinas, Inc
First Health/Montgomery Memorial Hospital
First Health Montgomery Memorial Hospital
First Health Richmond Memorial Hospital
Franklin Regional Medical
Freedom House Recovery Center
Fry Regional Medical Center Inc
Galloway Ridge Inc
Gaston Memorial Hospital
Goldston Family Medicine
Good Hope Hospital
Granville Medical Center
Haywood Regional Medical Center
Henderson County Hospital Corporation d/b/a Margaret R. Pardee Memorial Hospital
High Point Regional Health System
Holly Hill Hospital
Iredell Memorial Hospital
Johnston Memorial Hospital
Kindred Hospital Greensboro
Lake Normand Regional Medical Center
Laurels of Chatham
Lenoir Memorial Hospital Inc, Kinston NC
Lexington Memorial Hospital
Magnolia Gardens
Maria Parham Hospital
Martin General Hospital
McDowell Hospital
McLeod Regional Medical Center
Morehead Memorial Hospital
Moses H. Cone Memorial Hospital
Murdoch Center
Nash General Hospital
Neuse Correctional Institution
New Hanover Health Network
North Carolina Baptist Hospital (Wake Forest University Baptist)
North Carolina Specialty Hospital
Northeast Medical Center
Northern Hospital of Surry County
Onslow Memorial Hospital
Our Community Hospital
Park Ridge Hospital
Person Memorial Hospital
Piedmont Triad Council of Governments Regional - Emergency Medical Services Program
Pitt County Memorial Hospital

Presbyterian Hospital
Pungo District Hospital
Randolph Hospital
Rex Hospital Inc
Rowan Regional Medical Center
Rutherford Hospital
Sampson Regional Medical Center
Sandhills Regional Medical Center
Scotland Memorial Hospital
Blue Ridge Regional Hospital
Sunbridge Regency-North Carolina d/b/a Sunbridge Care and Rehabilitation for Siler City
The Cedars of Chapel Hill Health Care Center
Veterans Affairs Medical Center - Fayetteville
Wake County Hospital System Inc.
Wake Healthcare Center Inc. d/b/a The Oaks of Carolina
Washington County Hospital
Watauga Medical Center
Wayne Memorial Hospital
Wellmont Bristol Regional Medical Center
Western Wake Medical Center
Wilkes Regional Medical Center
Wilson Memorial Hospital
Womack Army Medical Center

Exhibit 19 contains a copy of a typical transfer agreement with a hospital.

(d) **Will the facility accept referrals from hospitals where physicians utilizing the facility have practice privileges? If so, identify the hospital. If not, explain why not.**

Response: UNC Hospitals will accept referrals from any hospital or physician, including hospitals where physicians utilizing the facility have practice privileges.

3. (a) **Describe the efforts made by the applicant to develop relationships with local physicians.**

Response: Through the existing referral practices already established between physicians throughout the state and the UNC Departments, the faculty in the School of Medicine regularly provide educational information to local community physicians, as well as state-wide, in a diverse number of medical specialties. These consultations are provided both on an individual basis and through other continuing medical education activities (e.g., grand rounds). Additionally, depending on the medical specialty or sub-specialty, physicians from around the State have come for periods of time to do preceptorships under the authority of a Department's attending. Also, UNC Hospitals and the School of Medicine are active in the AHEC system, and go to other geographical areas of the state

to participate in clinics and in education of local physicians.

The faculty of the School of Medicine has developed strong relationships with local physicians through numerous referral and educational activities. Existing referral practices are maintained and expanded by providing rapid and effective responses and thorough feedback. The Carolina Consultation Center provides convenient access to all UNC physicians through a single toll-free telephone number. The Care Management Department works with both groups of physicians to facilitate referrals, minimize delays, and provide regular and effective communications. The UNC Hospitals Clinical Information System sends copies of pertinent reports to many referring physicians as soon as they have been edited and signed.

Educational opportunities are provided to local and statewide physicians in most specialties and subspecialties through many avenues. Consultations are provided on an individual basis and through continuing medical educational activities such as grand rounds and outreach clinics. Some physicians have come to Chapel Hill for several-day preceptorships under the guidance of a UNC attending physician and faculty member. The School of Medicine is highly active in the AHEC system, and physician's travel to many areas of the state to participate in clinics and to provide educational programs to local physicians. The UNC Departments and Divisions organize and participate in many specialty and subspecialty educational conferences throughout the State.

As noted above, some community physicians have privileges at UNC Hospitals.

The faculty in the Department of Radiology regularly updates local community physicians about the role of MRI for diagnosing various disease entities. These consultations are provided both on an individual basis and through other continuing medical education activities (e.g., grand rounds). Based on feedback from referring physicians, the Department has designed ways to improve services to the community to by increasing the referrals, including the establishment of a central radiology scheduling office. This is in response to a series of customer requests to have a single number telephone access to services.

Through the existing referral practices already established between physicians throughout the state and the UNC Departments, the faculty in the School of Medicine regularly provide educational information to local community physicians, as well as statewide, in a diverse number of medical specialties. These consultations are provided both on an individual basis and through other continuing medical education activities (e.g., grand rounds). Additionally, depending on the medical specialty or sub-specialty, physicians from around the State have come for periods of time to do preceptorships under the authority of a Department's attending. Also, the School of Medicine faculty are active in the AHEC system, and travel to other geographical areas of the state to participate in clinics and educate local physicians.

UNC Hospitals operates a highly organized and successful Trauma Program which

coordinates with the critical care services provided to patients. UNC Hospitals is designated as a Level I Trauma Center. Services are provided for all urgent and emergent problems. The Emergency Department is a full-service program and is staffed 24 hours a day, seven days a week, by emergency physicians. UNC Hospitals admits over2,000 trauma patients each year with the majority of the patients being critically injured from multiple trauma, burns, or orthopedic injuries. The program provides local, regional, and state trauma educational opportunities for nurses, physicians, and paraprofessionals.

UNC Hospitals also participates actively in the MidCarolina Trauma Regional Advisory Committee (RAC) which was organized in 1998 for several of the purposes specified in the Rules and Regulations Governing Ambulance Service and Trauma Systems (refer to .2301 through .2303, North Carolina General Statute 131E-162; 10 NCAC 3D.). In August 1998, North Carolina legislation became effective requiring Level I and Level II Trauma Center's in North Carolina to organize into Trauma Regional Advisory Committees, also known as "RAC"s. These Regional Advisory Committees partner with community-based hospitals in the formation of a regional based system administratively supported by the Level I Or Level II Trauma Center. This RAC serves as a strong tool for regionalized trauma care, professional education, quality improvement, and community injury prevention outreach.

Other Departments conduct more specific community outreach programs such as the activities performed by the Burn Center. The North Carolina Jaycee Burn Center's outreach program is directed by Ernest Grant, RN, MSN. Each year, Mr. Grant and members of the burn-care team spend many hours and travel thousands of miles to make presentations on burn prevention to many groups, including schools, volunteer fire departments, rescue squads, local Jaycee chapters and other service clubs. One of the most influential components of the prevention program is "Sparky the Firedog", who helps youngsters learn about the dangers of fire.

(b) **List the physicians by specialty that have expressed support for the proposal and/or have indicated a willingness to refer patients to the facility or medical equipment for services. How have the physicians and other medical personnel crucial to the viability of the proposal been involved in the planning phase of the project? Indicate if other groups/individuals, who could affect the project's success, have expressed support for it.**

Response: Throposed facility has been discussed widely over the past sever months with a broad variety of medical personnel. Letters of support have been received from the following physicians:

Specialty	Physician	Title
Anesthesiology	David Zvara, MD	Chair of Anesthesiology
Anesthesiology	Nancy Wilkes, MD	Medical Director, Ambulatory Surgery Center
Anesthesiology	Eileen Tyler, MD	
Anesthesiology	Fred Spielman, MD	

Anesthesiology	Myungsa Kang, MD	
Anesthesiology	Paul Collins, DO	
Anesthesiology	Peggy Dietrich, MD	
Anesthesiology	Robert Valley, MD	
Anesthesiology	William Furman, MD	
Anesthesiology	Susan Martinelli, MD	
Anesthesiology	Jeffrey Berman, MD	
Emergency Medicine	Charles Cairns, MD	Chair of Emergency Medicine
Family Medicine	Warren Newton, MD, MPH	Chair of Family Medicine
Family Medicine	Timothy Daaleman, DO, MPH	Vice Chair and Associate Professor
Family Medicine	Martha Carlough, MD, MPH	
Family Medicine	Lauren Lingley, MD	Med Dir at UNCs Family Medicine clinic in Hillsborough
Family Medicine	Kia Williams, MD	Provider at UNCs Family Medicine clinic in Hillsborough
Family Medicine	Paul Dunn, FNP	Provider at UNCs Family Medicine clinic in Hillsborough
Family Medicine	Thomas Marsland, MD	Med Dir at UNCs Family Medicine clinic at Highgate
Family Medicine	John Corey, MD	Provider at UNCs Family Medicine Clinic in Pittsboro
Family Medicine	Mohan Kilukuri, MD	Medical Director at UNCs Durham Family Practice
Gastroenterology & Hepatology	Robert Sandler, MD	Chief of Gastroenterology & Hepatology
General Surgery	Anthony Meyer, MD	Chair of Surgery
General Surgery	Joseph Benedetto, DO	Provider at UNCs Chatham Surgical Associates
Gynecologic Oncology (Robotic)	John Boggess, MD	Director of Comp. & Robotic Enhanced Surgery Ctr(CARES)
Internal Medicine	Aaron Miller, MD	Provider at Chapel Hill North
Internal Medicine	Whitman Reardon, MD	Provider at Chapel Hill Internal Medicine
Medicine	Marschall Runge, MD	Chair of Medicine
Medicine	Cam Patterson, MD	Chief of Cardiology
Medicine	John Buse, MD	Chief of Endocrinology
Medicine	J. Paul Mounsey, MD	Director of Cardiac Electrophysiology
Medicine	Larry Klein, MD	Provider at UNCs Sanford Specialty Clinics - Cardiology
Neurology	William Powers, MD	Chair of Neurology
Neurology	Bradley Vaughn, MD	Chief of Sleep & Epilepsy
Neurology	Kevin Robertson, PhD	Director of Neuropsychology
Neurology	Alexander Troster, PhD	
Neurology	Daniel Kaufer, MD	
Neurology	John Douglas Mann, MD	
Neurology	Kirk Wilhelmsen, MD	
Neurology	Michael Tennison, MD	
Neurology	Zheng Fan, MD	
Obstetrics & Gynecology	Daniel Clarke-Pearson, MD	Chair of Obstetrics & Gynecology
Oncology	Richard Goldberg, MD	Chief of Hematology
Oncology	Kaushik Sen, MD	Provider at Sanford Hematology Oncology
Ophthalmology	Travis Meredith, MD	Chair of Ophthalmology
Orthopaedics	Douglas Dirschl, MD	Chair of Orthopaedics
Orthopaedics	Andy Lynch, MD	
Orthopaedics	Christopher Olcott, MD	
Orthopaedics	Edmund Campion, MD	
Orthopaedics	Laurence Dahners, MD	
Orthopaedics	Moe Lim, MD	
Orthopaedics	Richard Henderson, MD	
Orthopaedics	Robert Esther, MD	

Orthopaedics	Timothy Taft, MD	
Orthopaedics	Stephen Lang, MD	Director, Orthopaedic Prompt Care
Orthopaedics	Shepard Hurwitz, MD	
Orthopaedics	Donald Bynum, Jr, MD	
Orthopaedics & Sports Medicine	Jeffrey Spang, MD	
Orthopaedics & Sports Medicine	R.A. Creighton, MD	
Otolaryngology (Head & Neck)	Harold Pillsbury III, MD	Chair of Otolaryngology
Otolaryngology (Head & Neck)	Brent Senior, MD	
Otolaryngology (Head & Neck)	Adam Zanation, MD	
Otolaryngology (Head & Neck)	Carlton Zdanski, MD, FAAP, FACS	
Pathology & Laboratory Medicine	J. Charles Jennette, MD	Chair of Pathology & Laboratory Medicine
Pediatrics	Alan Stiles, MD	Chair of Pediatrics
Pediatrics	Ed Pickens, MD	Medical Director at University Pediatrics at Highgate
Pediatrics	Kimberly Kylstra, MD	Provider at UNCs Chatham Crossing Medical Center
Physical Medicine and Rehab	Michael Lee, MD	Chair of Physical Medicine & Rehabilitiation
Psychiatry	David Rubinow, MD	Chair of Psychiatry
Psychiatry	Karon Dawkins, MD	
Psychiatry	Michael Hill, MD	
Radiation Oncology	Lawrence Marks, MD	Chair of Radiation Oncology
Radiology	Matthew Maura, MD	Chair of Radiology
Radiology	Julia Fielding, MD	
Radiology	Paul Molina, MD	
Urogynecology	Ellen Wells, MD	Chief of Urogynecology
Urogynecology	AnnaMarie Connolly, MD	
Urologic Surgery (Robotic)	Raj Pruthi, MD	
Vascular Surgery	William Marston, MD	Chief of Vascular Surgery

Other groups and individuals who will be affected by this proposal have also provided letters of support. These groups and individuals are as follows:

Group	Name	Title
Chatham Hospital	Carol Straight	President
FirstHealth	Charles Frock	CEO
Nash Health Care Systems	Larry Chewning	President & CEO
New Hanover Regional Medical Center	Jack Barto	President & CEO
Rex Hospital	David Strong	President
Ronald McDonald House of Chapel Hill	Shelley Day	Executive Director
Scotland Memorial Hospital	Greg Wood	President & CEO
SECU Family House	Greg Kirkpatrick	Executive Director
Town of Hillsborough	Eric Peterson	Town Manager
Town of Hillsborough	Tom Stevens	Mayor
UNC Health Care System	William Roper, MD	CEO, UNC Health Care System, Dean, UNC School of Medicine
UNC Health Care System	Brian Goldstein, MD, MBA	Chief of Staff, UNC Hospitals
UNC Health Care System	Mary Tonges	Chief Nursing Officer
UNC HCS, Board of Directors	Charles Sanders, MD	Chair, UNC HCS Board of Directors
Wilson Medical Center	Richard Hudson	President & CEO

(c) Identify those physicians that have expressed a willingness to serve as Medical Director of the facility or to provide medical coverage for the facility or medical equipment.

Response: Historically at UNC Hospitals the medical direction for clinical services at UNC Hospitals is established by the chairs of the appropriate departments. Properly trained and credentialed faculty are recruited, appointed, and reviewed by the department chairs. UNC Hospitals plans to continue to provide medical direction and leadership through this arrangement at the proposed second campus as well as at the other locations. All Directors of the major programs involved in this project have indicated their support. Dr. Brian Goldstein serves as the Chief of Staff for UNC Hospitals and has endorsed this proposal, as well as Dr. Marschall G. Runge who provides overall medical direction for medicine services, Dr. Anthony A. Meyer who provides overall medical direction for the surgical services, and Dr. Charles B. Cairns who provides overall medical direction for emergency medicine. See **Exhibit 7** for letters of support from Drs. Goldstein, Runge, Meyer, Cairns and other physicians.

4. **(a) Describe efforts made by the applicant to develop relationships with other local healthcare providers.**

Response: UNC Hospitals is an existing provider in the community and is well established and is actively engaged with other healthcare providers. No new relationships with other local health care providers are required for the successful operation and renovation of the services planned in this application. See the response to question 3(a) above.

UNC Hospitals has an active institution-wide networking and outreach program that provides a link to other providers of care, and operates a host of programs (such as the Carolina Consultation Center or HealthLink) that provide support and assistance to community-based providers from throughout the State.

See the lists above in Response 3(b) for an indication of the breadth of support for this project across the state.

(b) For proposals to provide mobile medical equipment, provide letters from hospitals and other prospective clients that indicate a willingness to contract for mobile medical equipment services.

Response: Not applicable. This application does not propose the acquisition of mobile medical equipment.

(c) **Provide any documented evidence of specific support for your proposal from other groups/individuals who could affect the project's success, e.g., healthcare providers or health-related agencies.**

Response: In addition to the letters of support indicated in Response 3(b), **Exhibit 2** also contains an endorsement of the proposed project from Mr. Todd Peterson, Executive Vice President and Chief Operating Officer of UNC Hospitals and Dr. Mary Tonges, Chief Nursing Officer of UNC Hospitals. Support from these two individuals is very important to successfully beginning operations at a new site.

Note that all letters should reflect the extent to which the organization/person is familiar with the components of the proposed project.

5. Describe the efforts made by the applicant to involve the community in the planning and development of the project's services.

Response: This project involves the development of a hospital-based imaging and outpatient center. The provision of these services is not new to the community or to UNC Hospitals. This application does not propose the development of a new service, therefore community-based planning is not critical to its success. Several discussions have already occurred between UNC Hospitals, the Town of Chapel Hill's staff and board members, as well as the developers of an adjacent property, regarding the proposed site and its impact on the surrounding properties. Letters of support from members of the community are contained in **Exhibit 7**. Also, see responses to **Questions V.3(a) and V.4(a).**

6. Discuss the possibilities of a joint effort with other health care facilities and providers who are providing similar services or who are interested in providing similar services.

Response: This project involves renovation of existing internal patient care space, and therefore does not lend itself to a joint project with others. UNC Hospitals is the only provider of inpatient acute care services in the Orange-Caswell acute care service area. As part of an academic medical center teaching hospital, the facilities will be greatly utilized by UNC-CH for educational programs, clinical research, and patient care. Indirectly, the community, patients, educational and training programs will benefit from this project. In response to the changing health care marketplace, UNC Hospitals has been actively developing relationships with other health care providers as noted in question 4 (a) above.

7. Will the proposed project foster competition by promoting the cost effectiveness, quality, and access to services in the proposed service area? Explain how this will be accomplished and if it cannot, please provide an explanation.

Response: This proposal is not specifically being developed to foster competition, rather the project is required to allow care-givers the opportunity to provide appropriate care to

patients in a logical setting, and a more timely and efficient manner. The proposal is designed to more adequately distribute the licensed beds that UNC Hospitals is currently approved to operate. The proposal is also designed to enable UNC Hospitals to continue to provide patient populations the best care possible, while also being responsive in a health care environment that emphasizes cost containment, efficient utilization of existing resources, coordination with managed care, and continued health care system development. This project is not developed to foster competition per se, but rather to enhance the provision of timely, quality patient care, and to assist UNC Hospitals in meeting its four-fold mission of patient care, teaching, research, and community service. Therefore, this proposal is developed to enhance patient care and allow UNC Hospitals to meet the demands encountered in today's environment.

8. If the existing or proposed facility is NOT a hospital, respond to the following questions:

(a) Will physicians affiliated with the existing or proposed facility accept emergency room call in area hospitals?

(b) Will the existing or proposed facility accept referrals from hospitals where the physicians utilizing the facility have practice privileges?

(c) Will the physicians affiliated with the existing or proposed facility have practice privileges at a hospital in the county in which the facility is or will be located? If so, identify the hospital and, if not, explain.

Response: Not applicable.

Certificate of Need Application
ACUTE CARE FACILITY/
MEDICAL EQUIPMENT PROJECT
State of North Carolina, Department of Health and Human Services

OFFICE USE ONLY
Project I. D. Number: J-8500-10 **Batch Category:** _____
Proposal Type: _____ **Beginning of Review:** _____

I. IDENTIFICATION

1. **Legal Name of the Applicant: The applicants are the legal entities (i.e., persons or organizations) that will own the facility and any other persons who will offer, develop or incur an obligation for a capital expenditure for the proposed new institutional health service.**

   Response: University of North Carolina Hospitals at Chapel Hill ("UNC Hospitals")
   101 Manning Drive
   Chapel Hill, NC 27514
   Orange County

2. **Name of Parent Company (if applicable):** **Response:** Not Applicable

3. **Person to whom all correspondence and questions regarding this application should be directed:**

   Response: Dee Jay Zerman, Associate Director of Planning
   Hedrick Office Building, Suite G050,
   211 Friday Center Drive, Chapel Hill, NC 27517
   Phone: 919-966-1129Fax: 919-966-3815
   Email: dzerman@unch.unc.edu

EXHIBIT tabbies A2

4. **Name of Lessor (If applicable):** **Response:** Not Applicable

5. **Name of Lessee: (If applicable)** (Attach copy of lease agreement) **Response:** Not Applicable

6. **Name of Management Company: (If applicable)** **Response:** Not Applicable

7. **Name of existing/proposed facility:** **Response:** Existing and proposed follows:

   University of North Carolina Hospitals
   101 Manning Drive
   Chapel Hill, NC 27514
   Orange County

Received by the CON Section
15 APR 2010 11 : 13

EXHIBIT tabbies 2

positions will be complemented by this proposed linear accelerator as certified by William L. Roper, MD, MPH, Dean of the UNC-Chapel Hill School of Medicine, Vice Chancellor for Medical Affairs, and CEO of the UNC Health Care System. See Exhibit 13.

The Department of Radiation Oncology at the University of North Carolina has an extensive educational and research mission that justifies the acquisition of an additional linear accelerator. Further, we have had an increase in physician faculty and patients to support this additional linear accelerator. This growth in faculty and patients has increased the demands on the machines leading us to need additional capacity.

Educational Programs:

Medical Residents:
Prior to December 2008, the Department of Radiation Oncology at UNC was approved by the ACGME to have four (4) residents in training in radiation oncology. At that time, we petitioned the ACGME to increase our resident allotment. The basis of this request was an expansion in the educational opportunities at UNC, including an expansion of research opportunities. Effective April 2009, we were granted permission to expand our program from 4 to 6 residents. In July 2009, we added a fifth resident. In July 2010, we will increase to our full complement of six (6) residents.

This enlargement of the educational program illustrates the strong educational program in radiation oncology at UNC. Indeed, the ACGME has a fairly rigorous process for evaluation of requests for expansion of residency programs.

An active educational program requires additional capacity on the linear accelerator for several reasons:

- Resident involvement in patient treatment can create some inefficiencies. Patients are often seen initially by the resident and then by the faculty physician. Similarly, for patients on the treatment table, the radiation treatment field/set-up may be initially verified by a resident, and then re-verified by the faculty. Thus, resident involvement in treatment can make treatment delivery slower.

- The presence of residents requires that the faculty physicians spend some of their time overseeing resident clinical activities, and providing mentorship and formal/informal education. These activities take time. These educational commitments by the faculty place increasing time demands on the faculty. This presents some inefficiencies in clinical operation. For example, a physician may not be as readily available to see a patient or check a treatment plan, or a treatment field, before the patient is treated. This leads sometimes to delays in treatment.

Our residents have been extraordinarily academically productive. The Radiation Oncology residency program at UNC plays an integral part in the research activities of the

department. Our current group of residents has published 19 articles in peer-reviewed journals, co-authored 1 book chapter, and presented 43 abstracts at local and national meetings. We have two residents graduating in June 2010. Dr. Kimple has authored 10 research publications and has had 16 abstracts/presentations nationally, resulting from his work as a resident. Dr. Harris has 4 publications and 9 abstracts/presentations.

Note that many of the research studies conducted by the residents relate to clinical research; that is, studies involving patients receiving irradiation treatment on our linear accelerators. The enrollment of patients onto clinical trials involving radiation treatment places additional burdens on the capacity of our linear accelerators. Patients on study are often treated using complex techniques that place increased time demands on the treatment machines.

Medical Dosimetry Program and Radiation Therapist Program
The Department of Radiation Oncology at UNC has accredited programs for the training of Radiation Therapists (the people who align the patient on the treatment machine and actually press the buttons to deliver the radiation) as well as Medical Dosimetrists (the people who perform the calculations to determine how long to leave the radiation beam on, determine the optimal beam direction, etc.). These are two separate programs at UNC which are both directed by Dr. Robert Adams, a faculty member in the Department of Radiation Oncology. Dr. Adams is a certified therapist and certified dosimetrist.

The medical dosimetry program is a one year program that accepts 2 students per year. The program was developed six years ago to address the need for didactically- and clinically-trained medical dosimetrists in the nation. The UNC program was the first accredited medical dosimetry education program in the United States. The program has an eight-year accreditation through the US Department of Education. Among students from all programs nationally graduating over the last 5 years, the pass rate on the national dosimetry board exam has been 57%. The UNC program has a 100% pass rate on the national boards.

The radiation therapy program is a one year program has 4-7 students per year. The Radiation Therapists program was created over 20 years ago and is the longest-standing accredited program in the eastern part of the U.S. The program has over 300 alumni, with many working in North Carolina. The program has an eight-year accreditation through the US Department of Education. The UNC program has a 100% pass rate on the national radiation therapy boards.

Therefore, both our Therapist and Dosimetry programs are among the best in the country.

In 2009, Dr. Adams received *a competitive grant from the NIH to* develop a curriculum to improve instruction in three-dimensional anatomy for therapists and dosimetrists. Once developed, this curriculum will be made available, *without* charge, to therapy and dosimetry students nationally. These many achievements of the program are a testament to the hard work of the director, Dr. Robert Adams, the other members of the department

that assist with the educational programs, as well as the excellent facilities at UNC Hospitals.

Dr. Adams' Grant

The excellence of our educational programs is evidenced by our recent receipt of an Educational Development grant from the NIH. Dr. Robert D. Adams, the Director of our Medical Dosimetry and Radiation Therapy programs, is the PI of an R25 Grant to develop unique educational software.

Training programs for radiation therapists, dosimetrists, medical physicists and medical residents in radiation oncology, each teach the basic principles of radiation therapy in the classroom. Trainees often rely on access to computer-based treatment planning (RTP) systems for hands-on practice to solidify the principles taught in the classroom and to develop treatment planning skills. A major shortcoming of this approach is the often-limited access to clinical RTP systems. These work-stations are expensive and largely needed for clinical tasks.

Further, even when RTP workstations are available, the inflexibility of commercial RTP software makes them sub-optimal to meet education/training needs. There is currently no model curriculum for computer-based training; there is a lack of computer-based learning materials specifically structured to meet the needs of RTP education and training. The overall goal of this project is to develop instruction materials that reinforce the principles and practice of dosimetry/planning for external beam radiation treatment to be used in education/training programs. The proposed work is aimed primarily at radiation therapy technology and dosimetry programs, but also will be valuable for medical physics and radiation oncology programs.

The specific aims are to:

1. Develop a model curriculum for computer-aided instruction of the principles and practice of RTP;

2. Develop self-paced computer-based case studies grouped into anatomy-related modules with user and instructor manuals that implement major components of the curriculum;

3. Modify a widely used, freely licensed, open-source treatment planning system to guide students step-by- step through each case study using proven computer-aided techniques such as modal and non-modal "wizards", and on-line "help" query;

4. Evaluate the curriculum and modules in multiple training programs; and

5. Provide web-based dissemination of the treatment planning system, model curriculum, modules, and all user and instructor documentation.

The acquisition of an additional linear accelerator at UNC will increase the breadth of radiation therapy equipment that can be used in the curricular materials that are being developed as part of this project. Curricular materials are often created from the "author's point of view"- a view that is largely influenced by the equipment used by that author. Therefore, increasing diversity of the planning/treatment systems at UNC, and in particular adding a high-technology treatment unit, will increase the relevance/applicability of the software product to future students.

Faculty Expansions

In December 2007, the department had six (6) physicians practicing in the Department of Radiation Oncology at UNC Chapel Hill. One of these physicians discontinued their clinical practice and a new department Chair, Dr. Lawrence Marks, was hired at UNC in April 2008. Since then, four (4) additional physicians have been hired. Thus, faculty has grown from 6 to 10 physicians with a total of five new faculty. This rapid expansion and evolution of the faculty allowed us to increase the services available to our patients with cancer.

These new physicians brought with them requests for new and different treatment techniques. Some of these advanced treatment techniques place increased demands on the linear accelerator capacity as they can be time consuming. Some examples are described below.

Some of the expanded technological capabilities on our linear accelerators that tend to reduce the efficiency of clinical operations.

- We have expanded our image guided capabilities on our linear accelerators. Image guidance facilitates the generation of localization images of the patients prior to the treatment, and often during the treatment. This is a good thing for our patients as it increases the accuracy of the radiation delivery. However, this slows the treatment process. Images must be reviewed prior to treatment delivery. When we moved to the new North Carolina Cancer Hospital in September 2009, we expanded our image-guided capabilities from 1 machine to three machines. This includes the addition of cone-beam CT to one of our machines. This is a particularly time consuming technology as the acquisition of the cone beam images can be slow, and the degree of information afforded by cone beam CT is large, making image analysis somewhat slow as well.
- We have added the capability of performing surface imaging on one of our machines. This approach allows the therapists to view the patient's surface before and during therapy in order to improve the accuracy of therapy. However, this can reduce machine capacity as it can be time consuming. This technology was added to one of our linear accelerators in 2009.
- The use of Calypso seeds is an additional advanced technique to improve treatment accuracy. Seeds implanted into the patient's tumor emit a signal that can be detected by a device placed in the room adjacent to the patient. The device

monitors the portion of the tumor before and during therapy. This technique is particularly useful for patients with prostate cancer. We initiated our Calypso program in 2007 and have this capability on one of our machines.

- We have installed the capability to perform "gated treatment". This is a technique where the radiation beam is turned "on" only during specific parts of the respiratory cycle (e.g., during the end of inhalation). This is useful since the internal organs move during breathing, and their location relative to each other also changes during respiration. In some instances, it is preferable to treat only during one part of the breathing cycle as the relative positions between the organs is best at that one part of the cycle (e.g. treatment to the left breast may be best during inspiration as the heart moves "away" from the left breast during this time, thus reducing heart exposure). While this technique is powerful to reduce normal tissue exposure, it can slow treatment delivery. Indeed, we have not yet implemented this technique due to the lack of time on our accelerators.

New Medical Physics Residency Program

The Department of Radiation Oncology at UNC has applied for a Medical Physics residency training program. This application has been submitted and we anticipate enrolling our first medical physics resident in July 2010. This will be a two (2) year program, with two (2) residents per year. CAMPEP (Commission on Accreditation of Medical Physics Educational Programs) accreditation will also be obtained. The American Board of Radiology is requiring future participation in CAMPEP accredited programs phasing in between 2012 and 2014. This new program and accreditation will assist in fulfilling the need for providing educated professional meeting these standards.

Presently, the Department of Radiation Oncology at UNC has five (5) postdoctoral physics students, and medical physics graduate students. In essence, these students function as "informal medical physics residents." That is, most of the clinical physics training for medical physicists is presently conducted outside of formal medical physics residency programs. Mostly this is currently training through postdoctoral fellowships, and during their graduate training, as is the case with our existing cohort of students and postdoctoral fellows. Our Medical Physics residency program will better formalize the clinical training for these individuals. In essence, we are presently providing this educational experience for these students, but this is being done outside of the formal structure of the Medical Physics Residency Program.

Quality training in clinical medical physics (via a formal residency program, or formally during postdoctoral or predoctoral work) requires access to a wide breadth of radiation therapy technologies. The addition of another linear accelerator to the Department of Radiation Oncology at UNC will therefore enhance the educational experience for these students. The benefits here are similar to that described elsewhere in this application for our medical residents, and students of dosimetry and radiation therapy.

Image Guided Research

The University of North Carolina has a strong tradition of excellence in the field of image analysis and image guided radiation therapy. The unique combination of our outstanding computer science program, and our outstanding clinical radiation therapy program, facilitated unique collaborations between these departments. Doctors Chaney, Pizer, Rosenman, Chang (all with appointments in the Department of Radiation Oncology and/or Computer Science) have conducted outstanding research to advance the field of image guided radiation treatment.

There are many centers exploiting image guided therapy. Typically, pre-treatment images are compared to images taken immediately before each fraction of radiation (or even during each fraction of radiation). These two (2) image sets are compared, and the patient is moved to the appropriate position to align the radiation beam with the target. The underlying assumption of this approach is that the patient is a "rigid body" and that the two (2) image sets (the planning radiation image and the image obtained immediately prior to radiation) contain essentially the same structures, in their same relative position. As human beings are alive (breathing, with ongoing metabolic functions), this assumption is fundamentally not true. Therefore, most image-guided radiation therapy research and clinical work has this underlying inaccuracy. The major contribution of the UNC investigator is our ability to "warp" images. Our computer science colleagues are expert in understanding the elastic nature of tissues, and how movements in one part of an image relate to movements in other parts of an image.

Exploiting all this expertise, our scientists are conducting cutting edge research to improve image guided therapy, through consideration of changes in tissue anatomy/relative-position/structure. Doctors Rosenman, Pizer, Chaney, and Chang have received numerous industry and government-sponsored research grants to further study related issues.

Acquisition of an additional linear accelerator, especially one with advanced image guided capabilities, will further this research program. In particular, the tomotherapy machine being considered as part of this application is, widely considered as the "ultimate" in image guided approaches. Three dimensional computer images can be obtained prior to each fracture of radiation. In order to exploit this information, these pre-RT images need to be related, rapidly, to the planning images. This rapid image comparison can be facilitated/augmented by the image warping software/techniques throughout here at UNC.

Nanotechnology-Image Guided Research

Investigators in the Department of Radiation Oncology and Physics at UNC have been collaborating on the use of nanotechnology to improve radiation therapy. Nanotechnology devices afford the possibility for precision imaging of patients prior to, and actually during radiation treatment. The major advance here is that current technologies allow there to be either:

- Three dimensional imaging prior to treatment, and/or

- Two dimensional imaging during radiation treatment.

Presently, there are no technologies to allow for three dimensional imaging during radiation treatment. Investigators at UNC have developed sophisticated nanotechnology-based instruments to allow three dimensional imaging during treatment. The technology, termed nano-tomosynthesis, is available only at UNC. This work is further evidence of our leadership in the area of image guided radiation treatment. Acquisition of an additional linear accelerator, which includes sophisticated image guided techniques, will further foster this research.

The department already has several technologies for image guided therapy, including: a CT on rails, digital planar imaging, and cone beam CT. We are also developing nanotechnology-based imaging techniques as noted. Our institution is therefore conducting unique research that compares these different image guided techniques. The acquisition of an additional linear accelerator with complimentary image guided technologies (e.g., Tomotherapy unit with mega voltage helical CT) will further our ability to conduct this research.

SMFP Policy AC3: A project submitted by an Academic Medical Center Teaching Hospital under this policy that meets one of the above conditions shall also demonstrate that the Academic Medical Center Teaching Hospital's teaching or research need for the proposed project cannot be achieved effectively at any non-Academic Medical Center Teaching Hospital provider which currently offers the service for which the exemption is requested and which is within 20 miles of the Academic Medical Center Teaching Hospital.

<u>The impact of an additional radiation treatment machine on our Educational Programs: Medical Dosimetry Program and Radiation Therapist Program, and Residency in Radiation Oncology</u>

It is becoming increasingly difficult for us to provide a complete state-of-the-art educational experience for our therapy and dosimetry students, and residents. The practice of radiation therapy has become more complex, with increased reliance on complex technologies. There has been a recent expansion of the number of treatment techniques available (e.g., intensity modulated radiation therapy, radiosurgery, image guided therapy). This has made it more challenging for us to expose the students to the broad array of treatment techniques. For example, our current machines lack capabilities to perform arc-based conformal, or intensity-modulated, treatments. Further, the increased treatment volumes on our three conventional linear accelerators (see section below), makes it challenging for our students to observe/assist with treatments on these units. Having these students spend time working on these treatment machines is a critical "hands-on" component of their educational experience. To address these challenges, we have been rotating some of our students to other institutions. However, we do not consider this an effective long term solution.

Placement of an additional high-technology modern radiation treatment machine at UNC's main campus will help to improve the educational experiences for our students and residents. It will allow us to expose our students to additional types of emerging radiation therapy technologies, and free-up some time on our existing accelerators facilitating a better clinical-educational experience on those units as well.

For the medical residents in radiation oncology, the same concepts would apply. There is much peer-to-peer learning that is part of residency. It is not always practical to rotate residents to neighboring centers, and there are inherent inefficiencies for residents being off-site. It is harder for them to have continuity of care. For example, imagine a patient that they helped to treat last year comes back to the clinic with a great response, or with a complication (i.e. something that would be educational for the resident to see, and be a part of evaluating). A resident on an off-site rotation cannot fully benefit from UNC's educational opportunities.

There are some financial and logistic challenges to having residents rotate to other hospitals as well. Typically, the hosting center is not willing to cover the resident's salary. The home institution similarly is not anxious to pay for a resident's salary when that resident is at another institution.

Why a Tomotherapy unit?
There are several reasons why we are requesting a Tomotherapy unit as part of this AC3 application. These reasons can be broadly divided into clinical considerations and research/teaching considerations.

Clinically, the Tomotherapy unit will provide enhanced capabilities beyond what we currently have with our existing treatment units. We presently have three conventional linear accelerators and one Cyberknife unit. The three conventional accelerators are currently not capable of rotational therapies. These units deliver radiation using fixed static beams. Intensity modulation is achieved through creation of multiple sub-segments within each of these fixed beams. The use of fixed beams somewhat limits the number of orientations from which the patient can be treated. It is impractical to treat from a very large number of directions since each direction is treated as its own individual beam. Rotational therapy facilitates the delivery of treatment from multiple orientations.

There are several technologies available for rotational therapy. First, some linear accelerators provide arc-based intensity modulated therapy (known commercially as VMAT: volumetrically modulated arc therapy, and Rapid Arc). These two arc-based therapies that are possible on linear accelerators are only possible on two other units. All three of our conventional linear accelerators at UNC are Siemens, and these rotational arc therapies are <u>not</u> possible on these Siemens units.

These other brands of linear accelerator-based arc approaches essentially treat a "cone" of tissue simultaneously (one might call this "cone beam therapy"). This is both good and

bad. On the positive side, treatment can be faster, as a large volume is being treated simultaneously. However, this concurrent treatment of broad volume reduces the degrees of freedom when planning dose delivery. This is a complicated concept, but is illustrated in this example. Consider a large volume target where the superior aspect of the target is best treated with beams coming in from the right side of the patient, but where the inferior part of the same target is best treated with beams delivered from the front of the patient. It is not practical for the arc-based therapy to efficiently treat one part of the target from one direction while treating another part of the target from totally different directions. Thus, when one uses the volumetric arc technique (either VMAT or Rapid Arc), the treatment planner must make compromises regarding the dose delivery throughout the arc.

The Tomotherapy approach to rotational therapy (described below) obviates this challenge, since each "slice" of the target is essentially independently treated. Each "slice" can be treated with the weights and orientations that are best for that part of the tumor, without (much) consideration of how other parts of the tumor are being treated.

Second, rotational therapy can be delivered using a helical approach (as is used by Tomotherapy). Helical therapy is somewhat analogous to modern helical diagnostic CT scanners. The patient is treated through a series of thin arcs that are stacked on top of each other, until the whole volume is treated. Since each "slice" of the target is treated separately from other "slices" of the target (i.e., through the thin arc that covers that part of the target), the treatment can be more conformal. Compromises in the selection of beam weights and orientations are not as necessary. This enables better delivery of dose to the target and better sparing of dose to the non-target tissues. The negative part of helical therapy is that the treatment delivery times are somewhat longer than with the "cone-beam therapy" approach (i.e., VMAT or Rapid Arc). One is trading speed for conformality of dose.

A Tomotherapy unit with helical dose delivery will provide UNC with enhanced capabilities to deliver rotational therapy. This machine will well complement our existing treatment devices. The Tomotherapy unit is particularly well suited for patients with complex targets that are in close proximity to critical normal structures. These situations are best suited with intensity modulated radiation therapy. One of the main tumor sites where intensity modulated radiation therapy is widely recognized to improve therapy is the head and neck region. UNC Hospitals has a particularly large volume of head and neck cancer. We are one of the busiest head and neck cancer programs in the country, with approximately the fifth highest volume of patients seen per year nationally. Approximately 25% of our clinical volume in radiation oncology is derived from patients with head and neck cancer. Acquisition of a Tomotherapy unit therefore will help us provide better clinical care for these patients with very challenging complex three dimensional anatomy.

Education and Research:

V. COORDINATION WITH EXISTING HEALTH CARE PROVIDERS

1. (a) **Describe how the proposed project relates to the clinical needs of health professional training programs in the area, including any anticipated relationships.**

   (b) **Indicate the extent to which the schools in the area will have access to the facility for health professional training purposes.**

Responses to (a) and (b): Health professional training requires opportunities to participate in realistic patient care encounters in a variety of clinical settings. UNC Hospitals serves as a clinical teaching site for a broad range of health care disciplines including medical, dental, public health, pharmacy and nursing students, as well as post-graduate residents and trainees and students in medical technology, physical therapy, radiologic technology, respiratory care, phlebotomy, occupational therapy, pastoral care, and many more. The University of North Carolina at Chapel Hill is the *only* Academic Medical Center in North Carolina, and one of only a few nationwide, that has all 5 of the health professional schools on campus and actively learning at their affiliated teaching hospital.

The training of medical students, as well as interns, residents and fellows, in the disciplines of medicine, surgery, radiology, radiation therapy, urology, dermatology, ophthalmology, neurosurgery, pediatrics (oncology), and other disciplines, will all benefit from the inpatient and outpatient services housed in this facility. The education of nurses, pharmacy technicians, pharmacy students, physical therapists, radiation therapists, social workers, counselors, clinical researchers, geneticists, and other disciplines, will occur in the oncology services.

For the Department of Radiation Oncology, the new facility will provide critical space for the continuation and possible student expansion of the Department's School of Radiation Therapy Technology and School of Radiation Dosimetry. In addition, the Department provides training for Residents. There are many UNC medical students and visiting Residents from other institutions who do rotations and electives in this department. The department also serves as a training area for students from Biomedical Engineering, Genetics, Public Health, Computer Science, and Pharmacology.

The Department of Radiation Oncology allows outside medical students and residents to do rotations through the service. Often, international and nationally known medical and research faculty visit for months at a time. At any time, the department may have visiting medical students, residents, community college students, hospital-based radiation therapy students, high school health occupations students, and adjunct professors from other departments on the UNC-Chapel Hill campus.

Community physicians and health care workers are invited to visit the department for seminars and educational training programs. Community physicians are also invited to participate in cancer rounds and tumor boards after the multi-disciplinary clinics. The Department operates its own Residency program, Radiation Therapy Technology Program, and Medical Dosimetry Program.

In addition, staff is frequently asked to conduct tours through the Radiation Oncology Department for UNC-CH college students, for high school groups in health occupations classes, for civic groups during cancer awareness promotions, for all of Lineberger Cancer Center's new Board members, and for service organizations such as the Boy Scouts or Girl Scouts.

Further discussions of the Department of Radiation Oncology's educational programs are contained in Section II and III.

(c) **Describe the efforts made by the applicant to establish relationships with the training programs. In addition, provide any supporting documentation regarding these efforts.**

Response: Please also see the responses to Questions V.1(a) and (b) above. UNC Hospitals is a teaching institution with obligations to all of the Health Science Schools at UNC. The relationship between UNC Hospitals and the School of Medicine is evident in the organization and structure of UNC Hospitals. Allied Health Students are also part of the School of Medicine.

UNC Hospitals is accredited by the Accreditation Council for Graduate Medical Education (ACGME) in the following specialties: Anesthesiology; Pediatric Anesthesiology; Pain Medicine; Dermatology; Emergency Medicine; Family Medicine; Medical Genetics; Internal Medicine; Cardiovascular Diseases; Endocrinology, Diabetes, and Metabolism; Gastroenterology; Infectious Disease; Nephrology; Hematology; Geriatric Medicine; Interventional Cardiology; Clinical Cardiac Electrophysiology; Hematology and Oncology; Pulmonary Disease and Critical Care Medicine; Neurological Surgery; Neurology; Child Neurology; Molecular Genetic Pathology; Nuclear Medicine; Obstetrics and Gynecology; Ophthalmology; Orthopaedic Surgery; Otolaryngology; Pathology-Anatomic and Clinical; Blood Banking/Transfusion Medicine; Cytopathology; Forensic Pathology; Hematology; Neuropathology; Pediatrics; Pediatric Critical Care Medicine; Pediatric Endocrinology; Pediatric Hematology-Oncology; Pediatric Nephrology; Neonatal-Perinatal Medicine; Pediatric Pulmonology; Pediatric Gastroenterology; Pediatric Sports Medicine; Physical Medicine and Rehabilitation; Plastic Surgery; Preventative Medicine; Psychiatry; Child and Adolescent Psychiatry; Forensic Psychiatry; Radiology-Diagnostic; Neuroradiology; Vascular and Interventional Radiology; Radiation Oncology; Surgery-General; Surgical Critical Care; Vascular Surgery; Thoracic Surgery; and Urology.

Staff from Radiation Oncology travel to many community colleges and high schools within the state each year to discuss the department's training programs with community college students who are in Radiologic Sciences programs, and for high school students who are in Health Occupations classes. Informational mailings are disseminated to prospective applicants several times per year and the programs are advertised at the national meetings of the American Society for Therapeutic Radiology and Oncology and the American Society of Radiologic Technologists (ASTRO and ASRT).

2. (a) **Identify all facilities with which transfer agreements will be arranged.**

Response: The services will continue to serve as a site for clinical practice, training and research for the clinical staff at UNC Hospitals. As such, no transfer agreements are required, since the services are an integral part of the UNC School of Medicine and UNC Hospitals relationship.

The total UNC Hospitals' medical staff consists of 1,076 attending physicians and dentists, 738 fellows, residents, and interns, 243 Dependent Allied Health Professionals and 89 Independent Allied Health Professionals: for a total of 2,146 providers. Each of these providers has access to and will continue to utilize UNC Hospitals' services. These physicians, as well as all other referring physicians from the region and state, will have access to the services, as appropriate for their patients.

(b) **Provide copies of any correspondence <u>to</u> or <u>from</u> the hospital(s) or other local health care providers in the area that document your efforts to obtain commitments to establish transfer agreements.**

Response: While not required, written transfer agreements already exist and will be applicable to the proposed linear accelerator just as these are applicable to any other UNC Hospitals' service. See discussion that follows in response to question 2(c).

(c) **List the local hospitals with which any transfer agreements have been established. Provide a sample copy of a transfer agreement with a hospital.**

Response: UNC Hospitals is the only local hospital in hospital service area of Orange and Caswell Counties as defined in the SMFP. Written transfer agreements already exist with the following hospitals:

Alamance Regional Medical Center
Albemarle Hospital
Amisub of North Carolina, Inc d/b/a Central Carolina Hospital
Angel Medical Center
Annie Penn Memorial Hospital
Anson Community Hospital
Beaufort County Hospital

Bertie County Rural Health Association
Bertie Memorial Hospital
Betsy Johnson Memorial Hospital
Bladen County Hospital
Britthaven of Chapel Hill
Bryan Center
Cabarrus Memorial Hospital/Northeast Medical Center
Cape Fear Valley Health System
Carolina Medical Center - Union
Carteret General Hospital
Caswell Center
Catawba Valley Medical Center
Cedars of Chapel Hill Club, Inc.
Chapel Hill Rehabilitation and Health Care Center
Chatham Hospital, Inc.
Community General Health Partners, Inc d/b/a Thomasville Medical Center
Community Hospital of Rocky Mount
Craven Regional Medical Authority
Danville Urologic Clinic
Davis Community Hospital
Dorothea Dix Hospital
Dosher Memorial Hospital
Duke Raleigh Hospital
Duke University Health System
Duke University Health System, Inc. d/b/a Duke Hospital
Durham Regional Hospital
East Carolina Health - Chowan, Inc. d/b/a Chowan Hospital
First Health of the Carolinas, Inc.
First Health/Montgomery Memorial Hospital
First Health Montgomery Memorial Hospital
First Health Richmond Memorial Hospital
Franklin Regional Medical
Freedom House Recovery Center
Frye Regional Medical Center, Inc.
Galloway Ridge, Inc.
Gaston Memorial Hospital
Goldston Family Medicine
Granville Medical Center
Haywood Regional Medical Center
Henderson County Hospital Corporation d/b/a Margaret R. Pardee Memorial Hospital
High Point Regional Health System
Holly Hill Hospital
Iredell Memorial Hospital
Johnston Memorial Hospital

Kindred Hospital Greensboro
Lake Norman Regional Medical Center
Laurels of Chatham
Lenoir Memorial Hospital, Inc., Kinston NC
Lexington Memorial Hospital
Magnolia Gardens
Maria Parham Hospital
Martin General Hospital
McDowell Hospital
McLeod Regional Medical Center
Morehead Memorial Hospital
Moses H. Cone Memorial Hospital
Murdoch Center
Nash General Hospital
Neuse Correctional Institution
New Hanover Health Network
North Carolina Baptist Hospital (Wake Forest University Baptist)
North Carolina Specialty Hospital
Northeast Medical Center
Northern Hospital of Surry County
Onslow Memorial Hospital
Our Community Hospital
Park Ridge Hospital
Person Memorial Hospital
Piedmont Triad Council of Government – Regional Emergency Medical Services Program
Pitt County Memorial Hospital
Presbyterian Hospital
Pungo District Hospital
Randolph Hospital
Rex Hospital, Inc.
Rowan Regional Medical Center
Rutherford Hospital
Sampson Regional Medical Center
Sandhills Regional Medical Center
Scotland Memorial Hospital
Blue Ridge Regional Hospital
Sunbridge Regency-North Carolina, Inc. d/b/a Sunbridge Care and Rehabilitation for Siler City
The Cedars of Chapel Hill Health Care Center
Veterans Affairs Medical Center - Fayetteville
Wake County Hospital System, Inc.
Wake Healthcare Center, Inc. d/b/a The Oaks of Carolina
Washington County Hospital
Watauga Medical Center

Wayne Memorial Hospital
Wellmont Bristol Regional Medical Center
Western Wake Medical Center
Wilkes Regional Medical Center
Wilson Memorial Hospital
Womack Army Medical Center

Exhibit 15 contains a copy of a typical transfer agreement with a hospital.

(d) **Will the facility accept referrals from hospitals where physicians utilizing the facility have practice privileges? If so, identify the hospital. If not, explain why not.**

Response: UNC Hospitals will accept referrals from any hospital or physician, including hospitals where physicians utilizing the facility have practice privileges.

3. (a) **Describe the efforts made by the applicant to develop relationships with local physicians.**

Response: Through the existing referral practices already established between physicians throughout the state and the UNC Departments, faculty in the School of Medicine regularly provide educational information to local community physicians, as well as statewide, in a diverse number of medical specialties. These consultations are provided both on an individual basis and through other continuing medical education activities (e.g., grand rounds). Additionally, depending on the medical specialty or sub-specialty, physicians from around the State have come for periods of time to do preceptorships under the authority of a Department's attending. Also, the School of Medicine faculty are active in the AHEC system, and travel to other geographical areas of the state to participate in clinics and educate local physicians.

The faculty of the School of Medicine has developed strong relationships with local physicians through numerous referral and educational activities. Existing referral practices are maintained and expanded by providing rapid and effective responses and thorough feedback. The Carolina Consultation Center provides convenient access to all UNC physicians through a single toll-free telephone number. The Bed Management Department works with both groups of physicians to facilitate referrals, minimize delays, and provide regular and effective communications. UNC Hospitals' Clinical Information System sends copies of pertinent reports to the referring physicians as soon as they have been edited and signed.

Educational opportunities are provided to local and statewide physicians in most specialties and subspecialties through many avenues. Consultations are provided on an individual basis and through continuing medical educational activities such

as grand rounds and outreach clinics. Some physicians have come to Chapel Hill for several-day preceptorships under the guidance of a UNC attending physician and faculty member. The School of Medicine is highly active in the AHEC system, and physicians and other professionals travel to many areas of the state to participate in clinics and educate local providers. The UNC Departments and Divisions organize and participate in many specialty and subspecialty educational conferences throughout the State.

As noted above, several additional community physicians have privileges at UNC Hospitals. UNC Hospitals also has several managed care contracts in which physicians refer patients to UNC Hospitals' medical staff.

The Department of Radiation Oncology has also developed a relationship with New Hanover Regional Hospital through a collaborative NCI effort to gain grant funding for a telemedicine program. These community physicians are also invited into the department to join us for tumor boards and various other educational opportunities.

Trainees from UNC's residency program in radiation oncology include the current Chair of Radiation Oncology at Wake Forest University, and physician faculty at both Duke University and East Carolina University. Thus, UNC has strong bonds with other academic medical centers throughout the State. Furthermore, several UNC trained radiation oncologists are in private practice in the State.

(b) **List the physicians by specialty that have expressed support for the proposal and/or have indicated a willingness to refer patients to the facility or medical equipment for services. How have the physicians and other medical personnel crucial to the viability of the proposal been involved in the planning phase of the project? Indicate if other groups/individuals, who could affect the project's success, have expressed support for it.**

Response: The proposed linear accelerator has been discussed with a broad variety of medical personnel and the following letters of support have been received:

Physician	Title	Entity/Department	Specialty
Lawrence B. Marks, MD	Professor and Chair	UNC SOM, Department of Radiation Oncology	radiation oncology
Richard M. Goldberg, MD	Physician-in-Chief, NC Cancer Hospital, Chief, Division of Hematology and Oncology, Associate Director of Clinical Research, UNC Lineberger Comprehensive Cancer Center, Richard M. Goldberg Distinguished Professor of Gastrointestional Cancer	UNC SOM, Department of Medicine	oncology

Research

Luis A. Diaz, MD	CE Wheeler Jr Distinguished Professor and Chariman, Department of Dermatology	UNC SOM	dermatology
Robert S. Sandler, MD, MPH	Nina C. and John T. Sessions Distinguished Professor, Chief, Division of Gastroenterology & Hepatology, Director, Center for Gastrointestional Biology and Disease	UNC SOM	digestive disease and liver problems
John T. Soper, MD	Hendricks Professor of Gynecology	UNC SOM, Department of Obstetrics and Gynecology	gynecologic oncology
Marschall S. Runge, MD, PhD	Charles Addison and Elizabeth Ann Sanders Eistinguised Professor of Medicine; Chair, Department of Medicine; Vice Dean for Clinical Affairs	UNC SOM, Department of Medicine	cardiology
Julie L. Sharpless, MD	Director, UNC Multidisciplinary Pituitary Adenoma Clinic	UNC SOM, Department of Medicine	endocrinology and metabolism
Michael Y. Lee, MD, MHA	Professor and Chair	UNC SOM, Department of Physical Medicine and Rehabilitation	PM & R
Daniel L. Clarke-Pearson, MD	Robert A. Ross Distinguished Professor and Chair	UNC SOM; Department Obstetrics & Gynecology	gynecologic oncology
Bhishamjit Chera, MD	Assistant Professor	UNC SOM; Department of Radiation Oncology	radiation oncology
Harold C. Pillsbury III, MD	Thomas J. Dark Distinguished Professor of Otolaryngology / Head and Neck Surgery; Professor and Chair, Otolaryngology / Head and Neck Surgery	UNC SOM; Otolaryngology / Head and Neck Surgery	otolaryngology, head and neck cancer
Joel E. Tepper, MD	Hector MacLean Distinguished Professor of Cancer research	UNC SOM; Department of Radiation Oncology	radiation oncology
Charles B Cairns, MD, FACEP, FAHA	Professor and Chair	UNC SOM; Department of Emergency Medicine	critical care

Robert D. Adams, MD	Assistant Professor, Director of Education	UNC SOM: Department of Radiation Oncology	radiation oncology
Julian Rosenman, MD, PhD	Professor Department of Radiation Oncology; Adjunct Professor Department of Computer Science, UNC; Affiliated Professor, Department of Radiation Oncology ECU	UNC SOM; Department of Radiation Oncology	radiation oncology
Ronald Chen, MD, MPH	Assistant Professor	UNC SOM; Department of Radiation Oncology	radiation oncology
Eric C. Schreiber, PhD, DABR	Assistant Professor	UNC SOM; Department of Radiation Oncology	radiation oncology
Ellen L. Jones, MD, PhD	Professor and Associate Chair	UNC SOM; Department of Radiation Oncology	radiation oncology
Mahesh A. Varia, MD	Professor	UNC SOM; Department of Radiation Oncology	radiation oncology
Sha Chang PhD, DABR	Assistant Professor; Radiation Oncology Head of Division of Physics & Computing	UNC SOM; Department of Radiation Oncology and Department of Physics & Astronomy and Lineberger Clinical Cancer Center	radiation oncology
Brian P. Goldstein, MD, MBA	Executive Associate Dean for Clinical Affairs, Chief of Staff	UNC SOM; Department of Medicine	general medicine and epidemiology
Other			
Carol Straight	President	Chatham Hospital	

See Exhibit 16 for copies of these letters of support.

(c) **Identify those physicians that have expressed a willingness to serve as Medical Director of the facility or to provide medical coverage for the facility or medical equipment.**

Response: Dr. B. Lawrence Marks, Professor and Chair of the Department of Radiation Oncology at the UNC School of Medicine, currently serves, and will continue to serve, as the Medical Director of all of the radiation therapy services. See Exhibit 17 for his letter of support.

4. (a) **Describe efforts made by the applicant to develop relationships with other local healthcare providers.**

Response: See response to Question V.3.(a) above. UNC Hospitals has an active

networking and outreach program.

(b) **For proposals to provide mobile medical equipment, provide letters from hospitals and other prospective clients that indicate a willingness to contract for mobile medical equipment services.**

Response: Not applicable. UNC Hospitals does not propose the acquisition of mobile medical equipment.

(c) **Provide any documented evidence of specific support for your proposal from other groups/individuals who could affect the project's success, e.g., healthcare providers or health-related agencies.**

Response: Exhibits 17 and 18 contain an endorsement of the proposed project from Mr. Todd L. Peterson, Executive Vice President and Chief Operating Officer of UNC Hospital, and Dr. Dr. B. Lawrence Marks, Professor and Chair of the Department of Radiation Oncology at the UNC School of Medicine. Letters of support from other providers can also be found in Exhibit 16.

Note that all letters should reflect the extent to which the organization/person is familiar with the components of the proposed project.

5. **Describe the efforts made by the applicant to involve the community in the planning and development of the project's services.**

Response: This project involves the development of one new linear accelerator in a building that has already been approved for development by the community. The provision of this service is not new to the community or to UNC Hospitals. This application does not propose the development of a new service, therefore community-based planning is not critical to its success. Letters of support from members are contained in Exhibit 16. Also, see responses to Questions V.3(a) and V.4(a).

6. **Discuss the possibilities of a joint effort with other health care facilities and providers who are providing similar services or who are interested in providing similar services.**

Response: Imaging services must be immediately available and accessible to provide services to patients at UNC Hospitals. Because of the nature of the provision of the education of our learners and the provision of therapies, a joint venture with another health care provider would not be a reasonable alternative for a linear accelerator to be located within a hospital-based facility. The provision of immediate radiation treatment services and must likewise be coordinated with our existing programs and involve the educational /research/teaching aspects that separate our services from many other providers of care. The ability to provide a continuum of care inpatient through outpatient is essential to educating health care professionals of the future, as well as to allow UNC Hospitals to meet the continuing needs of the residents of the State of North Carolina.

Even so, a joint venture for an additional linear accelerator scanner would unnecessarily complicate these missions.

7. **Will the proposed project foster competition by promoting the cost effectiveness, quality, and access to services in the proposed service area? Explain how this will be accomplished and if it cannot, please provide an explanation.**

Response: This project will foster competition by promoting the cost effectiveness and quality of a broad range of health care services. Specifically, this proposal will increase necessary access of our educational programs that have been approved for expansion and other existing programs, to further state-of-the-art technologies. This will also provide increased access and convenience to patients in the service area to quality radiation therapy services. However, this project is not proposed to foster competition per se, but rather to expand access to state-of-the-art technology to educational programs that have been approved for expansion, other existing education programs, research activities, in addition to timely, quality patient care.

8. **If the existing or proposed facility is NOT a hospital, respond to the following questions:**

(a) **Will physicians affiliated with the existing or proposed facility accept emergency room call in area hospitals?**

(b) **Will the existing or proposed facility accept referrals from hospitals where the physicians utilizing the facility have practice privileges?**

(c) **Will the physicians affiliated with the existing or proposed facility have practice privileges at a hospital in the county in which the facility is or will be located? If so, identify the hospital and, if not, explain.**

Responses to (a), (b) and (c) above: Not applicable. UNC Hospitals is a hospital.