Wake Forest University Baptist
MEDICAL CENTER

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North Carolina Division
of Health Service Regulation
Medical Facilities Planning Section
701 Barbour Drive
Raleigh, NC 27603

VIA HAND DELIVERY AND E-MAIL TO
DHSR.SMFP.Petitions-Comments@dhhs.nc.gov

Re: Comments of Wake Forest University Baptist Medical Center Responding to Novant Health, Inc.'s Petition to the State Health Coordinating Council to Delete or Revise SMFP Policy AC-3

Dear Sir or Madam:

This letter is submitted on behalf of Wake Forest University Baptist Medical Center (WFUBMC) and its component institutions, to offer comments in opposition to the Petition filed by Novant Health, Inc. with the State Health Coordinating Council, seeking to delete or revise Policy AC-3 contained in the State Medical Facilities Plan, which provides that certain CON applications filed by Academic Medical Center Teaching Hospitals are exempt from the need determinations in the SMFP, provided those applications meet specific conditions related to their academic and research missions.

WFUBMC believes that Novant's Petition is an untimely effort to find a new forum to air its opposition to a the CON Section's approval of a Policy AC-3 CON application filed by North Carolina Baptist Hospital (NCBH), which is currently under appeal in the Office of Administrative Hearings.

Policy AC-3 is essential for NCBH and the other Academic Medical Center Teaching Hospitals (AMCs) to fulfill their obligations to train the next generation of physicians, many of whom ultimately work for and with the AMCs' competitors. In 2009 alone, Wake Forest University School of Medicine had over 479 medical students, and there are 494 medical residents, four dental residents, and 120 medical fellows in the accredited Graduate Medical Education programs. WFUBMC finds it ironic that Novant would seek to limit the ability of NCBH and the other AMCs to adequately train those future physicians.

For these and the other reasons discussed in more detail below, the Petition should be denied.

BACKGROUND

WFUBMC is an integrated health care system that operates 1,230 acute care, rehabilitation, long-term, and psychiatric care beds, outpatient services, and community health and information centers. The Medical Center's component institutions carry out a joint mission of patient care, education, research and community service. WFUBMC's two main components are NCBH and Wake Forest University Health Sciences (WFUHS), which includes the Wake Forest University School of Medicine and Wake Forest University Physicians.

NCBH is one of four Academic Medical Center Teaching Hospitals in the State of North Carolina, as that term is defined in SMFP Policy AC-3, along with Duke University Health System, UNC Hospitals and Pitt County Memorial Hospital.

AMCs play an essential role in supporting the teaching, research, and patient care missions of the academic medicine community. As the one the state's four AMCs, NCBH is obligated and required by its accrediting bodies to train future physicians, nurses, and allied health professionals in modern facilities using state-of-the-art technology. NCBH's academic and training missions have long been a key component of its identity, and in order to keep pace with the responsibility to continue training the country's future leaders, investments in state of the art technology and facilities are imperative to support this mission.

Today, Wake Forest University School of Medicine, which is located on the WFUBMC campus, occupies a firm position among the best medical schools in the United States. The desire to teach excellence in clinical medicine, promote strong clinical and basic research, render exemplary patient care, and stress service to the community has contributed to the tremendous growth occurring at WFUBMC.

DIFFERENCES BETWEEN AMCS AND OTHER HOSPITALS IN NORTH CAROLINA

AMCs in North Carolina have the following attributes that differentiate them from all of the other hospitals in the State:

- *Higher case mix* - The AMCs attract patients who require care of complex conditions that result in a higher case mix index. As an AMC, NCBH serves a much higher acuity level of patients than other regional health care providers and is a major tertiary/quaternary referral center that provides specialty and subspecialty care such as orthopedics/sports medicine, trauma and burn, diagnostic neurology, neonatal and perinatal medicine, and oncology services. As noted below the four AMCs in North Carolina have a combined case mix index of *1.70* versus *1.23* for all other hospitals. This demonstrates that the patients served at AMCs are sicker and often require more intensive services.

Case Mix Index	2005	2006	2007	2008	2009
NC Baptist	1.71	1.74	1.74	1.74	1.79
Duke University	1.76	1.81	1.75	1.83	1.86
UNC Hospitals	1.43	1.46	1.42	1.43	1.50
Pitt County	1.42	1.58	1.58	1.56	1.63
AMC avg.	1.59	1.65	1.62	1.64	1.70
Non-AMC avg.	1.14	1.15	1.16	1.20	1.23
All NC hospitals	1.20	1.22	1.22	1.26	1.30
Forsyth Med. Ctr.	1.20	1.20	1.22	1.26	1.29

See attached chart, Exhibit 1 hereto, for more detail.

- *Approved residency program* - Each of the four AMCs has residency programs accredited by the Office of Graduate Medical Education. In addition, each of the four AMCs affiliates with community hospitals of the State to bring this valuable resource to multiple communities. WFUBMC has a strong commitment to provide continuing medical education in the western region of North Carolina, and provided a total of 125 grand rounds last year for approximately 1, 016 physician participants for regional community hospitals in North Carolina.

- *On-site medical school* - Each of the four AMCs in North Carolina has an accredited medical school on the same campus as their Medical Center, which serves to provide an optimal balance of classroom teaching, clinical care, and research in one location. This ensures maximum availability to both students and patients at all times. The Wake Forest University School of Medicine's mission is to improve the health and well-being of all people by cultivating the discovery, teaching and applications of biomedical knowledge. *U.S. News & World Report* currently ranks NCBH among the nation's best in eight categories, which would not be possible without the on-site Medical School:

  - Cancer
  - Ear, Nose & Throat
  - Gynecology
  - Heart & Heart Surgery
  - Kidney Disorders
  - Neurology & Neurosurgery
  - Pulmonology
  - Urology

  Through its partnership with Wake Forest University School of Medicine, North Carolina Baptist Hospital is able to provide highly specialized services, treatments and access to cutting edge research that can only be provided in an AMC setting. As an example, WFUBMC is home to the Institute for Regenerative Medicine. The Institute for Regenerative Medicine was the first in the world to successfully implant a laboratory grown organ into humans and today is working to grow more than 22 different organs

and tissues. In addition, since 1970 WFUBMC has continuously been designated by the National Cancer Institute as a Comprehensive Cancer Center. This designation recognizes excellence in cancer research, teaching and clinical care. Through this comprehensive program we are able to offer innovative procedures not offered elsewhere. For example, we are one of the world's largest providers of Intraperitoneal Hyperthermic chemotherapy and one of only two providers in the State that offer gamma knife treatments for brain tumors.

- *Major Research Focus* - In the case of research, an enormous amount of clinical and translational research is conducted at NCBH and the same is true for the other three AMCs. This mission is essential for the continued development of the Wake Forest University School of Medicine, its departments, and faculty. In fact in 2009, WFUBMC received more than 270 grants from the National Institutes of Health worth approximately $103,073,147 for research grants, training and fellowships.

- *Large Multi-County/Out-of-State Service Area* - NCBH serves as a major referral center for over 5 million residents in northwestern North Carolina and southern Virginia. Referrals also are received from other parts of the State, as well as nationally and internationally. These providers expect NCBH to be able to meet their patients' needs in specialty and sub-specialty care. Approximately 66% of the all patients for whom NCBH provides healthcare services come from outside of Forsyth County, and the percentage is much higher for some sub-specialties. The four AMCs serve the highest proportion of patients outside of their home counties, which is indicative of their status as quaternary referral centers in and outside of North Carolina. See supporting data, Exhibit 2 hereto.

REASONS WHY NOVANT'S PETITION SHOULD BE DENIED

NOVANT'S PETITION TO THE SHCC IS UNTIMELY

The SHCC should not consider any of Novant's arguments at this time, because the Petition must be denied as untimely. Because the SMFP provides that a Petition such as the one filed by Novant should have been submitted to the SHCC no later than March 3, 2010, the SHCC should not consider the Petition in regard to any adjustments to the 2011 SMFP.

Chapter 2 of the 2010 SMFP identifies the procedures for seeking amendments and revisions to the SMFP. That chapter provides, in pertinent part, as follows:

Petitions to Revise the Next State Medical Facilities Plan

Anyone who finds that the N.C. State Medical Facilities Plan policies or methodologies, or the results of their application, are inappropriate may petition

for changes or revisions. Such petitions are of two general types: those requesting changes in basic policies and methodologies, and those requesting adjustments to the need projections.

Petitions for Changes in Basic Policies and Methodologies

People who wish to recommend changes that may have a statewide effect are asked to contact the Medical Facilities Planning Section staff as early in the year as possible, and to submit petitions no later than ***March 3, 2010****. Changes with the potential for a statewide effect are the addition, deletion, and revision of policies or projection methodologies. 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" (explained below) is being developed.*

...

Petitions for Adjustments to Need Determinations

A Proposed N.C. State Medical Facilities Plan is adopted annually by the North Carolina State Health Coordinating Council, and is made available for review by interested parties during an annual "Public Review and Comment Period." During this period, regional public hearings are held to receive oral/written comments and written petitions. The Public Review and Comment Period for consideration of each Proposed N.C. State Medical Facilities Plan is determined annually and dates are available from the Medical Facilities Planning Section and published in the N.C. State Medical Facilities Plan,

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 policies may submit a written petition requesting an adjustment be made to the need determination given in the Proposed N.C. State Medical Facilities Plan. These petitions should be delivered to the Medical Facilities Planning Section as early in the Public Review and Comment Period as possible, but no later than the last day of this period.

2010 SMFP, pp. 9, 11-12 (emphasis added).

Thus, the SMFP provides that Petitions seeking to make a fundamental change in the SMFP policies or need methodology must be submitted to the SHCC **no later than** March 3, 2010. Other petitions seeking to revise the adjustments made in the Proposed SMFP, may be submitted **after** the Proposed SMFP is published.

Novant's Petition was filed on August 2, 2010, after the Proposed 2011 SMFP was published.[1] It indisputably seeks a change "with the potential for a statewide effect," because it seeks the

[1] A portion of the Proposed 2011 SMFP is attached to Novant's Petition as Exhibit H.

deletion and/or revision of a policy contained in the SMFP. This request was submitted well after the March 3, 2010 deadline. Therefore, the SHCC should deny Novant's Petition on the grounds that it is untimely and not appropriate for consideration in the 2011 SMFP.

ADDITIONAL REASONS SUPPORTING DENIAL OF NOVANT'S PETITION

Novant's Petition also seeks to justify rescinding Policy AC-3 based on its assertion that:

1. The policy is no longer necessary, because health care has changed since its implementation in 1983, and because AMCs do not need Policy AC-3 to address their teaching and research needs;
2. It gives AMCs an unfair advantage; and
3. It is inconsistent with North Carolina's health planning process.

These contentions are addressed below.

Need for Policy AC-3

Novant raises three points in support of its contention that Policy AC-3 is not needed: (1) relatively few AC-3 CON applications are filed; (2) AMCs can file Petitions with the SHCC for special need determinations; and (3) the CON law contains a provision exempting from CON review new institutional health services to be used solely for research.

Rather than support its contentions, Novant's first point demonstrates that Policy AC-3 is not being abused by the four AMCs operating in the State. NCBH and the other AMCs have only relied on the policy to address specific needs of the AMCs to follow their missions to educate and train future physicians.

Below is a list of just some of the benefits of Policy AC-3:

- *Ensures opportunities for training programs and collaboration between the clinical enterprise and the research and training missions of AMCs* - Preservation of the policy allows for the expansion of capital and the acquisition of technology when necessary to support large increases in faculty, students and research. These increases can occur outside of the timeline and availability of resources in the State Medical Facilities Plan which can inhibit an AMC's ability to serve its mission and purpose. AMCs must provide state-of-the-art facilities and equipment to train tomorrow's clinicians, whether that be through training laboratories, simulation labs or at the patient's bedside; in order to accomplish this the appropriate facilities and resources must be planned and developed to accommodate additional faculty and students, which are determined by AMC leadership and not State Health Planners. Therefore, contrary to Novant's assertion, these needs cannot be met by petitions to the SHCC seeking a special need determination.

For example, even if such a petition were granted, the delay in waiting until the following year to file a CON application to meet that need would jeopardize the ability of the AMC to fulfill the needs identified in Policy AC-3.

- *Ensures AMCs can meet the impending demands of healthcare reform* - The recent Healthcare Reform legislation is expected to provide coverage to an additional 32 million people in the United States. However, there are serious concerns that there will not be enough doctors to serve all of the people that will be covered. AMCs have continued to see increases in their medical school enrollment and resident placements. Over the next decade the biggest demand is expected to be for more primary care physicians. The AMCs in North Carolina will have to ensure that the faculty and resources are in place to train additional primary care physicians; these physicians are important components to the medical home, chronic disease management and accountable care organization pilot programs outlined in the Healthcare Reform bill.
- *Allows AMCs to accommodate the growing demand for clinical research* – As noted above, AMCs such as WFUBMC are at the forefront of medical research. In order for new knowledge to be translated to main stream clinical practice it must first be transitioned to the clinical arena. While the exemption provision in G.S. 131E-179 for research activities is useful for projects where medical center faculty are conducting research activities which do not involve regular patient care, the statute prohibits those resources from being used for clinical care, unless a CON is granted. It is not always practical to designate resources and technology separately for exclusive clinical and research use. This would be inefficient and cost prohibitive to the AMCs and prevent or inhibit many effective patient studies that are comingled with a patient's care plan.
- *Allows for adequate training tools for future physicians* - One of the primary tools for training medical students and residents is to involve them in the patient care process, whether it be for primary care, surgery, or any of the myriad other specialties offered at an AMC. This training is not just for patients who are participating in a research study, but all patients being served in the AMC. Indeed, a resident who is trained only through research-related patient studies likely would not be qualified to care for other types of patients at the conclusion of his or her residency. Policy AC-3 allows AMCs to expand those educational opportunities without being limited to non-clinical research projects.

Allegations of Unfair Advantage

Novant's contention that AMCs have an unfair advantage really goes to the heart of its complaint – it does not agree with the CON Section's recent decision approving NCBH's CON application to expand surgery services under Policy AC-3. Indeed, on the first page of its Petition, Novant admits that its Petition was "prompted" by the NCBH application, and that the application "illustrates how Policy AC-3 is subject to being misused." WFUBMC strongly disagrees with

Novant's characterization of NCBH's CON application and the CON Section's Required State Agency Findings approving that application.

The SHCC planning process is not the appropriate forum to litigate a CON Section decision. North Carolina law clearly provides that such decisions are subject to appeal, and as noted in the Petition, Novant has appealed that approval. If Novant's position is correct, then NCBH's project will not be developed, and its concerns will have been addressed. However, whether NCBH's proposal should be developed should be a decided in the administrative appeal process after a full contested case hearing, not in the SHCC based upon Novant's self-serving characterization of NCBH's application and the CON Section's decision.

Notwithstanding, NCBH feels that it must respond to some of the most self-serving allegations in the Petition:

- In contending that the NCBH Application did not comply with the requirements of Policy AC-3, Novant's Petition quotes *two lines* of a letter contained in the Application from William P. Applegate, M.D., President of WFUHS and Dean of Wake Forest University School of Medicine, certifying that the project is "[n]ecessary to complement a specified and approved expansion of the number of types of students, resident or faculty," as required in Policy AC-3. Novant also complains that the Application did not include a recruitment policy, and therefore Dr. Applegate's certification could not be independently verified. Setting aside Novant's unsupported questions regarding Dr. Applegate's truthfulness, his letter, a copy of which is attached as Exhibit 3, contains much more information about the reasons why the service is needed than the Petition would lead one to believe. The Application also contains letters from numerous other Wake Forest University School of Medicine faculty members, confirming the need for the additional ORs to accommodate faculty growth and to improve training opportunities.

- With regard to Novant's contention that the NCBH Application failed to adequately address the "20-mile" provision contained in Policy AC-3, the Petition seems to imply that Novant or the other non-AMCs within 20 miles of NCBH are in a position to perform the types of surgeries proposed in the NCBH Application. This representation ignores the entire premise of the Application, which explained that:

  > *The unmet need that prompted the development of the proposed project is the continued and increasing demand for OR block time due to high growth in current and future faculty recruitment of 80+ surgeons at NCBH, the continued increase in the volume of ambulatory surgery and procedures performed at NCBH, and the need to expand training programs for surgical faculty, residents, fellows and nurses.* (Petition Exhibit I, Agency Findings, p. 8.)

The fact of the matter is, none of the other hospitals located within 20 miles of NCBH are AMCs, and none have medical school faculty on staff or provide medical student or residency training *unless* it is in conjunction with one of the AMCs. Other than Novant, none of the hospitals within that 20-mile area have opposed the NCBH Application or contended that they could meet the need for the services proposed in the Application.

- Novant contends that three operating rooms purchased by WFUHS from the Plastic Surgery Center of North Carolina should have been used to meet the needs addressed in the CON Application. However, those operating rooms cannot meet the research and educational needs of NCBH, as explained to the CON Section. Further, those operating rooms are not part of NCBH. As discussed below, the CON law does not require an AMC to demonstrate existing and future utilization of other facilities. The CON Section understands this fact and has consistently applied the law in this fashion.

The fact of the matter is, the NCBH Application contained extensive information regarding the need for the proposed project, which is explained in detail in the Agency Findings attached to Novant's Petition. In addition, during the CON Section's review of the NCBH Application, NCBH also addressed most of the written comments (attached to Novant's Petition as Exhibit J) raised by Novant about the Application in its Response to Comments filed with the CON Section. A copy of that Response is attached as Exhibit 4.

The notion that AMCs are (and NCBH specifically is) abusing Policy AC-3 also is inconsistent with Novant's assertion that Policy AC-3 CON applications are rarely filed and therefore, the policy is no longer needed. The AMCs cannot be abusing the policy if they are rarely relying on it. In fact, NCBH has not regularly relied on Policy AC-3 in its CON applications. Prior to the application which Novant has appealed, NCBH's most recent Policy AC-3 CON application was filed in 2003, to acquire a 3.0T MRI scanner and a PET/CT scanner. See Required State Agency Findings, Exhibit 5 hereto. Those Findings also belie the assertion on page 10 of Novant's Petition that "Policy AC-3 applications are rarely disapproved." As shown in the Findings, NCBH's Policy AC-3 CON application was disapproved. Novant is aware of this fact, as it filed comments opposing the 2003 application and also intervened in NCBH's contested case appeal of the denial of its CON. That contested case ultimately was settled, and NCBH was approved for the CON.[2]

These issues all were considered by the CON Section in its Findings, and are the subject of the current contested case. NCBH anticipates that there will be extensive discovery in the case, as well as a contested case hearing lasting well over a week. That is the proper forum for

[2] Novant did not seek to amend the SMFP at that time, presumably because unlike NCBH's most recent Policy AC-3 CON application, it was satisfied with the CON Section's initial decision.

addressing Novant's complaints, not a change in Policy AC-3 that would have statewide implications which have no bearing on the dispute between Novant and NCBH in that case.

Alleged Inconsistency with North Carolina's Health Planning Process

Contrary to Novant's assertions, Policy AC-3 clearly is consistent with North Carolina's health planning process. As noted in Novant's Petition, the policy has been in effect in some form for over 27 years. It also is implicitly supported in the CON law. As the SHCC may be aware, the CON Section has promulgated rules related to its review of CON applications for various services. A number of those rules require the applicant to demonstrate that similar services provided by existing and approved facilities in the applicant's service area historically have met specific utilization thresholds, and will continue to meet those thresholds after the proposed project is developed. However, the General Assembly has exempted AMCs from the requirements of these rules. Specifically, the CON law provides that:

> *(b) The Department is authorized to adopt rules for the review of particular types of applications that will be used in addition to those criteria outlined in subsection (a) of this section and may vary according to the purpose for which a particular review is being conducted or the type of health service reviewed. No such rule adopted by the Department shall require an academic medical center teaching hospital, as defined by the State Medical Facilities Plan, to demonstrate that any facility or service at another hospital is being appropriately utilized in order for that academic medical center teaching hospital to be approved for the issuance of a certificate of need to develop any similar facility or service.* [3]

G.S. 131E-183(b). Thus, the General Assembly recognized that in the CON process, AMCs may have needs related to a proposed service that cannot be met by other facilities, and determined that an AMC need not take those other facilities' utilization into account in order to demonstrate the need for its proposal. Policy AC-3 is entirely consistent with this legislative determination.

REQUESTED ACTION

Novant's Petition clearly is an effort to seek a new forum to challenge the CON Section's determination approving NCBH's most recent CON application. If the SHCC seriously believes that Novant's contentions related to that application should be considered in making a determination, then the SHCC and the Medical Facilities Planning Section must review the entire application, as well as the other information the CON Section reviewed in making its determination to approve the application. WFUBMC submits, however, that the SHCC should

[3] The underlined portion was added to G.S. 131E-183(b) by the General Assembly in 1991. See Exhibit 6, 1991 Session Laws, C. 692, p. 1065, attached hereto.

not become enmeshed in Novant's appeal of the CON Section's approval of NCBH's Policy AC-3 application, as that is neither the mandate of the SHCC nor sound health planning policy.

As discussed above, Novant's Petition to eliminate or revise the SMFP is without merit. Furthermore, under the clear instructions contained in the SMFP, Novant's Petition is untimely, because it seeks the deletion or revision of a policy which will have statewide effect but the Petition was not filed before the deadline for such petitions. Therefore, the SHCC need not and should not consider Novant's contentions, but should deny the Petition as untimely.

WFUBMC thanks the SHCC for its careful consideration of these comments.

Very truly yours,

WAKE FOREST UNIVERSITY BAPTIST MEDICAL CENTER

John D. McConnell, M.D.

John D. McConnell, M.D.
Chief Executive Officer

cc w/enc.: Members of the Acute Care Committee

EXHIBITS TO WFUBMC RESPONSE AND COMMENTS

1. Case Mix Index – Inpatient Discharges from NC Hospitals

2. Inpatient Discharges from Outside Home County

3. Letter in NCBH Application from William P. Applegate, M.D., President of WFUHS and Dean of Wake Forest University School of Medicine

4. NCBH Response to Comments filed with CON Section

5. Required State Agency Findings, Project I.D. No. G-6816-03/ North Carolina Baptist Hospital/ Acquire one 3.0T MRI scanner and one PET/CT scanner pursuant to Policy AC-3 in the 2003 SMFP for radiation therapy treatment planning/ Forsyth County

6. 1991 Session Laws, C. 692, p. 1065

Case Mix Index (1) - Inpatient Discharges From NC Hospitals

Federal Fiscal Year (October 1 - September 30)

EXHIBIT 1

	All Services										Excluding Obstetrics & Normal Newborns (3)									
	All Patients					Excluding Outliers & Data Anomalies (2)					All Patients					Excluding Outliers & Data Anomalies (2)				
Hospital	*'05*	*'06*	*'07*	*'08*	*'09*	*'05*	*'06*	*'07*	*'08*	*'09*	*'05*	*'06*	*'07*	*'08*	*'09*	*'05*	*'06*	*'07*	*'08*	*'09*
Summary																				
4 AMCs	1.59	1.65	1.62	1.64	1.70	1.57	1.62	1.59	1.61	1.66	1.76	1.84	1.80	1.81	1.87	1.75	1.81	1.77	1.78	1.83
All Non-AMCs	1.14	1.15	1.16	1.20	1.23	1.14	1.15	1.16	1.20	1.23	1.35	1.37	1.38	1.42	1.45	1.35	1.36	1.37	1.42	1.44
All NC Hospitals	1.20	1.22	1.22	1.26	1.30	1.20	1.21	1.21	1.25	1.29	1.41	1.43	1.44	1.48	1.51	1.40	1.43	1.43	1.47	1.50
AMCs																				
NC Baptist	1.71	1.74	1.74	1.74	1.79	1.69	1.71	1.71	1.70	1.76	1.72	1.75	1.74	1.74	1.80	1.70	1.72	1.71	1.71	1.76
Duke University	1.76	1.81	1.75	1.83	1.86	1.74	1.76	1.69	1.78	1.79	1.98	2.04	1.97	2.05	2.09	1.95	1.99	1.91	1.99	2.01
Univ of N Carolina	1.43	1.46	1.42	1.43	1.50	1.41	1.44	1.40	1.41	1.48	1.67	1.70	1.63	1.64	1.72	1.66	1.68	1.61	1.62	1.70
Pitt County	1.42	1.58	1.58	1.56	1.63	1.42	1.57	1.57	1.55	1.60	1.64	1.85	1.84	1.81	1.86	1.65	1.84	1.83	1.79	1.84
Non-AMCs																				
Alamance Regional	1.03	1.03	1.02	1.05	1.10	1.03	1.03	1.02	1.05	1.10	1.21	1.20	1.20	1.21	1.26	1.21	1.20	1.20	1.22	1.26
Albemarle	1.07	1.06	1.07	1.09	1.02	1.07	1.06	1.07	1.09	1.02	1.22	1.23	1.22	1.24	1.18	1.22	1.23	1.22	1.24	1.18
Alleghany Memorial	0.92	0.95	0.99	0.95	0.94	0.92	0.95	0.99	0.95	0.94	0.94	0.95	0.99	0.95	0.94	0.94	0.95	0.99	0.95	0.94
Angel Med Ctr	1.05	0.96	0.96	0.99	0.99	1.05	0.97	0.96	0.99	0.99	1.25	1.21	1.20	1.24	1.18	1.25	1.21	1.20	1.25	1.18
Annie Penn	0.98	1.02	1.00	1.07	1.18	0.98	1.02	1.00	1.07	1.18	1.09	1.17	1.15	1.20	1.18	1.09	1.16	1.15	1.20	1.18
Anson Community	1.06	1.11	1.07	1.10	1.19	1.06	1.11	1.07	1.10	1.19	1.06	1.11	1.08	1.10	1.19	1.06	1.11	1.08	1.10	1.19
Ashe Memorial	1.06	1.06	1.00	1.04	0.95	1.06	1.06	1.00	1.04	0.95	1.13	1.15	1.10	1.14	1.06	1.13	1.15	1.10	1.15	1.06
Beaufort County	0.95	0.95	0.93	0.96	0.96	0.95	0.95	0.93	0.96	0.96	1.09	1.10	1.09	1.12	1.12	1.09	1.10	1.09	1.12	1.12
Bertie Memorial	0.97	0.98	0.95	0.96	0.90	0.97	0.98	0.95	0.96	0.90	0.97	0.98	0.95	0.96	0.90	0.97	0.98	0.95	0.96	0.90
Betsy Johnson Reg	0.90	0.91	0.89	0.99	0.98	0.90	0.91	0.89	0.99	0.98	1.05	1.04	1.04	1.14	1.13	1.05	1.04	1.04	1.14	1.13
Bladen County	0.89	0.86	0.84	0.90	0.90	0.89	0.86	0.84	0.90	0.90	1.11	1.08	0.99	1.10	1.04	1.11	1.08	0.99	1.10	1.05
Blowing Rock	0.90	0.81	0.84	0.86	0.84	0.90	0.81	0.82	0.86	0.84	0.90	0.81	0.84	0.86	0.84	0.90	0.81	0.82	0.86	0.84
Blue Ridge Regional	0.95	1.02	1.01	1.02	0.97	0.95	1.02	1.01	1.02	0.97	1.03	1.11	1.10	1.12	1.04	1.03	1.11	1.10	1.12	1.04
Brunswick Community	0.99	0.97	0.98	1.00	1.06	0.99	0.97	0.98	1.00	1.06	1.07	1.06	1.10	1.15	1.24	1.07	1.06	1.10	1.15	1.24
Brynn Marr	0.61	0.62	0.67	0.71	0.81	0.61	0.62	0.67	0.74	0.81	0.61	0.62	0.67	0.71	0.81	0.61	0.62	0.67	0.74	0.81
Caldwell Memorial	0.99	0.99	1.06	1.13	1.22	1.00	1.00	1.07	1.14	1.25	1.19	1.17	1.27	1.33	1.45	1.20	1.19	1.28	1.36	1.49
Cannon Mem / Sloop	0.88	0.91	0.90	0.86	0.84	0.88	0.91	0.90	0.86	0.84	0.92	0.98	0.98	0.94	0.89	0.92	0.99	0.98	0.94	0.89
Cape Fear Valley	1.19	1.17	1.15	1.18	1.23	1.18	1.16	1.15	1.17	1.22	1.45	1.42	1.40	1.42	1.51	1.44	1.41	1.39	1.41	1.50
CarePartners Rehab	1.01	1.05	0.95	1.08	1.24	1.01	1.05	0.95	1.08	1.24	1.01	1.05	0.95	1.08	1.24	1.01	1.05	0.95	1.08	1.24
Carolinas Med Ctr	1.41	1.46	1.48	1.53	1.54	1.39	1.44	1.47	1.52	1.52	1.74	1.81	1.83	1.88	1.87	1.71	1.79	1.82	1.86	1.85
Carteret General	1.00	0.98	0.99	1.05	1.15	1.00	0.98	0.99	1.05	1.15	1.14	1.10	1.11	1.20	1.28	1.14	1.10	1.11	1.20	1.28
Catawba Valley MC	1.06	1.08	1.11	1.15	1.19	1.06	1.08	1.11	1.15	1.19	1.34	1.38	1.39	1.42	1.46	1.34	1.36	1.39	1.41	1.46
Central Carolina	0.95	0.92	0.93	0.97	0.98	0.95	0.92	0.92	0.97	0.98	1.20	1.17	1.16	1.24	1.18	1.19	1.17	1.16	1.23	1.18
Charlotte Rehab	0.89	0.88	0.96	1.09	1.27	0.89	0.88	0.96	1.09	1.27	0.89	0.88	0.96	1.09	1.27	0.89	0.88	0.96	1.09	1.27
Chatham (County)	1.05	1.11	1.02	1.02	1.00	1.05	1.10	1.02	1.02	1.00	1.05	1.11	1.02	1.02	1.01	1.06	1.10	1.02	1.02	1.01
Chowan	0.92	0.89	0.88	0.92	0.90	0.92	0.89	0.88	0.92	0.90	1.13	1.11	1.14	1.14	1.09	1.14	1.11	1.14	1.14	1.09
Cleveland Regional	1.07	1.08	1.09	1.18	1.23	1.06	1.08	1.09	1.17	1.23	1.23	1.23	1.27	1.39	1.45	1.23	1.23	1.27	1.38	1.45
Columbus Regional	1.01	1.04	1.09	1.14	1.09	1.01	1.04	1.09	1.14	1.09	1.12	1.16	1.21	1.28	1.23	1.12	1.16	1.21	1.28	1.23

	All Services										Excluding Obstetrics & Normal Newborns (3)									
	All Patients					Excluding Outliers & Data Anomalies (2)					All Patients					Excluding Outliers & Data Anomalies (2)				
Hospital	'05	'06	'07	'08	'09	'05	'06	'07	'08	'09	'05	'06	'07	'08	'09	'05	'06	'07	'08	'09
Craven Regional	1.30	1.25	1.23	1.19	1.23	1.30	1.26	1.23	1.19	1.23	1.41	1.37	1.36	1.33	1.39	1.41	1.38	1.36	1.33	1.39
Crawley Memorial	0.87	0.79	0.79	0.59		0.87	0.79	0.79	0.59		0.87	0.79	0.79	0.59		0.87	0.79	0.79	0.59	
Davie County	0.90	0.86	0.82	0.80	0.77	0.90	0.86	0.82	0.80	0.77	0.90	0.86	0.82	0.80	0.77	0.90	0.86	0.82	0.80	0.77
Davis Reg Med Ctr	0.92	0.93	0.93	1.03	1.06	0.92	0.93	0.93	1.03	1.06	1.04	1.05	1.03	1.14	1.14	1.04	1.05	1.03	1.14	1.14
Duplin General	0.69	0.70	0.70	0.76	0.80	0.69	0.70	0.70	0.76	0.80	0.93	0.94	0.93	1.02	1.01	0.93	0.94	0.93	1.02	1.01
Durham Regional	1.17	1.19	1.22	1.23	1.23	1.17	1.19	1.22	1.23	1.23	1.42	1.43	1.44	1.48	1.47	1.42	1.43	1.44	1.48	1.47
Fellowship Hall	0.38	0.39	0.44			0.39	0.39	0.44			0.38	0.39	0.44			0.39	0.39	0.44		
Forsyth Med Ctr	1.20	1.20	1.22	1.26	1.29	1.20	1.19	1.21	1.26	1.29	1.52	1.51	1.56	1.60	1.62	1.51	1.51	1.55	1.59	1.61
Franklin Regional	1.30	1.34	1.29	1.22	1.10	1.29	1.34	1.30	1.22	1.10	1.30	1.34	1.30	1.22	1.10	1.29	1.34	1.30	1.22	1.10
Frye Regional	1.35	1.39	1.41	1.40	1.40	1.33	1.38	1.40	1.39	1.38	1.48	1.51	1.53	1.51	1.50	1.46	1.51	1.52	1.49	1.49
Gaston Memorial	1.14	1.14	1.13	1.22	1.24	1.13	1.14	1.13	1.22	1.24	1.34	1.34	1.34	1.46	1.46	1.34	1.34	1.34	1.46	1.46
Good Hope	0.97	1.00				0.97	1.00				0.97	1.00				0.97	1.00			
Grace	0.89	0.90	0.92	0.93	0.99	0.89	0.90	0.92	0.93	0.99	1.08	1.11	1.13	1.18	1.23	1.08	1.11	1.13	1.18	1.23
Granville Med Ctr	0.92	0.92	0.92	1.00	1.05	0.91	0.92	0.92	1.00	1.05	1.17	1.15	1.16	1.22	1.29	1.17	1.15	1.16	1.22	1.29
Halifax Regional	0.92	0.97	1.01	1.03	1.06	0.92	0.97	1.01	1.03	1.06	1.02	1.07	1.13	1.14	1.16	1.02	1.07	1.13	1.14	1.16
Harris Regional	0.99	1.03	1.04	1.12	1.12	0.99	1.03	1.04	1.12	1.12	1.23	1.26	1.26	1.32	1.33	1.24	1.26	1.26	1.32	1.33
Haywood Regional	1.14	1.21	1.17	1.13	1.14	1.15	1.20	1.17	1.13	1.14	1.24	1.31	1.28	1.25	1.24	1.24	1.31	1.28	1.25	1.24
Heritage	0.96	1.00	1.02	1.08	1.06	0.96	1.00	1.02	1.08	1.06	1.15	1.19	1.20	1.24	1.20	1.15	1.18	1.20	1.24	1.20
High Point Regional	1.16	1.15	1.16	1.21	1.26	1.16	1.15	1.16	1.21	1.26	1.34	1.34	1.35	1.40	1.45	1.34	1.34	1.35	1.40	1.45
Highlands-Cashiers	1.06	0.97	0.92	1.09	1.10	1.06	0.97	0.92	1.09	1.10	1.06	0.97	0.92	1.09	1.10	1.06	0.97	0.92	1.09	1.10
Holly Hill	0.60	0.59	0.66	0.73	0.80	0.60	0.59	0.66	0.73	0.80	0.60	0.59	0.66	0.73	0.80	0.61	0.59	0.66	0.73	0.80
Hoots Memorial	0.95	0.96	1.05	1.07	1.00	0.95	0.95	1.05	1.07	0.99	0.95	0.96	1.05	1.07	1.00	0.95	0.95	1.05	1.07	0.99
Hugh Chatham Mem	1.01	1.06	1.01	1.03	1.02	1.01	1.06	1.01	1.03	1.02	1.13	1.18	1.16	1.16	1.16	1.13	1.18	1.16	1.16	1.16
Iredell Memorial	1.12	1.09	1.13	1.14	1.19	1.12	1.09	1.13	1.14	1.18	1.27	1.26	1.28	1.30	1.33	1.27	1.26	1.29	1.29	1.33
J Arthur Dosher	1.04	1.07	1.03	1.16	1.16	1.04	1.07	1.03	1.16	1.16	1.04	1.07	1.03	1.16	1.16	1.04	1.07	1.03	1.16	1.16
Johnston Memorial	0.99	1.02	0.98	1.03	1.05	0.99	1.02	0.98	1.04	1.05	1.20	1.22	1.18	1.22	1.27	1.20	1.22	1.18	1.22	1.26
Kindred - Greensboro	2.75	2.92	3.41	3.57	4.14	2.50	2.59	3.07	3.31	3.85	2.75	2.92	3.41	3.57	4.14	2.50	2.59	3.07	3.31	3.85
Kings Mountain	0.90	0.92	0.96	1.04	1.09	0.90	0.92	0.96	1.04	1.09	0.90	0.92	0.96	1.04	1.09	0.90	0.92	0.96	1.04	1.09
Lake Norman Reg	1.04	1.01	1.07	1.09	1.14	1.03	1.01	1.05	1.09	1.13	1.25	1.23	1.29	1.33	1.42	1.24	1.23	1.27	1.33	1.41
Lenoir Memorial	1.01	0.99	1.05	1.12	1.11	1.01	0.99	1.05	1.12	1.11	1.10	1.10	1.14	1.22	1.20	1.10	1.10	1.14	1.22	1.20
Lexington Memorial	0.92	0.89	0.93	0.95	0.98	0.92	0.89	0.93	0.95	0.98	1.16	1.17	1.20	1.25	1.25	1.17	1.18	1.20	1.25	1.25
Lincoln Med Ctr	1.00	0.97	0.95	1.05	1.05	1.00	0.97	0.95	1.05	1.05	1.18	1.13	1.13	1.22	1.22	1.18	1.13	1.13	1.22	1.22
Margaret Pardee Mem	1.10	1.11	1.08	1.15	1.24	1.10	1.11	1.08	1.15	1.24	1.21	1.21	1.16	1.22	1.29	1.21	1.21	1.16	1.22	1.29
Maria Parham	0.97	0.94	0.95	0.97	0.96	0.96	0.93	0.95	0.97	0.96	1.19	1.16	1.19	1.21	1.19	1.19	1.16	1.19	1.20	1.19
Martin General	0.91	0.89	0.90	0.95	0.96	0.91	0.89	0.90	0.95	0.96	0.98	0.97	1.01	1.02	1.01	0.98	0.97	1.01	1.02	1.00
McDowell	0.95	0.96	0.95	1.09	1.14	0.95	0.96	0.95	1.09	1.14	1.12	1.19	1.16	1.19	1.19	1.12	1.19	1.16	1.19	1.19
Medical Park	1.51	1.41	1.43	1.49	1.42	1.51	1.41	1.43	1.49	1.41	1.51	1.41	1.43	1.49	1.42	1.51	1.41	1.43	1.49	1.41
Mercy	1.12	1.12	1.15	1.21	1.26	1.11	1.11	1.15	1.21	1.26	1.35	1.38	1.41	1.48	1.55	1.34	1.37	1.41	1.47	1.54
Mission / St. Joseph's	1.55	1.57	1.54	1.49	1.51	1.54	1.57	1.54	1.49	1.51	1.80	1.85	1.82	1.73	1.74	1.80	1.84	1.82	1.73	1.74
Montgomery Mem	1.01	1.00	1.04	0.98	0.98	1.01	1.00	1.04	0.98	0.98	1.01	1.00	1.04	0.98	0.98	1.01	1.00	1.04	0.98	0.98
Moore Regional	1.33	1.35	1.34	1.40	1.38	1.33	1.34	1.33	1.39	1.38	1.50	1.52	1.51	1.57	1.52	1.50	1.51	1.50	1.56	1.52
Morehead Memorial	0.97	0.98	0.94	0.99	1.02	0.97	0.98	0.94	0.99	1.02	1.08	1.10	1.03	1.10	1.14	1.08	1.10	1.03	1.10	1.14
Moses Cone / W. Long	1.24	1.26	1.28	1.31	1.30	1.24	1.26	1.28	1.31	1.30	1.49	1.52	1.53	1.56	1.56	1.49	1.52	1.53	1.56	1.56
Murphy Med Ctr	1.13	1.19	1.22	1.25	1.17	1.13	1.19	1.22	1.25	1.17	1.27	1.31	1.30	1.33	1.24	1.27	1.31	1.30	1.33	1.24
Nash General	1.05	1.07	1.06	1.11	1.16	1.05	1.07	1.05	1.11	1.16	1.18	1.20	1.19	1.25	1.30	1.18	1.20	1.18	1.25	1.31
NC Specialty	1.85	1.74	1.75	1.84	1.86	1.85	1.74	1.75	1.85	1.88	1.85	1.74	1.75	1.84	1.86	1.85	1.74	1.75	1.85	1.88
New Han / Cape Fear	1.29	1.32	1.33	1.40	1.41	1.29	1.32	1.33	1.40	1.41	1.54	1.58	1.60	1.64	1.65	1.54	1.57	1.59	1.64	1.64
Northeast Med Ctr	1.21	1.20	1.21	1.24	1.28	1.21	1.20	1.21	1.23	1.27	1.47	1.46	1.44	1.44	1.48	1.47	1.46	1.43	1.44	1.48
Northern of Surry	0.92	0.98	1.02	1.10	1.18	0.92	0.98	1.02	1.10	1.18	1.09	1.15	1.20	1.27	1.38	1.09	1.15	1.20	1.27	1.38
Onslow Memorial	0.86	0.90	0.92	0.98	0.99	0.86	0.90	0.92	0.98	0.98	1.12	1.19	1.20	1.23	1.27	1.11	1.19	1.20	1.23	1.26
Our Community	0.86	0.92	0.89	0.83	0.79	0.86	0.92	0.89	0.83	0.79	0.86	0.92	0.89	0.83	0.79	0.86	0.92	0.89	0.83	0.79
Outer Banks	0.79	0.75	0.81	0.88	0.82	0.79	0.75	0.81	0.88	0.82	1.12	1.07	1.12	1.19	1.13	1.12	1.07	1.12	1.19	1.13
Park Ridge	1.02	1.04	1.11	1.20	1.17	1.02	1.04	1.11	1.20	1.17	1.17	1.21	1.25	1.33	1.32	1.17	1.21	1.24	1.34	1.32
Pender Memorial	0.90	0.91	0.96	0.90	0.84	0.90	0.91	0.96	0.90	0.84	0.90	0.91	0.96	0.90	0.84	0.90	0.91	0.96	0.90	0.84

	All Services										Excluding Obstetrics & Normal Newborns (3)									
	All Patients					Excluding Outliers & Data Anomalies (2)					All Patients					Excluding Outliers & Data Anomalies (2)				
Hospital	'05	'06	'07	'08	'09	'05	'06	'07	'08	'09	'05	'06	'07	'08	'09	'05	'06	'07	'08	'09
Person Memorial	1.01	1.12	1.06	1.11	1.19	1.01	1.12	1.06	1.11	1.19	1.09	1.18	1.17	1.20	1.22	1.09	1.18	1.17	1.20	1.22
Presbyterian	1.20	1.13	1.15	1.19	1.24	1.19	1.13	1.14	1.18	1.24	1.49	1.41	1.44	1.52	1.56	1.49	1.41	1.43	1.51	1.55
Presbyterian - Hunt	0.89	0.83	0.93	0.98	1.12	0.89	0.83	0.93	0.98	1.12	1.09	1.07	1.18	1.29	1.42	1.09	1.07	1.18	1.29	1.42
Presbyterian - Matt	0.87	0.87	0.87	0.98	1.05	0.87	0.87	0.87	0.98	1.05	1.14	1.11	1.11	1.23	1.27	1.14	1.12	1.11	1.23	1.27
Pungo District	0.92	0.91	0.89	0.91	0.85	0.92	0.91	0.89	0.91	0.85	0.92	0.91	0.89	0.91	0.85	0.92	0.91	0.89	0.92	0.85
Raleigh Hospital	1.18	1.55	1.61	1.71	1.78	1.18	1.55	1.61	1.71	1.78	1.45	1.60	1.61	1.71	1.78	1.45	1.60	1.61	1.71	1.78
Randolph	1.03	1.06	1.03	1.12	1.14	1.03	1.06	1.03	1.12	1.14	1.23	1.28	1.24	1.34	1.34	1.23	1.28	1.24	1.34	1.34
Rex	1.17	1.12	1.12	1.13	1.18	1.17	1.12	1.11	1.12	1.17	1.56	1.52	1.52	1.57	1.60	1.56	1.52	1.52	1.57	1.60
Richmond Memorial	0.86	0.84	0.85	0.87	0.84	0.87	0.85	0.85	0.87	0.84	1.01	1.03	1.03	1.04	0.98	1.02	1.03	1.03	1.04	0.98
Roanoke-Chowan	0.99	1.01	1.04	1.05	1.04	0.99	1.02	1.04	1.05	1.04	1.12	1.15	1.17	1.19	1.17	1.12	1.15	1.17	1.19	1.17
Rowan Regional	1.12	1.14	1.17	1.21	1.21	1.12	1.14	1.17	1.21	1.21	1.28	1.29	1.33	1.38	1.38	1.27	1.29	1.33	1.38	1.38
Rutherford	0.99	0.98	0.98	1.01	1.02	0.99	0.98	0.98	1.01	1.02	1.14	1.13	1.13	1.15	1.15	1.14	1.13	1.13	1.15	1.15
Sampson Regional	0.97	0.88	0.93	0.91	1.00	0.97	0.88	0.93	0.91	1.00	1.12	1.08	1.10	1.17	1.24	1.12	1.08	1.10	1.17	1.24
Sandhills Regional	1.01	1.00	1.03	1.03	1.02	1.01	1.00	1.03	1.03	1.02	1.01	1.00	1.03	1.03	1.02	1.01	1.00	1.03	1.03	1.02
Scotland Memorial	0.95	1.00	1.03	1.06	1.05	0.95	1.00	1.03	1.06	1.05	1.08	1.16	1.22	1.24	1.20	1.08	1.16	1.22	1.24	1.20
Southeastern Reg	0.88	0.92	0.97	1.07	1.09	0.88	0.92	0.97	1.07	1.09	1.00	1.05	1.12	1.23	1.27	1.00	1.05	1.12	1.23	1.27
St. Luke's	1.13	1.20	1.26	1.22	1.16	1.13	1.20	1.26	1.22	1.16	1.13	1.20	1.26	1.22	1.16	1.13	1.20	1.26	1.22	1.16
Stanly Memorial	0.94	0.97	0.94	0.98	1.09	0.94	0.97	0.94	0.98	1.09	1.10	1.18	1.12	1.16	1.31	1.10	1.18	1.13	1.17	1.31
Stokes-Reynolds Mem	0.91	0.92	0.96	0.92	0.88	0.91	0.92	0.96	0.92	0.88	0.91	0.92	0.96	0.92	0.88	0.91	0.92	0.96	0.92	0.88
Swain County	0.92	0.89	0.89	0.84	0.83	0.92	0.89	0.89	0.84	0.83	0.92	0.89	0.89	0.84	0.83	0.92	0.89	0.89	0.84	0.83
Thomasville Med Ctr	0.91	0.87	0.89	0.96	1.03	0.91	0.87	0.89	0.96	1.02	1.09	1.04	1.06	1.15	1.22	1.09	1.04	1.06	1.15	1.21
Transylvania Comm	1.10	1.03	1.04	1.06	1.11	1.10	1.02	1.04	1.05	1.11	1.26	1.22	1.20	1.20	1.21	1.26	1.22	1.20	1.19	1.21
Union Regional	0.98	1.02	1.02	1.07	1.08	0.98	1.02	1.02	1.07	1.08	1.21	1.26	1.25	1.29	1.29	1.21	1.26	1.26	1.29	1.29
University (Charlotte)	0.95	0.93	0.94	0.99	1.02	0.95	0.94	0.94	0.99	1.02	1.28	1.26	1.36	1.41	1.41	1.28	1.26	1.36	1.41	1.41
Valdese General	1.17	1.17	1.15	1.27	1.35	1.17	1.17	1.15	1.26	1.35	1.17	1.17	1.15	1.27	1.35	1.17	1.17	1.15	1.26	1.35
Wake Alc Trtmt Ctr	0.36	0.36	0.40	0.54	0.55	0.37	0.36	0.40	0.55	0.55	0.36	0.36	0.40	0.54	0.55	0.37	0.36	0.40	0.55	0.55
Wake Med - Cary	0.89	0.89	0.92	0.97	1.01	0.89	0.89	0.92	0.97	1.01	1.29	1.32	1.34	1.33	1.35	1.29	1.32	1.34	1.33	1.35
Wake Med Ctr	1.41	1.41	1.39	1.40	1.41	1.40	1.41	1.38	1.39	1.40	1.76	1.76	1.72	1.70	1.70	1.75	1.76	1.71	1.69	1.69
Washington County	0.89	0.90	0.88	0.89	0.80	0.89	0.90	0.88	0.89	0.80	0.89	0.90	0.88	0.89	0.80	0.89	0.90	0.88	0.89	0.80
Watauga Med Ctr	0.99	0.98	1.00	1.07	1.10	0.99	0.98	1.00	1.07	1.10	1.16	1.14	1.16	1.22	1.26	1.16	1.15	1.16	1.22	1.25
Wayne Memorial	1.09	1.10	1.08	1.15	1.19	1.09	1.10	1.08	1.15	1.19	1.26	1.27	1.24	1.32	1.34	1.26	1.27	1.24	1.32	1.34
Wilkes Regional	0.92	0.90	0.92	1.02	1.11	0.92	0.90	0.92	1.02	1.11	1.05	1.02	1.07	1.19	1.26	1.05	1.02	1.07	1.19	1.26
Wilson Med Ctr	0.98	1.00	1.01	1.06	1.14	0.98	1.00	1.01	1.06	1.14	1.18	1.19	1.21	1.28	1.36	1.18	1.19	1.21	1.28	1.36

	All Services										Excluding Obstetrics & Normal Newborns (3)									
	All Patients					Excluding Outliers & Data Anomalies (2)					All Patients					Excluding Outliers & Data Anomalies (2)				
Hospital	*'05*	*'06*	*'07*	*'08*	*'09*	*'05*	*'06*	*'07*	*'08*	*'09*	*'05*	*'06*	*'07*	*'08*	*'09*	*'05*	*'06*	*'07*	*'08*	*'09*

NOTES

(1) **Case Mix Index** - Case Mix Index is a proxy for the severity or intensity of hospital inpatients. Each DRG/MS-DRG is assigned a weight by CMS representing the relative cost to treat the average patient with that diagnosis. Case Mix Index is determined by multiplying the number of patients in each DRG/MS-DRG by that DRG/MS-DRG's weight. Results are added together and then divided by the total number of patients to produce the final Case Mix Index. Weights for each DRG/MS-DRG are recalculated annually (FFY). The average Case Mix Index for all U.S. hospitals is 1.0.

(2) **Outliers & Data Anomalies** - The source data vendor uses the following criteria to exclude certain records considered "data anomalies or outliers:"
Age incalculable
Age <15 and diagnosis only for adults
Age >17 and diagnosis only for children
Age >124 years or negative values
Age not between 12 and 55 and diagnosis or procedure only appropriate for women of childbearing age
Charges <$0 or >$500,000
Diagnosis inconsistent with sex of patient
Inconsistent principle diagnosis and procedure
Invalid or missing: other diagnoses or other procedures, patient discharge status, principle diagnosis, and/or principle procedure
Invalid zip code
Length of stay: incalculable, <1 day, or >365 days
Missing or invalid sex
Probable aborted fetus and still births
Procedure inconsistent with sex of patient
DRGs for "Principal diagnosis invalid as discharge diagnosis" or "Ungroupable"

(3) **Obstetrics & Normal Newborns** - Identified by DRGs 370-384, 391 (through FFY '07) and MS-DRGs 765-770, 774-782, 795 (beginning FFY '08).

SOURCE: NC Hospital Association Patient Data System.
Medical Center Strategic Planning RML 8/16/10

Inpatient Discharges From Outside Home County - All NC Hospitals

Federal Fiscal Year 2009 (Oct 1, 2008 - Sept 30, 2009)

EXHIBIT 2

Academic Medical Center
Critical Access
General Acute

Hospital Name	From Home County	Outside Home County	Total	Percent From Outside Home County
Univ of N Carolina	7,644	30,850	38,494	80.1%
Duke University	13,113	27,435	40,548	67.7%
NC Baptist	11,617	22,181	33,798	65.6%
Pitt County	16,718	22,422	39,140	57.3%
Roanoke-Chowan	2,132	2,846	4,978	57.2%
Frye Regional	5,638	7,445	13,083	56.9%
Moore Regional	10,580	12,373	22,953	53.9%
Harris Regional	2,117	2,450	4,567	53.6%
Hugh Chatham Mem	2,642	3,034	5,676	53.5%
Chowan	1,130	1,234	2,364	52.2%
Blue Ridge Regional	1,218	1,170	2,388	49.0%
New Han / Cape Fear	19,947	19,038	38,985	48.8%
Medical Park	552	507	1,059	47.9%
Mission / St. Joseph's	23,183	20,386	43,569	46.8%
Presbyterian - Matt	4,789	4,168	8,957	46.5%
Scotland Memorial	3,950	3,423	7,373	46.4%
Durham Regional	9,981	8,277	18,258	45.3%
Albemarle	3,520	2,916	6,436	45.3%
Highlands-Cashiers	143	118	261	45.2%
Park Ridge	2,659	2,187	4,846	45.1%
High Point Regional	10,785	8,708	19,493	44.7%
Nash General	8,795	6,769	15,564	43.5%
Watauga Med Ctr	3,218	2,465	5,683	43.4%
Cannon Mem / Sloop	1,148	836	1,984	42.1%
Mercy	9,205	6,702	15,907	42.1%
Valdese Hospital	1,360	942	2,302	40.9%
Kings Mountain	1,574	1,081	2,655	40.7%
Carolinas Med Ctr	30,854	20,958	51,812	40.5%
Forsyth Med Ctr	27,290	18,177	45,467	40.0%
Pungo District	400	257	657	39.1%
Davis Reg Med Ctr	3,328	1,945	5,273	36.9%
Maria Parham	3,431	1,972	5,403	36.5%
Swain County	479	262	741	35.4%
Lake Norman Reg	4,558	2,452	7,010	35.0%
Murphy Med Ctr	1,930	1,005	2,935	34.2%
Pender Memorial	487	248	735	33.7%
Duplin General	2,657	1,339	3,996	33.5%
Raleigh Hospital	4,340	2,160	6,500	33.2%
Wake Med Ctr	27,228	13,485	40,713	33.1%
Cape Fear Valley Health System	208	102	310	32.9%
Presbyterian - Hunt	4,028	1,903	5,931	32.1%
St. Luke's	729	340	1,069	31.8%
Craven Regional	11,800	5,407	17,207	31.4%
CMC-NorthEast	17,195	7,784	24,979	31.2%
Central Carolina	4,055	1,827	5,882	31.1%
Catawba Valley MC	7,864	3,383	11,247	30.1%
CMC-Union	7,705	3,284	10,989	29.9%
Sandhills Regional	2,588	1,102	3,690	29.9%
Halifax Regional	6,042	2,514	8,556	29.4%
Lenoir Memorial	6,987	2,822	9,809	28.8%
Moses Cone / W. Long	36,109	14,255	50,364	28.3%
Morehead Memorial	4,515	1,759	6,274	28.0%
Betsy Johnson Reg	5,106	1,986	7,092	28.0%

Hospital Name	From Home County	Outside Home County	Total	Percent From Outside Home County
Heritage	3,682	1,393	5,075	27.4%
Grace	5,670	2,120	7,790	27.2%
Stanly Memorial	4,046	1,506	5,552	27.1%
Cape Fear Valley / HR	26,350	9,553	35,903	26.6%
Granville Med Ctr	1,803	652	2,455	26.6%
Presbyterian	25,403	9,078	34,481	26.3%
Northern of Surry	3,449	1,189	4,638	25.6%
Thomasville Med Ctr	3,523	1,174	4,697	25.0%
Beaufort County	2,730	890	3,620	24.6%
Outer Banks	1,313	427	1,740	24.5%
Blowing Rock	79	25	104	24.0%
Margaret Pardee Mem	5,663	1,785	7,448	24.0%
Cleveland Regional	7,143	2,187	9,330	23.4%
Wilson Med Ctr	7,258	2,205	9,463	23.3%
Iredell Memorial	7,282	2,203	9,485	23.2%
Lincoln Med Ctr	3,353	965	4,318	22.3%
Alleghany Memorial	558	153	711	21.5%
Chatham (County)	700	180	880	20.5%
CMC-University	5,668	1,384	7,052	19.6%
Gaston Memorial	19,990	4,881	24,871	19.6%
Franklin Regional	1,352	324	1,676	19.3%
Rex	27,094	6,089	33,183	18.3%
Rowan Regional	8,535	1,706	10,241	16.7%
Washington County	481	95	576	16.5%
Haywood Regional	4,561	890	5,451	16.3%
Wayne Memorial	11,461	2,182	13,643	16.0%
Carteret General	6,023	1,130	7,153	15.8%
Person Memorial	1,702	307	2,009	15.3%
Wake Med - Cary	10,335	1,793	12,128	14.8%
Johnston Memorial	8,144	1,391	9,535	14.6%
Annie Penn	2,254	372	2,626	14.2%
Bladen County	1,066	169	1,235	13.7%
Southeastern Reg	13,478	2,056	15,534	13.2%
Alamance Regional	9,414	1,435	10,849	13.2%
Sampson Regional	2,949	446	3,395	13.1%
Columbus Regional	4,149	606	4,755	12.7%
Richmond Memorial	3,349	466	3,815	12.2%
Martin General	2,088	278	2,366	11.7%
Davie County	259	34	293	11.6%
Stokes-Reynolds Mem	170	22	192	11.5%
Lexington Memorial	3,802	483	4,285	11.3%
Angel Med Ctr	1,533	194	1,727	11.2%
Caldwell Memorial	4,049	512	4,561	11.2%
Transylvania Comm	1,576	188	1,764	10.7%
Onslow Memorial	7,933	898	8,831	10.2%
Rutherford	5,714	611	6,325	9.7%
Randolph	7,041	749	7,790	9.6%
Montgomery Mem	419	42	461	9.1%
Hoots Memorial	176	16	192	8.3%
Our Community	22	2	24	8.3%
Brunswick Community	3,343	289	3,632	8.0%
Bertie Memorial	418	36	454	7.9%
Ashe Memorial	1,433	121	1,554	7.8%
J Arthur Dosher	1,145	92	1,237	7.4%
McDowell	1,566	105	1,671	6.3%
Wilkes Regional	4,655	256	4,911	5.2%
Anson Community	949	43	992	4.3%
Total:	701,572	405,069	1,106,641	36.6%

Hospital Name	From Home County	Outside Home County	Total	Percent From Outside Home County

Source: NC Hospital Association Patient Data System
Medical Center Strategic Planning CDS 8/16/2010

EXHIBIT
3

WAKE FOREST
UNIVERSITY
HEALTH SCIENCES

Office of the President

William B. Applegate MD, MPH, FACP
President
Dean, Wake Forest University
School of Medicine

January 15, 2010

Craig Smith, Chief
Certificate of Need Section
Division of Health Service Regulation
NC Department of Health and Human Services
27014 Mail Service Center
Raleigh, NCH 27699-2704

Re: Policy AC-3 Certification

Dear Mr. Smith:

The purpose of this letter is to certify that the expansion of ambulatory care surgical facilities on the North Carolina Baptist Hospital West Campus proposed in a certificate of need application to be submitted by North Carolina Baptist Hospital on January 15, 2010 is:

> "Necessary to complement a specified and approved expansion of the number of types of students, residents, or faculty"

With the support of North Carolina Baptist Hospital, the Wake Forest University School of Medicine and Wake Forest Health Sciences has begun an expansion of the clinical and research faculty within the Division of Surgical Sciences. The expansion is driven by four factors:

- The increasing specialization of clinical and surgical practices at academic medical centers
- The increasing involvement of faculty research, especially clinical trials involving new diagnostic, surgical and therapeutic tools and techniques
- The increasing demand for surgical services
- The changing paradigms for surgical training

Over the last three years, we have successfully recruited 36 new clinical faculty within the Division of Surgical Sciences, which has largely contributed to the operating room capacity issues on the NCBH campus. The current number of surgeons practicing within the Division is 113; however, we now project to add a total of 51 faculty in the Division of Surgical Sciences, including 39 clinical FTEs by 2020. It is anticipated that by 2020 there will be a total of 193 surgical faculty within the Division of Surgical

Sciences. Pertinent to the expansion of surgical capacity on the West Campus, we anticipate significant additions in the specialties essential to meeting the demands of our patients and research as outlined below:

	Current Faculty- Jan 2010			Projected Faculty- 2010-2020			Total Faculty		
Specialty	Clinical FTES	Research FTES	Total FTES	Clinical FTES	Research FTES	Total FTES	Clinical FTES	Research FTES	Total FTES
Cardiothoracic Surgery	9	1	10	2	0	2	11	1	12
Emergency	23	4	27	6	0	6	29	4	33
General	25	4	29	6	0	6	31	4	35
Hypertension	0	8	8	0	2	2	0	10	10
Neurosurgery	7	4	11	6	4	10	13	8	21
Ophthalmology	16	0	16	4	0	4	20	0	20
ENT	11	1	12	3	1	4	14	2	16
Plastics	6	4	10	3	3	6	9	7	16
Urology	8	3	11	6	2	8	14	5	19
Vascular	8	0	8	3	0	3	11	0	11

In the recruitment of these additional faculty, the Wake Forest University School of Medicine will be competing with its peers across North Carolina and the nation. We must be able to offer our faculty the facilities, equipment and training essential to academic medical center practice in the 21st century or we will not be competitive.

The expansion of the ambulatory surgery capacity and facilities on the NCBH West Campus will also allow the Wake Forest University School of Medicine to enhance the training and education of our medical students, faculty and fellows. The simulation and robotics training rooms proposed on the West Campus will simulate high-acuity conditions and utilize scenarios and associated instructor feedback to provide a safe yet lifelike learning environment for students and faculty to acquire essential skills required in surgical care. There is a great need to expand our teaching facilities for our surgical residents and medical students to ensure they have an appropriate environment to practice the fundamental skills of operating outside the clinical field in a laboratory setting where operations can be simulated. NCBH serves as a national training site for the National Training Robotics program and it is critical that Wake Forest be able to continue to provide this program and meet the requirements of the Accreditation Council of Graduate Medical Education. NCBH will also seek future accreditation as a nationally accredited Institute of Robotic Surgery through the Society of Urologic Robotics Surgery.

The expansion of the surgical capacity on the West Campus proposed in the certificate of need application to be submitted January 15, 2010 is essential to the recruitment and retention of these new faculty as well as our existing faculty. I therefore certify the proposed project as "Necessary to

complement a specified and approved expansion" of the faculty of the Wake Forest University Health Sciences. Thank you for your consideration of this letter. If there is further information I can provide, please let me know.

Sincerely,

William B. Applegate, MD, MPH, MACP
President, Wake Forest University Health Sciences
Dean, Wake Forest University School of Medicine

Rec. 3/8/10

EXHIBIT 4

Response to Comments on North Carolina Baptist Hospital
PROJECT ID # G-8460-10
NCBH Policy AC-3 OR CON Application

North Carolina Baptist Hospital ("NCBH") is responding to the comments made by Novant Health, Inc. on the above-referenced application to acquire 7 incremental operating rooms, 2 procedure rooms, one simulation operating room and one robotic surgery training room.

Please note that in no way does NCBH intend for these comments to change or amend its application which was filed on January 15, 2010. These responses are submitted to rebut comments submitted to the CON Section regarding the application. If the CON Section considers any of these responses to be amending NCBH's application, those responses should not be considered.

Novant Comment: Novant contends that NCBH provides insufficient documentation and explanation needed to demonstrate compliance with the SMFP Policy AC-3 Requirement for the Necessity to Support an Expansion of Students, Residents or Faculty

NCBH Response: In its comments, Novant is in error when it suggests that CON Policy AC-3 imposes a higher burden of proof on academic medical centers than other providers. The fact is that that the intent of this policy section is not to apply a higher burden of proof, but rather to apply a different burden of proof for teaching hospitals. NCBH provided a letter from the Dean of the Wake Forest University Medical School certifying the number of clinical and research faculty that are currently practicing and those proposed to be recruited over the next decade. This alone would satisfy this requirement.

However, it should be noted that NCBH continually demonstrated throughout its CON application that the training requirements and surgical needs are unique to NCBH and could not currently be served by the non-AMC providers in Forsyth or contiguous counties in about four different locations throughout the CON application. Specifically, NCBH provided written documentation in Section III (1) (a) regarding its status as the only academic medical center in western North Carolina. It stated, "As an academic medical center, NCBH serves a much higher acuity level of patients than other regional health care providers and is a major tertiary/quaternary referral center that provides specialty and subspecialty care such as orthopedics/sports medicine, trauma and burn, diagnostic neurology, neonatal and perinatal medicine, and oncology services."

With the scope of services offered at NCBH, it is absolutely essential to have capacity to meet the highly specialized surgical needs of the patients in our 24 county service area. NCBH accepts referrals from other health care providers within the service area, the state, as well as nationally and internationally. These providers expect NCBH, regarded as a leader in innovative surgical applications and research, to be able to meet their patient needs in specialty and sub-specialty care.

Response to Comments on North Carolina Baptist Hospital
PROJECT ID # G-8460-10
NCBH Policy AC-3 OR CON Application

Approximately 70% of the patients for whom NCBH provides surgical services for come from outside of Forsyth County. For quantitative data and demonstration of this fact, please refer to the patient origin tables on pages 70-77 of the CON application. In addition, please refer to the response on page 64 of the CON application, question 2 in Section III as quoted below.

> ***Document that the facility is needed at the proposed site as opposed to another area of the service area.***
>
> *Given the combination of facilities and services required to provide the surgical services, simulation operating rooms, training facilities, equipment, and the fact that the resources are already in place at NCBH, the clinical model the Surgical Services department has developed, and the deep involvement of Wake Forest University researchers, NCBH has concluded that expanding the campus to accommodate the outpatient surgery center on the NCBH campus would benefit our patients and their families, our clinicians, and our researchers far more than establishing the expanded OR and training capacity at another off-campus location. Since all Wake Forest University Faculty provide clinics and have their offices housed on the NCBH campus it would not make sense to relocate services off campus away from where faculty currently practice.*

In addition on page 80 of the CON application, NCBH states that it "serves a unique patient population by functioning as the regional referral facility for tertiary, quaternary care. The extremely high acuity levels of tertiary care patients require a facility that has intensive resources, medical expertise and staffing in order to provide appropriate care. According to NC Hospital Association data, NCBH has one of the highest Case Mix Severity Indexes of any acute care hospital in the State."

As also noted in the NCBH application discussion of alternatives, the location of the proposed OR project was chosen on the NCBH campus as opposed to any off-site location. This is necessary because the Wake Forest University faculty hold clinics and have academic responsibilities housed on this campus and utilizing off-campus operating rooms would make these physicians less efficient.

Novant Comment: Novant states the faculty recruitment plans "seem like a modest and manageable rate of growth in surgical faculty that may also be offset by future retirements of surgical faculty".

Response to Comments on North Carolina Baptist Hospital
PROJECT ID # G-8460-10
NCBH Policy AC-3 OR CON Application

NCBH Response: In the Policy AC-3 OR application, NCBH documented the fact that the project is necessary to support a "specified and approved expansion" of the number of faculty at the associated professional school. NCBH shared specifics of the WFUHS approved recruitment plans by specialty and detailed the research and clinical effort of these incremental faculty. The additional 39 clinical surgical FTE's when added to the current 113 surgeons on staff represent a 35% growth in faculty and will create a significant need for additional OR capacity. This growth is incremental to the continued volume growth that is experienced due to the recent faculty additions.

In its comments, Novant is in error when attempting to exclude certain incremental faculty from the NCBH need calculations by deeming that they would not perform surgeries at the proposed surgery center. The fact is WFUHS has not indicated that these additional surgeons would perform only outpatient surgery. Furthermore, there is nothing in the NCBH application that would suggest that only the West Campus OR need is being calculated. On the contrary, NCBH demonstrated a total need for additional ORs, and then clearly documented the caseload that would shift to the proposed outpatient setting. The surgical volumes generated by these additional faculty members would be a mix of inpatient and outpatient cases, which is consistent with the methodology used by NCBH in its volume projections.

The comments provided by Novant on the NCBH AC-3 application, are in error and attempt to understate the need demonstrated by NCBH in various ways. In particular, the comments include the following misrepresentations:

- Novant stated that 14 of the incremental surgeons would not perform procedures in the proposed West Campus OR location and should therefore be excluded from any future need, despite the fact that these surgeons will clearly increase overall NCBH OR caseload (p. 4 Novant comments). The fact is NCBH pointed out that the existing surgical suites are operating at 110% utilization and the benefit of shifting much of the ambulatory surgical procedures to the new facility would be to provide the space necessary for the new surgeons to have surgical time in the inpatient ORs.
- Novant believe that potential retirement of current faculty should reduce the future FTE additions despite the fact that the historical growth rate would obviously account for any routine attrition (p. 4 Novant comments).
- Novant suggests that NCBH should plan for 1 additional FTE each for Plastics, General, Vascular, Urological and ENT surgeons, for a total of 5 additional surgeons, resulting in a need for 4 ORs despite the fact that 39 incremental surgeons are proposed as detailed in the application (p. 5 Novant comments).
- Novant declared that it would be more appropriate to request and build enough ORs for 2.5 new surgeons each year, despite the fact that this approach would add cost to the project due to the inefficiencies of revising construction plans on an annual basis (p. 5 Novant comments).
- Finally, Novant stated that this application was flawed because it suggested that all of the additional surgical faculty would perform only outpatient surgeries on the West Campus,

despite the fact that they clearly will perform inpatient and outpatient surgeries, substantially increasing overall need for incremental surgical capacity at NCBH (p. 5 Novant comments).

Novant's comments are in error, misrepresent the facts of the application and ignore prudent health planning. NCBH clearly documents the specified and approved incremental WFUHS faculty that support the need for this OR expansion under Policy AC-3.

Novant Comment: Novant makes several comments regarding the NCBH surgical growth rates used in the NCBH Application.

NCBH Response: Novant is in error when it states that there must have been a rapid decrease in inpatient and outpatient surgical case volumes for the last quarter of FFY 2009, which is inaccurate and represents a misunderstanding of growth rate comparisons. There were in fact several errors found in FMCs comments beginning on page 8.

The facts are that when using surgical volumes reported in NCBH License Renewal Applications, the compound annual growth rate (CAGR) for FFY 2005-FFY 2009 is actually 3.0% for inpatient surgical cases and 4.5% for outpatient surgical cases, not .8% for inpatient cases as reported in the FMC comments. In error, FMC used the annual growth rates for FFY 2008-FFY 2009 as the CAGR for FFY 2005- FFY 2009. See the corrected table below:

Corrected NCBH Annual Surgical Growth

NCBH	FFY 2005	FFY 2006	FFY 2007	FFY 2008	FFY 2009	CAGR FFY 2005 -FFY 2008
Inpatient Cases	11,847	11,900	12,208	13,251	13,357	3.0%
Annual Growth Rate		0.4%	2.6%	8.5%	0.8%	
Ambulatory Cases	15,656	15,842	16,717	17,999	18,693	4.5%
Annual Growth Rate		1.2%	5.5%	7.7%	3.9%	

Source: NCBH LRA

By utilizing fiscal year data, Novant contends that NCBH actually overstated the historical inpatient growth rate. In the NCBH application we reported a CAGR of 2.10%. The Novant comments

include a lengthy discussion and analysis of which data period and which growth rates it suggests should have been used by NCBH. Many of these comments are incorrect, and the resulting conclusions are not logical. For example, Novant claims that the rate of growth since the end of FY 2009 must have "dropped precipitously" in the last quarter of 2009. It should be noted that when comparing two different twelve month timeframes, the number of cases will never be the same. From July 2008 – June 2009, NCBH OR case volumes totaled 32,129. For the twelve months from October 2008 – September 2009, NCBH reported OR case volumes of 32,050. The variance between the totals is 79 cases; a mere 79 cases does not have a material impact on NCBH's application as Novant suggests. Please refer to the table below to demonstrate the difference:

NCBH Annual Surgical Growth Comparison

NCBH	FY 2009	FFY 2009	Difference
Inpatient Cases	13,446	13,357	89
Ambulatory Cases	18,683	18,693	-10
Total	32,129	32,050	79

It is important to consider that volumes will fluctuate from period to period and therefore growth rates can change simply due to the math involved. Because financial projections and volume projections were being completed on an NCBH fiscal year period, NCBH felt it was most appropriate to use a growth rate calculated on a consistent fiscal year basis.

Novant states in error on page 8 of its comments that "two years of data, such as that used by NCBH on pages 46 and 55 of its application, is not typically enough to establish a trend or a reliable growth rate for use in estimating future surgical cases…". It is clear from Novant's analysis that they did not read or understand NCBH's methodology for developing interim and project year growth rates. The fact is that NCBH's growth rates, as demonstrated in the table below, were developed utilizing a combination of quantitative and qualitative data:

GROWTH RATE		
	IP	OP
Interim Years	4.50%	5.00%
Project Years	5.00%	5.50%

The fact is NCBH stated clearly on page 54 of its CON application that broad based planning discussions took place to "address the issues the Division of Surgical Sciences were experiencing

as it relates to current OR capacity, block scheduling, the increased number of faculty and planned recruitment efforts." The planning process and subsequent development of the interim and project year growth rates included a review of historical growth rates for surgical case volumes, assessment of current and future capacity constraints and proposed growth methodologies to project future OR demand. Population growth of our 19-county service area and the growth rates reported in the Pediatrics ED and Cancer Center Expansion Certificate of Need applications were considered as well. The projections were vetted through senior leadership and growth rates that reflected all of these variables were developed (outlined on page 54 of the CON application).

In addition, on page 55 of the CON application, NCBH states that "using the historical growth rates along with assumptions for future growth ***including primarily faculty recruitment***, NCBH calculated inpatient and outpatient surgical case volumes for FY 2010 through FY 2015 in the following table utilizing an inpatient growth rate of 5% for the project years and an outpatient growth rate of 5.5% for the project years."

Novant Comment: Novant states that NCBH failed to acknowledge the recent purchase of Plastic Surgery Center of North Carolina by Wake Forest University Health Sciences, which is responsible for teaching, research and physician clinical care.

NCBH Response: Novant is in error when contends that Wake Forest University Health Sciences and NCBH are related entities. The fact is, Wake Forest University Health Sciences ("WFUHS") is a legal entity separate from NCBH with no common parent organization and the boards of which are distinct and separate with no crossover membership. No change in legal structure has taken place that would alter this historical relationship for CON purposes. NCBH relied on the State CON definitions provided in the rules to ensure that it was compliant with the application requirements, and as such did not include an unrelated entity in its application.

Plastic Surgery Center of North Carolina is owned by Wake Forest University Health Sciences (WFUHS. As such these operating rooms are owned by WFUHS, and as noted by Novant in their comments have not been used for NCBH surgical cases. Historically, the Department of Plastic Surgery has not represented a substantial portion of the outpatient surgical activity identified in the Top 20 CPT listing in the NCBH CON application. Based on discussion with WFUHS leadership, any volumes that would be performed in these operating rooms would not have been historically performed in the NCBH operating rooms, and therefore would not impact the volume projections. In addition, due to the off-campus location of these ORs, it would not be feasible to use them in support of teaching needs. Based on these discussions, the Plastic Surgery Center of North Carolina ORs are not a viable alternative for consideration nor was it appropriate for NCBH to include them in its inventory of operating rooms. NCBH has no control of how these ORs are used and would

have no more control over their use than Novant would have over physicians on their medical staff who may own surgical suites.

Novant Comment: Novant states on page 11 that volumes for the Davie County Hospital Replacement project ORs were not taken into consideration.

NCBH Response: The fact is that the Davie County Hospital OR volumes were factored into the growth projections. Please refer to the Rules Section and the response to 10A NCAC 14 C.2103 Performance Standard Requirements Table II.7 on page 35 of NCBH's CON application. NCBH was very conscientious when developing its OR methodology to ensure that the future OR volume for Davie County and Lexington Memorial Hospital were sustainable and mutually exclusive from the volumes projected for the NCBH campus.

Novant comment: Novant states on page 6 of its comments that the evaluation of need for ORs on the NCBH campus should be adjusted for an additional two operating rooms that might be added to the Forsyth County inventory under a demonstration project (applications proposed for a March 15, 2010 filing date).

NCBH Response: The fact is that the Single Specialty Demonstration Project approved in the 2010 State Medical Facilities Plan in no way anticipates in which county or which specialty of surgery will be awarded the CON and it has not material impact on this application's CON review. The demonstration project covers both Guilford County and Forsyth County, and the resulting approved project may well be outside Forsyth County. Furthermore, there is a good chance that the successful application will be one that has no impact on NCBH case volumes. And finally, the CON is likely to be contested, putting the operational date of the ORs in question. Finally, NCBH cannot not be expected to defer planning for OR services until the resolution of that CON application process, while its affiliated surgical staff move forward with faculty expansion. It should also be noted that this demonstration project cannot be legally considered by the Agency in this review.

Novant Comment: Novant states in their concluding comments that a less costly project, with a significantly smaller compliment of new ORs and greater relocation of existing ORs seems to be the more reasonable course at this point in time.

NCBH Response: In its concluding comments, Novant notes that the last NCBH CON application under SMFP Policy AC-3 was filed in May 2003. This is accurate, and proves that NCBH only seeks approval under this policy when there is a strong need for a project to support research or medical education. The fact is that as one of the state's few teaching hospitals, NCBH has a

responsibility to ensure adequate facilities to support its affiliated medical school. There are no specific limits to the magnitude of investment that may be needed in support of an academic medical center mission. In fact, Duke University was recently approved for $261,849,601 for a Cancer Center expansion under an AC-3 exemption. Clearly, Novant's suggestion that this $38 million request is excessive under the AC-3 policy is inaccurate and inapplicable. NCBH has justified the need for the proposed ORs and the facility is appropriately sized to meet that need.

EXHIBIT
5

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS
C = Conforming
CA = Conditional
NC = Nonconforming
NA = Not Applicable

DECISION DATE:	October 28, 2003
FINDINGS DATE:	October 29, 2003
PROJECT ANALYST:	Martha J. Frisone
CHIEF:	Lee B. Hoffman
PROJECT I.D. NUMBER:	G-6816-03/ North Carolina Baptist Hospital/ Acquire one 3.0T MRI scanner and one PET/CT scanner pursuant to Policy AC-3 in the 2003 SMFP for radiation therapy treatment planning/ Forsyth County

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

NC

North Carolina Baptist Hospital (Baptist) proposes to acquire a 3.0T MRI scanner and a PET/CT scanner pursuant to Policy AC-3 in the 2003 State Medical Facilities Plan (2003 SMFP) for radiation therapy (RT) treatment planning (i.e., simulation). In Section II.1, page 24, the applicant states

"NCBH proposes to purchase a General Electric Signa 3.0T magnetic resonance imaging scanner to be used primarily as a MRI-simulator for RT treatment planning. This system will include the following features:

- *3.0 Tesla system will perform whole body imaging using a wide variety of pulse sequences.*
- *Production of high resolution thin slices.*
- *Includes chemical-shift spectroscopy imaging.*
- *Radiation therapy simulation software, including CT-MRI fusion software and laser tracking system for MRI simulation.*

NCBH also proposes to purchase a General Electric Discovery ST PET/CT scanner to be used as a CT – simulator and PET/CT simulator for RT treatment planning. This system will include the following features:

- *High system sensitivity for both PET and CT.*
- *Large 70cm bore with short tunnel length (which is optimal for radiation therapy patient positioning).*
- *2-D and 3-D imaging capabilities.*
- *Four slice CT for thinner images also important for radiation therapy planning and rapid attenuation correction.*
- *Radiation therapy simulation software package, including PET / CT fusion software and laser tracking system for CT simulation.*

The proposed equipment will be located on the first floor of the Outpatient Comprehensive Cancer Center (OCCC), now under construction on the WFUBMC campus."

Construction of the outpatient cancer center was approved in Project I.D. #G-6376-01.

Policy AC-3 in the 2003 SMFP states

"Exemption from the provisions of need determinations of the State Medical Facilities Plan shall be granted to projects submitted by Academic Medical Center Teaching Hospitals designated prior to January 1, 1990 which projects comply with one of the following conditions:

(i) 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

(ii) 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

(iii) 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 Medical Center Teaching Hospital."

By letter dated February 17, 1983, the Medical Facilities Planning Section, DFS, notified Baptist that it is designated as an Academic Medical Center Teaching Hospital.

Regarding a *"specified and approved"* expansion of the number or types of students, residents or faculty, in Section III.2, pages 65-68, the applicant states

"As a consequence of obtaining the proposed bioanatomic imaging devices (PET /CT and MRI scanners to be used for radiation therapy simulation devices), there will be an expansion of education and training programs in three areas: clinical oncology, radiation physics, and radiation biology.

- *The Department of Radiation Oncology is submitting an application to the National Institutes of Health in response to PAR-03-083, 'Institutional Clinical Oncology Research Career Development Program'. ... The Program trains physicians (primarily recent graduates of radiation, medical, surgical or pediatric oncology residencies/fellowships) to perform clinical oncology research that develops and tests scientific hypotheses in specified areas of cancer research. ... The Program will be two to three years in length, and we anticipate recruiting two to three individuals per year for a maximum of 7 trainees at any given time. The Program Director will be W. Robert Lee, M.D., Vice-Chairman, Department of Radiation Oncology, and Director of the Radiation Oncology Residency Training Program.*
- *The Department of Radiation Oncology, Section of Radiation Physics ... and Section of Radiation Biology ... will be submitting an application this summer for a T32 Research Training Program Grant. ... The Grant will fund pre-doctoral graduate students ... and post-doctoral research fellows ... in basic cancer research, including translational research, (i.e., the movement of laboratory discoveries into patient and population research.) The main areas of training and research will be as follows:*

    - *Radiation Biology – two areas will be emphasized, the development of novel strategies to combat radiation resistance and the pathogenesis of radiation-induced brain injury. ...*
    - *Radiation Physics – four areas will be emphasized, including multimodality imaging, tumor volume determination, tumor control and normal tissue complication probabilities, and radiation dose distributions. ...*

Pre-doctoral training will be two to three years in length and post-doctoral training will be two to three years in length. We anticipate recruiting one to two individuals per year for a maximum of 6 trainees at any given time. ...

Please see the letter of support from William B. Applegate, M.D., M.P.H. Dean and Senior Vice President for Health Sciences attesting to the necessity of this project to complement a specified and approved expansion of the number or types of students, residents or faculty in Exhibit 9."

Exhibit 9 includes an April 29, 2003 letter addressed to the President and CEO of Baptist from William B. Applegate, M.D., M.P.H, Dean and Senior Vice President for Health Sciences, Wake Forest University School of Medicine, which states

"Because the application is being submitted under the academic teaching hospital research exemption, I thought it would be of benefit to expand on the superb opportunities for oncology research and education that will be afforded to the School of Medicine with the acquisition of this technology.

I have recently completed my annual review of all departments and sections in the School, including the Department of Radiation Oncology and the Sections of Radiation Physics and Radiation Biology. Dr. Robert Lee, Vice Chair of Radiation Oncology, is about to submit a K12 application to the National Institutes of Health and National Cancer Institute to support clinical fellows in oncology, most of whom will be in Radiation Oncology. The two (or three) year fellowships will be thematically structured with one of the major themes being bioanatomic radiation treatment planning and treatment delivery. The application has been motivated by the anticipation of the acquisition of the MRI-CT-PET simulators. Furthermore, Drs. Dan Bourland (Physics Section Head) and Mike Robbins (Radiation Biology Section Head) are going to submit a T32 training grant to the NIH/NCI later this summer to support graduate and post-graduate positions in Radiation Physics and Biology."

Dr. Applegate is the *"head of the relevant associated professional school."* However, the letter does not demonstrate that any of the proposed expansions of the number of students, residents or faculty have actually been approved, as required by the policy. In particular, the letter states that funding for the proposed expansion of students has yet to be applied for, and thus has not been approved by the National Institute of Health (NIH) or the National Cancer Institute (NCI). Alternatively, the applicant does not demonstrate that an

approval has been obtained to expand the number of students in the event that the grant approvals are not obtained. Therefore, the applicant failed to adequately demonstrate compliance with the first condition in the policy.

Regarding a *"specified and approved"* expansion of research activities, in Section III.2, pages 68-69, the applicant states

> *"As outlined in the discussion related to Criterion 1, each of the three areas of training program expansion revolves around research. Basic radiation biology and physics research will be translated into clinical trials of safety (Phase I studies) and efficacy (Phase II studies) as well as randomized Phase III studies in which bioanatomic treatment planning approaches are compared to standard methods. Conduct of these Phase I, II, and III clinical trials will be facilitated by the Clinical Research Program of the Comprehensive Cancer Center of Wake Forest University. ... At any given time, the Cancer Center has approximately 50 investigator-initiated studies open, which accrue approximately 600 patients year per year. ... Financial support for the clinical trials will come from the Cancer Center, grants from the National Cancer Institute and similar NIH funding agencies, non-profit associations, foundations, and societies, and industry .... For example, Varian now sponsors research in bioanatomic imaging and treatment with Dan Bourland, Ph.D. as principal investigator. A letter of support from Varian documenting their commitment to research sponsorship is included in Exhibit 17."*

Exhibit 17 includes a May 2, 2003 letter signed by the Manager, Research Partnerships, Varian Medical Systems, Oncology Systems, which states

> *"Varian Medical Systems enthusiastically and fully supports the CON application by North Carolina Baptist Hospital (NCBH) for two radiation treatment planning simulator devices that use advanced imaging: 1) an MR-Simulator and 2) a PET-CT-simulator. ...*
>
> *The acquisition and installation by NCBH/WFUHS of the MR-simulator and PET-CT-simulator is essential to the development of a strong and long-term collaboration in the*

area of bioanatomic imaging and treatment. In support of this promising educational and research initiative, Varian Medical systems currently sponsors the WFUHS Department of Radiation Oncology with a research grant of $150,000 per year. This grant, titled Bioanatomic Radiation Treatment for Brain and Lung, is directed by J. Daniel Bourland, PhD, Associate Professor and Head, Physics Section. ...

Future funding of bioanatomic research at WFUHS is anticipated as subsequent research projects are proposed by Dr. Bourland and his faculty."

Varian Medical Systems is funding current research performed by the Department of Radiation Oncology. However, the letter does not document that an expansion of this research has been approved by Varian Medical Systems and that the proposed equipment is needed for that expansion. Further, the applicant did not document that NIH or NCI have approved grants to fund any proposed research in this area. Therefore, the applicant did not adequately demonstrate that the proposed MRI and PET/CT scanners are "[n]*ecessary 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"* as required by Policy AC-3. (Emphasis added.)

With regard to the requirement to demonstrate the teaching or research need cannot be achieved at a non-academic medical center teaching hospital, in Section II.1, pages 25-26, the applicant states

"While MRI and PET scanners exist in non-teaching hospitals, appropriate and optimal use of the proposed MRI and PET/CT scanners as radiation therapy simulation and bioanatomic treatment planning devices is not possible in a non-teaching setting for the following reasons:

- *Most non-teaching hospitals do not have PET or PET/CT scanners . The CT component of the PET / CT scanner is essential for image co-registration, that is, the precise superimposition of anatomic CT images with anatomic MRI and PET images and biologic MRI spectroscopic and PET images/information. The CT component also provides rapid attenuation correction.*
- *Most non-teaching hospitals do not have volume of patients or resources to justify the ancillary equipment and software necessary to perform MRI spectroscopy. Non-teaching hospitals with MRI spectroscopy, are limited to single-voxel spectroscopy, which is adequate for qualitative diagnostic information. The 2-dimensional and 3-dimensional quantitative biologic information needed for bioanatomic radiation therapy treatment planning are not currently provided in the non-teaching hospital setting.*
- *To perform the full range of bioanatomic imaging with PET, there must be a capability to synthesize a wide variety of radiopharmaceuticals other than standard FDG-18 (e.g., C-11 methionine and thymidine for proliferation imaging, F-18 misonidazole for hypoxia imaging, and others). To synthesize these specialized imaging agents, a cyclotron and radiochemicals to develop and implement safe processes for quality assurance is needed. There are no non-teaching hospitals in North Carolina that have a cyclotron. They rely on vendors or teaching hospitals like Wake Forest that have their own cyclotron to purchase FDG-18."*
- *A multidisciplinary team of physicists and physicians is necessary to utilize the anatomic and biologic information from MRI and PET/CT scanners for bioanatomic radiation therapy simulation, treatment, planning, and treatment delivery. This includes subspecialized physicists, including diagnostic radiology physicists specializing in MRI and PET physics, and radiation oncology physicists specializing in molecular imaging and treatment planning. It also includes subspecialized physicians, including disease-site oriented diagnostic radiologists (in CT, MRI), nuclear medicine radiologists (in PET), and radiation oncologists. ... The number and diversity of individuals involved and the integration of multiple disciplines would be difficult to*

recruit and maintain in a cost-effective manner in a non-teaching hospital."

In addition, in Section III.2, page 64, the applicant states

"the project cannot be implemented through the use of MR and PET/CT scanners at other facilities within 20 miles of Winston-Salem. In fact, the proposed equipment with both the MRI and PET/CT simulation modules are not available anywhere in the State of North Carolina at the present time."

There are no existing or approved PET or PET/CT scanners located within 20 miles of Baptist. Therefore, there is no other facility in the designated area that could meet the teaching or research need for the PET scanner at this time. However, the applicant makes only general and unsupported statements regarding the ability of other hospitals to meet the teaching or research need for the proposed MRI scanner. The applicant fails to identify the hospitals, located within 20 miles of Baptist, that currently offer MRI services. Further, the applicant fails to document that these hospitals cannot effectively meet the research need for the proposed MRI scanner. For example, the applicant fails to document that the research need for the proposed MRI scanner cannot be effectively met using the existing MRI scanner located at Forsyth Medical Center (FMC), which is located less than two miles from Baptist. Particularly since FMC currently serves as a clinical training site for Wake Forest University School of Medicine residents and is a tertiary hospital.

In summary, the applicant did not adequately demonstrate that the acquisition of the MRI or PET/CT scanner is consistent with Policy AC-3 in the 2003 SMFP. Therefore, the application is nonconforming with this criterion.

(2) Repealed effective July 1, 1987.

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

NC

Baptist proposes to acquire a 3.0T MRI scanner and a PET/CT scanner for radiation therapy (RT) treatment planning (i.e., simulation). Baptist currently owns and operates one PET scanner, five MRI scanners, one CT simulator and one conventional simulator. The applicant proposes to replace the existing CT simulator with the proposed PET/CT scanner. Thus, upon completion of the project, Baptist would own and operate one PET scanner, six MRI scanners (one used for simulation), one PET/CT scanner (used for simulation) and one conventional simulator.

Population to be Served

In Section III.5(d), page 83, the applicant states

> *"NCBH currently has the capability to perform conventional and CT simulation procedures for treatment planning within its Department of Radiation Oncology. Projected patient origin for the proposed equipment is projected to be very similar to the existing patient origin."*

The following table illustrates current patient origin for radiation oncology services and projected patient origin for the proposed MRI and PET/CT scanners, as reported by the applicant in Section III.4(b), pages 74-76, and Section III.5(c), pages 78-83.

COUNTY	% OF TOTAL PATIENTS	
	CURRENT RADIATION ONCOLOGY	PROJECTED PROPOSED MRI & PET/CT SCANNERS
Forsyth	24.5%	24.5%
Davidson	11.5%	11.5%
Surry	6.2%	6.2%
Guilford	5.8%	5.8%
Wilkes	4.6%	4.6%
Catawba	3.3%	3.3%
Iredell	2.8%	2.8%
Rowan	2.6%	2.6%
Stokes	2.6%	2.6%
Yadkin	2.5%	2.5%
Randolph	2.4%	2.4%
Davie	1.8%	1.8%
Carroll, VA	1.7%	1.7%
Henry, VA	1.6%	1.6%
Rockingham	1.4%	1.4%
Caldwell	1.3%	1.3%
Burke	0.8%	0.8%
Grayson, VA	0.8%	0.8%
Patrick, VA	0.8%	0.8%
Alleghany	0.7%	0.7%
Ashe	0.6%	0.6%
Gaston	0.4%	0.4%
Mecklenburg	0.3%	0.3%
Watauga	0.3%	0.3%
Alexander	0.2%	0.2%
Pittsylvania, VA	0.2%	0.2%
Other NC and VA Counties (1)	15.1%	15.1%
Other States	3.2%	3.2%
Total	100.0%	100.0%

(1) The applicant identifies the other North Carolina counties in Section III.4(b), pages 74-76, and Section III.5(c), pages 78-83. The percentage of total patients from any one of these counties is 1% or less.

The applicant adequately identifies the population it proposes to serve.

Need for the Proposed MRI and PET/CT Services

In Section II.1, pages 17-27, the applicant describes the proposal and explains why it believes the proposed MRI and PET/CT scanners are needed as follows.

"This application is for a GE Signa 3T magnetic resonance imaging (MRI) scanner and a GE Discovery ST-8 computed tomographic positron emission tomography (PET/CT) scanner to be used as radiation therapy (RT) simulation devices. Simulation is the initial step and most essential component of the treatment planning process necessary to accurately administer radiation therapy for cancer (and certain benign diseases). ... Therefore, accurate definition of the target volume, (i.e., the areas of gross and microscopic involvement of cancer), is essential to achieving local tumor control and a cure. Prior to CT and MRI scanners, target volume definition for RT was crude .... CT and MRI began the era of so-called anatomic RT treatment planning. CT has the advantages of being able to image the soft tissues of the neck, visceral structures and other soft tissues of the chest, abdomen, pelvis, and bone cortex with high resolution. MRI is complementary to CT and provides high resolution images of the brain, spinal cord, spine, muscles, and internal structure of the bones. ... CT scanners adapted specifically for the RT treatment process are called 'CT-simulators' and are now common place in most modern radiation therapy departments.

MRI-simulators are less common except in large radiation oncology departments in medical centers where high volumes of diseases best imaged by MRI are treated with radiation therapy. The application of MRI and PET/CT to simulation in treatment planning is relatively recent. ...

In 2000, the Duke University Medical Center Department of Radiation Oncology applied for and obtained an MRI scanner to be used as a MRI-simulator, the first and only known instance of this in North Carolina. The proposed project would introduce for the first time in North Carolina, an R/F (existing), MR and PET/CT simulator within the same Department of Radiation Oncology."

In Section III.1(a), pages 56-63, the applicant states

"NCBH has identified the following areas of unmet need that necessitate the inclusion of each of the proposed project components ....

Molecular and Biologic Imaging

Advanced imaging modalities that better show tumor anatomy and demonstrate tumor biology are needed for radiation therapy treatment planning and delivery in order to improve the local tumor control rate, increase the cure rate, decrease treatment-related-side-effects, and reduce the overall burden of cancer. ... Molecular imaging provides three-dimensional information about cancer that cannot be provided by non-invasive methods like CT and MRI, or by invasive approaches such as histopathologic analysis such as biopsy or surgical resection. Examples of molecular imaging include magnetic resonance spectroscopy and positron emission tomography. ...

...

Current Imaging Modalities Do Not Adequately Image Tumor Anatomy

Magnetic resonance spectroscopy is a biochemical analysis of a region (called a voxel) of tissue otherwise imaged by a conventional MRI scan. ... Unlike MRI, which produces high resolution anatomic images, MRS generates chemical spectra that reflect the quantity of certain metabolites in normal and cancerous tissues. MRS can detect the presence of cancer in structures and tissues that appear anatomically normal on MRI, and conversely can disprove the presence of cancer of structures/tissues that are anatomically abnormal on a MRI scan. Therefore, MRS and MRI are complementary imaging modalities. ...

...

Positron emission tomography is a method of measuring metabolic, biochemical, and functional activity in living tissue via electronic detection of short-lived positron emitting radiopharmaceuticals. PET is able to detect the presence of cancer for nearly all human tumors ..., often when conventional anatomic CT or MRI images appear normal. PET and MRS are complementary imaging modalities, and both are emerging as important imaging technologies for radiation therapy treatment. ...

Current Imaging Modalities Do Not Image Tumor Biology

Presently, the radiation therapy treatment planning process is entirely anatomically based on either CT or MRI scans. Tumor biology is completely ignored. It has been known for nearly three decades that certain biologic characteristics of tumors, such as hypoxia, are associated with radiation resistance. The dose of radiation needed to kill a hypoxic cancer cell is three-fold greater than that needed to kill an oxic one. ... PET using the radiopharmaceutical F-18 misonidazole is one method of non-invasively imaging tumor hypoxia. ... Hypoxia is quite common in human tumors. ... The implication for radiation therapy is two-fold. First, areas of hypoxia should receive up to 3 times more radiation dose than non-hypoxic regions. Using the combination of PET and MRS, the degree of hypoxia for a given tumor can be defined, and radiation dose then administered in proportion to the degree of hypoxia. ... Second, patients with hypoxic tumors might benefit from the administration of drugs ... that increase the likelihood that a hypoxic cancer cell will be killed by a given dose of radiation.

Another method of intensifying radiation dose besides intensity modulated radiation therapy (IMRT) is with the use of Gamma Knife stereotactic radiosurgery (SRS). ...

Future Demand for Bioanatomic Radiation Therapy Treatment Planning

We believe the combination of anatomic and biologic imaging of cancer for radiation therapy treatment planning using MRI, MRS, and PET/CT will become the new standard of care for all patients with potentially curative cancer in whom radiation will play a role in their management. Bioanatomic imaging better defines the extent of gross and microscopic tumor, facilitates selective radiation dose escalation with techniques such as IMRT and SRS, and permits the selection of biologically specific drugs, all of which contributes to an individualized approach to the radiotherapeutic management of cancer, rather than the somewhat generic methods currently in use. This should translate into improved local tumor control, survival, and quality of life. Furthermore, we envision that bioanatomic imaging will be of great value to other members of the

oncology treatment team, including the surgeon, who will be better able to define the complete tumor volume of a given cancer for surgical resection, and the medical oncologist, who will be able to identify biologically specific targets for drug treatment.

Increased Accuracy of Treatment Planning Leads to Improved Patient Experience

As discussed previously, implementing MRI Simulation and PET/CT Simulation technology for treatment planning will allow physicians to locate tumors with pinpoint accuracy. The improved accuracy of tumor definition translates into improved focus of radiation oncology treatment delivery. NCBH anticipates that this will not only improve the outcomes of patients, but will also improve the quality of patient care and the patient's radiation oncology treatment experience. The side affects [sic] *often associated with radiation therapy will be greatly reduced because physicians will be able to reduce radiation exposure to healthy cells while increasing the strength of radiation to malignant cells. Destroying malignant tumor sooner and reducing the side effects of radiation exposure will allow patients to recover from treatment more rapidly."* (Emphasis in original.)

In Section III.1(b), pages 64-65, the applicant states

"Cancer is the second leading cause of death in the United States, following heart disease. ... At the North Carolina level, 39,600 new cancer cases and 16,500 cancer deaths are expected in 2003 .... It is anticipated that the cancer affliction on the population will only increase in the coming years with the aging of the baby boomer segment of the population. Estimates from the Solucient database indicate that 15,914 new cancer cases occurred in 2002 in the Medical Center's 26-county service area alone (21 North Carolina counties and 5 Virginia counties). Therefore, it is increasingly important that new technologies are discovered to treat and potentially cure this powerful disease.

The disease sites of focus for the new equipment will be primary and metastatic brain, breast, esophagus, head and neck, pancreas, prostrate, and lung cancer. Data on analytic cancer cases (newly diagnosed cancer cases) submitted to the

Cancer Registry database indicates that NCBH is a leader in diagnosing these types of cancers. According to this database, NCBH diagnosed the following new cancer cases in 2001:

- *Lung: 293 cases*
- *Breast: 253 cases*
- *Prostate: 185 cases*
- *Central Nervous System (including brain): 141 cases*
- *Head and Neck: 96 cases*
- *Pancreas: 72 cases*
- *Esophagus: 20 cases"*

Further, in Section III.2, pages 65-69, the applicant states

"As a consequence of obtaining the proposed bioanatomic imaging devices (PET /CT and MRI scanners to be used for radiation therapy simulation devices), there will be an expansion of education and training programs in three areas: clinical oncology, radiation physics, and radiation biology.

...

As outlined in the discussion related to Criterion 1, each of the three areas of training program expansion revolves around research. Basic radiation biology and physics research will be translated into clinical trials of safety (Phase I studies) and efficacy (Phase II studies) as well as randomized Phase III studies in which bioanatomic treatment planning approaches are compared to standard methods. Conduct of these Phase I, II, and III clinical trials will be facilitated by the Clinical Research Program of the Comprehensive Cancer Center of Wake Forest University. ... At any given time, the Cancer Center has approximately 50 investigator-initiated studies open, which accrue approximately 600 patients year per year. ... Financial support for the clinical trials will come from the Cancer Center, grants from the National Cancer Institute and similar NIH funding agencies, non-profit associations, foundations, and societies, and industry .... For example, Varian now sponsors research in bioanatomic imaging and treatment with Dan Bourland, Ph.D. as principal investigator."

Baptist provides adequate arguments for the value of the clinical research anticipated to be performed on the proposed MRI and PET/CT scanners. However, the applicant fails to demonstrate that its plan to purchase new equipment, which results in increasing the number of units it operates, is less costly or more effective than relocating its existing PET scanner and one of its existing MRI scanners to the Outpatient Comprehensive Cancer Center. Further, the applicant fails to demonstrate that its plan to increase the number of MRI and PET scanners it owns is less costly or more effective than replacing its existing PET scanner with a PET/CT scanner and one of its existing MRI scanners with equipment configured to perform simulations.

In addition, the applicant does not adequately demonstrate that all of the persons it projects to serve need the proposed services because it did not demonstrate the reasonableness of the projected number of procedures to be performed, as discussed separately below for each item of equipment.

Projected Utilization of the Proposed PET/CT Scanner

The following table illustrates projected utilization of the proposed PET/CT scanner, as reported by the applicant in Exhibit 13.

PROPOSED PET/CT SCANNER

	YEAR ONE	YEAR TWO	YEAR THREE
"Radiation Volume"	397	433	472
"Surgical Volume"	193	232	258
Funded Research	78	104	130
Unfunded Research	78	104	130
"Radiology shift (PET only, not CT)"	76	152	230
Total	822	1,025	1,220

As shown in the above table, the applicant projects that the proposed PET/CT scanner will perform 1,220 procedures during Year Three. Regarding the assumptions and methodology used to project utilization of the proposed PET/CT Scanner, in Section IV.3(a), page 89, the applicant states

> *"In order to develop both the MRI and PET/CT Simulator utilization projections, a detailed analysis occurred of the anticipated need for radiation oncology treatment planning,*

surgical oncology treatment planning, and funded and unfunded research. In addition, ... a small proportion of diagnostic procedures would be relocated from the Department of Radiology to relieve the capacity pressure on their existing machines. ...

Please see the detailed tables in Exhibit 13. The inpatient/outpatient split is 8% inpatient and 92% outpatient for external beam procedures on both PET/CT and MRI Simulators and 20% inpatient and 80% outpatient for both PET/CT and MRI Simulations. Projections by type of procedure for each machine were based on NCBH's anticipated capacity and anticipated demand for the new technology."

However, the applicant did not adequately document the reasonableness of its assumptions regarding the number of procedures to be performed by the proposed PET/CT scanner. In particular, the applicant did not provide the following:

- The detailed analysis which the applicant states is the basis for projected utilization of the proposed scanner.
- The specific assumptions, statistical data or methodology used to project the number of PET/CT procedures to be performed, such as:
  1) historical utilization data for the existing simulator(s);
  2) projected number of new cancer cases diagnosed and treated at Baptist through Year Three; and
  3) projected number of cancer patients who will need RT treatment planning through Year Three.

Further, the 1,220 procedures projected to be performed during Year Three includes 230 *"Radiology Shift (PET only, not CT)"* procedures currently being performed on the existing PET scanner. However, the applicant fails to document the basis for assuming these patients who are served on the existing PET scanner need the services offered on the proposed PET scanner.

Projected Utilization of the Proposed MRI Scanner

The following table illustrates projected utilization of the proposed MRI scanner, as reported by the applicant in Exhibit 13.

PROPOSED MRI SCANNER

	YEAR ONE	YEAR TWO	YEAR THREE
"MRI Sim Volume"	419	520	623
"Surgical Volume"	245	277	306
Funded Research	78	104	130
Unfunded Research	78	104	130
Gamma Knife® Tx Planning	300	300	300
"Radiology Diagnostic"	48	197	411
Total	1,168	1,502	1,900

As shown in the above table, the applicant projects that the proposed MRI scanner will perform a total of 1,900 procedures during Year Three. Regarding the assumptions and methodology used to project utilization of the proposed MRI Scanner, in Section IV.3(a), page 89, the applicant states

> *"In order to develop both the MRI and PET/CT Simulator utilization projections, a detailed analysis occurred of the anticipated need for radiation oncology treatment planning, surgical oncology treatment planning, and funded and unfunded research. In addition, ... a small proportion of diagnostic procedures would be relocated from the Department of Radiology to relieve the capacity pressure on their existing machines. ...*
>
> *Please see the detailed tables in Exhibit 13. The inpatient/outpatient split is 8% inpatient and 92% outpatient for external beam procedures on both PET/CT and MRI Simulators and 20% inpatient and 80% outpatient for both PET/CT and MRI Simulations. Projections by type of procedure for each machine were based on NCBH's anticipated capacity and anticipated demand for the new technology."*

However, the applicant did not adequately document the reasonableness of its assumptions regarding the number of procedures to be performed by the proposed MRI scanner. In particular, the applicant did not provide the following:

- The detailed analysis which the applicant states is the basis for projected utilization of the proposed scanner.
- The specific assumptions, statistical data or methodology used to project the number of MRI procedures to be performed, such as:

1) historical utilization data for the existing simulator(s);
2) projected number of new cancer cases diagnosed and treated at Baptist through Year Three; and
3) projected number of cancer patients who will need RT treatment planning through Year Three.

Further, the 1,900 procedures projected to be performed during Year Three includes 411 *"Radiology Diagnostic"* procedures currently being performed by one of the five existing MRI scanners. However, the applicant fails to document that patients who are served by the existing MRI scanners need the services offered on the proposed MRI scanner.

In summary, Baptist provides adequate arguments for the value of the clinical research anticipated to be performed on the proposed MRI and PET/CT scanners. However, the applicant did not adequately document the reasonableness of the projected number of procedures to be performed with either scanner and therefore, failed to demonstrate that all persons proposed to be served need the services to be offered with the new equipment. Consequently, the application is nonconforming with this criterion.

(3a) In the case of a reduction or elimination of a service, including the relocation of a facility or a service, the applicant shall demonstrate that the needs of the population presently served will be met adequately by the proposed relocation or by alternative arrangements, and the effect of the reduction, elimination or relocation of the service on the ability of low income persons, racial and ethnic minorities, women, handicapped persons, and other underserved groups and the elderly to obtain needed health care.

NA

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

NC

In Section II.5, pages 29-32, the applicant states that it considered the following alternatives:

Maintain the status quo – The applicant states

"Presently, bioanatomic imaging is not performed routinely for a number of reasons. First, the MRI and PET scanners are too busy with one to two week delays in scheduling procedures not being uncommon. Presently, in order for a patient to have bioanatomic imaging for RT simulation and treatment planning, they would first have to undergo CT simulation in the Department of Radiation Oncology, followed by an MRI scan in the MRI Center on a different day and then a PET scan in the PET Center on yet another separate day. This would come at great inconvenience to the patient whose conditions often leave them in a state of physical and emotional weakness, and the staff in Radiation Oncology who must be present at the time of the MRI and PET images to make sure the patient is properly set up. In this regard, conventional MRI and PET scanners that are not specifically radiation therapy simulation devices do not have the proper immobilization systems, laser light alignment systems, and the flatter and wider table tops that are necessary for a proper patient set-up. As a consequence, non-radiation therapy simulation devices increase the potential for image registration inaccuracies which may increase the potential for errors in the treatment planning and delivery process, perhaps necessitating the use of larger treatment volumes, irradiation of more normal tissue, and possibly greater side effects of treatment."

Obtain only one type of simulator – The applicant states.

"MRI and PET/CT are complementary rather than overlapping imaging modalities for radiation therapy treatment planning. These modalities are often used in concert to create a more complete picture, thus allowing for enhanced treatment of disease. As stated previously, there are certain situations in which MRI imaging has an advantage over CT (superior imaging of the brain, spine, spinal cord, muscles and internal structures of the bone). ...

... While PET does not have the same high degree of resolution as MRI, the range of tumor biology and physiology that can be imaged by PET radiopharmecuticals is essentially endless .... The biologic information obtained from PET is displayed anatomically, unlike the biologic data from MRI spectroscopy, which

requires further processing before it can be converted into anatomic data. Therefore, MRI and PET are both essential components of the bioanatomic imaging process, complementary for both the anatomic and biologic information they provide for RT simulation and treatment planning. Obtaining either the MRI or PET would allow for improved treatment planning over the status quo but would not achieve the goal of the proposed project which is to study and research the applications of conventional MRI and PET/CT simulation used in combination."

Obtain a 1.5T MRI scanner rather than a 3.0T scanner – The applicant states

"The proponents in the Department of Radiation Oncology have determined, in consultation with colleagues in the Department of Radiology and other institutions, that the 3.0T is most suited for the intended purpose in the proposed project for the following reasons: First, the higher magnet size in the 3.0T is believed to allow for greater MRI spectroscopic capabilities. Second, the 3.0T provides a more accurate image with a wider variety of chemical measures than is possible on the 1.5T. Third, it is believed that the 3.0T is quickly becoming the standard of care in all MRI applications and particularly in cancer diagnosis and management purposes. Finally, the relative cost of the 3.0T has dropped since its introduction."

Obtain a "conventional" PET scanner rather than a PET/CT scanner – The applicant states

"The proposed project with a PET/CT simulator will allow NCBH to remove its existing CT simulator from operation, thus increasing cost-efficiency of equipment and space by obtaining a technology that will perform, [sic] *PET/CT simulations and CT simulations. The PET/CT machine is necessary to achieve the goals of the project and allow the capability of performing PET/CT simulations that would not be possible with a conventional PET machine."*

However, the applicant fails to demonstrate that its plan to purchase new equipment, which results in increasing the number of units it owns and operates, is less costly or more effective than relocating its existing PET scanner and one of its an existing MRI

scanners to the Outpatient Comprehensive Cancer Center. Further, the applicant fails to demonstrate that its plan to acquire additional equipment is less costly or more effective than replacing the existing PET scanner and one of its existing MRI scanners with equipment configured to perform simulations.

Further, the application is not conforming with all other applicable statutory and regulatory review criteria. See Criteria (1), (3), (5), (6), (18a), 10A NCAC 14C .2700, and 10A NCAC 14C .3700. Therefore, the applicant did not adequately demonstrate that it proposed the least costly or most effective alternative. Consequently, the application is nonconforming with this criterion.

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

NC

In Section VIII.1, pages 129-130, the applicant projects that the total capital cost of the project will be $6,080,546, including $585,025 for upfit costs, $5,272,321 for fixed equipment, $75,000 for movable equipment, $15,000 for furniture, $98,000 for consultant fees, and $35,200 for miscellaneous costs (CON filing fee, information systems and signage). In Section IX, page 137, the applicant states that there will be no start up or initial operating expenses because the project *"is an expansion of an existing service."* In Section VIII.3, page 132, the applicant states that 100% of the capital cost will be funded with Baptist's accumulated reserves. Exhibit 31 contains a May 7, 2003 letter signed by the chief financial officer for Baptist, which states

> *"The North Carolina Baptist Hospitals, Inc. agrees to make available from its accumulated reserves a total of $6,080,546 for the capital costs incurred in the acquisition of an MRI Simulator ($3,117,615) and PET/CT Simulator ($2,962,931) for Radiation Oncology Treatment Planning."*

Exhibit 32 contains the audited financial statements for Baptist. As of June 30, 2002, Baptist had $57,634,000 in cash and cash equivalents, $59,221,000 in short-term investments, $252,840,000 in

total assets, and $677,566,000 in net assets (total assets less total liabilities). The applicant adequately demonstrated the availability of sufficient funds for the capital needs of the project.

In Section X.10, Form B-1, the applicant projects the following revenues and operating costs for the proposed MRI and PET/CT scanners during each of the first three years of operation following completion of the project, as illustrated in the following table.

	PROPOSED 3.0T MRI SCANNER			PROPOSED PET/CT SCANNER		
	YEAR ONE	YEAR TWO	YEAR THREE	YEAR ONE	YEAR TWO	YEAR THREE
Gross Revenues	$1,876,656	$2,299,338	$2,719,157	$2,601,226	$3,018,558	$3,410,038
Net Revenues	$1,137,757	$1,381,136	$1,622,644	$1,560,596	$1,781,226	$1,984,711
Operating Costs	$850,053	$1,270,034	$1,367,428	$1,140,136	$1,600,990	$1,709,426
Profit (Loss)	$287,704	$111,102	$255,216	$420,460	$180,236	$275,285

As shown in the above table, the applicant projects that revenues will exceed operating costs for each scanner during Years One, Two and Three. However, the applicant did not adequately document the reasonableness of the projected number of procedures to be performed by the proposed MRI and PET/CT scanners. See Criterion (3) for discussion. Consequently, revenues and operating costs, which are based on the projected number of procedures to be performed, are unsupported and unreliable.

Further, the applicant did not adequately demonstrate that all revenues and operating costs associated with the proposed MRI and PET/CT scanners are included in its projections. In Exhibit 13, the applicant projects that the proposed scanners, which will be located in the Department of Radiation Oncology, will perform some diagnostic MRI and PET procedures currently performed by existing MRI scanners and the PET scanner located in the Department of Radiology. These diagnostic procedures are in addition to the MRI and PET/CT simulation procedures projected to be performed with the proposed scanners. In Section IV.3, page 89, the applicant states that these diagnostic procedures *"are excluded from the financial statements because these procedures currently are performed at NCBH, are a minority of the procedures in the utilization projection for this project and are an extended benefit and not a primary driver of the need in this application."* However, costs and revenues associated with the procedures to be "shifted" from the Department of Radiology should be included in Form B-1 and Form B-1a since they are proposed to be performed on the new equipment.

In summary, the applicant did not adequately demonstrate that the financial feasibility of the proposal is based on reasonable projections of revenues and operating costs for operation of the new equipment. Therefore, the application is nonconforming with this criterion.

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

NC

Baptist proposes to acquire a 3.0T MRI scanner and a PET/CT scanner pursuant to Policy AC-3 in the 2003 SMFP for radiation therapy treatment planning. However, the applicant did not adequately demonstrate the need the population projected to be served has for the proposed scanners. See Criteria (1), (3) and (4) for discussion. Therefore, the applicant did not adequately demonstrate that acquisition of the proposed MRI and PET/CT scanners would not result in an unnecessary duplication of existing MRI and PET services and the application is nonconforming with this criterion.

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

C

The following tables illustrate the incremental staff for the proposed MRI and PET/CT scanners, as reported by the applicant in Section VII.2, page 119.

MRI SCANNER

POSITION	# OF FULL-TIME EQUIVALENT POSITIONS		
	YEAR ONE	YEAR TWO	YEAR THREE
Radiation Therapist	2	3	3
Staff Nurse	1	1	1
Scheduler	1	1	1
Total	4	5	5

PET/CT SCANNER

POSITION	# OF FULL-TIME EQUIVALENT POSITIONS		
	YEAR ONE	YEAR TWO	YEAR THREE
Radiation Therapist [1]	2	4	4
Radiation Onc. Engineer	1	1	1
Total	3	5	5

(l) In Section VII.2, page 120, the applicant states *"Present staff in the Radiation Oncology Department for the existing CT Simulator will be used for the PET/CT Simulator."* In Section I.13, page 11, the applicant states that the existing CT simulator *"will be replaced by the PET/CT Simulator."*

In Section VII.3, pages 120-121, the applicant states

> *"NCBH acknowledges that there is a national shortage of Imaging Technologists including Computerized Tomography (CT), Positron Emission Topography* [sic], *Nuclear Medicine, Magnetic Resonance Imaging (MRI) and Radiation Therapists. While NCBH has from time to time had one or two imaging technologist positions open due to natural turnover on* [sic] *in its diagnostic machines, as a regional tertiary and quaternary referral center, it has not experienced the shortages present in community hospitals. ... Nonetheless, for informational purposes, in the event that NCBH finds it necessary to recruit externally for any of the new positions, it will pursue the following strategies either individually or in concert. Traditionally, NCBH has made an effort to hire and train any needed FTE's that arises as the result of expanded or additional services. NCBH will continue this effort to hire from within the organization. NCBH is also actively involved with the 'Code Blue' area health care recruitment program and has recruiting relationships with Forsyth Technical Community College and other area schools. If these methods prove to be unsuccessful, the Department of Radiation Oncology at NCBH will use 'word of mouth' to advertise for the position and will also utilize area newspapers. If the above methods fail, NCBH will use a professional recruiting firm."*

In Section V.3(c), page 101, the applicant states

> *"The Medical Directors of the proposed MRI simulator and PET/CT simulator will be Dr. Edward Shaw, Chairman, Department of Radiation Oncology and Dr. Dan Bourland, Section Head, Radiation Physics, Department of Radiation Oncology. The medical directorship will be a shared responsibility because of the dual clinical and radiation physics/imaging expertise required to oversee the bioanatomic radiation therapy simulation, treatment planning, and treatment delivery process."*

Exhibit 2 contains curriculum vitae for Dr. Shaw and Dr. Bourland. Both are board certified and have training and experience in MRI and PET services. The applicant adequately documented the availability of sufficient health manpower and management personnel to provide the proposed services. Therefore, the application is conforming with this criterion.

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

C

In Section IV.5, page 95, the applicant states *"As a current provider of radiation oncology services, NCBH already provides all the necessary ancillary and support services, including registration, billing and medical records. The administrative services do not require expansion as a direct result of the proposed project."* Further, in Section II.8, page 42, the applicant states that Baptist already provides the support services required by 10A NCAC 14C .2704(a), including anesthesiology, radiology, oncology, neurology, internal medicine, orthopedics, neurosurgery, pathology and surgery. In addition, in Section II.8, pages 51-52, the applicant states that it will provide the support services required by 10A NCAC 14C .3704, including a system for responding to medical emergencies, a source for radioisotopes, and a clinical oversight committee for PET services.

In Section V.2, page 98, the applicant states *"As an academic medical center and a regional referral center for tertiary care, NCBH receives transfers from many providers throughout its 26 county service area and the Southeast."* Exhibit 23 contains a list of health care facilities with which Baptist has a transfer agreement. In Section V.3, page 99, the applicant states *"NCBH has developed strong referral relationships with the medical community, including physicians. As part of the planning process for the proposed project, NCBH has solicited and obtained support from WFUHS physicians who will refer patients to the MRI simulator and PET/CT simulator."* Exhibit 9 contains letters from WFUHS physicians supporting the proposed project.

In summary, the applicant adequately demonstrated that it will provide all necessary ancillary and support services and that the

proposal will be coordinated with the existing health care system. Therefore, the application is conforming with this criterion.

(9) An applicant proposing to provide a substantial portion of the project's services to individuals not residing in the health service area in which the project is located, or in adjacent health service areas, shall document the special needs and circumstances that warrant service to these individuals.

NA

(10) When applicable, the applicant shall show that the special needs of health maintenance organizations will be fulfilled by the project. Specifically, the applicant shall show that the project accommodates:

(a) The needs of enrolled members and reasonably anticipated new members of the HMO for the health service to be provided by the organization; and

NA

(b) The availability of new health services from non-HMO providers or other HMOs in a reasonable and cost-effective manner which is consistent with the basic method of operation of the HMO. In assessing the availability of these health services from these providers, the applicant shall consider only whether the services from these providers:

(i) would be available under a contract of at least 5 years duration;

(ii) would be available and conveniently accessible through physicians and other health professionals associated with the HMO;

(iii) would cost no more than if the services were provided by the HMO; and

(iv) would be available in a manner which is administratively feasible to the HMO.

NA

(11) Repealed effective July 1, 1987.

(12) Applications involving construction shall demonstrate that the cost, design, and means of construction proposed represent the most reasonable alternative, and that the construction project will not unduly increase the costs of providing health

services by the person proposing the construction project or the costs and charges to the public of providing health services by other persons, and that applicable energy saving features have been incorporated into the construction plans.

NA

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

(a) The extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved;

C

In Section VI.2, page 108, the applicant states *"NCBH provides access to care to all patients including those listed above and does not discriminate based on age, race, national or ethnic origin, disability, sex, income, or ability to pay."* In Section VI.10, page 114, the applicant reports the following payor mix for the entire hospital.

FISCAL YEAR 2002 PAYOR MIX

PAYOR CATEGORY	% OF TOTAL
Self Pay, Indigent, Charity Care	3.2%
Medicare	39.5%
Medicaid	19.7%
Commercial Insurance (includes managed care contracts)	37.0%
Other	0.6%
TOTAL	100.0%

The applicant demonstrated that medically underserved populations currently have adequate access to Baptist's existing services.

(b) Its past performance in meeting its obligation, if any, under any applicable regulations requiring provision of uncompensated care, community service,

or access by minorities and handicapped persons to programs receiving federal assistance, including the existence of any civil rights access complaints against the applicant;

C

An examination of the licensure and certification files in the Division of Facility Services for North Carolina Baptist Hospital indicates there have been no civil rights access complaints filed against the facility.

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

C

In Section VI.2, page 108, the applicant states *"NCBH provides access to care to all patients including those listed above and does not discriminate based on age, race, national or ethnic origin, disability, sex, income, or ability to pay. ... The NCBH policies and philosophy of access will extend to the proposed project."* In Section VI.12, pages 116-117, the applicant projects the following payor mix for the proposed MRI and PET/CT scanners.

PROPOSED MRI SCANNER
FISCAL YEAR 2006 PAYOR MIX

PAYOR CATEGORY	% OF TOTAL
Self Pay, Indigent, Charity Care	2.4%
Medicare	17.5%
Medicaid	5.9%
Commercial Insurance (includes managed care contracts)	73.2%
Other	1.0%
TOTAL	100.0%

PROPOSED PET/CT SCANNER
FISCAL YEAR 2006 PAYOR MIX

PAYOR CATEGORY	% OF TOTAL
Self Pay, Indigent, Charity Care	1.0%
Medicare	32.5%
Medicaid	8.5%

Commercial Insurance (includes managed care contracts)	56.3%
Other	1.7%
TOTAL	100.0%

The applicant demonstrated that medically underserved populations will have adequate access to the proposed health services.

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

C

In Section VI.7, page 111, the applicant states *"Physicians on the medical staff at the hospital currently refer patients to the existing radiation oncology services at NCBH. This will continue with both the MRI and PET/CT Simulators.... Please see Exhibit 26 for a list of the external and internal (WFUHS) physicians that most frequently refer patients to the Department of Radiation Oncology."* Exhibit 26 consists of two lists of physicians. One is identified as the *"Top Internal Referring Physicians for FY 2002"* and the other as the *"Top External Referring Physicians for FY 2002."* Further, in Section II.8, page 47, the applicant states *"As part of an NCI designated cancer center and one housed in an academic medical center teaching hospital, this service* [PET/CT scanner] *will naturally serve as a regional resource."*

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

C

In Section V.1, page 97, the applicant states *"NCBH has established relationships with many clinical training programs in the Southeast and continues to provide teaching opportunities for these schools. With the proposed project, NCBH will be able to provide additional training support to the numerous clinical programs utilizing educational opportunities at the hospital."* Exhibit 22 contains a list of area health professional training programs with which Baptist has an existing relationship. The applicant adequately demonstrates that the proposed services will accommodate the clinical needs of area

health professional training programs and the application is conforming with this criterion.

(15) Repealed effective July 1, 1987.

(16) Repealed effective July 1, 1987.

(17) Repealed effective July 1, 1987.

(18) Repealed effective July 1, 1987.

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

NC

The applicant did not adequately demonstrate that the proposal will have a positive impact upon the cost effectiveness of the proposed services. See Criteria (3) and (5).

(19) Repealed effective July 1, 1987.

(20) An applicant already involved in the provision of health services shall provide evidence that quality care has been provided in the past.

C

North Carolina Baptist Hospital is accredited by the Joint Commission of Accreditation of Health Care Organizations and certified for Medicare and Medicaid participation. According to the files in the Licensure and Certification Section, DFS, no incidents occurred, within the eighteen months immediately preceding the date of this decision, for which any sanctions or penalties related to quality of care were imposed by the State. Therefore, the application is conforming with this criterion.

(21) Repealed effective July 1, 1987.

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

NC

In Section II.1, page 17, Baptist states that the proposed 3.0T MRI and PET/CT scanners will be used primarily for *"radiation therapy (RT) simulation."* However, the applicant also proposes to use the proposed MRI scanner and the proposed PET/CT Scanner for a significant number of routine diagnostic procedures. Thus, the Criteria and Standards for Magnetic Resonance Imaging Scanner, promulgated in 10A NCAC 14C .2700, and the Criteria and Standards for Positron Tomography Scanner, promulgated in 10A NCAC 14C .3700, are applicable to this review. The applicant does not propose to use the proposed PET/CT scanner to perform routine diagnostic CT scans and therefore, the Criteria and Standards for Computed Tomography Equipment are not applicable.

The application is not conforming with all applicable Criteria and Standards for Magnetic Resonance Imaging Scanner or Positron Tomography Scanner as discussed below.

CRITERIA AND STANDARDS FOR MAGNETIC RESONANCE IMAGING SCANNER

.2702 INFORMATION REQUIRED OF APPLICANT

.2702(a) This rule states *"An applicant proposing to acquire an MRI scanner, including a Mobile MRI scanner, shall use the Acute Care Facility/Medical Equipment application form."*

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

.2702(b) This rule states *"Except for proposals to acquire mobile MRI scanners that serve two or more host facilities, both the applicant and the person billing the patients for the*

MRI service shall be named as co-applicants in the application form."

-NC- The applicant fails to state whether or not it will be the entity billing the patients for the proposed MRI service.

.2702(c)(1) This rule states *"An applicant proposing to acquire a magnetic resonance imaging scanner, including a mobile MRI scanner, shall also provide the following additional information: (1) documentation that the MRI scanner shall be available and staffed for use at least 66 hours per week, with the exception of a mobile MRI scanner."*

-NC- In Section II.8, page 37, the applicant states *"The proposed scanner will be staffed and available from 6:45 AM to 4:45 PM, Monday through Friday, for a total of 50 hours per week, with all other hours available and covered with on-call arrangements."* The applicant proposes to staff the MRI scanner for only 50 hours per week, the rule requires at least 66 hours per week. Therefore, the application is nonconforming with this rule.

.2702(c)(2) This rule states *"An applicant proposing to acquire a magnetic resonance imaging scanner, including a mobile MRI scanner, shall also provide the following additional information: ... (2) projections of the annual number of procedures to be performed for each of the first three years of operation after completion of the project."*

-C- The applicant provides projections of the annual number of procedures to be performed for each of the first three years of operation after completion of the project in Exhibit 13. However, see Criterion (3) for discussion of the reasonableness of these projections.

.2702(c)(3) This rule states *"An applicant proposing to acquire a magnetic resonance imaging scanner, including a mobile MRI scanner, shall also provide the following additional information: ... (3) the average charge to the patient, regardless of who bills the patient, for each of the 20 most frequent MRI procedures to be performed for each of the first three years of operation after completion of the project and a description of items included in the charge; if the*

professional fee is included in the charge, provide the dollar amount for the professional fee."

-NC- In Section X.2, page 147, the applicant provides the charge to the patient for the 20 most frequent MRI procedures to be performed on the proposed MRI scanner for only the first year of operation following completion of the project. However, the rule requires that the applicant provide charges for each of the first three years of operation following completion of the project, not just one year. Therefore, the application is nonconforming with this rule because the applicant did not provide each procedure charge for operating years two and three.

.2702(c)(4) This rule states *"An applicant proposing to acquire a magnetic resonance imaging scanner, including a mobile MRI scanner, shall also provide the following additional information: ... (4) if the proposed MRI service will be provided pursuant to a service agreement, the dollar amount of the service contract fee billed by the applicant to the contracting party for each of the first three years of operation."*

-NA- The applicant does not propose that the MRI service will be provided pursuant to a service agreement.

.2702(c)(5) This rule states *"An applicant proposing to acquire a magnetic resonance imaging scanner, including a mobile MRI scanner, shall also provide the following additional information: ... (5) documentation of the need for an additional MRI scanner in the proposed MRI service area and description of the methodology used to project need, including all assumptions regarding the population to be served."*

-NC- The applicant did not provide sufficient information to document the need for the proposed MRI scanner for the population it proposes to serve. Further, the applicant did not adequately describe the methodology used to project need, including all assumptions regarding the population to be served. See Criterion (3) for a detailed discussion. Therefore, the application is not conforming with this rule.

.2702(c)(6) This rule states *"An applicant proposing to acquire a magnetic resonance imaging scanner, including a mobile MRI scanner, shall also provide the following additional information: ... (6) letters from physicians indicating their intent to refer patients to the proposed magnetic resonance imaging scanner."*

-C- The applicant provides letters from area physicians indicating their intent to refer patients to the proposed MRI scanner in Exhibit 9.

.2702(d) This rule states *"An applicant proposing to acquire a mobile MRI scanner shall provide copies of letters of intent from, and proposed contracts with, all of the proposed host facilities of the new MRI scanner."*

-NA- The applicant does not propose to acquire a mobile MRI scanner.

.2702(e) This rule states *"An applicant proposing to acquire a dedicated fixed breast MRI scanner shall: (1) provide a copy of a contract or working agreement with a radiologist or practice group that has experience interpreting images and is trained to interpret images produced by an MRI scanner configured exclusively for mammographic studies; (2) document that the applicant performed mammograms continuously for the last year; and (3) document that the applicant's existing mammography equipment is in compliance with the U.S. Food and Drug Administration Mammography Quality Standards Act."*

-NA- The applicant does not propose to acquire a dedicated fixed breast MRI scanner.

.2703 REQUIRED PERFORMANCE STANDARDS

.2703(a) This rule states *"An applicant proposing to acquire a mobile magnetic resonance imaging (MRI) scanner shall: (1) demonstrate that at least 2900 MRI procedures were performed in the last year on each of its existing mobile MRI scanners operating in the Health Service Area(s), (e.g., HSA I), in which the proposed mobile MRI scanner will be located [Note: This is not the average number of procedures performed on all of the applicant's mobile MRI*

scanners.]; (2) demonstrate annual utilization in the third year of operation is reasonably projected to be at least 2900 MRI procedures on each of its existing, approved and proposed mobile MRI scanners to be operated in the Health Service Area(s), (e.g., HSA I), in which the proposed equipment will be located [Note: This is not the average number of procedures performed on all of the applicant's mobile MRI scanners.]; and (3) document the assumptions and provide data supporting the methodology used for each projection required in this Rule."

-NA- The applicant does not propose to acquire a mobile MRI scanner.

.2703(b) This rule states *"An applicant proposing to acquire a magnetic resonance imaging (MRI) scanner for which the need determination in the State Medical Facilities Plan was based on the utilization of fixed MRI scanners, shall: (1) demonstrate that its existing MRI scanners, except mobile MRI scanners, operating in the proposed MRI service area in which the proposed MRI scanner will be located performed an average of at least 2900 MRI procedures per scanner in the last year; (2) demonstrate annual utilization in the third year of operation is reasonably projected to be an average of 2900 procedures per scanner for all existing, approved and proposed MRI scanners or mobile MRI scanners to be operated by the applicant in the MRI service area(s) in which the proposed equipment will be located; and (3) document the assumptions and provide data supporting the methodology used for each projection required in this Rule."*

-NA- The applicant did not apply pursuant to a need determination in the 2003 SMFP. Rather, the applicant applied pursuant to Policy AC-3: Exemption from Plan Provisions for Certain Academic Medical Center Teaching Hospital Projects.

.2703(c) This rule states *"An applicant proposing to acquire a magnetic resonance imaging (MRI) scanner for which the need determination in the State Medical Facilities Plan was based on utilization of mobile MRI scanners, shall: (1) if the applicant does not own or lease an MRI scanner or have an approved MRI scanner, demonstrate annual*

utilization in the third year of operation is reasonably projected to be at least 2080 MRI procedures per year for the proposed MRI scanner; (2) if the applicant already owns or leases an MRI scanner or has an approved MRI scanner, demonstrate annual utilization is reasonably projected to be an average of 2900 MRI procedures per scanner for all existing, approved and proposed MRI scanners or mobile MRI scanners to be operated by the applicant in the MRI service area(s) in which the proposed equipment will be located; and (3) document the assumptions and provide data supporting the methodology used for each projection required in this Rule."

-NA- The applicant did not apply pursuant to a need determination in the 2003 SMFP. Rather, the applicant applied pursuant to Policy AC-3: Exemption from Plan Provisions for Certain Academic Medical Center Teaching Hospital Projects.

.2703(d) This rule states *"An applicant proposing to acquire a magnetic resonance imaging (MRI) scanner for which the need determination in the State Medical Facilities Plan was based on the absence of an existing or approved fixed MRI scanner in the MRI service area shall: (1) demonstrate annual utilization of the proposed MRI scanner in the third year of operation is reasonably projected to be at least 2080 MRI procedures per year; and, (2) document the assumptions and provide data supporting the methodology used for each projection required in this Rule."*

-NA- The applicant did not apply pursuant to a need determination in the 2003 SMFP. Rather, the applicant applied pursuant to Policy AC-3: Exemption from Plan Provisions for Certain Academic Medical Center Teaching Hospital Projects.

.2704 REQUIRED SUPPORT SERVICES

.2704(a) This rule states *"An applicant proposing to acquire a magnetic resonance imaging scanner, including a mobile MRI scanner, shall make available through written affiliation or referral agreements the following services:*

(1) anesthesiology,
(2) radiology,
(3) oncology,
(4) neurology,
(5) internal medicine,
(6) orthopedics,
(7) neurosurgery,
(8) pathology, and
(9) surgery."

-C- In Section II.8, page 42, the applicant states that all of the services listed above are currently available at Baptist.

.2704(b) This rule states *"An applicant proposing to acquire a mobile MRI scanner shall provide referral agreements between each host site and at least one other provider of MRI services in the proposed MRI service area to document the availability of MRI services if patients require them when the mobile unit is not in service at that host site."*

-NA- The applicant does not propose to acquire a mobile MRI scanner.

.2705 REQUIRED STAFFING AND STAFF TRAINING

.2705(a) This rule states *"An applicant proposing to acquire an MRI scanner shall demonstrate that one board certified diagnostic radiologist shall be available to provide the proposed services who has had:*

(1) training in magnetic resonance imaging as an integral part of his or her residency training program; or
(2) six months of supervised MRI experience under the direction of a qualified diagnostic radiologist; or
(3) at least six months of fellowship training, or its equivalent, in MRI; or
(4) an appropriate combination of MRI experience and fellowship training equivalent to Subparagraph (a)(1), (2) or (3) of this Rule."

-C- In Section II.8, page 43, the applicant states *"Due to the unique application of the technology (for use in radiation*

oncology treatment planning), Dr. Ed Shaw and Dr. Dan Bourland will share the medical directorship. They will work in concert with the Medical Director of Magnetic Resonance Imaging, Dr. Kerry Michael Link and Dr. Allen Elster, Chair of the Department of Radiology." Exhibit 2 contains curriculum vitae for Dr. Shaw, Dr. Link, and Dr. Elster. These physicians are board certified and have training and experience in MRI services.

.2705(b) This rule states *"An applicant proposing to acquire a dedicated fixed breast MRI scanner shall provide documentation that the radiologist is trained and has experience in interpreting images produced by an MRI scanner configured exclusively to perform mammographic studies."*

-NA- The applicant does not propose to acquire a dedicated fixed breast MRI scanner.

.2705(c) This rule states *"The applicant shall provide evidence of the availability of two full-time MRI technologist-radiographers and that one of these technologists shall be present during the hours of operation of the MRI scanner."*

-C- In Section II.8, page 44, the applicant states *"Due to the unique application of the technology, NCBH proposes to train radiation therapists and require AART certification for each, making them in effect the equivalent to an 'MRI Technologists* [sic]. *At least one of these AART certified radiation therapist or "MRI technologist equivalents' will be present for the operation of the scanner."*

.2705(d)(1) This rule states *"An applicant proposing to acquire an MRI scanner shall demonstrate that the following staff training is provided: (1) certification in cardiopulmonary resuscitation (CPR) and basic cardiac life support."*

-C- In Section II.8, page 44, the applicant states *"All radiation therapists at NCBH are certified in CPR and basic cardiac life support (BCLS)."* Exhibit 10 contains a copy of the job description which documents that CPR and BCLS certification are required. Exhibit 11 contains copies of

staff training policies for Baptist that document that training in CPR and BCLS is provided.

.2705(d)(2) This rule states *"An applicant proposing to acquire an MRI scanner shall demonstrate that the following staff training is provided: ... (2) an organized program of staff education and training which is integral to the services program and ensures improvement in technique and the proper training of new personnel."*

-C- Exhibit 11 contains copies of staff training policies for Baptist that document that the hospital has an organized program of staff education and training.

.2705(e) This rule states *"An applicant proposing to acquire a mobile MRI scanner shall document that the requirements in Paragraphs (a) and (c) of this Rule shall be met at each host facility."*

-NA- The applicant does not propose to acquire a mobile MRI scanner.

CRITERIA AND STANDARDS FOR POSITRON EMISSION TOMOGRAPHY SCANNER

.3702 INFORMATION REQUIRED OF APPLICANT

.3702(a) This rule states *"An applicant proposing to acquire a PET scanner, including a mobile PET scanner, shall use the Acute Care Facility/Medical Equipment application form."*

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

.3702(b)(1) This rule states *"An applicant proposing to acquire a PET scanner, including a mobile PET scanner, shall provide the following information for each facility where the PET scanner will be operated: (1) The projected number of procedures to be performed and the projected number of patients to be served for each of the first three years following completion of the proposed project. Projections shall be listed by clinical area (e.g., oncology, cardiology),*

and all methodologies and assumptions used in making the projections shall be provided."

-NC- The applicant provides the projected number of procedures to be performed for each of the first three years of operation following completion of the project. However, the applicant failed to provide the projected number of patients for each of the first three years of operation as required by this rule. Further, the applicant did not provide all of the assumptions and methodology used in making its projections as required by this rule. See Criterion (3) for detailed discussion. Therefore, the application is nonconforming with this rule.

.3702(b)(2) This rule states *"An applicant proposing to acquire a PET scanner, including a mobile PET scanner, shall provide the following information for each facility where the PET scanner will be operated: ... (2) Documentation that all of the following services were provided, at each facility where the PET scanner will be operated, continuously throughout the 12 months immediately prior to the date on which the application is filed:*

(A) nuclear medicine imaging services;
(B) single photon emission computed tomography (including brain, bone, liver, gallium and thallium stress);
(C) magnetic resonance imaging scans;
(D) computerized tomography scans;
(E) cardiac angiography;
(F) cardiac ultrasound; and
(G) neuroangiography."

-C- In Section II.8, page 46, the applicant states that all of the services listed above were provided continuously throughout the 12 months immediately prior to the date on which the application was filed. See also the letter in Exhibit 7 which states that all of these services were provided continuously throughout the 12 months immediately prior to the date on which the application was filed.

.3702(b)(3)(A) This rule states *"An applicant proposing to acquire a PET scanner, including a mobile PET scanner, shall provide the following information for each facility where the PET scanner will be operated: ... (3) Documentation that the*

facility will: (A) establish the clinical PET unit, and any accompanying equipment used in the manufacture of positron-emitting radioisotopes, as a regional resource that will have no administrative, clinical or charge requirements that would impede physician referrals of patients for whom PET testing would be appropriate."

-C- In Section II.8, page 47, the applicant states *"As part of an NCI* [National Cancer Institute] *designated cancer center and one housed in an academic medical center teaching hospital, this service will naturally serve as a regional resource. There are no known administrative, clinical or charge requirements planned that would impede physician referrals of patients for whom PET testing would be appropriate."*

.3702(b)(3)(B) This rule states *"An applicant proposing to acquire a PET scanner, including a mobile PET scanner, shall provide the following information for each facility where the PET scanner will be operated: ... (3) Documentation that the facility will: ... (B) provide scheduled hours of operation for the PET scanner of a minimum of 12 hours per day, six days a week, except for mobile scanners."*

-NC- In Section II.8, page 47, the applicant states *"The PET/CT Simulator will operate from 6:45 AM – 9:00 PM (14.25 hours per day) from Monday – Friday. The PET/CT Simulator will be available during the non-scheduled hours on an on-call basis subject to patient need and demand."* The applicant proposes to staff the PET/CT scanner for scheduled hours of operation only <u>five</u> days per week. However, the rule requires that the applicant provide <u>scheduled</u> hours of operation for a minimum of <u>six</u> days per week. Therefore, the application is nonconforming with this rule.

.3702(b)(3)(C) This rule states *"An applicant proposing to acquire a PET scanner, including a mobile PET scanner, shall provide the following information for each facility where the PET scanner will be operated: ... (3) Documentation that the facility will: ... (C) implement a referral system which shall include a feedback mechanism of providing patient information to the referring physician and facility."*

-C- In Section II.8, page 47, the applicant states *"Referring physicians and facilities will receive a copy of the results report following completion of the procedure."*

.3702(b)(4) This rule states *"An applicant proposing to acquire a PET scanner, including a mobile PET scanner, shall provide the following information for each facility where the PET scanner will be operated: ... (4) A description of the protocols that will be established to assure that all clinical PET procedures performed are medically necessary and cannot be performed using other, less expensive, established modalities."*

-C- In Section II.8, page 48, the applicant states *"The protocols that are currently utilized at NCBH will extend to these services and they are attached in Exhibit 12. In addition, the Clinical Oversight Committee will be charged with ensuring that appropriate policies are in place and adhered to and that clinical PET procedures performed are medically necessary and cannot be performed using other, less expensive, established modalities. The proposed Clinical Oversight Committee policy and the Admission policy for the PET Simulator are provided in Exhibit 12."* Exhibit 12 contains a copy of the Positron Emission Tomography Center Procedure Manual for Clinical Patients.

.3702(c) This rule states *"An applicant proposing to acquire a mobile PET scanner shall provide copies of letters of intent from and proposed contracts with all of the proposed host facilities at which the mobile PET scanner will be operated."*

-NA- The applicant does not propose to acquire a mobile PET scanner.

.3702(d) This rule states *"An applicant proposing to acquire a mobile PET scanner shall demonstrate that each host facility offers or contracts with a hospital that offers comprehensive cancer services including radiation oncology, medical oncology, and surgical oncology."*

-NA- The applicant does not propose to acquire a mobile PET scanner.

.3702(e) This rule states *"An applicant shall document that all equipment, supplies and pharmaceuticals proposed for the service have been certified for use by the U.S. Food and Drug Administration or will be used under an institutional review board whose membership is consistent with U.S. Department of Health and Human Services' regulations."*

-C- Exhibit 8 contains a letter from the U.S. Food and Drug Administration notifying General Electric that the proposed PET/CT scanner has been certified for clinical use.

.3702(f)(1) This rule states *"An applicant shall document that each PET scanner and cyclotron shall be operated in a physical environment that conforms to federal standards, manufacturers specifications, and licensing requirements. The following shall be addressed: (1) quality control measures and assurance of radioisotope production of generator or cyclotron-produced agents."*

-C- In Section II.8, page 49, the applicant states *"NCBH owns a cyclotron that is operated by PET Net. Quality control measures and assurance production and testing are currently in place."*

.3702(f)(2) This rule states *"An applicant shall document that each PET scanner and cyclotron shall be operated in a physical environment that conforms to federal standards, manufacturers specifications, and licensing requirements. The following shall be addressed: ... (2) quality control measures and assurance of PET tomograph and associated instrumentation.*

-C- In Section II.8, page 49, the applicant states *"NCBH will conduct daily quality control measures of the equipment to include phantom studies, flooding of detectors and any other measures recommended by the equipment manufacturer."*

.3702(f)(3) This rule states *"An applicant shall document that each PET scanner and cyclotron shall be operated in a physical environment that conforms to federal standards, manufacturers specifications, and licensing requirements. The following shall be addressed: ... (3) radiation protection and shielding.*

-C- In Section II.8, page 49, the applicant states *"NCBH's/WFUHS's experience with FDG will assist in ensuring that proper radiation protection and shielding is in place for the proposed equipment. Patient waiting areas and open service areas will be located sufficiently far from the FDG so that there is no significant increase in radiation to individuals."*

.3702(f)(4) This rule states *"An applicant shall document that each PET scanner and cyclotron shall be operated in a physical environment that conforms to federal standards, manufacturers specifications, and licensing requirements. The following shall be addressed: ... (4) radioactive emission to the environment.*

-C- In Section II.8, page 49, the applicant states *"Handling of radioactive materials will be strictly adhered to as directed by North Carolina and federal codes."*

.3702(f)(5) This rule states *"An applicant shall document that each PET scanner and cyclotron shall be operated in a physical environment that conforms to federal standards, manufacturers specifications, and licensing requirements. The following shall be addressed: ... (5) radioactive waste disposal.*

-C- In Section II.8, page 50, the applicant states *"Syringes, needles, gloves and other contaminated articles will be stored in an appropriate lead container and allowed to decay for nine half-lives or until normal background levels are achieved, at which time they will be discarded as regular biologic waste."*

.3703 PERFORMANCE STANDARDS

.3703(a)(1) This rule states *"An applicant proposing to acquire a dedicated PET scanner, including a mobile dedicated PET scanner, shall demonstrate that: (1) the proposed dedicated PET scanner, including mobile dedicated PET scanners, shall be utilized at an annual rate of at least 1,220 PET procedures by the end of the third year following completion of the project."*

-NC- In Section II.8, page 50, and Exhibit 13, the applicant projects that the proposed PET/CT scanner will perform 1,220 procedures in Year Three. However, the applicant did not provide sufficient information to demonstrate that the proposed PET/CT scanner will perform at least 1,220 PET procedures in Year Three. See Criterion (3) for a detailed discussion. Therefore, the application is not conforming with this rule.

.3703(a)(2) This rule states *"An applicant proposing to acquire a dedicated PET scanner, including a mobile dedicated PET scanner, shall demonstrate that: ... (2) its existing dedicated PET scanners, excluding those used exclusively for research, performed an average of 1,220 PET procedures per PET scanner in the last year."*

-C- In Section II.8, page 50, the applicant states that the existing PET scanner performed 1,383 procedures during Fiscal Year 2002 (July 1, 2001 to June 30, 2002), which was the last full fiscal year of operation prior to submission of the application.

.3703(a)(3) This rule states *"An applicant proposing to acquire a dedicated PET scanner, including a mobile dedicated PET scanner, shall demonstrate that: ... (3) its existing and approved dedicated PET scanners shall perform an average of at least 1,220 PET procedures per PET scanner during the third year following completion of the project."*

-NC- In Fiscal Year 2002, the existing PET scanner performed 1,383 procedures and the applicant projects that it will perform 2,256 procedures in Year Three (FY 2007). Thus, the applicant projects that the number of procedures to be performed on the existing PET scanner will increase an average of 12.6% per year [2,256 – 1,383 = 873; 873 / 1,383 = 0.63; 63% / 5 years = 12.6% per year]. However, the applicant does not provide the assumptions or methodology used to project utilization of the existing PET scanner to demonstrate that the projected increases are reasonable. Particularly, given the additional procedures to be performed on the new PET scanner, including some existing routine diagnostic procedures that are proposed to be shifted to the new PET scanner. Therefore, the application is nonconforming with this rule.

.3703(b) This rule states *"The applicant shall describe the assumptions and provide data to support and document the assumptions and methodology used for each projection required in this Rule."*

-NC- The applicant did not adequately describe the assumptions or provide data to support and document the assumptions and methodology used for each projection required in this rule. See Criterion (3) for a detailed discussion. Therefore, the application is nonconforming with this rule.

.3704 SUPPORT SERVICES

.3704(a) This rule states *"An applicant proposing to acquire a PET scanner, including a mobile PET scanner, shall document how medical emergencies within the PET scanner unit will be managed at each facility where the PET scanner will be operated."*

-C- In Section II.8, page 51, the applicant states *"A radiation therapist with specialized training as a technologist who is licensed by the State of North Carolina to handle radioisotopes will always be present at the PET Simulator. This radiation therapist will be immediately available to manage any medical emergency and activate the local hospital code procedures if necessary. An emergency crash cart appropriate to the Department of Radiation Oncology will be located within close proximity to the PET/CT Simulator."*

.3704(b) This rule states *"An applicant proposing to acquire a PET scanner, including a mobile PET scanner, shall document that radioisotopes shall be acquired from one or more of the following sources and shall identify the sources which will be utilized by the applicant: (1) an off-site medical cyclotron and radioisotope production facility that is located within two hours transport time to each facility where the PET scanner will be operated; (2) an on-site rubidium-82 generator; or (3) an on-site medical cyclotron for radio nuclide production and a chemistry unit for labeling radioisotopes."*

-C- In Section II.8, page 51, the applicant states *"WFUBMC owns a cyclotron that is managed by PET.NET*

Pharmaceuticals. PET.Net has a national network of facilities and is able to supply NCBH with pharmaceutical radioisotopes in the unlikely event that the NCBH cyclotron is not operational."

.3704(c) This rule states *"An applicant proposing to acquire an on-site cyclotron for radioisotope production shall document that these agents are not available or cannot be obtained in an economically cost effective manner from an off-site cyclotron located within 2 hours total transport time from the applicant's facility."*

-NA- The applicant does not propose to acquire an on-site cyclotron. There is already a cyclotron located on the campus of Wake Forest University Baptist Medical Center.

.3704(d) This rule states *"An applicant proposing to develop new PET scanner services, including mobile PET scanner services, shall establish a clinical oversight committee at each facility where the PET scanner will be operated before the proposed PET scanner is placed in service that shall: (1) develop screening criteria for appropriate PET scanner utilization; (2) review clinical protocols; (3) review appropriateness and quality of clinical procedures; (4) develop educational programs; and (5) oversee the data collection and evaluation activities of the PET scanning service."*

-NA- The applicant does not propose to develop new PET scanner services. PET scanner services have been provided at Baptist since 1990.

.3705 STAFFING AND STAFF TRAINING

.3705(a)(1) This rule states *"An applicant proposing to acquire a PET scanner, including a mobile PET scanner, shall document that the scanner will be staffed by the following personnel: (1) One or more full-time nuclear medicine imaging physicians who:*

(A) are licensed by the State to handle medical radioisotopes;

(B) have specialized in the acquisition and interpretation of nuclear images, including tomographic studies, for at least one year;
(C) have acquired knowledge about PET through experience or postdoctoral education; and
(D) have had practical training with an operational PET scanner.

-C- In Section II.8, page 53, the applicant states *"Dr. Ed Shaw and Dr. Dan Bourland, will serve as co-medical Directors for the PET Simulator. ... In addition, Dr. Kathryn Morton, Section Chief for Nuclear Medicine/PET Services practices full-time for WFUHS and Medical Director for the fixed diagnostic PET, will support his project and possesses all the qualifications set forth in .3705 (A-D)."* Exhibit 2 contains curriculum vitae for each physician identified by the applicant in response to this rule. These physicians are board certified and have training and experience in PET services.

.3705(a)(2) This rule states *"An applicant proposing to acquire a PET scanner, including a mobile PET scanner, shall document that the scanner will be staffed by the following personnel: ... (2) Engineering and physics personnel with training and experience in the operation and maintenance of PET scanning equipment.*

-C- In Section II.8, page 53, the applicant states *"The purchase of the equipment includes vendor supplied maintenance of the PET scanning equipment for the first year. The radiation oncology engineer will have specified training to maintain the equipment after year one. Dr. Dan Bourland will be the lead physicist for the PET Simulator. In addition to Dan Bourland, Ph.D., WFUBMC employs three physicists who will be available to provide consultations and maintenance as needed for the PET/CT Simulator."* Exhibit 2 contains a copy of Dr. Bourland's curriculum vitae, which documents that he has training and experience in the operation of PET scanners.

.3705(a)(3) This rule states *"An applicant proposing to acquire a PET scanner, including a mobile PET scanner, shall document that the scanner will be staffed by the following personnel: ... (3) Radiation safety personnel with training and*

experience in the handling of short-lived positron emitting nuclides.

-C- In Section II.8, page 53, the applicant states *"All of the staff will be radiation therapists with training in nuclear medicine including specific training in the handling of short-lived positron emitting nuclides. All staff will be required to participate in continuing education related to the safe handling of radioactive materials and other safety considerations."*

.3705(a)(4) This rule states *"An applicant proposing to acquire a PET scanner, including a mobile PET scanner, shall document that the scanner will be staffed by the following personnel: ... (4) Nuclear medicine technologists certified in this field by the Nuclear Medicine Technology Certification Board or the American Registry of Radiologic Technologists with training and experience in positron emission computed tomographic nuclear medicine imaging procedures."*

-C- In Section II.8, page 54, the applicant states *"the radiation therapists who will administer the radioisotope and operate the machine will be certified or registry eligible with the American Registry Radiologic Technology (ARRT) which is the equivalent training of a nuclear medicine technologist."*

.3705(b) This rule states *"An applicant proposing to acquire a cyclotron shall document that the cyclotron shall be staffed by radiochemists or radiopharmacists who: (1) have at least one year of training and experience in the synthesis of short-lived positron emitting radioisotopes; and (2) have at least one year of training and experience in the testing of chemical, radiochemical, and radionuclidic purity of PET radiopharmaceutical synthesis."*

-NA- The applicant does not propose to acquire a cyclotron.

.3705(c) This rule states *"An applicant proposing to acquire a PET scanner, a mobile PET scanner, or a cyclotron, shall document that the personnel described in Paragraphs (a) and (b) of this Rule shall be available at all times that the scanner or cyclotron are operating."*

-C- In Section II.8, page 54, the applicant states *"The personnel described in Paragraph (a) will be available at all times that the scanner is operating."*

.3705(d) This rule states *"An applicant proposing to acquire a PET scanner, including a mobile PET scanner, shall document that a program of continuing staff education will be provided that will insure training of new personnel and the maintenance of staff competence as clinical PET applications, techniques and technology continue to develop and evolve."*

-C- In Section II.8, page 54, the applicant states *"all staff are subject to continuing staff education requirements. The NCBH PET department has established competencies as required by the Joint Commission on Health Care Accreditation. These competencies are reviewed within 30 days of initial employment, 90 days, and then annually thereafter."* Exhibit 11 contains copies of staff training policies for Baptist that document that the hospital has an organized program of staff education and training.

EXHIBIT 6

CHAPTER 692
SENATE BILL 816

AN ACT TO MAKE TECHNICAL AND CLARIFYING AMENDMENTS TO THE CERTIFICATE OF NEED STATUTES.

The General Assembly of North Carolina enacts:

G.S. 131E-176

Section 1. G.S. 131E-176 reads as rewritten:

"**§ 131E-176. Definitions.**

As used in this Article, unless the context clearly requires otherwise, the following terms have the meanings specified:

(1) 'Ambulatory surgical facility' means a facility designed for the provision of an ambulatory surgical program. An ambulatory surgical facility serves patients who require local, regional or general anesthesia and a period of post-operative observation. An ambulatory surgical facility may only admit patients for a period of less than 24 hours and must provide at least one designated operating room and at least one designated recovery room, have available the necessary equipment and trained personnel to handle emergencies, provide adequate quality assurance and assessment by an evaluation and review committee, and maintain adequate medical records for each patient. An ambulatory surgical facility may be operated as a part of a physician or dentist's office, provided the facility is licensed under G.S. Chapter 131E, Article 6, Part D, but the performance of incidental, limited ambulatory surgical procedures which do not constitute an ambulatory surgical program as defined in subdivision (1a) and which are performed in a physician's or dentist's office does not make that office an ambulatory surgical facility.

(1a) 'Ambulatory surgical program' means a formal program for providing on a same-day basis those surgical procedures which require local, regional or general anesthesia and a period of post-operative observation to patients whose admission for more than 24 hours is determined, prior to surgery, to be medically unnecessary.

(2) 'Bed capacity' means space used exclusively for inpatient care, including space designed or remodeled for licensed inpatient beds even though temporarily not used for such purposes. The number of beds to be counted in any patient room shall be the maximum number for which adequate square footage is provided as established by rules of the Department except that single beds in single rooms are counted even if the room contains inadequate square footage. The term 'bed capacity' also refers to the number

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clearly requires otherwise, the following

ity' means a facility designed for the ry surgical program. An ambulatory lients who require local, regional or eriod of post-operative observation. An may only admit patients for a period of nust provide at least one designated it one designated recovery room, have pment and trained personnel to handle ate quality assurance and assessment by committee, and maintain adequate atient. An ambulatory surgical facility rt of a physician or dentist's office, sed under G.S. Chapter 131E, Article ance of incidental, limited ambulatory o not constitute an ambulatory surgical vision (1a) and which are performed in office does not make that office an

gram' means a formal program for basis those surgical procedures which general anesthesia and a period of o patients whose admission for more ed, prior to surgery, to be medically

e used exclusively for inpatient care, remodeled for licensed inpatient beds t used for such purposes. The number y patient room shall be the maximum ate square footage is provided as Department except that single beds in iven if the room contains inadequate ed capacity' also refers to the number

of dialysis stations in kidney disease treatment centers, including freestanding dialysis units.

(2a) 'Capital expenditure' means an expenditure which under generally accepted accounting principles is not properly chargeable as an expense of operation and maintenance.

(3) 'Certificate of need' means a written order of the Department setting forth the affirmative findings that a proposed project sufficiently satisfies the plans, standards, and criteria prescribed for such projects by this Article and by rules of the Department as provided in G.S. 131E-183(a) and which affords the person so designated as the legal proponent of the proposed project the opportunity to proceed with the development of such project.

(4) 'Certified cost estimate' means an estimate of the total cost of a project certified by ~~the proponent of the project within 60 days prior to or subsequent to the date of submission of the proposed new institutional health service to the Department and which is based on:~~ a licensed architect or engineer which is based on:

a. Preliminary plans and specifications;
b. Estimates of the cost of equipment certified by the manufacturer or vendor; and
c. Estimates of the cost of management and administration of the project.

(5) 'Change in bed capacity' means (i) any relocation of health service facility beds, or dialysis stations from one licensed facility or campus to another, or (ii) any redistribution of health service facility bed capacity among the categories of health service facility bed as defined in G.S. 131E-176 (9c), or (iii) any increase in the number of health service facility beds, or dialysis stations in kidney disease treatment centers, including freestanding dialysis units.

(5a) 'Chemical dependency treatment facility' means a public or private facility, or unit in a facility, which is engaged in providing 24-hour a day treatment for chemical dependency or substance abuse. This treatment may include detoxification, administration of a therapeutic regimen for the treatment of chemically dependent or substance abusing persons and related services. The facility or unit may be:

a. A unit within a general hospital or an attached or freestanding unit of a general hospital licensed under Article 5, Chapter 131E, of the General Statutes,
b. A unit within a psychiatric hospital or an attached or freestanding unit of a psychiatric hospital licensed under Article 1A of General Statutes Chapter 122 or Article 2 of General Statutes Chapter 122C,
c. A freestanding facility specializing in treatment of persons who are substance abusers or chemically dependent licensed under Article 1A of General Statutes Chapter 122 or Article 2 of General Statutes Chapter 122C; and may be identified as 'chemical dependency, substance abuse, alcoholism, or drug abuse treatment units,' 'residential chemical dependency, substance abuse, alcoholism or drug abuse facilities,' 'social setting detoxification facilities' and 'medical detoxification facilities,' or by other names if the purpose is to provide treatment of chemically dependent or

substance abusing persons, but shall not include halfway houses or recovery farms.

(5b) 'Chemical dependency treatment beds' means beds that are licensed for detoxification or for the inpatient treatment of chemical dependency. Residential treatment beds for the treatment of chemical dependency or substance abuse are chemical dependency treatment beds but those residential treatment beds that were developed and operated without a certificate of need shall not be counted in the inventory of chemical dependency treatment beds in the State Health Plans prepared by the Department pursuant to G.S. 131E-177(4) after July 1, 1987. The State Health Plans prepared after July 1, 1987, shall also contain no limitation on the proportion of the overall inventory of chemical dependency treatment beds located in any of the types of chemical dependency treatment facilities identified in subdivision (5a). (11) (12)

(6) 'Department' means the North Carolina Department of Human Resources.

(7) To 'develop' when used in connection with health services, means to undertake those activities which will result in the offering of institutional health service not provided in the previous 12-month reporting period or the incurring of a financial obligation in relation to the offering of such a service.

(8),(9) Repealed by Session Laws 1987, c. 511, s. 1.

(9a) 'Health service' means an organized, interrelated medical, diagnostic, therapeutic, and/or rehabilitative activity that is integral to the clinical management of a sick, injured, or disabled person. 'Health service' does not include administrative and other activities that are not integral to clinical management.

(9b) 'Health service facility' means a hospital; psychiatric facility; rehabilitation facility; long term care facility; kidney disease treatment center, including freestanding hemodialysis units; intermediate care facility for the mentally retarded; home health agency office; chemical dependency treatment facility; and ambulatory surgical facility.

(9c) 'Health service facility bed' means a bed licensed for use in a health service facility in the categories of (i) acute care beds; (ii) psychiatric beds; (iii) rehabilitation beds; (iv) ~~intermediate nursing care or skilled nursing care beds;~~ nursing care beds; (v) intermediate care beds for the mentally retarded; and (vi) chemical dependency treatment beds. (13

(10) 'Health maintenance organization (HMO)' means a public or private organization which has received its certificate of authority under Article 67 of Chapter 58 of the General Statutes and which either is a qualified health maintenance organization under Section 1310(d) of the Public Health Service Act or:

a. Provides or otherwise makes available to enrolled participants health care services, including at least the following basic health care services: usual physician services, hospitalization, laboratory, X ray, emergency and preventive services, and out-of-area coverage; (13

b. Is compensated, except for copayments, for the provision of the basic health care services listed above to enrolled

participants by a payment which is paid on a periodic basis without regard to the date the health care services are provided and which is fixed without regard to the frequency, extent, or kind of health service actually provided; and

c. Provides physicians' services primarily (i) directly through physicians who are either employees or partners of such organizations, or (ii) through arrangements with individual physicians or one or more groups of physicians organized on a group practice or individual practice basis.

~~(11) 'Health systems agency' means an independent, private, nonprofit corporation, incorporated in this State, that engages in regional health planning and development functions.~~

(12) 'Home health agency' means a private organization or public agency, whether owned or operated by one or more persons or legal entities, which furnishes or offers to furnish home health services.

'Home health services' means items and services furnished to an individual by a home health agency, or by others under arrangements with such others made by the agency, on a visiting basis, and except for paragraph e. of this subdivision, in a place of temporary or permanent residence used as the individual's home as follows:

a. Part-time or intermittent nursing care provided by or under the supervision of a registered nurse;
b. Physical, occupational or speech therapy;
c. Medical social services, home health aid services, and other therapeutic services;
d. Medical supplies, other than drugs and biologicals and the use of medical appliances;
e. Any of the foregoing items and services which are provided on an outpatient basis under arrangements made by the home health agency at a hospital or nursing home facility or rehabilitation center and the furnishing of which involves the use of equipment of such a nature that the items and services cannot readily be made available to the individual in his home, or which are furnished at such facility while he is there to receive any such item or service, but not including transportation of the individual in connection with any such item or service.

(13) 'Hospital' means a public or private institution which is primarily engaged in providing to inpatients, by or under supervision of physicians, diagnostic services and therapeutic services for medical diagnosis, treatment, and care of injured, disabled, or sick persons, or rehabilitation services for the rehabilitation of injured, disabled, or sick persons. The term includes all facilities licensed pursuant to G.S. 131E-77 of the General Statutes.

(13a) 'Hospice' means any coordinated program of home care with provision for inpatient care for terminally ill patients and their families. This care is provided by a medically directed interdisciplinary team, directly or through an agreement under the direction of an identifiable hospice administration. A hospice program of care provides palliative and supportive medical and other health services to meet the physical, psychological, social,

spiritual and special needs of patients and their families, which are experienced during the final stages of terminal illness and during dying and bereavement.

(14) Repealed by Session Laws 1987, c. 511, s. 1, effective July 1, 1987.

(14a) 'Intermediate care facility for the mentally retarded' means facilities licensed pursuant to Article 2 of Chapter 122C of the General Statutes for the purpose of providing health and habilitative services based on the developmental model and principles of normalization for persons with mental retardation, autism, cerebral palsy, epilepsy or related conditions.

~~(14b) 'Intermediate nursing care' means the provision of health related care and services on a regular basis to individuals who do not require the degree of care and treatment that hospitals or skilled nursing care provide, but who because of their mental or physical condition require health related care and services above the level of room and board.~~

(14c) 'Long term care facility' means a health service facility whose bed complement of health service facility beds is composed principally of ~~skilled nursing beds or intermediate~~ nursing care facility ~~beds, or both.~~ beds.

(15) Repealed by Session Laws 1987, c. 511, s. 1.

(16) 'New institutional health services' means:

a. The construction, development, or other establishment of a new health service facility;

b. The obligation by any person of any capital expenditure on behalf of or for a health service facility as defined in subsection(9b) of this section exceeding two million dollars ($2,000,000), other than one to acquire an existing health service facility or to replace such a facility destroyed or irreparably damaged by accident or natural disaster. The cost of any studies, surveys, designs, plans, working drawings, specifications, and other activities, including staff effort and consulting and other services, essential to the acquisition, improvement, expansion, or replacement of any plant or equipment with respect to which an expenditure is made shall be included in determining if the expenditure exceeds two million dollars ($2,000,000);

c. Any change in bed capacity as defined in G.S.131E-176(5);

d. The offering of dialysis services or home health services by or on behalf of a health service facility if those services were not offered within the previous 12 months by or on behalf of the facility;

e. A change in a project that was subject to certificate of need review and for which a certificate of need was issued, if the change is proposed during the development of the project or within one year after the project was completed. For purposes of this subdivision, a change in a project is a change of more than fifteen percent (15%) of the approved capital expenditure amount or the addition of a health service that is to be located in the facility, or portion thereof, that was constructed or developed in the project;

f. The offering of a health service by or on behalf of a health service facility if the service was not offered by or on behalf

of the health service facility in the previous 12 months and if the annual operating costs of the service equal or exceed one million dollars ($1,000,000), or the expansion of an existing health service when an annual operating cost of one million dollars ($1,000,000) is directly associated with the offering of the expanded portion of the service;

g. to k. Repealed by Session Laws 1987, c. 511, s. 1.

l. The purchase, lease, or acquisition of any health service facility, or portion thereof, or a controlling interest in the health service facility or portion thereof, if the health service facility was developed under a certificate of need issued pursuant to G.S. 131E-180;

m. Any conversion of nonhealth service facility beds to health service facility beds;

n. The construction, development, or other establishment of a hospice if the operating budget thereof is in excess of one hundred thousand dollars ($100,000).

o. The opening of an additional office by an existing home health agency within its service area as defined by rules adopted by the Department; or the opening of any office by an existing home health agency outside its service area as defined by rules adopted by the Department.

(17) 'North Carolina State Health Coordinating Council' means the Council that prepares, with the Department of Human Resources, the State Medical Facilities Plan, a component of the State Health Plan.

(17a) 'Nursing care' means:

a. Skilled nursing care and related services for residents who require medical or nursing care;

b. Rehabilitation services for the rehabilitation of injured, disabled, or sick persons; or

c. Health-related care and services provided on a regular basis to individuals who because of their mental or physical condition require care and services above the level of room and board, which can be made available to them only through institutional facilities.

These are services which are not primarily for the care and treatment of mental diseases.

(18) To 'offer,' when used in connection with health services, means that the health service facility or health maintenance organization holds itself out as capable of providing, or as having the means for the provision of, specified health services.

(19) 'Person' means an individual, a trust or estate, a partnership, a corporation, including associations, joint stock companies, and insurance companies; the State, or a political subdivision or agency or instrumentality of the State.

(20) 'Project' or 'capital expenditure project' means a proposal to undertake a capital expenditure that results in the offering of a new institutional health service as defined by this Article. A project, or capital expenditure project, or proposed project may refer to the project from its earliest planning stages up through the point at which the specified new institutional health service may be offered. In the case of facility construction, the point at

which the new institutional health service may be offered must take place after the facility is capable of being fully licensed and operated for its intended use, and at that time it shall be considered a health service facility.

(21) 'Psychiatric facility' means a public or private facility licensed pursuant to Article 2 of Chapter 122C of the General Statutes and which is primarily engaged in providing to inpatients, by or under the supervision of a physician, psychiatric services for the diagnosis and treatment of mentally ill persons.

(22) 'Rehabilitation facility' means a public or private inpatient facility which is operated for the primary purpose of assisting in the rehabilitation of disabled persons through an integrated program of medical and other services which are provided under competent, professional supervision.

~~(23) 'Skilled nursing care' means the provision of that degree of care to inpatients who require medical or nursing care, or rehabilitation services for the rehabilitation of injured, disabled, or sick persons.~~

(24) 'State Health Plan' means the plan prepared by the Department of Human Resources and the North Carolina State Health Coordinating Council and approved by the Governor.

(25) 'State Medical Facilities Plan' means a component of the State Health Plan prepared by the Department of Human Resources and the North Carolina State Health Coordinating Council, and approved by the Governor.

(26) Repealed by Session Laws 1983 (Regular Session, 1984), c.1002, s. 9.

(27) Repealed by Session Laws 1987."

G.S. 131E-177

Sec. 2. G.S. 131E-177 reads as rewritten:

"**§ 131E-177. Department of Human Resources is designated State Health Planning and Development Agency; powers and duties.**

The Department of Human Resources is designated as the State Health Planning and Development Agency for the State of North Carolina, and is empowered to exercise the following powers and duties:

(1) To establish standards and criteria or plans required to carry out the provisions and purposes of this Article and to adopt rules pursuant to Chapter 150B of the General Statutes, to carry out the purposes and provisions of this Article;

(2) Adopt, amend, and repeal such rules and regulations, consistent with the laws of this State, as may be required by the federal government for grants-in-aid for health service facilities and health planning which may be made available by the federal government. This section shall be liberally construed in order that the State and its citizens may benefit from such grants-in-aid;

(3) Define, by rule, procedures for submission of periodic reports by persons or health service facilities subject to agency review under this Article;

(4) Develop policy, criteria, and standards for health service facilities planning, conduct statewide inventories of and make determinations of need for health service facilities, and develop a State Health Plan;

(5) Implement, by rule, criteria for project review;

(6) Have the power to grant, deny, or withdraw a certificate of need and to impose such sanctions as are provided for by this Article;

(7) Solicit, accept, hold and administer on behalf of the State any grants or bequests of money, securities or property to the Department for use by the Department ~~or health systems agencies~~ in the administration of this Article; and

(8) Repealed by Session Laws 1987, c. 511, s. 1.

(9) Establish and collect fees for submitting applications for certificates-of-need, which fees shall be based on the total cost of the project for which the applicant is applying. This fee may not exceed fifteen thousand dollars ($15,000) and may not be less than four hundred dollars ($400.00).

(10) The authority to review all records in any recording medium of any person or health service facility subject to agency review under this Article which pertain to construction and acquisition activities, staffing or costs and charges for patient care, including but not limited to, construction contracts, architectural contracts, consultant contracts, purchase orders, cancelled checks, accounting and financial records, debt instruments, loan and security agreements, staffing records, utilization statistics and any other records the Department deems to be reasonably necessary to determine compliance with this Article.

The Secretary of Human Resources shall have final decision-making authority with regard to all functions described in this section."

Sec. 3. G.S. 131E-178 reads as rewritten: G.S. 131E-178

"**§ 131E-178. Activities requiring certificate of need.**

(a) No person shall offer or develop a new institutional health service without first obtaining a certificate of need from the Department; provided, however, no hospital licensed pursuant to Article 5 of this Chapter that was established to serve a minority population that would not otherwise have been served and that continues to serve a minority population may be required to obtain a certificate of need for transferring up to 65 beds to ~~skilled nursing home~~ nursing care facility beds.

(b) No person shall make an acquisition by donation, lease, transfer, or comparable arrangement without first obtaining a certificate of need from the Department, if the acquisition would have been a new institutional health service if it had been made by purchase. In determining whether an acquisition would have been a new institutional health service the fair market value of the asset shall be deemed to be the purchase price.

(c) No person shall incur an obligation for a capital expenditure which is a new institutional health service without first obtaining a certificate of need from the Department. An obligation for a capital expenditure is incurred when:

(1) An enforceable contract, excepting contracts which are expressly contingent upon issuance of a certificate of need, is entered into by a person for the construction, acquisition, lease or financing of a capital asset;

(2) A person takes formal action to commit funds for a construction project undertaken as his own contractor; or

(3) In the case of donated property, the date on which the gift is completed.

(d) Where the estimated cost of a proposed capital expenditure is certified by a licensed architect or engineer to be equal to or less than the expenditure minimum for capital expenditure, such expenditure shall be deemed not to exceed the

expenditure minimum for capital expenditures regardless of the actual amount expended, provided that the following conditions are met:

(1) The certified estimated cost is prepared in writing 60 days or more before the obligation for the capital expenditure is incurred. Certified cost estimates shall be available for inspection at the facility and sent to the Department upon its request.

(2) The facility on whose behalf the expenditure was made notifies the Department in writing within 30 days of the date on which such expenditure is made if the expenditure exceeds the expenditure minimum for capital expenditures. The notice shall include a copy of the certified cost estimate.

(e) The Department may grant certificates of need which permit capital expenditures only for predevelopment activities. Predevelopment activities include the preparation of architectural designs, plans, working drawings, or specifications, the preparation of studies and surveys, and the acquisition of a potential site."

G.S. 131E-179

Sec. 4. G.S. 131E-179 reads as rewritten:

"**§ 131E-179. Research activities.**

(a) Notwithstanding any other provisions of this Article, a health service facility may offer new institutional health services to be used solely for research, or incur the obligation of a capital expenditure solely for research, without a certificate of need, if the Department grants an exemption. The Department shall grant an exemption if the health service facility files a notice of intent with the Department in accordance with rules promulgated by the Department and if the Department finds that the offering or obligation will not:

(1) Affect the charges of the health service facility for the provision of medical or other patient care services other than services which are included in the research;

(2) Substantially change the bed capacity of the facility; or

(3) Substantially change the medical or other patient care services of the facility.

(b) After a health service facility has received an exemption pursuant to subsection (a) of this section, it shall not offer the new institutional health services, or use a facility acquired through the capital expenditure, in a manner which affects the charges of the facility for the provision of medical or other patient care services, other than the services which are included in the research and shall not charge patients for the use of the service for which an exemption has been granted, without first obtaining a certificate of need from the ~~Department.~~ Department; provided, however, that any facility or service acquired or developed under the exemption provided by this section shall not be subject to the foregoing restrictions on its use if the facility or service could otherwise be offered or developed without a certificate of need.

(c) Any of the activities described in subsection (a) of this section shall be deemed to be solely for research even if they include patient care provided on an occasional and irregular basis and not as a part of the research program."

G.S. 131E-181

Sec. 5. G.S. 131E-181 reads as rewritten:

"**§ 131E-181. Nature of certificate of need.**

(a) A certificate of need shall be valid only for the defined scope, physical location, and person named in the application. A certificate of need shall not be transferred or assigned except as provided in 131E-189(c).

(b) A recipient of a certificate of need, or any person who may subsequently acquire, in any manner whatsoever permitted by law, the service for which that certificate of need was issued, is required to materially comply with the representations made in its application for that certificate of need. The Department

shall require any recipient of a certificate of need, or its successor, whose service is in operation to submit to the Department evidence that the recipient, or its successor, is in material compliance with the representations made in its application for the certificate of need which granted the recipient the right to operate that service. In determining whether the recipient of a certificate of need, or its successor, is operating a service which materially differs from the representations made in its application for that certificate of need, the Department shall consider cost increases to the recipient, or its successor, including, but not limited to, the following:

(1) Any increase in the consumer price index;

(2) Any increased cost incurred because of Government requirements, including federal, State, or any political subdivision thereof; and

(3) Any increase in cost due to professional fees or the purchase of services and supplies.

(c) Whenever a certificate of need is issued more than 12 months after the application for the certificate of need began review, the Department shall adjust the capital expenditure amount proposed by increasing it to reflect any inflation in the Department of Commerce's Construction Cost Index that has occurred since the date when the application began review; and the Department shall use this recalculated capital expenditure amount in the certificate of need issued for the project."

Sec. 6. G.S. 131E-183(b) reads as rewritten:

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

G.S. 131E-185

Sec. 7. G.S. 131E-185 reads as rewritten:

"**§ 131E-185. Review process.**

(a) Repealed by Session Laws 1987, c. 511, s. 1.

(a1) Except as provided in subsection (c) of this section, there shall be a time limit of 90 days for review of the applications, beginning on the day established by rule as the day on which applications for the particular service in the service area shall begin review.

(1) Any person may file written comments and exhibits concerning a proposal under review with the Department, not later than ~~45~~ 30 days after the date on which the application begins review. These written comments may include:

a. Facts relating to the service area proposed in the application;

b. Facts relating to the representations made by the applicant in its application, and its ability to perform or fulfill the representations made;

c. Discussion and argument regarding whether, in light of the material contained in the application and other relevant factual material, the application complies with relevant review criteria, plans, and standards.

(2) ~~At least 15, but no~~ No more than ~~30~~ 20 days from the conclusion of the written comment period, the Department shall ensure that a public hearing is conducted at a place within the appropriate

health service area ~~at which oral presentations~~ if one or more of the following circumstances apply; the review to be conducted is competitive; the proponent proposes to spend five million dollars ($5,000,000) or more; a written request for a public hearing is received before the end of the written comment period from an affected party as defined in G.S. 131E-188(c); or the agency determines that a hearing is in the public interest. At such public hearing oral arguments may be made regarding the application or applications under review; and this public hearing shall include the following:

a. An opportunity for the proponent of each application under review to respond to the written comments submitted to the Department about its application;
b. An opportunity for any affected person as defined in G.S. 131E-188(c), except one of the proponents, to present comments regarding the applications under review;
c. An opportunity for a representative of the Department, or such other person or persons who are designated by the Department to conduct the hearing, to question each proponent of applications under review with regard to the contents of the application;

The Department shall maintain a recording of ~~the~~ any required public hearing on ~~each~~ an application until such time as the Department's final decision is issued, or until a final agency decision is issued pursuant to a contested case hearing, whichever is later; and any person may submit a written synopsis or verbatim statement that contains the oral presentation made at the hearing.

(3) The Department may contract or make arrangements with a person or persons located within each health service area for the conduct of such public hearings as may be necessary. The Department shall publish, in each health service area, notice of the contracts that it executes for the conduct of those hearings. ~~If a health systems agency is in operation in a health service area, the Department shall use that health systems agency for the conduct of the public hearings in that area. A health systems agency may make recommendations on any matter covered in this Article, but no such recommendation shall interfere with the timetables of the review process contained in this Article.~~

(4) Within 15 days from the beginning of the review of an application or applications proposing the same service within the same service area, the Department shall publish notice of the deadline for receipt of written comments, of the time and place scheduled for the public hearing regarding the application or applications under review, and of the name and address of the person or agency that will preside.

(5) The Department shall maintain all written comments submitted to it during the written comment stage and any written submissions received at the public hearing as part of the Department's file respecting each application or group of applications under review by it. The application, written comments, and public hearing comments, together with all documents that the Department used in arriving at its decision, from whatever source, and any

documents that reflect or set out the Department's final analysis of the application or applications under review, shall constitute the Department's record for the application or applications under review.

(b) The Department shall issue as provided in this Article a certificate of need with or without conditions or reject the application within the review period.

(c) The Department shall promulgate rules establishing criteria for determining when it would not be practicable to complete a review within 90 days from the beginning date of the review period for the application. If the Department finds that these criteria are met for a particular project, it may extend the review period for a period not to exceed 60 days and provide notice of such extension to all applicants."

Sec. 8. G.S. 131E-188 reads as rewritten: G.S. 131E-188

"**§ 131E-188. Administrative and judicial review.**

(a) After a decision of the Department to issue, deny or withdraw a certificate of need or exemption, any affected person, as defined in subsection (c) of this section, shall be entitled to a contested case hearing under Article 3 of Chapter 150B of the General Statutes. A petition for a contested case shall be filed within 30 days after the Department makes its decision. When a petition is filed, the Department shall send notification of the petition to the proponent of each application that was reviewed with the application for a certificate of need that is the subject of the petition.

A contested case shall be conducted in accordance with the following timetable:

(1) An administrative law judge or a hearing officer, as appropriate, shall be assigned within 15 days after a petition is filed.

(2) The parties shall complete discovery within 90 days after the assignment of the administrative law judge or hearing officer.

(3) The hearing at which sworn testimony is taken and evidence is presented shall be held within 45 days after the end of the discovery period.

(4) The administrative law judge or hearing officer shall make his recommended decision within 75 days after the hearing.

(5) The Department shall make its final decision within 30 days of receiving the ~~recommended decision.~~ official record of the case from the Office of Administrative Hearings.

The administrative law judge or hearing officer assigned to a case may extend the deadlines in subdivisions (2) through (4) so long as the administrative law judge or hearing officer makes his recommended decision in the case within 270 days after the petition is filed. The Department may extend the deadline in subdivision (5) for up to 30 days by giving all parties written notice of the extension.

(a1) ~~As a condition precedent to proceeding with~~ On or before the date of filing a petition for a contested case hearing on the approval of an applicant for a certificate of need, the petitioner shall deposit a bond with the clerk of superior court where the new institutional health service that is the subject of the petition is proposed to be located. The bond shall be secured by cash or its equivalent in an amount equal to five percent (5%) of the cost of the proposed new institutional health service that is the subject of the petition, but may not be less than five thousand dollars ($5,000) and may not exceed fifty thousand dollars ($50,000). A petitioner who received approval for a certificate of need and is contesting only a condition in the certificate is not required to file a bond under this subsection.

The applicant who received approval for the new institutional health service that is the subject of the petition may bring an action against a bond filed under this subsection in the superior court of the county where the bond was filed. Upon finding that the petition for a contested case was frivolous or filed to delay the

applicant, the court may award the applicant part or all of the bond filed under this subsection.

(b) Any affected person who was a party in a contested case hearing shall be entitled to judicial review of all or any portion of any final decision of the Department in the following manner. The appeal shall be to the Court of Appeals as provided in G.S. 7A-29(a). The procedure for the appeal shall be as provided by the rules of appellate procedure. The appeal of the final decision of the Department shall be taken within 30 days of the receipt of the written notice of decision required by G.S. 131E-187 and notice of appeal shall be filed with the Division of Facility Services, Department of Human Resources and with all other affected persons who were parties to the contested hearing.

(b1) Before filing an appeal of a decision by the Department granting a certificate of need, the affected person shall deposit a bond with the Clerk of the Court of Appeals. The bond shall be secured by cash or its equivalent in an amount equal to five percent (5%) of the cost of the proposed new institutional health service that is the subject of the appeal, but may not be less than five thousand dollars ($5,000) and may not exceed fifty thousand dollars ($50,000). A holder of a certificate of need who is appealing only a condition in the certificate is not required to file a bond under this subsection.

If the Court of Appeals finds that the appeal was frivolous or filed to delay the applicant, the court shall remand the case to the superior court of the county where a bond was filed for the contested case hearing on the certificate of need. The superior court may award the holder of the certificate of need part or all of the bond. The court shall award the holder of the certificate of need reasonable attorney fees and costs incurred in the appeal to the Court of Appeals.

(c) The term 'affected persons' includes: the applicant; the health systems agency for the health service area in which the proposed project is to be located; health systems agencies serving contiguous health service areas or located within the same standard metropolitan statistical area; any person residing within the geographic area served or to be served by the applicant; any person who regularly uses health service facilities within that geographic area; health service facilities and health maintenance organizations (HMOs) located in the health service area in which the project is proposed to be located, which provide services similar to the services of the facility under review; health service facilities and HMOs which, prior to receipt by the agency of the proposal being reviewed, have formally indicated an intention to provide similar services in the future; third party payers who reimburse health service facilities for services in the health service area in which the project is proposed to be located; and any agency which establishes rates for health service facilities or HMOs located in the health service area in which the project is proposed to be located."

Sec. 9. G.S. 131E-190 reads as rewritten:

G.S. 131E-190

"**§ 131E-190. Enforcement and sanctions.**

(a) Only those new institutional health services which are found by the Department to be needed as provided in this Article and granted certificates of need shall be offered or developed within the State.

(b) No formal commitments made for financing, construction, or acquisition regarding the offering or development of a new institutional health service shall be made by any person unless a certificate of need for such service or activities has been granted.

(c) Nothing in this Article shall be construed as terminating the P.L. 92-603, Section 1122, capital expenditure program or the contract between the State of North Carolina and the United States under that program. The sanctions available under that program and contract, with regard to the determination of whether the amounts attributable to an applicable project or capital expenditure project should be included

or excluded in determining payments to the proponent under Titles V, XVIII, and XIX of the Social Security Act, shall remain available to the State.

(d) If any person proceeds to offer or develop a new institutional health service without having first obtained a certificate of need for such services, the penalty for such violation of this Article and rules hereunder may include the withholding of federal and State funds under Titles V, XVIII, and XIX of the Social Security Act for reimbursement of capital and operating expenses related to the provision of the new institutional health service.

(e) The ~~Medical Care Commission~~ Department may revoke or suspend the license of any person who proceeds to offer or develop a new institutional health service without having first obtained a certificate of need for such services.

(f) The Department may assess a civil penalty of not more than twenty thousand dollars ($20,000) against any person who knowingly offers or develops any new institutional health service within the meaning of this Article without a certificate of need issued under this Article and the rules pertaining thereto, or in violation of the terms or conditions of such a certificate, whenever it determines a violation has occurred and each time the service is provided in violation of this provision. In determining the amount of the penalty the Department shall consider the degree and extent of harm caused by the violation and the cost of rectifying the damage. A person who is assessed a penalty shall be notified of the penalty by registered or certified mail. The notice shall state the reasons for the penalty. If a person fails to pay a penalty, the Department shall refer the matter to the Attorney General for collection. For the purpose of this subsection, the word "person" shall not include an individual in his capacity as an officer, director, or employee of a person as otherwise defined in this Article.

(g) No agency of the State or any of its political subdivisions may appropriate or grant funds or financially assist in any way a person, applicant, or facility which is or whose project is in violation of this Article.

(h) If any person proceeds to offer or develop a new institutional health service without having first obtained a certificate of need for such services, the Secretary of Human Resources or any person aggrieved, as defined by G.S. 150B-2(6), may bring a civil action for injunctive relief, temporary or permanent, against the person offering, developing or operating any new institutional health service. The action may be brought in the superior court of any county in which the health service facility is located or in the superior court of Wake County.

(i) If the Department determines that the recipient of a certificate of need, or its successor, is operating a service which materially differs from the representations made in its application for that certificate of need, the Department may bring an action in Wake County Superior Court or the superior court of any county in which the certificate of need is to be utilized for injunctive relief, temporary or permanent, requiring the recipient, or its successor, to materially comply with the representations in its application. The Department may also bring an action in Wake County Superior Court or the superior court of any county in which the certificate of need is to be utilized to enforce the provisions of this subsection and G.S. 131E-181(b) and the rules adopted in accordance with this subsection and G.S. 131E-181(b)."