COMMENTS BY NOVANT HEALTH, INC. ON THE PETITION FOR A CHANGE IN POLICY AC-3 SUBMITTED BY THE ACADEMIC MEDICAL CENTERS

Novant Health, Inc. ("Novant") submits these comments in opposition to the Petition submitted to the State Health Coordinating Council ("SHCC") on March 2, 2011 by the State's four academic medical centers ("AMCs"): Duke University Health System, Inc. d/b/a Duke University Hospital ("Duke"), North Carolina Baptist Hospital ("Baptist"), Pitt County Memorial Hospital ("Pitt"), and UNC Hospitals at Chapel Hill ("UNC").[1]

EXECUTIVE SUMMARY

The State Medical Facilities Plan ("SMFP") is the foundation of health planning in North Carolina. The SHCC, in conjunction with the Division of Health Service Regulation ("DHSR") Medical Facilities Planning Staff, spends countless hours every year studying data and analyzing important policy issues to ensure that all North Carolinians have access to health care. The process of developing the SMFP need determinations is a public process that is open and fair, and ensures that all stakeholders have an opportunity to participate.

Policy AC-3 undermines the foundation of health planning by allowing the AMCs to propose additional facilities and services that the SMFP says are not needed. Policy AC-3 ignores the SHCC's work and experience. Policy AC-3 is not a public process that allows everyone to participate. Rather, Policy AC-3 gives special benefits only to the AMCs based on the AMCs' self-determined needs. Policy AC-3 has been abused, and there is strong incentive for the AMCs to continue to abuse it. As discussed in Novant's Petition, and in these comments, the health planning process should be open and equitable. If a provider believes that there is a need for additional facilities and services, it should petition the SHCC, and if the

[1]Novant also submitted a Petition to the SHCC on March 2, 2011, requesting the repeal or revision of Policy AC-3. Many of the same arguments contained in that Petition support Novant's opposition to the AMCs' Petition.

SHCC, after reviewing the petition, comments and other relevant data, determines there is a need, the need should be placed in the next year's SMFP so that any interested provider can apply to meet the need. This process is open and fair and ultimately serves to protect the public interest.

The AMCs now propose dramatic expansion of Policy AC-3 to cover two more health care systems in this State, Carolinas Healthcare System ("CHS") and Mission Health System ("Mission"), because of the "changing academic landscape." *See* Petition, p. 3. Novant agrees that the "academic landscape" is vastly different from what it was in 1983, when Policy AC-3 was born, and that it is no longer workable in today's environment. For example:

- In 1983, CHS was required to completely comply with the SMFP. At that time, CHS was mainly providing regulated services in Mecklenburg County. Today, CHS employs nearly 2,000 physicians and controls, either through ownership or management, more than 6,300 licensed beds in 33 hospitals in two states. CHS is multi-billion dollar operation with operations throughout North Carolina.

- In 1983, Memorial Mission Hospital, as Mission was known in 1983, was required to comply completely with the SMFP. At that time, Mission was one of two acute care hospitals in Buncombe County. Today, it is a monopoly in Buncombe County through its merger with St. Joseph's in 1998. Mission is a major economic force in 17 counties in Western North Carolina.

- In 1983, Pitt was a county hospital only operating in one county. Today, Pitt is a major economic enterprise no longer controlled by Pitt County. Pitt's influence extends throughout eastern North Carolina.

- In 1983, UNC was focused on its academic mission from its campus in Chapel Hill. Since that time, it has used hundreds of millions of state funds to acquire other facilities, build new facilities off its academic campus, acquire private physician practices, and propose a community hospital in Hillsborough, near the Alamance County line.

- In 1983, Duke was focused on its academic mission from its campus in Durham. Since then, it has aggressively acquired private physician practices and other hospitals, and entered into a joint venture with a publicly-traded proprietary hospital company, LifePoint, so it can further

its competitive interests. Duke now operates in multiple North Carolina counties and is a major economic enterprise.

- In 1983, Baptist and its academic partner, Wake Forest University Health Sciences ("WFUHS"), focused on their academic mission from their campus on Hawthorne Hill in Winston-Salem. Since then, Baptist and WFUHS have acquired a number of private physician practices. Baptist owns one community hospital, Lexington Memorial Hospital and manages another community hospital, Davie County Hospital. Baptist is now using the Policy AC-3 exemption to build a freestanding ambulatory surgery center that does simple outpatient procedures that are done in hundreds of facilities in the State. Last week, the combined Baptist/WFUHS enterprise unveiled a new corporate identity, Wake Forest Baptist Health, at cost of $3.5 million, to promote its regional health care system in a 19-county service area.

In 1983, when Policy AC-3 was adopted, the four AMCs were only focused on four hospitals in four counties in North Carolina. They owned no other hospitals or private physician practices. The concept of a "clinical" faculty member did not exist. At that time, all faculty were devoted to the academic missions of teaching and research. There was minimal competition between the AMCs and the community hospitals back in the early 1980s, because their missions and their services were completely different.

Today, that is not at all the case. The AMCs' Petition would apply to multi-million (and in some cases, multi-billion) dollar corporations that provide billions of dollars of services, consuming a significant and ever growing part of our Medicaid budget, and providing services in all 100 counties of our State. They employ, or are affiliated with, hundreds of "clinical" faculty whose teaching and research activities are minimal and comparable to many private practice physicians in North Carolina.

Today's AMCs clearly are not the same institutions they were in 1983. Academic medicine and academic medical centers are big business, providing a major proportion of our health care economy and consuming billions of dollars in State funds and insurance costs for

the citizens of North Carolina. Hardly a week goes by without an announcement from the AMCs about their growth initiatives, be they hospital or physician practice acquisitions, joint ventures with for-profit companies to acquire or manage other providers, or multi-million dollar branding initiatives. As the recent experience with the Baptist Policy AC-3 ambulatory surgery center project shows, the AMCs have a powerful economic initiative to use their Policy AC-3 status to avoid health planning and achieve maximum return on investment.

As the SHCC reviews Policy AC-3, it needs to ask the following questions:

1. Why do six of the wealthiest, most economically sound health care corporations in our State need expanded exemption from health planning to compete unfairly with other hospitals, private practice physicians and surgery centers in the State?

2. Why are "clinical" faculty, who are compensated like private practice physicians, who perform research like private practice physicians, and who teach like private practice physicians, allowed to have outpatient surgery centers that are not needed in the SMFP, when their counterparts in private practice cannot apply for new operating rooms unless they are needed in the SMFP?

3. Why can't these major corporations, which employ dozens of staff planners, take the time to file special need petitions to adjust the SMFP when they perceive a need for additional facilities and services, just like their counterparts in the non-academic setting?

4. Does the SHCC believe that it is essential to use the existing planning process so that all health assets that generate costs for our State budget and employer health plans are regulated fairly and completely?

5. Why is North Carolina the only State in the country with a health planning process that allows such a massive exemption from health planning?

6. Why does the State of North Carolina spend hundreds, possibly thousands, of hours every year developing an SMFP, if some providers are not required to comply with it completely?

Novant strongly supports rational health planning because it helps reduce unnecessary duplication of services that drive up health care costs. But health planning only works when the State of North Carolina demands that all providers, regardless of title, comply completely with the SMFP. The current program, which gives certain providers the ability to opt out of health planning, without an empirical basis for doing so, is neither rational nor fair. Expanding that system to give two more providers special treatment jeopardizes health planning in North Carolina.

The AMCs' Petition should be denied. Instead, the SHCC should require all providers to comply completely with the SMFP, as recommended in the Novant Petition on Policy AC-3, also filed on March 2, 2011.

COMMENTS ON THE AMCS' PETITION

Attached to Novant's comments as Exhibit A is the Affidavit of Jay Wolfson, DrPH, JD. Dr. Wolfson is the Distinguished Service Professor of Public Health and Medicine and Associate Vice President of Health Law, Policy and Safety at the University of South Florida in Tampa, Florida and Professor of Health Law at Stetson University College of Law in Gulfport, Florida. Dr. Wolfson has over thirty years' experience in health policy and planning, and has served as a trustee and finance chair of a major university teaching hospital, Tampa General Hospital, in Tampa, Florida. He has advised federal and state legislators and judges on many health policy issues. Based on his training, education and experience, Dr. Wolfson concludes that the AMCs' proposal raises significant policy concerns, and he recommends that the SHCC not adopt the AMCs' recommendations. These comments will outline the reasons why the AMCs' recommendations should not be adopted, citing relevant portions of Dr. Wolfson's affidavit.

Novant notes that while the AMCs' Petition is replete with statistics, none of these statistics is particularly relevant to Policy AC-3 or to the precise issue before the SHCC, *i.e.*, should Policy AC-3 be repealed or modified. For example:

- Pages 6-7 of the Petition, which describe the number of "learners" that the AMCs teach: Numbers of medical students, residents, fellows and non-physician providers at these institutions do not explain why the AMCs need to be exempt from the "normal" planning process, which both Pitt and Duke have successfully used, or why Policy AC-3 needs to be expanded. In fact, no recent Policy AC-3 application has been premised on growing residency slots or adding medical school spaces.

- Page 7 of the Petition, which asserts that "[i]nserting teaching into the provision of these clinical services necessarily adds time and costs to the AMCs' operations" and that "AMCs must bear the costs for its additional trainees through other sources, including its clinical services revenue": Nothing in Policy AC-3 states or implies that its purpose was to help the AMCs make money or save time. Nor does the AMCs' assertion take into account that many non-AMCs train residents and students (*e.g.*, Forsyth Medical Center, Moses Cone, and WakeMed) and they also have costs (*e.g.*, resident salaries) associated with training.

- Page 7 of the Petition, which notes that according to a 2005 Sheps Center report, almost 40% of North Carolina medical school graduates practice in North Carolina, and more than 40% of those physicians who did their residency in North Carolina stay in State: There is no connection between these statistics and Policy AC-3. Indeed, one of Novant's major arguments for the reform of Policy AC-3 is that we do not know how, if at all, Policy AC-3 has actually benefitted any medical students or residents.

- Page 8 of the Petition, which lists various grants which the AMCs have been awarded: There is no explanation of how Policy AC-3 relates to this grant money. The award of these grants certainly could not have been premised on the AMCs' being able to take advantage of Policy AC-3, and there is also no evidence to suggest that the normal petitioning process could not be used by the AMCs for expansion purposes, if their grant obligations required them to pursue expansion opportunities.[2] As the Petition itself reveals, the recipients of these grants do not necessarily have to be AMCs. The Petition refers to New Hanover Regional Medical Center, a non-AMC, and its family medicine residency

[2]This section of the Petition also refers to a grant that Methodist University received for its physician assistant program. It is not clear why this is in the Petition, since there is no such institution in North Carolina.

program, as recipients of a grant. This also underscores the point Novant made in its Petition that non-AMCs play a vital role in training physicians.[3] These non-AMCs experience similar needs and costs as their AMC counterparts, but only the AMCs are eligible for the Policy AC-3 exemption. In fact, today in North Carolina, there are only four Policy AC-3 eligible AMCs, and about 120 non-AMCs that are not Policy AC-3 eligible. One could argue that the non-AMC hospitals, by their sheer number, have the ability to offer extensive training opportunities and venues beyond the finite capacity of the four AMCs. After all, the majority of physicians practicing in North Carolina are associated with non-AMC hospitals, and the majority of patients in North Carolina are cared for in non-AMC hospitals.

- Page 9 of the Petition, which states that Duke developed a protocol for whole body PET imaging, particularly for legs: There is no explanation about how Policy AC-3 relates to this protocol.

- Page 10 of the Petition, which states that cases at AMCs tend to take longer and are more complex, and that AMCs are the only providers of certain kinds of services: Case length and acuity levels are not discussed at all in Policy AC-3. If these factors were relevant to the drafters of Policy AC-3, they likely would have been included in Policy AC-3, but they are not. "Sole provider" status is also not discussed in Policy AC-3. Many non-AMCs are the sole providers of hospital and outpatient services in their home counties, but nobody has ever suggested that they be exempt from the SMFP because they are the only providers of services. Further, the Novant proposal would accommodate the AMCs' esoteric needs because they could petition the SHCC for a need determination and if the need determination is approved, they could later apply for it. If, as the AMCs suggest in their Petition, they are the "only" providers offering certain services, then it stands to reason that they would have a very good chance of being approved for the service, provided they demonstrate the need in their CON application.[4]

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[3]For instance, during 2010, more than 100 residents from Baptist trained at Novant facilities in Winston-Salem in the following specialties: OB Anesthesia; Anesthesia/Pain Management (fellowship program); emergency medicine (doing an OB rotation); family medicine; general surgery; OB/GYN; ophthalmology (fellowship program); pathology; pediatric neonatology; pediatrics; and plastic surgery. Likewise, during the same period, more than 100 medical students from Baptist received training at Forsyth Medical Center.

[4]In the unlikely event that a genuine "emergency" occurred that required an AMC to develop an SMFP-regulated service in a time frame that would not accommodate the normal petitioning process (*e.g.*, the ACGME threatened an AMC with immediate loss of accreditation for a residency program unless it developed an SMFP-limited service), the State of North Carolina would undoubtedly come to the aid of the AMC to address the situation. This is shown by the flexibility the State has shown in similar situations. For example, a health service facility does not need to file a CON to address a life safety code issue. A health service facility can also apply for permission to exceed, on a temporary basis, its licensed bed capacity. The Governor was also able to eliminate, on short notice, a need determination in the 2011 SMFP for home health agencies, when it was discovered that there was a mistake in the 2011 SMFP need determination for additional home health agencies.

- Pages 11 and 12 of the Petition, which discusses that the AMCs "demonstrate a patient base dramatically different from even the most sophisticated non-academic facilities" and that AMCs tend to treat more patients from outside their home counties than do the tertiary-level non-AMCs: It is not clear why this should make any difference in determining who is subject to the SMFP and who is not subject to the SMFP. For example, according to its 2011 Hospital License Renewal Application, Forsyth Medical Center treated patients from 73 of North Carolina's 100 counties. Baptist served patients from 90 of North Carolina's 100 counties. There is no logical basis for asserting that a difference in 17 counties entitles Baptist to a broad-based exemption from the SMFP. Nor would there be a logical basis for asserting that the non-AMC provider that served 88 of the 100 counties should be required to follow the SMFP (Cape Fear Valley Medical Center in Fayetteville) while the AMC provider that served 90 out of 100 counties (Baptist) should be exempt from the SMFP.[5] And, if Policy AC-3 is really a contest to see who serves the most counties, then Baptist and Pitt would lose, because they only served 90 and 87 counties respectively, whereas Duke and UNC each served all 100 counties. Clearly, important health planning and policy decisions cannot be based on such arbitrary and minute distinctions. In fact, the SMFP gives providers "full credit" for every patient they serve, regardless of where the patient comes from, so the AMCs' contention about patient origin is irrelevant.

Thus, as the SHCC reviews the Novant Petition and the AMCs' Petition, the SHCC should not allow itself to be distracted by irrelevant points. Instead, the SHCC must remain focused on the core issues: should a policy that was first implemented in 1983, at a time when there was a vast difference between AMCs and community hospitals, remain in effect in 2012? And if it should remain in effect, are any changes necessary to ensure that all providers, regardless of their title, have an equal opportunity to compete? Novant respectfully submits that the changes the AMCs are seeking to Policy AC-3 would be even more damaging to North Carolina's health care planning process than present Policy AC-3 and should not be adopted.

[5]These statistics are taken from the hospitals' patient origin for general acute care services as stated in their 2011 Hospital License Renewal Applications. These are publicly-available documents.

I. THE SHCC SHOULD NOT ADOPT THE AMCS' REVISIONS TO POLICY AC-3.

The AMCs assert that Policy AC-3 should be expanded, under the guise of "fairness" to other providers who are not allowed to take advantage of the policy. *See* Petition, p. 2. Expansion of Policy AC-3 only exacerbates the inherent unfairness that exists today and further threatens the integrity of North Carolina's health planning process.

A. Expansion Of Policy AC-3 To New Medical Schools and Satellite Campuses of Medical Schools Is Unwarranted.

The AMCs have asked the SHCC to remove the date limitation in current Policy AC-3 (January 1, 1990) and expand the policy to facilities to "*any* designated Academic Medical Center Teaching Hospital which either 1) is under common ownership with a school of medicine, or 2) has the majority of the hospital's chiefs of service serving as medical school clinical department chair, or 3) which is the sole designated teaching site of a separate campus of an accredited North Carolina medical school which is determined adequate by the Liaison Committee on Medical Education, where such separate campus provides at least two years of clinical medical education to enrolled students." *See* Petition, p. 21 (emphasis added). This change is intended to benefit "new" medical schools, and satellite campuses of existing medical schools, specifically Carolinas Medical Center ("CMC") in Charlotte and Mission in Asheville. *See* Petition, p. 3. Thus, the AMCs would expand the reach of Policy AC-3 to two more institutions, including Novant's chief competitor in Mecklenburg County. The impact would be that Novant, which plays a significant role in training medical students and residents, but is excluded from Policy AC-3, would be operating in two markets (Winston-Salem and Charlotte) with AMC competitors that enjoy a competitive advantage that Novant does not. As Dr. Wolfson states:

> The proposed expansion of Policy AC-3's exemption to additional and new AMC related entities further erodes the integrity of the health planning process by permitting more wish lists and short term, often expensive and anti-competitive projects to escape the rational process of SMFP need determinations.
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> Affording branch campuses and portions of AMC programs throughout communities in the state to arbitrarily trump the resources and needs of local, non-AMC hospitals and other providers creates a broader, state-sanctioned monopoly with reduced benefits to the community.

Exhibit A, pp. 11-12.

The stated reason for expansion of Policy AC-3 is to address a shortage of physicians, as stated by the President of the American Medical Association. No details are provided about the precise nature of the shortage, how North Carolina would be impacted by this shortage, or how expanding Policy AC-3 would help address the shortage. The AMCs do not indicate what additional resources in terms of SMFP-regulated assets are needed to meet the shortage. The AMCs do not explain why CMC and Mission, which have been involved in training residents for many years without the benefit of Policy AC-3 protection, suddenly need the unique benefits of Policy AC-3 protection. The AMCs do not explain why they and their satellite campuses could not use the normal petitioning process to meet the physician shortage, if additional SMFP-regulated assets are needed to help address the physician shortage. It is interesting to note that no Policy AC-3 CON application in recent times has proposed to add more medical school or residency slots. To do so would require verification from a third party and could not be done simply by obtaining a letter from the Dean of the AMC applying for the CON.

On page 13 of the Petition, the AMCs note that Duke successfully used the petitioning process in 1999 for an MRI scanner. The need determination was written in such a way that Duke was the only viable applicant. Duke was, in fact, the only applicant and its CON was

approved. The Petition states, however, that the petitioning process "delayed implementation by at least one year." This statement assumes that project implementation would have proceeded *exactly* according to the CON timetable, and would not have been affected by construction delays, funding issues or other organizational priorities. It is rare, at least in today's environment, for there to be no delays whatsoever in project implementation and for a project to come on line on the precise date identified in the CON timetable. The Petition also does not provide any details about how, if at all, the alleged delay affected Duke's ability to provide patient care. Thus, the reader cannot assume that the alleged delay of one year was meaningful.[6]

Moreover, it is important to put into context the one year delay that Duke says it experienced. The effects of health planning decisions made today can have effects decades into the future. For example, if a need is placed in the SMFP for additional beds, and the beds are ultimately approved and developed, one can reasonably expect those beds to remain in existence for decades. A one year delay, to make sure that the State of North Carolina gets it right and does not promote the unnecessary development of facilities and services that can drive up costs and put greater burdens on already-stressed payment systems like Medicaid for years to come, is not significant when considering the lasting effects of health planning decisions.

The Petition also neglects to mention Pitt's successful 2007 petition to add operating rooms, which is discussed in Novant's Petition. Clearly, the AMCs can and do use the normal

[6]The fact that relatively few Policy AC-3 CON applications are filed would also suggest that Policy AC-3 is not the indispensible tool the AMCs imagine it to be, and that they do indeed have the time and the resources to go through the normal planning process.

petitioning process and there is no reason why they and their satellites cannot continue to do so.

The Petition also asserts, without any factual support, that following the normal petitioning process might cause an AMC to lose the ability to pursue research grants. *See* Petition, pp. 13-14. This statement seems to suggest that research grants are applied for on an "emergency basis" without time to go through the petitioning process. Dr. Wolfson has first-hand experience in academia and participates directly in grant-funded research himself. *See* Wolfson CV, attached as Exhibit 1 to Exhibit A. He disabuses the reader of the notion that grant opportunities and research are "emergency" situations that are ill-suited for the petitioning process:

> AMCs will not be forgoing grant opportunities if they are required to go through the petitioning process to obtain approval for projects. AMC-based research is a deliberate, incremental effort, built upon years of previously funded and published work and does not involve quick turnaround times or emergencies for faculty hiring decisions. This is especially true for NIH and major foundation grants. AMCs and their researchers are in a constant state of grant development and response to known requests for proposals. It is uncommon for a major, totally unexpected request for proposals to be issued by a granting agency, and for a researcher in an AMC to develop a cold response without having laid the groundwork with years of developmental research – much of it already funded by other sources. Clinical and basic research at AMCs is not a quick game – it is an incremental, deliberate and highly-competitive process.
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> There are few emergency resource decisions associated with bona fide grant, faculty recruitment and other institutional decisions that would not and should not be incorporated within a rational planning process and time frame.

Exhibit A, pp. 15-16.

The time involved in obtaining grants is illustrated by Baptist's experience in 2003, when it prematurely applied for a Policy AC-3 exemption for MRI and PET/CT scanners

before the grants were approved. *See* Exhibit B attached hereto, Findings on Project I.D. No. G-8616-03, page 7 ("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).

Given the lengthy and complex process involved in applying for grant money, the petitioning process does not unduly burden the AMCs or interfere with their research efforts. In fact, the alleged "delay" could be far less than even the year Duke says it experienced. A special needs petition could be filed in the August petitioning time frame, and depending on the nature of the service and the CON Sections' timetable, a review could be scheduled as early as the following winter. The time associated with the actual CON review would not be counted in determining the "delay" because, as the AMCs acknowledge, they would have to file CON applications anyway.

On page 13, the Petition notes that N.C. Gen. Stat. § 131E-184[7] provides an exemption for research projects, but the AMCs state this provision of the CON Law provides little value to them because they cannot charge for the services provided on the assets obtained through the

[7]The research exemption is found in N.C. Gen. Stat. § 131E-179, not N.C. Gen. Stat. § 131E-184, as stated in the AMCs' Petition.

research exemption.[8] The AMCs' complaint about the perceived shortcomings of the research exemption highlights why they zealously guard Policy AC-3: Policy AC-3 can be a tremendous money making opportunity for the AMCs.

This is perfectly illustrated by the recently-approved Baptist Policy AC-3 application proposing seven new operating rooms in Forsyth County. Forsyth County already has a surplus of almost six operating rooms. All of the counties adjacent to Forsyth also have a significant surplus of operating rooms. If developed, the Baptist project will cost Novant between $7 million to $11 million annually. *See* Novant Petition for further discussion. Novant appreciates that all not-for-profit health care providers must make money over and above their expenses to support their charitable missions and to reinvest in the continuous improvement of their facilities and services, but nothing in the plain language of Policy AC-3 states or suggests that it was intended to serve as a device to allow the AMCs to achieve the highest possible return on investment. Further, the AMCs' concerns about the statutory research exemption do not provide a basis for the expansion of Policy AC-3.

The AMCs' extensive discussion about research also implies, incorrectly, that they are the only health care providers doing any research. They fail to note that many community hospitals are also involved in research. For example, Novant Clinical Research Institute ("NCRI") was established in 2001 and has grown from a staff of 4 with a focus on cardiovascular studies to a staff of 14 who conduct and manage trials in a wide range of therapeutic indications. Forsyth Medical Center has an Institutional Review Board or IRB that reviews the research done by NCRI. *See* Exhibit C. WakeMed is another example of a non-

[8]N.C. Gen. Stat. § 131E-179(c) does allow the research exempted assets to be used for patient care provided on an occasional and irregular basis and not as part of the research program. The statute does not define "occasional and irregular basis." Baptist has been allowed to temporarily use equipment acquired pursuant to the research exemption for paying patients as a back-up while its non-research equipment was being replaced.

AMC with an IRB. *See* Exhibit D. The AMCs do not have a monopoly on research in North Carolina.

The Petition also asserts that "[r]equiring the SHCC as well as the CON Section to evaluate all academic projects also increases the administrative costs and the costs to the provider in seeking such an adjustment, with no benefit to patients." *See* Petition, p. 14. The AMCs do not describe the nature or amount of these "administrative" costs, or how these costs compare to the hundreds of thousands of dollars that are often spent on consulting fees, in addition to staff time, to provide the internal justification for a project, long before anyone even thinks of filing a petition or CON application. The AMCs do not discuss how the "administrative" costs compare to the revenues that will be realized from the development of Policy AC-3 project.

The AMCs' argument also fails to take into consideration the fact that the relatively small amount of "administrative" cost associated with filing a petition to the SHCC pales in comparison to the millions of dollars that are spent on the construction of Policy AC-3 projects. For example, the Baptist Policy AC-3 ambulatory surgery center project is reported to cost more than $38 million. Nor does the AMCs' argument take into consideration the cost to patients and payors of having to pay for unnecessary duplication of services, which can occur when the health planning process is not followed, and certain providers are allowed to bypass the SMFP.

The petitioning process protects patients, who are the ultimate beneficiaries of health planning and CON, to ensure that only those services and facilities that are actually needed are developed and deployed in an accessible and geographically dispersed manner. The benefit to

patients of following the health planning process far outweighs the relatively minor inconvenience and expense that the AMCs must "endure." As Dr. Wolfson observes:

> The benefits associated with reducing, rather than expanding exemptions and exceptions accrue to communities and patients and are consistent with the legislative intent of the health planning law.

Exhibit A, p. 15.

Novant is particularly concerned about an extension of Policy AC-3 to CMC, which directly competes with Novant's Presbyterian Hospital, in the greater Charlotte region, the most populous area of the State. This would mean that Novant would be competing in two major markets (Charlotte and Winston-Salem) with unfair regulation. It can propose SMFP-regulated services only when there is a need for them, and only if it prevails in a CON review that may be a competitive review with an AMC.[9] The AMCs, however, can file CON applications for SMFP-regulated assets whenever they wish, *and* they can also file CON applications in SMFP-regulated reviews. The assets that are at issue are not just "esoteric" forms of technology that only the AMCs use (*e.g.*, gamma knife). Rather, the assets include the building blocks of hospitals, such as beds, operating rooms, MRI scanners and cardiac catheterization units. One of the most recent Policy AC-3 applications, the Baptist ambulatory surgery center project, proposes to do relatively minor outpatient surgery, such as tonsillectomies and cataracts removal. These procedures are done every day in non-AMCs throughout this State and throughout this country.

Why should the State of North Carolina require Novant, or any non-AMC and private physician practice, to operate at such an extreme competitive disadvantage? This is not a hypothetical question. As discussed in Novant's Petition, the Baptist Policy AC-3 application

[9]The same is true for private physician practices. They can only apply for an SMFP-regulated service like operating rooms when there is a need in the SMFP.

will cost Novant $7 million to $11 million annually. Yet Novant, like every other provider, faces rising levels of indigent care every year, and has an obligation, like every other provider, to stay on top of technological developments and to maintain its facilities at optimum levels for patients. Novant is also the employer of more than 22,000 people in North Carolina. Many of the non-AMCs are, in fact, major employers in their respective communities, and are vitally important to the economy of North Carolina. The AMCs suggest that their proposal is really "fair" to everyone, but there is nothing fair about a system that gives some providers a distinct competitive advantage over others, when all providers are facing the same challenges. The AMCs' proposal to expand the reach of Policy AC-3 is doubly unfair to those providers, like Novant, that offer tertiary-level services, train residents, and perform clinical research, but are not deemed worthy of the Policy AC-3 exemption.

As discussed at length in Novant's Petition, the purpose of health planning and CON is to protect the community, not the interests of individual providers. The expansion of the two-tier system of health planning in North Carolina would suggest that North Carolina is less interested in health planning for community needs than it is in protecting and enhancing the bottom line of certain institutions. This not only disadvantages and discourages community physicians and private physicians that are providing services in North Carolina now, but also discourages potential future investment in North Carolina by health care companies and physicians that may perceive North Carolina's health planning process as inherently unfair and biased in favor of certain providers. This is not the message North Carolina should be sending at a time of extreme budget shortfalls.

As Dr. Wolfson notes:

> If anything, Policy AC-3 needs to be retracted, not expanded, and the State of North Carolina should take a long, hard look at the Policy and how it has been applied before it considers an expansion.
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> As a health policy expert, I would suggest that North Carolina approach any possible expansion of Policy AC-3 with extreme caution. Otherwise, the integrity of the health planning process will be called into serious question and further concerns about inequities are likely to be created (*i.e.*, the AMCs and those who are 'aligned' with the AMCs being allowed to avoid the SMFP, but those who are not 'aligned' with the AMCs having to follow the SMFP.)
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> In my opinion, health planning principles should be applied uniformly; otherwise, health planning will have failed its intended purpose. States should avoid creating or encouraging situations where some providers are treated or perceived as 'special' or 'more important' or 'better' than others, especially where such distinctions cannot be defended with empirical evidence.

Exhibit A, p. 17.

There is no demonstrable benefit to patients that flows from having a two-tier system of health planning in North Carolina. In fact, instead of benefitting patients, the two-tier system harms patients by creating an avenue for the unnecessary duplication of services that drive up health care costs. Accordingly, the SHCC should reject the AMCs' proposal to expand Policy AC-3.

B. Adding Adjectives To The 20 Mile Rule Is Unnecessary.

The AMCs also propose that the language of Policy AC-3 be changed, so that instead of being required to show that a project "cannot be achieved effectively" at a non-AMC within 20 miles of the AMC (the "20 Mile Rule"), the AMC will be required to demonstrate that it "cannot be met in a cost effective and clinically efficient manner." As Dr. Wolfson explains in his Affidavit, the problem is not the adjectives used in the Policy. The problem is the application and enforcement of the 20 Mile Rule, which is a mandatory provision in Policy AC-3. As the recent experience with the Baptist Policy AC-3 application shows, Baptist

simply did not address the 20 Mile Rule anywhere in its CON application, but its application was approved anyway by the CON Section. The 20 Mile Rule is meaningful because it serves as a further "check and balance" on the health planning process: to make sure that services and facilities are added only when they are genuinely needed, and not added simply because they can be added. If an existing provider is already doing what the AMC proposes to do in its Policy AC-3 application, and has existing capacity, the State must consider whether that resource can be used to meet a purported need.

There is no reason why an AMC, in answering the 20 Mile Rule as presently written, could not use the words "cost effective" and "clinically efficient." But the key is that the AMC must actually *answer* the 20 Mile Rule, not ignore it, as Baptist did. And the CON Section must deny those applicants that do not answer the 20-Mile Rule. As Dr. Wolfson observes:

> Lax or non-enforcement of the 20-mile requirement, along with presumptions about the completeness and validity of justifications included in exemption requests and Dean's letters, create incentives to exploit Policy AC-3.
>
> Regardless of whether the perverse incentive embodied in Policy AC-3 is ever used by an AMC, as a matter of sound health policy, it would be prudent to remove the incentive and its effects (that are manifestly contrary to the State's health planning law), if North Carolina intends to have a credible, consistent, and meaningful health planning process.

Exhibit A, pp. 10; 6.

The AMCs' proposed change does not address the fundamental problem of lax or non-enforcement of the 20 Mile Rule, and accordingly, the proposed change should be rejected.

C. The SMFP Inventory Should Reflect Assets and Utilization of All Assets Used to Provide Care.

The AMCs propose to exclude both the Policy AC-3 assets and the utilization of those assets from the SMFP. This simply does not make any sense from a health planning

perspective. *All* of these assets are available to be used by patients and their physicians. The State of North Carolina needs to have a complete inventory of all the health care assets available to serve people in this State, and it needs to know how well or how poorly these assets are being used, so that intelligent decisions about future planning needs can be made. The citizens of this State receive no benefit from the exclusion of these assets and the resulting utilization from official inventory. The AMCs, however, receive a major benefit, because exclusion of the assets and the related volumes makes it appear that the AMCs are busier and more efficient than they really are. An AMC can, in turn, leverage this in future competitive CON applications against a non-AMC to show that the AMC needs the CON more than the non-AMC. As Dr. Wolfson explains:

> The current exclusion of exempted resources artificially reduces the 'official' counts used by state agencies, and affords AMCs the illusion of doing more with less in future need determinations and CON competitions because their exempted projects never count.
>
> The AMCs state that expanding the exclusion on counting exempted services and projects will 'eliminate the risk of any *distortion* of the resulting need determination' (emphasis added), and 'prevents the delay in the demonstration of need that could result if the need determination reflected new services such as operating rooms that were approved, but not yet developed'. This is a hyperbolic spin that reflects exactly the opposite of its effect --- and implies that an exclusion in the counting of exempted projects is necessary to address some kind of emergency decision that must be made, rather than an integral part of the rational process of health planning, which the AMCs assiduously seek to avoid.
>
> Exempted projects/assets and those that have effectively traversed the reasonable hurdles of empirical health planning are all presumably available to treat patients. The State of North Carolina should reasonably want to count and know about the utilization of these assets, so that it has an accurate and complete picture of the health care resources available to serve citizens in their communities.

Exhibit A, pp. 12-13.

Instead, both Policy AC-3 facilities and their utilization should be *included* in the State's official health planning inventory. The reality is that these facilities exist, and they should not be ignored when the State takes inventory of what facilities are in the State and available to be used by patients and their physicians. Indeed, the AMCs' argument for exclusion contradicts their argument about why the research exemption in N.C. Gen. Stat. § 131E-179 is ineffective to meet their needs – they want to use their Policy AC-3 assets to treat patients and receive reimbursement for it. If so, the assets used to treat these patients, and the resulting volumes, need to be counted in the inventory so that the State and its citizens have a complete picture of health care assets available in this State.

This part of the Petition also contradicts the AMCs' offer to report the utilization of their Policy AC-3 assets in their annual Hospital License Renewal Applications. *See* Petition, p. 22. Data from the Hospital License Renewal Applications is in turn used to create some of the data tables in the SMFP. *See, e.g.*, Table 6A (operating rooms); Table 6E (endoscopy rooms); Table 9E (linear accelerators); Table 9I (PET Scanners); Table 9K (MRI scanners); and Table 9R (fixed cardiac catheterization units). There is no logical reason for including the data in one public document (the Hospital License Renewal Application) but excluding it from another document (the SMFP, which is the vehicle that actually uses the data reported in the Hospital License Renewal Application) that actually *uses* the data in the need formulas that specify the need for many types of healthcare assets in North Carolina. The data reporting needs to be consistent across all venues, and the data needs to be used, so that policy makers can make intelligent and well-informed planning decisions for the future.

D. The AMCs Need To Report More Data.

In the AMCs' Petition, they offer to report minimal data about their Policy AC-3 assets in the Hospital License Renewal Applications, but, as explained above, they do not want the data used for any health planning purposes in the SMFP. Further, the AMCs' minimalistic data reporting effort does not address key questions such as:

- Is the Policy AC-3 asset actually being used for research, or to train medical students or residents? Is the asset being used for other purposes?
- How many medical students and residents actually used the asset?
- Is the Policy AC-3 asset being used to provide care to medically underserved patients, and if so, how many medically underserved patients were served?

See also the data list proposed on pages 6 and 7 of Novant's Petition. Meaningful data should be reported, and it should be used to guide the health planning process in North Carolina.

E. The CON Process and Litigation Do Not Address The Fundamental Concerns About Policy AC-3.

On pages 14 and 15 of their Petition, the AMCs suggest that CON review and subsequent litigation are sufficient safeguards to ensure that Policy AC-3 "does not . . . provide a free pass to AMCs." *See* Petition, p. 14.[10] Unfortunately, it has been Novant's recent experience in the Baptist Policy AC-3 review that CON review does not always ensure that Policy AC-3 will be properly applied. As discussed in Novant's Petition, Baptist simply failed to answer the 20-Mile Rule, and the Agency approved the application anyway, despite the fact that: (a) the Agency knew, from prior reviews, that Novant provided the same services

[10]The AMCs also state that opposition to Policy AC-3 applications "has historically been very rare" and that in most cases in the past, "AMCs have faced no opposition from other providers to their Policy AC-3 projects." *See* Petition, p. 15. The relative lack of Policy AC-3 litigation should not be taken to mean that Policy AC-3 has been applied correctly in the past and that non-AMCs "agree" with the decisions reached on those applications. It should be noted that three of the four AMCs (UNC, Duke and Pitt) operate the only full-service acute care hospitals in their "home" counties and therefore, they do not face much competition in their "home" counties. Historically, the AMCs do not usually litigate against each other. Instead, they tend to work as a group, as evidenced by their joint Petition.

about three miles away from Baptist; (b) the Agency also knew, from prior reviews, that residents from Baptist train at Forsyth Medical Center; and (c) Novant explicitly pointed out in its comments that Baptist failed to answer the 20-Mile Rule. The matter is now in litigation, which is lengthy, expensive and uncertain.[11] Regardless of the outcome in the Baptist case, there is no guarantee that Policy AC-3 will not be abused in the future. Litigation is not a process that should be relied upon as a cogent and comprehensive health planning tool in North Carolina.

Further, the AMCs' discussion about the alleged "sufficiency" of CON review and litigation seems to assume that other agencies and the judicial system are better equipped than the SHCC to address health planning for the State of North Carolina. But it is the SHCC, not the CON Section and not the courts, that is charged with developing the SMFP. The SHCC represents a broad cross section of North Carolinians from all over the State. Many SHCC members work directly in the heath care industry, and have first-hand knowledge of health care delivery and the pressing needs that many North Carolina communities face. The SHCC members spend hundreds, possibly thousands, of hours working with the DHSR Medical Facilities Planning Staff developing the SMFP, which in turn presented to the Governor. CON review and litigation are in no way "substitutes" for the work of the SHCC.

Novant respectfully submits that the better approach is to prevent abuses before they happen and for the SHCC, which represents consumers, providers (including AMCs), physicians, insurers, and State and County government to address health policy issues that affect all North Carolinians, rather than leaving these issues for piecemeal litigation.

[11]The SHCC should also consider that not every provider has the economic ability to undertake litigation because of the extreme expensive.

F. Changes in the Health Care Environment Do Not Support the AMCs' Proposed Changes to Policy AC-3.

The AMCs argue that changes in the health care environment will make Policy AC-3 even more critical. *See* Petition, p. 16. They suggest that if Policy AC-3 goes away, "the important process of discovering, developing, and perfecting new treatments may come to a halt, and North Carolina will fall behind other states in the arena of medical care." *See* Petition, p. 16.[12]

The AMCs' fears are unfounded. No one, least of all Novant, is trying to stand in the way of these institutions discovering, developing and perfecting new treatments.[13] Novant's proposal for the reform of Policy AC-3 recognizes that the AMCs may have unique needs, and so AMCs can file petitions to have need determinations included in future SMFPs to address their situations. As explained above, this process is not unduly burdensome and is not likely to have any material impact on the AMCs' teaching or research activities. Duke and Pitt have already successfully used the petitioning process, and there is no reason why they, and the other two AMCs, could not do so in the future.

In addition, the SHCC may also want to consider that on March 21, 2011, the Department of Health and Human Services ("DHHS") released the National Strategy for Quality Improvement in Health Care ("National Strategy") to Congress. *See* Exhibit E. This report was required by the health care reform law, the Affordable Care Act, in an effort to create national goals and strategies to improve the accessibility and quality of health care in the

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[12] The AMCs also assert that losing Policy AC-3 may hinder faculty recruitment. They provide no evidence that any potential faculty member was ever informed of Policy AC-3 by a North Carolina AMC during the recruitment process; that any potential faculty member accepted an employment offer from a North Carolina AMC because of Policy AC-3; or that any potential faculty member declined an employment offer from a North Carolina AMC because of the concern that Policy AC-3 would be repealed or reformed.

[13] It remains to be seen, however, if Policy AC-3 has actually enabled any of the AMCs to discover, develop and perfect new treatments.

country. This National Strategy emphasizes the importance of coordination of care and communication among providers on a local level, to eliminate waste and unnecessary duplication that increase costs. It recognizes that while it is setting nationwide goals, it must rely on individual states' leadership to ensure that the national strategy reflects local needs. The goals in the National Strategy are consistent with the principles behind North Carolina's CON Law, but are contrary to Policy AC-3.

In pursuit of the goals of the National Strategy, DHHS has recognized that "all health care is local," and has made it a priority to promote effective communication and coordination of care among providers. *Id.* at p. 4. This emphasis on coordination indicates that *all* providers in a community, not just AMCs, are essential, and they must work together. "Collaborative efforts at the local level are also a vital resource for measuring, monitoring, and improving quality of care." *Id.* at p. 19. The National Strategy's focus on coordination is due in part to its finding that "too often, these improved models [of care delivery] are not known outside of the organization that created them." *Id.* at p. 21. The goal of achieving quality health care cannot be achieved by having silos of innovation; advances in care must be shared in communities for the benefit of the patient.

The AMCs' argument that only certain providers should remain entitled to the Policy AC-3 exemption, while other community providers are handicapped by it, contradicts the National Strategy's emphasis on coordination and collaboration among providers. Under the system envisioned by the National Strategy, which indicates the direction of health care nationwide, all providers have a critical role to play in providing quality health care to their communities.

The AMCs' argument that Policy AC-3 should be expanded further contradicts the goals of the National Strategy. Among the problems with the existing health care system, as cited by the National Strategy, is that the system is "characterized by unnecessary duplication of services and long waiting times and delays." *Id.* at p. 6. The National Strategy further faults the current system's overuse of services, which pose mores risks than potential benefits. *Id.* These problems are the same problems that North Carolina's CON Law seeks to prevent, by regulating new institutional health services in order to ensure that residents of North Carolina have access to the health care resources that are needed, while preventing unnecessary duplication of existing services.

As explained in Novant's Petition, Policy AC-3 is contrary to the premise of the CON Law, and would be at odds with the health care system identified in the National Strategy. It would allow the AMCs, and any new medical schools or satellite campuses that are entitled to use the policy, to circumvent the need determinations in the SMFP and essentially ignore the State's health planning process, without any evidence that the AMCs' use of the Policy provides measurable benefits to patients.

G. Other Flaws In The AMCs' Petition Need To Be Addressed.

In Exhibit A to their Petition, which is the AMCs' "new" version of Policy AC-3, the AMCs perpetuate a major problem with existing Policy AC -3: the self-serving, impossible to verify letter from the Dean of the Medical School, certifying that the project is "necessary." *See* Petitioner, p. 22. The Dean of the Medical School, who is employed or affiliated with the applicant applying for the Policy AC-3 exemption, will undoubtedly sign the letter presented to him or her by the AMC's staff. No external body is called upon to verify or validate that the proposed expansion of students, residents or faculty is needed. The CON Section does not do

any investigation to test the validity of any of the statements in the Dean's letter, but will instead accept the statements in the letter at face value. With hardly any effort, the AMC is able to avoid the need determinations in the SMFP.

The process that Novant is recommending (special needs petitions, which would involve public hearings and public comments where people debate issues and ask questions, and the SHCC ultimately decides whether there is a need, would eliminate this serious flaw in North Carolina's health planning process.

CONCLUSION

As stated by Dr. Wolfson:

> In the face of current and growing economic challenges facing all sectors of our communities – especially health and social services, rational health planning and a coordinated, community-oriented basis for determining need and approving the deployment of health care resources, is needed more than ever. Real health planning based on the sensible principles of North Carolina's legislatively articulated health policy principles is a public policy imperative.
>
> It is indeed imprudent in these challenging times to afford four entities in the state (the four academic medical centers) a relatively painless and easy way to achieve exemption from the rational and demanding process of health planning. North Carolina cannot afford to 'have it both ways'. . . .
>
> . . .
>
> At the very minimum, this health policy analyst strongly encourages modifications to Policy AC-3 policy to require a far greater degree of empirical justification by an academic medical center beyond a dean's letter – and far greater evidence that bona fide efforts have been made in advance to coordinate and collaborate with existing, local health care resources (*i.e.*, within the immediate 20 mile service area) that have like and similar services and resources. This, at the very least, would encourage the legislature's health planning policy intentions: coordinated planning and resource sharing to reduce waste and duplication, avoidance of geographic maldistribution and mitigation of costly, excess capacity. I believe that the suggestions made by Novant in its 2 March 2011 Petition seek to further these goals.

Exhibit A, pp. 16-17.

Accordingly, Novant respectfully submits that the SHCC reject the AMCs' proposed changes to Policy AC-3. Instead, the SHCC should adopt the changes proposed by Novant in its March 2, 2011 Petition and require all providers, including the AMCs, to comply completely with the SMFP.

This the 23rd day of March, 2011.

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Affidavit of Jay Wolfson, DrPH, JD
Regarding North Carolina State Health Coordinating Council
Policy AC-3 Rule

1. Statement of my name and position/title
    a. My name is Jay Wolfson.
    b. I am the Distinguished Service Professor of Public Health and Medicine and Associate Vice President of Health Law, Policy and Safety at the University of South Florida in Tampa, Florida, and Professor of Health Law at Stetson University College of Law, in Gulfport, Florida, and I have a private health law and policy legal and consulting practice.
    c. My address is P.O. Box 342548, Tampa, Florida 33694.
    d. A copy of my CV is attached to this affidavit as Exhibit 1.

2. The experiences and qualifications that afford me particular expertise in the immediate matter include:
    a. I have provided policy analysis and research consultation to local, state and federal agencies and government leaders regarding health policy, finance, planning and management for more than thirty years.

    b. I have been selected by federal and state legislators, executives and judges to serve on special tasks forces, panels or in unique advisory capacities on a panoply of health policy and finance issues. Examples include:
        i. Appointed as Special Guardian Ad Litem for Theresa Marie Schiavo, with report to Governor Bush and the Florida Courts (2003-2004);
        ii. Special Expert on Health Law, Finance and Policy to Florida Attorney General in matters relating to Dialysis Fraud and Abuse in Florida (2003 – 2009); and
        iii. Appointed to the Medicare Competitive Pricing Review Commission (1998-2004)

    c. I have conducted extensive funded research and published on matters of health policy and practice on topics directly related to health planning and certificate of need.

    d. I have participated personally and extensively in the health planning and CON processes as a trustee and finance chair of a major university (1,000 bed) teaching hospital, Tampa General Hospital, in Tampa, Florida, and

EXHIBIT
A

as a lead collaborator on CON projects between an academic medical center and community hospitals.

e. I have taught health care finance, health care financial policy and health policy and law for more than 30 years in graduate public health and law school venues.

3. Purpose of this Affidavit
   a. I have prepared this statement to reflect my findings and conclusions with respect to aspects of Policy AC-3 in the 2011 North Carolina State Medical Facilities Plan ("SMFP").

   b. I submit this affidavit to provide policy analysis and commentary relative to two petitions filed on 2 March 2011 with the North Carolina State Health Coordinating Council by Novant Health Inc., and by a consortium of four academic medical centers (AMCs) in North Carolina: Duke University Health System, Pitt County Memorial Hospital, North Carolina Baptist Hospital and University of North Carolina Hospitals.

4. Outline of approach taken and sources relied upon to reach conclusions proffered.
   a. In preparing this Affidavit, I relied upon the following:
      i. State laws and regulatory provisions in the 50 states regarding the health planning process and certificate of need guidelines, with an emphasis on existing and previous exceptions or exemptions afforded to academic medical centers;
      ii. North Carolina health planning statutory and regulatory provisions, with a particular emphasis on the history and application of the AC-3 exemption provision;
      iii. Select North Carolina Certificate of Need applications and State Agency decisions involving the application of the AC-3 exemption provision;
      iv. Novant's 2010 Policy AC-3 Petition and Responses to Novant's 2010 Petition from Pitt, UNC, Duke and NCBH;
      v. Novant's 2011 Petition to repeal or modify Policy AC-3;
      vi. Duke, UNC, Pitt and NCBH 2011 Petition to modify Policy AC-3 (the AMC Petition); and
      vii. More than 30 years of personal experience participating in, studying and writing about the history and practice of health planning and policy

making in the United States and the several states, including researching, teaching and participating in the health planning and policy making process, with a particular emphasis on the Certificate of Need process as it relates to academic medical centers.

5. Affiant statements:
    a. North Carolina's Policy AC-3 (a non-rule, agency policy) which affords an exemption to AMCs with respect to the need determinations in the State Medical Facilities Plan, does not comport with North Carolina statutory language regarding health planning or with the express statutory purpose of the Certificate of Need Law. Further, it is contrary to the evolving provisions of national health planning policies.

    b. The history of health planning in the United States includes a combination of federal and state statutory and regulatory initiatives to encourage and/or require formal planning and process initiatives. Since the 1970s, the intention of these efforts was to inject a greater degree of rationalization into the construction of health care facilities and the offering of complex and expensive health care services. Much has been learned since health planning and Certificate of Need programs were first deployed and as a consequence, many states have made many changes to their health planning processes – including Certificate of Need. These changes range from dropping various categories of care and services from CON review, increasing the dollar threshold for CON review, to eliminating entirely the CON process. Some states afforded exemptions or exceptions from health planning to AMCs in various forms.
        i. For example, Florida afforded AMCs an opportunity to intervene, by way of a special exemption, in competitors' CON-related projects. Unlike the broad-brush, far sweeping provisions of the North Carolina's Policy AC-3, Florida's provision was statutory. Florida, like some other states, offered AMCs the prerogative of intervening against any CON filed by any other entity if the AMC deemed that its research, education and service functions were compromised by the proposed CON. But even in those cases, there was no automatic veto – since the substantive

adverse effects on research, education and service had to be quantified and proved up. Florida eliminated its AMC-protectionist provision in 1994.

ii. Florida and other states have experienced a narrowing of the gap between the scope and quality of clinical services offered by AMCs and other health care providers in those same communities across the state – especially those community facilities that have established teaching and research affiliations with AMCs. As a consequence, Florida and other states have deemed pro-AMC health planning exemptions to be contrary to public policy, anti-competitive, and not supportive of cost containment and improved access to care.

c. It is my understanding that Policy AC-3 was intended to recognize that AMCs have certain unique needs, such as teaching and research obligations, and to assist AMCs in being able to fulfill their academic missions. But the policy language and the history of its application indicate that it is both out of step with health planning principles and practices and that it can be and has been misapplied in ways that are contrary to the North Carolina Legislature's express intent with respect to health planning and certificate of need.

i. Based on my research, North Carolina appears to be standing alone among the states with a health planning process that employs AMC protection language that is as far reaching as Policy AC-3.

ii. Policy AC-3 is unique in that the AMC must do very little to qualify for the exemption.

iii. To benefit from the exemption, an AMC need only submit a letter from the Dean of its medical school and state that the teaching and research need for the project cannot be achieved effectively at any non-AMC that offers the same service within 20 miles of the AMC.

iv. The Policy does not require that the petitioner afford any consideration to adverse impacts that may occur to patients, communities and other providers if the AMC is permitted to duplicate existing facilities and services.

v. The Policy does not require any demonstration by the AMC that the exempt assets will provide tangible benefit to the state or the community, i.e.,

that they will be used to provide care to medically underserved populations.

vi. Most alarmingly, with an apparent blind eye toward being able to assess the impact and value of an exemption post approval and implementation, AMCs are not required to demonstrate that the exempted project was actually used for any academic purpose, such as teaching, research or expanded training opportunities for medical students and residents. Nor does Policy AC-3 require demonstration of the relative value of the purported academic purpose in terms of measurably improved quality, access, safety and costs. Rather, the current policy permits the fulfillment of what can amount to undocumented and quickly assembled "wish list" requests that are grounded in competition and market share goals - cloaked in academic regalia.

vii. Consequently, Policy AC-3 does not afford the policy makers or the people of North Carolina a rational means by which to know whether or to what extent Policy AC-3 fulfills its intended purpose.

d. It is with exceptional ease that AMCs can obtain a Policy AC-3 exemption. And there are no provisions to determine if the exempted projects were actually used for bona fide academic purposes (if at all). Therefore, the AMCs have a strong and natural incentive to exploit Policy AC-3 in order to avoid the reasonable planning and justification rigors of the SMFP.

   i. The malignant flaw in the current Policy AC-3 wording and use is that it is a license that permits AMCs to conveniently avoid the statutory premises of health planning in order to add services and facilities their competitors are precluded by law from adding, unless there is a need determination in the SMFP.

   ii. Contrary to reason, the AMCs, in their joint petition, actually seek to expand this flaw, further diluting the express legislative policy intentions that define the very purpose of health planning in North Carolina law for everybody else. And they shamelessly propose the expansion of Policy AC-3 to their greater benefit in the name of ensuring 'fairness' to other providers in the health planning

process." (AMC Petition, Page 2 'Reasons for Proposed Change')

e. Regardless of whether the perverse incentive embodied in Policy AC-3 is ever used by an AMC, as a matter of sound health policy, it would be prudent to remove the incentive and its effects (that are manifestly contrary to the State's health planning law), if North Carolina intends to have a credible, consistent, and meaningful health planning process.
    i. By affording some providers an option to avoid the SMFP, North Carolina's Policy AC-3 has fostered an inequitable health planning process and outcome.
    ii. Indeed, Policy AC-3 as written and implemented and the recent AMC petition for modification, underscore what has become an 'imperial' as opposed to an empirical health policy process.
    iii. This is indefensible, not only from a clear and unequivocal reading of the North Carolina health planning and CON statutes and their legislative intent, but also in terms of fundamental equity, fairness and good health policy practice.
    iv. The license afforded AMCs by the Policy AC-3 is particularly inappropriate, outdated and onerous given the leveled playing field in the health care marketplace. Non-AMCs are now also tertiary care providers; they conduct funded and unfunded clinical research; and they participate in the training of medical and nursing students and residents.

f. Acuity is not a legitimate basis upon which AMCs can distinguish themselves from non-AMCs according to the AC-3 policy.
    i. In their Petition for Change in Policy AC-3, the AMCs present data demonstrating differential acuity and severity for patients in AMCs versus non-AMCs as a basis for further justifying both the application and the expansion of Policy AC-3.
    ii. While AMCs generally provide a more complex, higher acuity level of care than the average community hospital, I can find no reference, directly or indirectly, to acuity levels serving as a basis for differential consideration in Policy AC-3.
    iii. This leads me to conclude that the AMCs' attempt to use claims of differential acuity levels is a sham

argument, not grounded in the policy, but used principally as an additional device to distract attention from a re-examination of Policy AC-3's substance and application.

iv. There is no reason why an AMC, even one with a very high acuity index, could not pursue the filing of a petition with the SMFP to meet the needs of its patient population. I understand that one of the AMCs, Pitt, actually did file a petition to add operating rooms a few years ago, that the petition was ultimately approved, and that Pitt applied for and received a CON for the operating rooms. Duke also states on page 13 of the AMC's Petition that it too has successfully used the "normal" health planning process. Certainly if they were able to follow the "normal" process with success, then other AMCs should also be able to follow the "normal" process.

v. Similarly, while the AMCs tend to serve patients from a broad geographic area, many non-AMCs, especially the tertiary providers, also serve patients from a broad geographic area. For example, Forsyth Medical Center routinely serves patients from more than 50 of North Carolina's 100 counties, and it also serves patients from other states. Likewise, other non-AMCs, such as Moses Cone, New Hanover and Presbyterian, also serve patients from a broad geographic region. In my opinion, patient origin is not a reason to exempt certain providers from the SMFP.

6. Policy AC-3 expressly contravenes and works against the legislative intent and principles of health policy and planning clearly articulated in North Carolina statutory law.

    a. Contrary to legislative intent, Policy AC-3 contravenes the express deliberative and planning process assigned to the State Health Coordinating Council, which devotes countless hours of voluntary time of appointed members who seek to meticulously and empirically craft rational health policy and plans for the state – efforts that can be undone with the stroke of a self-serving letter from the Dean of a medical school.

b. North Carolina's health planning policy is clearly and unambiguously articulated by the Legislature in its statutory findings of fact regarding the CON Law:

i. § 131E-175. Findings of fact (by the North Carolina General Assembly)

(1) That the financing of health care, particularly the reimbursement of health services rendered by health service facilities, limits the effect of free market competition and government regulation is therefore necessary to control costs, utilization, and distribution of new health service facilities and the bed complements of these health service facilities.

(3) That if left to the market place to allocate health service facilities and health care services, geographical maldistribution of these facilities and services would occur and, further, less than equal access to all population groups, especially those that have been medically underserved, would result.

(4) That the proliferation of unnecessary health service facilities results in costly duplication and underuse of facilities, with the availability of excess capacity leading to unnecessary use of expensive resources and overutilization of health services.

(6) That excess capacity of health service facilities places an enormous economic burden on the public who pay for the construction and operation of these facilities.

c. By this language, North Carolina health policy makers at the highest level have recognized and stated that costs, excess capacity, duplicated services, and geographic maldistribution were to be avoided by way of a rational and thoughtful process of planning and allocating resources at the community level, and with a clear eye toward coordination, collaboration and use of existing resources and opportunities. Only in the case of special research for distinctive services, were exceptions to be made, as set forth in N.C. Gen. Stat. § 131E-179.

7. Abuse of Policy AC-3 and the importance of the 20 mile provision

a. Policy AC-3 has gone far beyond the intention of the legislature, and affords a "back door" that allows certain providers to avoid the SMFP so that they can add services and facilities even when the SHCC has already said additional

services and facilities of the type being proposed are not needed. This "back door" becomes especially insidious and adverse to public policy if and when Policy AC-3 is not completely or consistently applied.

b. Based on my review of North Carolina Baptist Hospital's 2010 CON application to add seven new operating rooms in a county that already had a surplus of almost six operating rooms, and the CON Section's decision on that application, I am concerned that the Policy is being abused.

c. In that particular case, the applicant failed to address the express policy language requirement that it demonstrate that no other non-AMC within 20 miles could not effectively meet the purported teaching and research need for the project.

d. Despite the fact that objective data demonstrated that like and similar services already existed within three miles of the proposed project, the CON Section approved the application.
    i. The particular project involved an AC-3 exemption request for operating rooms be used for lower complexity procedures routinely performed at non-AMCs all over the country.
    ii. The justification proffered by the applicant included emphasis on a projected ten-year faculty recruitment plan. But there was no indication of when the faculty would arrive, the number of cases they would perform or even if they would use the proposed operating rooms.
    iii. Despite a well documented, long-standing teaching relationship with Forsyth Medical Center, an institution located only three miles from the proposed, exempted project – unambiguously within the '20 mile' directive of Policy AC-3, NCBH never mentioned either the relationship or Forsyth's identical services and resources in the exemption request, as if they did not exist.
    iv. Given that the proposed faculty recruitment was to occur over ten years, there was certainly nothing to indicate that this project was predicated on an emergency situation (such as the threatened loss of accreditation). There was

nothing in this application to afford the exemption applicant, NCBH, the special privilege of an exemption from the normal channel of petitioning the SMFP to add more operating rooms.

v. In another case I reviewed from 2003, the CON Section denied an NCBH application to add a PET/CT and MRI scanner under a Policy AC-3 application where NCBH also failed to address the 20-mile requirement. I do not understand how such different results could have been reached, considering that there was no change in the relevant language of Policy AC-3 between 2003 and 2010. It appears that somewhere between the two periods (2003-2010) there was an informal and unpromulgated decision to relax enforcement of the 20-mile requirement. Yet I am unaware of any evidence that the SHCC authorized the relaxation of the 20-mile rule. It is my understanding that only the SHCC has the authority to change Policy AC-3. Informal and unpromulgated relaxation of "controls" in Policy AC-3 is very dangerous from a health policy perspective. It not only leads to potential duplication of health services, but also erodes public confidence in the health planning process.

e. Given my reading and understanding of North Carolina's health planning statutory provisions, legislative intent and the clear and unambiguous language of the AC-3 policy, I believe that the 20-mile requirement speaks to a fundamental health policy and planning purpose of the Legislature: to reduce the possibility of unnecessary duplication of expensive community health services.

i. This purpose is entirely consistent with, indeed, it is central to the stated purpose of the CON Law.

ii. Lax or non-enforcement of the 20-mile requirement, along with presumptions about the completeness and validity of justifications included in exemption requests and Dean's letters, create incentives to exploit Policy AC-3. Such exploitations are evidenced in past applications, and in the current AMC petition for expansion of the fundamentally flawed Policy AC-3 language.

iii. Unless the provisions of Policy AC-3 are eliminated or substantially revised, North Carolina's health planning process affords imperial privileges to a

select few without the empirical, legislatively intended obligations that affect the rest of the state's health care providers. Maintenance (or expansion) of the Policy AC-3 status quo relegates the health planning process to a relatively expensive sham process for non-AMC providers and the people of North Carolina.

8. Critique of The Petition filed by the AMCs on 2 March 2011 to Modify Policy AC-3
    a. The AMCs' 2 March 2011 Petition calls for expansion of Policy AC-3's currently flawed provisions, to include, among other things, endowment of the exemption privileges to other institutions with which the AMCs are or may become aligned, excluding more exempted projects from formal 'counts' of existing resources, modifying the 20 mile provision, and requiring certain reporting post award of an exemption.

    b. Premises and statements contained in the AMCs' petition are not always consistent with history, fact and state law, and warrant critical analysis presented herein.

    c. Policy AC-3 is not, as the AMCs contend, "crucial to the ongoing teaching and research missions of the state's medical schools and by extension, the health care system of the state as a whole."
        i. The premise of a "crucial" character of Policy AC-3 is belied by the express legislative intent, statutory language, and history and use of the Policy AC-3.
        ii. As noted elsewhere in this analysis, Policy AC-3 has disproportionally benefited only AMCs, not the broader needs of the state, while avoiding, not ensuring 'fairness' to other providers.

    d. The proposed expansion of Policy AC-3's exemption to additional and new AMC related entities further erodes the integrity of the health planning process by permitting more wish lists and short term, often expensive and anti-competitive projects to escape the rational process of SMFP need determinations.
        i. Affording branch campuses and portions of AMC programs throughout communities in the state to arbitrarily trump the resources and needs of local, non-AMC hospitals and other providers creates a

broader, state-sanctioned monopoly with reduced benefits to the community.

e. Modifying the adjectives in the current Policy AC-3 from "achieved effectively" to "met in a cost effective and clinically efficient manner" treat the non-rule policy, AC-3, as if it were statutory, legislative intent language. It is not.
    i. If anything, stronger wording, highlighting the importance of health planning grounded in the health planning principles of coordination of community resources and the avoidance of costly duplication should be inserted.

f. The AMC petition proposes expanding the current perverse provision that excludes exempted resources from need determinations.
    i. The current exclusion of exempted resources artificially reduces the "official" counts used by state agencies, and affords AMCs the illusion of doing more with less in future need determinations and CON competitions because their exempted projects never count.
    ii. The AMCs state that expanding the exclusion on counting exempted services and projects will "eliminate the risk of any *distortion* of the resulting need determination" (emphasis added), and "prevents the delay in the demonstration of need that could result if the need determination reflected new services such as operating rooms that were approved, but not yet developed". This is a hyperbolic spin that reflects exactly the opposite of its effect --- and implies that an exclusion in the counting of exempted projects is necessary to address some kind of emergency decision that must be made, rather than an integral part of the rational process of health planning, which the AMCs assiduously seek to avoid.
    iii. Exempted projects/assets and those that have effectively traversed the reasonable hurdles of empirical health planning are all presumably available to treat patients. The State of North Carolina should reasonably want to count and know about the utilization of these assets, so that it has an accurate and complete picture of the

health care resources available to serve citizens in their communities.

g. The AMCs' petition also proposes changes to the 20-mile requirement in Policy AC-3. The language of the 20-mile requirement is not the problem; the problem is whether the 20-mile requirement is being applied within the application by the AMCs or by the State in its review of the Policy AC-3 application. The decision on the 2010 Baptist exemption application suggests that the 20-mile requirement – an essential concept clearly linked to the statutory goal of reducing unnecessary and costly duplication -- is not being honored.

h. The AMCs' petition suggests modifications in data reporting associated with AC-3 exemptions. Their proposal is a modest but insufficient step forward, and remains inconsistent with the principles of health planning and the intentions of the legislature.
    i. In addition to the few data points the AMCs suggest reporting, additional information should be reported, such as proposed in Novant's petition, regarding demonstration of how and the extent to which the exempted project actually met the teaching and research needs stated in the exemption request, along with data on outcome, quality, access, cost and the number of additional medical students and residents achieved expressly as a consequence of the exempted project.

i. The AMCs state confusingly in their Petition that expansion of Policy AC-3 is needed to reduce physician shortages by 2025. Correlating the exemption from the SMFP need determinations with physician shortage reduction is at best a curious slight of hand and distraction from the flaws inherent in the existing Policy AC-3. There is no relationship that has been shown between Policy AC-3 and physician shortage reduction per se.
    i. Addressing the shortage relates to increasing both the size of the undergraduate medical (UME) class, increasing the number of graduate medical education (GME) slots, and recognizing that nurse practitioners and physician extenders, not physicians, will be making up a significant portion of the care provider gap.

ii. Expansion of Policy AC-3 does not correlate with physician shortages – and any resources needed to address this matter could surely be applied for through the normal petitioning process by the AMCs and those who are aligned with them to seek to add more services and facilities.
iii. The claim within the AMCs' petition that an expansion of Policy AC-3 will "ensure fairness to other providers in the health planning process" is oxymoronic given the fact that such an expansion would only enhance a 2-class system at the explicit expense of the statutory health planning intentions of the Legislature.

j. The AMCs' petition to modify Policy AC-3 includes an extensive discussion about how research distinctly affects all AMC operations. The purpose of this argument is to support the contention that AMCs' research activities dramatically distinguish them from non-AMC facilities.
   i. Research also substantially affects non-AMCs' operations.
   ii. Non-AMCs have substantially leveled the playing field, not only in the scope and complexity of clinical services they provide (many are tertiary care facilities), but also with respect to the conduct of funded and unfunded research. Research also affects non-AMCs' operations in a substantial way.
   iii. As an example, Novant, and other non-AMC institutions across the nation, have extensive clinical research programs, supported by public and private sources. Novant's Clinical Research Institute utilizes an formal, internal institutional review board (IRB) and has as its goal the improvement of the health of communities it serves through development of new therapies, treatments and clinical trials.
   iv. Research needs are not and should not be short-term emergencies requiring sudden policy and practice exemptions. The AMCs put the cart well before the horse in proposing modifications to Policy AC-3 that would further bypass the legislature's intended rational planning process and guidelines in the name of improved research - in order to allow AMCs unobstructed benefits from

wish list, knee jerk, or prospective programmatic initiatives.

v. AMCs will not be forgoing grant opportunities if they are required to go through the petitioning process to obtain approval for projects. AMC-based research is a deliberate, incremental effort, built upon years of previously funded and published work and does not involve quick turnaround times or emergencies for faculty hiring decisions. This is especially true for NIH and major foundation grants. AMCs and their researchers are in a constant state of grant development and response to known requests for proposals. It is uncommon for a major, totally unexpected request for proposals to be issued by a granting agency, and for a researcher in an AMC to develop a cold response without having laid the groundwork with years of developmental research -- much of it already funded by other sources. Clinical and basic research at AMCs is not a quick game -- it is an incremental, deliberate and highly competitive process.

k. The AMCs claim that the current process of empirically-grounded, community-need based health planning and resource requests "can make it impossible for AMCs to pursue research grants, recruit faculty or meet accreditation standards." This is a distortion and misrepresentation – even of the current Policy AC-3 provisions.

i. The current Policy AC-3 provisions easily provide for accreditation and essential educational and research requests, and the statutory provision at N.C. Gen Stat Section 131E-179 makes special provisions for research requests;

ii. Educational and research "needs" are not and should not be short term emergencies UNLESS required by an accreditation body – in which case, AC-3 provides a clear and unambiguous vehicle. Yet it is my understanding that Policy AC-3 is rarely used because a third party, such as the ACGME, requires an AMC to do something. Rather, it appears that most Policy AC-3 applications are filed on a purely voluntary basis because the AMC wants to do something.

iii. The AMCs' example of Duke's use of the SMPF to obtain approval for an MRI (page 13 of AMC petition) is evidence that the process works. As noted above, Pitt has also used the "normal" petitioning process successfully.

iv. There are few emergency resource decisions associated with bona fide grant, faculty recruitment and other institutional decisions that would not and should not be incorporated within a rational planning process and time frame. The benefits associated with reducing, rather than expanding exemptions and exceptions accrue to communities and patients and are consistent with the legislative intent of the health planning law.

9. Conclusions

a. In the face of current and growing economic challenges facing all sectors of our communities – especially health and social services, rational health planning and a coordinated, community-oriented basis for determining need and approving the deployment of health care resources, is needed more than ever. Real health planning based on the sensible principles of North Carolina's legislatively articulated health policy principles is a public policy imperative.

b. It is indeed imprudent in these challenging times to afford four entities in the state (the four academic medical centers) a relatively painless and easy way to achieve exemption from the rational and demanding process of health planning. North Carolina cannot afford to 'have it both ways'. As a health policy analyst, researcher and expert, I believe that the current Policy AC-3 and application make no sense.

c. After nearly thirty years of experience with Policy AC-3 in the North Carolina health care arena, it is time for the State of North Carolina to ask whether the policy is rational and sensible and if the exemption, as it has been developed and used, is still warranted. And if it is still warranted, it is also important to ask whether changes need to be made to ensure that it is used for its intended purpose and is not exploited.

d. At the very minimum, this health policy analyst strongly encourages modifications to Policy AC-3 to require

a far greater degree of empirical justification by an academic medical center beyond a Dean's letter – and far greater evidence that bona fide efforts have been made in advance to coordinate and collaborate with existing, local health care resources (*i.e.,* within the immediate 20 mile service area) that have like and similar services and resources. This, at the very least, would encourage the legislature's health planning policy intentions: coordinated planning and resource sharing to reduce waste and duplication, avoidance of geographic maldistribution and mitigation of costly, excess capacity. I believe that the suggestions made by Novant in its 2 March 2011 Petition seek to further these goals.

e. If anything, Policy AC-3 needs to be retracted, not expanded, and the State of North Carolina should take a long, hard look at the Policy and how it has been applied before it considers an expansion.

f. As a health policy expert, I would suggest that North Carolina approach any possible expansion of Policy AC-3 with extreme caution. Otherwise, the integrity of the health planning process will be called into serious question and further concerns about inequities are likely to be created (*i.e.,* the AMCs and those who are "aligned" with the AMCs being allowed to avoid the SMFP, but those who are not "aligned" with the AMCs having to follow the SMFP.)

g. In my opinion, health planning principles should to be applied uniformly; otherwise, health planning will have failed its intended purpose. States should avoid creating or encouraging situations where some providers are treated or perceived as "special" or "more important" or "better" than others, especially where such distinctions cannot be defended with empirical evidence.

h. In my years of researching, practicing and teaching health policy, finance and planning, North Carolina has always been an example of careful, thoughtful, sensible health planning processes and policies. Historically, North Carolina's State Health Coordinating Council, in collaboration with the Medical Facilities Planning Section, have sought to produce a good faith, empirical and community based articulation of what is actually needed in health care at the community level. Policy AC-3, as

written and deployed, does not comport with that history and with sound health planning principles.

10. Attestation and notarization

Further, Affiant states nothing.

21 March 2011

Jay Wolfson, DrPH, JD

Notarization:

The foregoing was acknowledged before me this 21nd day of March 2011 by Jay Wolfson, who is personally known to me.

NANCY L. BEASLEY
MY COMMISSION # DD 753395
EXPIRES: May 21, 2012
Bonded Thru Notary Public Underwriters

Seal

My commission expires:

The above has been sworn to and signed in my presence.

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PROFESSIONAL EXPERIENCE

Associate Vice President, Health Law, Policy and Safety, and Director of Outcomes, Center for Advanced Health Care, University of South Florida, 2005 -

Distinguished Service Professor of Public Health and Medicine, University of South Florida, 2005

Director, The Florida Health Information Center, College of Public Health University of South Florida, Tampa, 1990 -

Director, Suncoast Center for Patient Safety, Health Sciences Center (AHRQ funded), University of South Florida, Tampa 2001 - 2008

Professor, Health Law, Finance and Policy, and Internal Medicine, Colleges of Public Health and Medicine, University of South Florida, 1995, from Associate Professor, 1984 -

Professor of Health Law, Stetson University College of Law, 2000 -

Professor of Medicine, Florida State University College of Medicine, 2002 – 2010

General Counsel, American Board of Public Health Examiners, 2006 –

Governing Board Member, Florida Joint Medical Malpractice Underwriting Association (representing the Florida Bar), 2008 - 2010

Board Member (President 2009-2010), Health News Florida, 2007-

Executive Board Member, USA Africa Enterprise Foundation, 2008-

Associate Director, National Patient Safety Center of Inquiry, Veterans Health Administration, VISN 8, Florida and Puerto Rico 1999 – 2006

Member, Medicare Competitive Pricing Review Committee, Health Care Financing Administration, U.S. Dept. of Health and Human Services, 1998-2004

EXHIBIT
1

Board Member, Florida Health Sciences Center, Inc. (Tampa General Hospital), 1997-2000

President and Chairman, The Florida Kids Health Care Foundation, Inc., 1997-2005

President/CEO and Executive General Counsel, Care One, Inc., Tampa, Florida, 2002.

Vice Chair and Board Member, HealthEase Medicaid HMO, Tampa Florida, 1995-2000

Trustee, Vice Chair and Chair of Finance, Hillsborough County Hospital Authority (Tampa General), 1987-1999

General Counsel, American Board of Healthcare Risk Management, 1994–2000

Editorial Advisory Board, Men's Health magazine, 1998-2001

Acting Chairperson, Department of Health Policy and Management, College of Public Health, University of South Florida, Tampa, 1989-1991

Visiting Fulbright Professor, The University of Tokyo Medical School, and the National Institute of Public Health, Tokyo, Japan 1985.

Vice-President, Health Cost Management, Inc., Tampa, 1985 - 1993

Associate Professor of Health Administration, from Assistant Professor, College of Public Health, University of Oklahoma, Oklahoma City, 1981-1984

President, Jay Wolfson Associates, Houston and Oklahoma City, 1981-1984

Associate Director, Ideas, Inc., New York, Silver Spring, Columbia, Houston, 1976-1981

Faculty Associate, School of Public Health, The University of Texas, Houston, 1981

Assistant Professor of Health Services Administration and Program Evaluation, College of Public Health, University of South Carolina, Columbia, 1978-1980

SPECIAL ENGAGEMENTS

Appointed as Special Guardian Ad Litem for Theresa Marie Schiavo, with report to Governor Bush and the Florida Courts (2003-2004)

Special Expert on Health Law, Finance and Policy to Florida Attorney General in matters relating to Dialysis Fraud and Abuse in Florida (2003 – 2009)

EDUCATION

Doctor of Public Health, Health Services Organization and Administration, The University of Texas, School of Public Health, 1981

Juris Doctor, Stetson University, College of Law, 1993

Graduate Studies in Health and Hospital Administration, The University of Chicago, Graduate School of Business, Center for Health Administration Studies, 1976

Graduate Studies in Gerontology, The University of Southern California, Andrus Gerontology Center, 1975

Master of Public Health, cum laude, Community Health Organization and Administration, Indiana University, 1975

Master of Arts, European History and History of Thought, New York University, 1974

Bachelor or Arts, cum laude, History, The University of Illinois, Chicago, 1973

HONORS AND AWARDS

Distinguished Service Professor, University of South Florida, 2005
Faculty Scholar, U.S. Centers for Disease Control and Prevention, 1998-99
Licensed Health Care Risk Manager, Florida, 1995
Defense Research Institute, 1995
Admitted to the Florida Bar, 1994
Folmer Outstanding Service Award, Healthcare Financial Management Association, 1993
Senior Fulbright Fellow, 1984-1985 (Japan)
W.K. Kellogg Fellow, 1982-1983 (Health Care Finance)
Sigma Xi, 1981
U.S. DHEW Public Health Service Traineeship, 1975-1977
Marcus and Theresa Levi Scholarship for Graduate Studies in Human Services, 1974-1975
New York City Department of Health, Health Research Fellowship, 1974

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Dialysis Fraud and Abuse in Florida: Financial and Legal Relationships and Opportunities for Legislative and Regulator Action, Senior Author with Ronald P. Kaufman. The Florida Legislature and the Florida Agency for Health Care Administration, February 2001.

Recommendations to Preserve the Safety Net Health Care System in Florida, Senior Author with Michael Reid, Alan Friedlob, et al. The Florida Legislature and the Florida Agency for Health Care Administration, January 2001.

Preserving the Safety Net Health Care Provider System in Florida: Health Policy Analysis, Senior author with Michael Reid, Alan Friedlob, et al. The Florida Legislature and the Florida Agency for Health Care Administration, December 2000.

A Comparison of Utilization and Cost Patterns Between Services Provided to Injured Workers in Managed versus Unmanaged Care Environments in Florida's Mandatory Managed Care System. Senior Author with Stuart M. Brooks, Catherine Johnson, Yiliang Zhu, Andrea Spehar and Trevor Smith, State of Florida, Department of Labor, Division of Workers' Compensation, June 1998.

Implementation of Managed Care in Workers' Compensation at the Employer Level, Senior Author with Stuart M. Brooks, Catherine Johnson, Carl Newman and Trevor Smith, State of Florida, Department of Labor, Division of Workers' Compensation, October 1997

Evaluation of Florida's Mandatory Managed Care Workers' Compensation Initiative, Senior Author with Stuart M. Brooks and Cathy Johnson, State of Florida, Department of Labor, Division of Workers' Compensation, June 1997.

Validity of Cost and Utilization Estimates in Quality of Care Measures for Hospitals in Florida, The Employers Alliance, January 1997

Physician Perceptions of HMO Quality, The Hillsborough County Medical Association, May 1996

An Evaluation of the Full Service School: Working Toward Unity in the Community Project, with Barbara Clark-Alexander, The School Board of Manatee County, Florida, September 1995.

The Tax Exempt Status of Georgia Hospitals, Columbia Hospital Corporation, April 1994

The Tax Exempt Status of Florida Hospitals: What Does Not Get Paid, senior author, The Florida League of Hospitals, October 1993

The Appropriateness of Using Taxing Districts in Florida for the Support of Local Health Care Needs, senior author with S. Hopes, The Florida League of Hospitals, August 1993.

Feasibility Analysis for the Volusia County, Florida Indigent Health Care Plan, with S. Hopes. County of Volusia, Florida, August 1993.

Lessons Learned About How Health Care Institutions Can Prepare for a Hurricane or Other Worst Case Scenario, Wolfson, J., and G. Walker. American Hospital Association and Florida Hospital Association, July 1993

Comparison of Administrative Costs Between Japanese and U.S. Hospitals, Wolfson, J., N. Ikegami, and I. Ishi. Seminar on Comparative Health Care Costs, Ito, Japan, February 1993

The Florida Medicaid Managed Care Demonstration: Evaluation of Implementation, senior author with Gary Walker and Barbara Clark-Alexander, Florida Department of Health and Rehabilitative Services, January 1993

Comparative Admission and Service Use Patterns Between Physicians Who Have Equity Ownership Interests in Hospitals vs Those Who Do Not, with Scott Hopes, Columbia Health Care Corporation, February 1993

An Evaluation of the Drug Free Schools and Communities, (with Barbara Clark-Alexander, Robert McDermott, Gary Walker and Dino Contis) School Board of Manatee County, Florida, October 1992

Spiegel v University of South Florida: Property and Liberty Rights versus Service at Will for Department Chairs, Law and Higher Education National Conference, Stetson University College of Law, May, 1992

Cost and Quality Variations Between Free-Standing and Hospital-Based Ambulatory Surgery Centers (senior author with G. Walker) Ambulatory Surgery Centers, Inc., January 1992

Quality, Cost and Convenience: The Expanding Role of Freestanding Ambulatory Surgery (senior author with G. Walker) Medical Corporation International, October 1991

Strategic Plan for the Blake-Just Community Full-Service School Program in Hillsborough County, Florida, (senior author with D. Contis, B. Clark and G. Walker), Hillsborough County School District, July, 1991

Financial Viability of Adult Congregate Living Facilities in Florida. (contributing author, with J. Skinner and P.J. Levin) Florida Department of Health and Rehabilitative Services, September 1989

The Future of HMOs in Florida, (senior author with contributions of P.J. Levin, N. Fleming and R.R. Campbell) Florida Department or Insurance, July, 1989

Aging Access to Health Care in Florida, (with P.J. Levin and J. Skinner) Florida Office of the Governor and Florida Legislature, March 1989

Statutory and Regulatory Provisions Affecting Payment of Workers Compensation Claims in the U.S., Conservco, Inc., October 1988

The Florida Child Health Study (with Marti Coulter) Florida Department of Health and Rehabilitative Services, August, 1988

Cost Shifting and Florida Hospitals, Florida Office of the Public Counsel, September, 1987

HMO/Managed Care Legislative Recommendations for Florida, Florida Department of Insurance, March 1987, (senior author, with P.J. Levin and R. Campbell)

Report on HMO Quality and Financial Guidelines: A Legislative Summary, Florida Department of Insurance, February, 1987, (senior author, with P.J. Levin and R. Campbell

New Insurance Products in Japan and Coverage for Long Term Care, Beverly Enterprises, Rockville, Md., February 1987

Analysis of Claims Management and Financial Control Systems in Japan's Private Health Insurance Programs, Dun & Bradstreet, Plan Services, Tampa, Fl, January 1987

Costs of Health Care to Employees of Mitsubishi Companies, Mitsubishi Research Institute, Tokyo, November, 1986

Utilization-Cost Trends for Health Costs at the Nissan Corporation, Nissan Automobile Corporation, Tokyo, October 1986

Quality of Care and Financial Viability Measures for HMOs and PPOs in Florida, Florida Department of Insurance, September 1986, (senior author with P.J. Levin)

Appropriate Use of Detailed Case Mix Data in the Review and Analysis of Hospital Budgets by Florida's Hospital Cost Containment Board, Florida Office of the Public Counsel, July, 1986

The Application of the Main Penalty Rule by Florida's Hospital Cost Containment Board, Florida Office of the Public Counsel, June, 1986

Operating Margins, Deductions from Revenue and Other Indices of Financial Conditions of Florida's Public Hospitals Relative to Other Hospitals in Florida, Tampa General Hospital, June, 1986

Health Care Bond Issues in Florida and an Analysis of Capital and Working Capital Needs of Florida's Hospitals, Donaldson, Lufkin & Jenrette, New York, March, 1986, (senior author, with P.J. Levin).

Health Benefit Cost Control in Japan, U.S. Administrators, Los Angeles, January, 1986

Health Insurance Systems in Japan, U.S. Administrators, Los Angeles, October, 1985

The Japanese Health Benefits System Design, U.S. Administrators, Los Angeles, July, 1985

Employee Health Benefits Systems Design, Hospital Corporation of America, Tampa, February 1985 (senior author, with P.J. Levin).

Analysis of Options for Financing and Delivering Employee Health Benefits, Occidental Petroleum Corporation, Tulsa, September, 1983, (senior author, with P.J. Levin).

Alternative Health Cost Management Strategies in Insurance Companies vs Third Party Administrators, Cities Service Corporation, Tulsa, July, 1983, (senior author, with P.J. Levin).

A Utilization-Cost Trend Analysis of Health and Workers Compensation Costs, Anta Corporation, Oklahoma City, October, 1982

Cost Containment and Financing Arrangements Among Large, Houston Based Business Organizations, Houston Business Group on Health, October 1981

Data System Needs of the South Carolina Crippled Children's Division, South Carolina Department of Health and Environmental Control, November, 1980

Health Cost Management Systems in the Public Sector, CDP Corporation, Sliver Spring, MD, October, 1980

Harnessing Consumers to Improve Ambulatory Services, Bureau of Community Health Services, U.S. Department of Health and Human Services, August, 1980, (senior author, with J. Cahn)

Validity of Cost Estimates of Family Planning Services to Teenagers in the United States, Bureau of Community Health Services, U.S. Department of Health and Human Services, October, 1978, (with J. Cahn)

SELECTED GRANTS AND CONTRACTS

Principal Investigator, "PaperFree Florida Regional HIT Extension Center" Office of the National Coordinator for Health Information Technology, USDHHS, $5,884,132, 2010.

Principal Investigator, "Florida Family AIDS Network", U.S. Department of Health and Human Services, Health Resources and Services Administration, $1,228,090, 2009-2010.

Principal Investigator, "Florida Family AIDS Network", U.S. Department of Health and Human Services, Health Resources and Services Administration, $1,228,090, 2008-2009.

Co-Principal Investigator "The Tampa Bay Regional Health Information Organization Pilot System Development" Florida Agency for Health Care Administration, through the Tampa Bay Partnership, $235,000, 2007-2008.

Principal Investigator, "Florida Family AIDS Network" U.S. Department of Health and Human Services, Health Resources and Services Administration, $1,228,090, 2007-2008.

Co-Principal Investigator "The Tampa Bay Regional Health Information Organization Pilot System Development" Florida Agency for Health Care Administration, through the Tampa Bay Partnership, $330,000, 2006-2007.

Principal Investigator, "Florida Family AIDS Network" U.S. Department of Health and Human Services, Health Resources and Services Administration, $1,228,090, 2006-2007.

Principal Investigator, "Florida Patient Safety Initiative Advancement", Florida Patient Safety Corporation, $300,000, 2006.

Co-Principal Investigator, "The Tampa Bay Regional Health Information Organization Implementation Demonstration" Florida Agency for Health Care Administration, through the Tampa Bay Partnership Foundation, $467,000, 2006.

Principal Investigator, "Florida Family AIDS Network" U.S. Department of Health and Human Services, Health Resources and Services Administration, $1,228,090, 2005-2006.

Principal Investigator, "Incentives to Best Practices and Risk Management to Reduce Litigation in Medical Malpractice", Florida Agency for Health Care Administration, $106,400, 2004.

Principal Investigator, "The Role of Hospital Chief Executives and Board Members in Patient Safety Improvement", Subagreement with Florida State University College of Medicine, Florida Agency for Health Care Administration, $4,000, 2004.

Principal Investigator, "Florida Family AIDS Network" U.S. Department of Health and Human Services, Health Resources and Services Administration, $1,228,090, 2004-2005.

Principal Investigator, "Retraining Physician's Following Disciplinary Actions for Medical Negligence", Subagreement with University of Florida College of Medicine, Florida Agency for Health Care Administration, $10,000, 2004.

Principal Investigator, "Litigation Alternatives and a No-Fault Demonstration for Medical Malpractice in Florida", Subagreement with University of Miami College of Medicine, Florida Agency for Health Care Administration via University of Miami Consortium Agreement, $86,000, 2004.

Principal Investigator, "Florida Family AIDS Network" U.S. Department of Health and Human Services, Health Resources and Services Administration, $1,228,090, 2003-2004

Principal Investigator, Suncoast Developmental Center for Patient Safety Evaluation and Research, U.S. Agency for Healthcare Research and Quality, $198,000, 2003-2004

Principal Investigator, "Florida Family AIDS Network" U.S. Department of Health and Human Services, Health Resources and Services Administration, $1,228,090, 2002-2003

Principal Investigator, Suncoast Developmental Center for Patient Safety Evaluation and Research, U.S. Agency for Healthcare Research and Quality, $198,000, 2002-2003

Co-Principal Investigator "Adolescent Clinical Trials for HIV/AIDS" National Institutes of Health, $700,000, 2000-2003.

Principal Investigator, "Florida Family AIDS Network" U.S. Department of Health and Human Services, Health Resources and Services Administration, $1,228,090, 2001-2002

Principal Investigator, Suncoast Developmental Center for Patient Safety Evaluation and Research, U.S. Agency for Healthcare Research and Quality, $198,000, 2001-2002

Principal Investigator, "The Florida Dialysis Fraud Study" Florida Agency for Health Care Administration, $201,593, 2000-2001

Principal Investigator, "Managed Health Care Effects on Safety Net Providers in Florida", Florida Agency for Health Care Administration, $253,000, 2000-2001

Principal Investigator, "Florida Family AIDS Network" U.S. Department of Health and Human Services, Health Resources and Services Administration, 1,064,364, 2000-2001

Principal Investigator, "Targeted Outreach to Pregnant Woman with AIDS" (TOPWA), Florida State Department of Health, $100,000, 2000-2001

Principal Investigator, "The Impact of Implementing Telemedicine Technology in a Spinal Cord Injury Home Environment" American TeleCare, $36,000, 2000

Principal Investigator, "Florida Family AIDS Network" U.S. Department of Health and Human Services, Health Resources and Services Administration, $962,000, 1999-2000

Principal Investigator, "Congressional Black Caucus Grant for High Risk Populations Affected by HIV/AIDS", $80,000, 1999-2000

Principal Investigator, "Targeted Outreach to Pregnant Woman with AIDS" (TOPWA), Florida State Department of Health, $100,000, 1999-2000

Associate Project Director and Investigator, "Prevention and Management of Spinal Cord Injuries" U.S. Department of Veteran's Affairs, VISN 8, 180,000, 1999-2001

Principal Investigator, "Targeted Outreach to Pregnant Woman with AIDS" (TOPWA), Florida State Department of Health, $50,000, 1998-1999

Principal Investigator, "The Florida Family AIDS Network Program" U.S. Department of Health and Human Services, Health Resources and Services Administration, $880,000,1998-99

Principal Investigator, "The Tampa Bay Pediatric and Family AIDS Program" U.S. Department of Health and Human Services, Health Resources and Services Administration, $750,000, 1997-1998

Principal Investigator, "Creating a Healthy Kids Program in Tampa", Florida Healthy Kids Foundation, 18,000, 1997

Principal Investigator, "Tampa Bay Pediatric and Family AIDS Program" U.S. Health Resources and Services Administration, $428.900, 1996-1997.

Co-Principal Investigator, "Evaluation of Florida's Mandatory Managed Care Workers Compensation Initiative" Florida Department of Labor, Division of Workers Compensation, $150,000, 1996-1997,

Principal Investigator, "Physician's Perceptions of HMO Quality Issues" The Hillsborough County Medical Association, 1996, $1,000

Principal Investigator "Evaluation of Tobacco Use Education Project" Sarasota County Public Schools, 1996, $2,000

Principal Investigator, "The Tampa Bay Pediatric AIDS Project", U.S. Health Resources and Services Administration, $354,000, 1995-1996

Principal Investigator, "Evaluation of Manatee County Full Service School Program" 1995, $5,000

Principal Investigator, "Evaluation of the Full-Service School Program for Sarasota County Public Schools, 1994-1995, $14,000

Principal Investigator, "Evaluation of the Full-Service School Program for Sarasota County Public Schools, 1993-1994, $5,000

Principal Investigator, "Extension and Expansion of the Pediatric AIDS Project" 1994-1995", HRSA, USDHHS, $260,000

Principal Investigator, "The Ability of Health Care Organizations to Prepare and Respond to 'Worst Case Scenario' Natural Disasters – Follow Up to Hurricane Andrew in South Florida" 1993, The Florida Hospital Association and the American Hospital Association. $10,000

Principal Investigator, "Supplement to Tampa Bay Pediatric AIDS Project" 1992-1993, The All Children's Hospital Foundation. $14,000

Principal Investigator "The Tampa Bay Pediatrics AIDS Project" 1992-1995, Health Resources and Services Administration, USDHHS. $1,500,000.

Principal Investigator, "Evaluation of the Full-Service School Program for Manatee County Florida Schools, 1992-1993, $5,000

Principal Investigator, "Evaluation of the High Risk Drug Program for Manatee County Schools" 1991-1992, $5,000

Principal Investigator, "Evaluation of the Full Service School Program for Manatee County Schools" 1991, $5,000

Principal Investigator, "The Florida MediPass Program Evaluation: The Florida Medicaid, Managed Care Demonstration" 1991 through 1993, $101,000

Principal Investigator, "The Blake-Just Full-Service School Program Design and Evaluation Plan" Hillsborough County School District, 1991, $60,000

Investigator "Factors Associated with Viability in the Operation of Adult Congregate Care Facilities" Southmark Foundation on Gerontology, April 1989 through October, 1989, $75,000

Investigator "Project FAVA: ACLF Financial and Managerial Viability" Florida Department of Health and Rehabilitative Services, May 1989 through October 1989 $60,000

Principal Investigator "The Future Health of HMOs in Florida" STAR Grant, State of Florida, July 1988 through June 1989, $37,000

Co-Principal Investigator "Aging Access to Health Care in Florida" Florida State Legislature and Office of the Governor, September 1988 through December 1988, with P.J. Levin, $50,000

Co-Principal Investigator "Florida Child Health Study" Florida State Legislature, September 1988 through December 1988, with Martie Coulter, $67,000

Associate Principal Investigator and Associate Project Director "Healthy Beginnings: The Pregnancy Improvement Project for Florida" Florida Medicaid Program Office, DHRS, December 1988 - 1992, $325,000/year ($1,300,000)

Principal Investigator "The Japanese and U.S. Health Care Systems" The Associated Japan America Societies of America, November 1987 through April 1988, $12,000

Principal Investigator, "Updates on Health Insurance and Health Care Financing in Japan" Beverly Enterprises, Dun & Bradstreet Plan Services, U.S. Administrators, Inc., and Mitusi Mutual Life Insurance Company, 1986-1987 $30,000

Investigator "Long Term Industrial Hygiene Training Grant" The National Institutes of Health, 1984-88, $300,000.

Principal Investigator "The Financing of Japan's Health Care System" The Japanese Fulbright Commission, 1985, $60,000

Co-Principal Investigator "The Organization and Financing of Japanese Health Care" The Japan/U.S. Friendship Commission, 1985, with P.J. Levin, $20,000

Principal Investigator, "Use of Video Games to Stimulate Nursing Home Residents", Mattel Corporation, March 1983 through September 1984, $10,000

Principal Investigator, "Effects of Imposing Cost-Sharing on Users of a State's Health Service Program" South Carolina Department of Health and Environmental Control, 1981, $20,000.

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:

EXHIBIT
B

- *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	1168	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

[1] 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 five days per week. However, the rule requires that the applicant provide scheduled hours of operation for a minimum of six 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 C

Go to Services Overview

Clinical Research
- Sponsors
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  - Investigators
  - Previous Studies
- Investigators
- Volunteers
- Resources for Researchers
- Institutional Review Board (IRB)
- Clinical Trials

Novant HEALTH
CLINICAL RESEARCH INSTITUTE

Sponsors

Novant Clinical Research Institute was established in 2001 and has grown from a staff of 4 with a focus on cardiovascular studies to a staff of 14 who conduct and manage trials in a wide range of therapeutic indications.

Staff

NCRI staff includes 7 CRCs, 2 regulatory professionals, as well as support and management professionals. Five of these are ACRP certified and all CRCs are either certified or on track to certification. The current Director, Bob Romanchuk holds certification as CCRC, CHRC (Certified in Health Research Compliance), CIP (Certified IRB Professional) and CRCP (Clinical Research Contract Professional) with 30 years of clinical experience as a Registered Respiratory Therapist.

Regulatory

The IRB of record for NCRI is Forsyth Medical Center IRB. This IRB meets monthly (first Thursday) with a submission deadline of 10 days prior and approval time of 5 days post for new studies. FMC-IRB will defer review to external IRBs on a case-by-case basis.

Contracts/Budgets

Contracts are negotiated directly with NCRI with a usual turnaround of one week, NCRI complies with Novant's Fair Market Value in Clinical Research Pricing policy to assure equitable pricing in compliance with AKS and Stark rules. A robust process of tracing clinical trial billing and coding assures compliance with CMS regulations governing billing for clinical trial participants.

Experience

NCRI's investigators have conducted over 200 phase II-IV drug and device studies in the following therapeutic areas:

- Hyperlipidemia
- Diabetes
- Hypertension
- Arrhythmia
- DVT/PE treatment and prophylaxis
- Infectious disease including
  - CAP, HAP
  - HIV
  - Bacteremia
  - Influenza
  - CSSI
- Stroke
- Cardiac/vascular including
  - ACS
  - STEMI/NSTEMI
  - DES
  - PFO
  - Cardiac CT and IVUS
  - CHF
- Carotid artery disease/occlusion
- PAD
- Long term sedation
- General Surgery

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Previous research sponsor partners include: Amgen, Pfizer, Cubist, Glaxo, Forest Labs, Sanofi-Aventis, Amplatzer, Abbott, Invatec, Merck, Possis, Roche, Idev, Takeda, Trivascular, Abiomed, Medtronic, GSK, AstraZeneca, Baxter, Bayer, Berlex, Atrium, CVRx, J&J, GE Healthcare, Hospira, Lifecell, SJM, Eli Lilly, TriActiv, Volcano, Wyeth and others.

Previous CRO partners include: PPDI, Quintiles, Covance, Parexel, HCRI, DCRI, J Tyson, Global Research, Global Clinical Trial Operations, RCRI, Clinametrix, Weststat, Scimetrica, Symbios, TIMI, Paragon, MBS and other.

Contracts & Budgeting

The director, Bob Romanchuk facilitates negotiation of contracts and budgets and has signatory authority. A turnaround of two weeks is typical. Forward contracts to:

Director: Robert Romanchuk, BS, CIP, CCRC, CHRC
Novant Clinical Research Institute
1405 South Broad Street
Winston-Salem, NC 27127
Phone: 336-277-0932
Fax: 336-277-9153
Email: rhromanchuk@novanthealth.org

EXHIBIT
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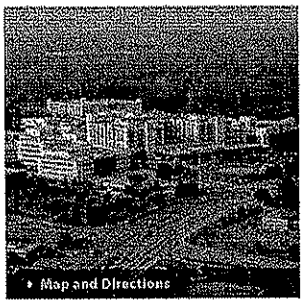

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Institutional Review Board (IRB)

The Institutional Review Board (IRB) is the appropriately constituted group at WakeMed designated to review research to assure the protection of the rights and welfare of the human subjects involved.

The IRB office is located at the WakeMed Raleigh Campus on the third floor, just before the beginning of C Hall. The phone number is (919) 350-8795 and the hours of operation are 8:00 a.m. until 4:30 p.m. Monday through Friday except on official holidays.

Contact Us

Email: wakemed_irb_office@wakemed.org
Phone: 919-350-8795

IRB Members

Investigators

Submission Packet - Downloadable Forms:

Essential Elements for Consent Forms
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Consent Form Template
Word | PDF

Principal Investigators Checklist
PDF

Investigator Agreement
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Waiver of Authorization Request Form
Word | PDF

Financial Disclosure Form
Word | PDF

IRB Application (initial and renewal)
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Continuing Review Form
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After Study Questionnaire (English)
Word | PDF

After Study Questionnaire (Spanish)
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Corporate Accounting Form
Excel

Medical Records Submission
Word | PDF

Pathology Submission
Word | PDF

Pharmacy Submission
Word | PDF

Meetings

IRB meetings are held on every second and fourth Wednesday at 7:30 a.m. in Conference Dining at WakeMed Raleigh Campus except March and December when there will be only one IRB meeting.

Click here for a printable version of the WakeMed IRB Meeting Dates for 2011.

2011 IRB Meeting Dates	2011 Deadline for Submissions
	IRB submissions must be completely and accurately filled out, including all signatures.
January 12	December 22, 2010
January 26	January 5, 2011
February 9	January 19
February 23	February 2
March 9	February 16
April 13	March 23
April 27	April 6
May 11	April 20
May 25	May 4

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- FDA - Good Clinical Practice
- FDA - Running Clinical Trials
- HIPAA - Medical Privacy
- Department of Health and Human Services OHRP
- National Institutes of Health - Bioethics
- Centers for Disease Control

Training:

National Institutes of Health

Department of Health and Human Services

North Carolina State University

Links

- **IRB Policies and Procedures**
- **Training & Education**
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HealthCare.gov

Implementation Center

Report to Congress:

National Strategy for Quality Improvement in Health Care

March 2011

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EXHIBIT

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Executive Summary

The Affordable Care Act seeks to increase access to high-quality, affordable health care for all Americans. To that end, the law requires the Secretary of the Department of Health and Human Services (HHS) to establish a National Strategy for Quality Improvement in Health Care (the National Quality Strategy) that sets priorities to guide this effort and includes a strategic plan for how to achieve it. This report describes the initial Strategy and plan for implementation.

The National Quality Strategy will promote quality health care in which the needs of patients, families, and communities guide the actions of all those who deliver and pay for care. It will incorporate the evidence-based results of the latest research and scientific advances in clinical medicine, public health, and health care delivery. It will foster a delivery system that works better for clinicians and provider organizations—reducing their administrative burdens and helping them collaborate to improve care. It is guided by principles (available at www.ahrq.gov/workingforquality) that were developed with input by stakeholders across the health care system, including Federal and State agencies, local communities, provider organizations, clinicians, patients, businesses, employers, and payers. Most importantly, the implementation of this Strategy will lead to a measurable improvement in outcomes of care, and in the overall health of the American people.

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National Aims

The National Quality Strategy will pursue three broad aims. These aims will be used to guide and assess local, State, and national efforts to improve the quality of health care.

- **Better Care:** Improve the overall quality, by making health care more patient-centered, reliable, accessible, and safe.
- **Healthy People/Healthy Communities:** Improve the health of the U.S. population by supporting proven interventions to address behavioral, social and, environmental determinants of health in addition to delivering higher-quality care.
- **Affordable Care:** Reduce the cost of quality health care for individuals, families, employers, and government.

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Setting Priorities

To advance these aims, we plan to initially focus on six priorities. These priorities are based on the latest research, input from a broad range of stakeholders, and examples from around the country. These priorities have great potential for rapidly improving health outcomes and increasing the effectiveness of care for all populations. As the National Quality Strategy is implemented in 2011 and beyond, we will work with stakeholders to create specific quantitative goals and measures for each of these priorities. They are:

- Making care safer by reducing harm caused in the delivery of care.
- Ensuring that each person and family are engaged as partners in their care.
- Promoting effective communication and coordination of care.
- Promoting the most effective prevention and treatment practices for the leading causes of mortality, starting with cardiovascular disease.
- Working with communities to promote wide use of best practices to enable healthy living.
- Making quality care more affordable for individuals, families, employers, and governments by developing and spreading new health care delivery models.

These priorities can only be achieved with the active engagement of clinicians, patients, provider organizations, and many others in local communities across the country, something the National Quality Strategy supports. Since different communities have different assets and needs, they will likely take different paths to achieving the six priorities. This Strategy will help to assure that these local efforts remain consistent with shared national aims and priorities.

Over time, our goal is to ensure that all patients receive the right care, at the right time, in the right setting, every time. The United States leads the world in discovering new approaches to prevent, diagnose, manage, and cure illness. Our institutions educate and train exceptional doctors, nurses, and other health care professionals. Yet Americans don't consistently receive a high level of care. Achieving optimal results every time requires an unyielding focus on eliminating patient harms from health care, reducing waste, and applying creativity and innovation to how care is delivered. That's what the National Quality Strategy will provide.

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Supporting Action to Address Priorities

The National Quality Strategy articulates broad aims and priorities that have been informed by extensive consultation with stakeholders across the country. At the same time, it explicitly recognizes that in the end, all health care is local.

Many stakeholders have important roles in promoting high quality care. It starts with clinicians and health professionals, but employers, government, advocates, and many others also have an interest in improving the quality of care. Employers and other private purchasers, for example, have been leaders in demanding better quality by pushing provider organizations to achieve new levels of excellence.

Until now, few of these efforts have been coordinated or aligned. The National Strategy will change that, outlining a common path forward that makes high quality, affordable care more available to

patients everywhere.

The Strategy will be updated annually and will provide an ongoing opportunity to identify and learn from those providers and communities that are ahead of the curve in delivering high quality, affordable care. It is our hope that this national strategy creates a new level of cooperation among all the stakeholders seeking to improve health and health care for all Americans.

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The Path Forward

The Affordable Care Act calls on the National Quality Strategy to include HHS agency-specific plans, goals, benchmarks, and standardized quality metrics where available. By design, this first-year Strategy does not include these elements, in order to allow them to be developed with additional collaboration and engagement of the participating agencies along with private sector consultation. We believe nation-wide support and subsequent impact is optimized when those needed to implement strategic plans participate fully in their development. We have begun implementation planning across HHS and have established a mechanism to obtain additional private sector input on specific goals, benchmarks, and quality metrics in 2011. The Agency for Healthcare Research and Quality is tasked with supporting and coordinating the implementation planning and further development and updating of the Strategy.

The National Quality Strategy is designed to be an evolving guide for the Nation as we continue to move forward with efforts to measure and improve health and health care quality. As implementation proceeds, we will monitor our progress in achieving the Strategy's three aims along with other short- and long-term goals, and will refine the Strategy accordingly. We will provide updates annually to Congress and to the public.

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Section I. Introduction

The Affordable Care Act is improving the quality, affordability, and access to health care for all Americans. The law provides new protections for consumers in the private health insurance market, creates new coverage options for individuals and small business owners, and extends premium tax credits to moderate- and low-income Americans to make health care more affordable.

In addition, the Affordable Care Act has an array of provisions designed to enhance coordination, innovation, efficiency, and the quality of health care. These reforms build on progress that was already being made as a result of existing legislation such as the Children's Health Insurance Program Reauthorization Act of 2009 and the American Recovery and Reinvestment Act of 2009. Further, these provisions complement a wide range of State and local activities that also seek to make care more affordable, improve the quality of care, and promote better health.

To help guide and coordinate these public and private sector activities, the Affordable Care Act calls on the HHS Secretary to establish a National Strategy for Quality Improvement in Health Care (the National Quality Strategy) that sets priorities to guide this effort and includes a strategic plan for how to achieve it.

This report outlines the initial National Quality Strategy and plan. It identifies broad aims and priorities

for achieving better health and health care and describes examples of HHS initiatives that address the priorities. The Affordable Care Act also calls on the Secretary to establish a National Prevention and Health Promotion Strategy. The National Prevention and Health Promotion Strategy will align with the National Quality Strategy and will provide a more specific plan for improving population health.

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The Need for Improvement

The need to improve the quality and affordability of health care in the United States has been documented repeatedly. For example:

- In its groundbreaking 2001 report *Crossing the Quality Chasm: A New Health System for the 21st Century*, the Institute of Medicine's Committee on Quality of Health Care wrote:

The performance of the health care system varies considerably. It may be exemplary, but often is not, and millions of Americans fail to receive effective care…The health care system as currently structured does not, as a whole, make the best use of its resources. There is little doubt that the aging population and increased patient demand for new services, technologies, and drugs are contributing to the steady increase in health care expenditures, but so, too, is waste. Many types of medical errors result in the subsequent need for additional health care services to treat patients who have been harmed. A highly fragmented delivery system that largely lacks even rudimentary clinical information capabilities results in poorly designed care processes characterized by unnecessary duplication of services and long waiting times and delays. And there is substantial evidence documenting overuse of many services—services for which the potential risk of harm outweigh the potential benefits. What is perhaps most disturbing is the absence of real progress toward restructuring health care systems to address both quality and cost concerns, or toward applying advances in information technology to improve administrative and clinical processes.

- Researchers at the RAND Corporation have found that nearly half of all adult patients fail to receive recommended care.
- Since 2003, the Agency for Healthcare Research and Quality (AHRQ), together with its partners in HHS, has published annual National Healthcare Quality and Disparities Reports. (Available at http://www.ahrq.gov/qual/measurix.htm#quality). Overall, these reports find that while health care quality is improving, the pace of that improvement is slow.
- The Business Roundtable, in its *2010 Health System Value Comparability Study*, compared the United States with its five largest trading partners on both quality and cost of care. While noting potential for improvement on many fronts, it also noted that costs are far higher in the United States than in any other country. The report found that for every dollar spent on health care in the United States, other major competitors spent just 47 cents. Despite this increased spending, evidence suggests United States health care quality is no better, or in some cases worse, than other countries.

When looking at how our health care system works, these results are not surprising. The United States leads the world in developing new approaches to prevent, diagnose, manage, and cure illness, thereby improving health. Our academic institutions educate and train exceptional physicians, nurses, and other health care professionals. But while these advances have dramatically improved care for millions of people, they do not consistently reach all who would benefit.

That's because health care in the United States is often fragmented and disorganized. Patients,

caregivers, and families are forced to retell their stories to each new medical professional they encounter. Tests are duplicated because medical records are lost or unavailable. Doctors, nurses, and other health care professionals spend hours on paperwork. This fragmentation leaves both patients and clinicians dissatisfied, and adds significantly to the cost of care—and it's reinforced by payment systems that reward piecemeal care instead of care delivered in a seamless, coordinated manner.

The National Quality Strategy aims to change that by focusing on eliminating patient harms, reducing waste, and applying innovation in how care is delivered with the goal of ensuring that each patient receives the right care, at the right time, in the right setting, every time.

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Developing the National Quality Strategy

The Secretary developed this initial National Quality Strategy and plan through a participatory, transparent, and collaborative process that reached out to a range of stakeholders for comment. More than 300 groups, organizations, and individuals provided comments, representing all sectors of the health care industry and the general public. In addition, the Strategy incorporates input gathered at national meetings and from the National Priorities Partnership, a coalition of some 50 organizations committed to revamping the health care system. (See www.nationalprioritiespartnership.org.) These public comments led to revisions and enhancements to the Strategy and gathered support for the principles, aims, and priorities that form the foundation of this report. A full summary of the public comments made in the development of the National Quality Strategy is available at www.ahrq.gov/workingforquality. This dialogue will continue in 2011 and beyond, as the National Quality Strategy evolves and develops a sharper focus on specific goals, measures, and additional actions to be taken by the government and private sector partners.

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An Initial Outline of the Plan

The National Quality Strategy will focus national, State, and local efforts to improve health care quality on common aims, priorities and goals.

It will promote health and health care centered on the needs of patients, families, and communities. It will incorporate the evidence-based results of research and scientific advances in clinical medicine, public health, and health care delivery. It will foster a delivery system that works better for clinicians and provider organizations—reducing their administrative burdens and helping them collaborate to improve care. It will be guided by a set of core aims and priorities that reflect shared values and best practices. Most importantly, the implementation of this Strategy will have a measurable impact on the experience and outcomes of care, and on the health of the American people.

The National Quality Strategy will pursue three broad aims that will be used to guide and assess local, State, and national efforts to improve health and the health care delivery system.

- **Better Care:** Improve the overall quality, by making health care more patient-centered, accessible, and safe.
- **Healthy People/Healthy Communities:** Improve the health of the U.S. population by supporting proven interventions to address behavioral, social and, environmental determinants of health in

addition to delivering higher-quality care.
- **Affordable Care:** Reduce the cost of quality health care for individuals, families, employers, and government.

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Setting Priorities

To advance these aims, we plan to initially focus on six priorities. These priorities are based on research, input from a broad range of stakeholders, and examples from around the country, which suggest that we have great potential for rapidly improving health outcomes and increasing the value and effectiveness of care for all populations. As the National Quality Strategy is implemented in 2011 and beyond, we will work with stakeholders to create specific quantitative goals and measures for each of these priorities. They are:

- Making care safer by reducing harm caused in the delivery of care.
- Ensuring that each person and family are engaged as partners in their care.
- Promoting effective communication and coordination of care.
- Promoting the most effective prevention and treatment practices for the leading causes of mortality, starting with cardiovascular disease.
- Working with communities to promote wide use of best practices to enable healthy living.
- Making quality care more affordable for individuals, families, employers, and governments by developing and spreading new health care delivery models.

These priorities can only be achieved with the active engagement of clinicians, patients, provider organizations, and many others in local communities across the country, something the National Quality Strategy supports. Since different communities across the Nation have different assets and needs, they will likely take different paths to achieving the six priorities. This Strategy will help assure that these local efforts are consistent with shared national aims and priorities.

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Building on Work in Progress

The National Quality Strategy builds on the work, achievements, and recommendations of millions of concerned and committed clinicians and other stakeholders. Over the past two decades, these stakeholders have devoted enormous energy and enthusiasm to defining, measuring, and improving quality. Many of these efforts have occurred through partnerships between government, private organizations, and consumers. And while some of these have been nationwide efforts, many have been deeply rooted in local communities.

Communities and States have often served as laboratories for expanding health coverage, improving quality, and controlling costs. That will be even truer in the years to come as States take the lead in implementing key parts of the Affordable Care Act, such as new State-based Health Insurance Exchanges. State Exchanges will improve health care quality by providing transparent information for consumers and by creating quality standards for health plans. And as we move forward, State leadership will be crucial to ensuring that the National Quality Strategy continues to reflect local needs.

Notably, these State and local efforts to improve quality have often occurred in spite of payment systems

and incentives that do not reward value or improve quality. In addition, for many clinicians and provider organizations, these efforts have been undertaken in the midst of competing incentives, regulations, and administrative complexity that foster confusion and create barriers to improvement. The National Quality Strategy will help change this.

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The Path Forward

The National Quality Strategy is designed to be an adaptable and evolving guide for the Nation. It is a broad roadmap that will require the ongoing development of specific goals, measures, benchmarks, and initiatives, through a continued transparent collaborative process with all stakeholders. It will continue to draw from pockets of excellence from which others can learn and which could eventually be brought to scale. At the Federal level, the National Quality Strategy will guide the development of HHS programs, regulations, and strategic plans for new initiatives, in addition to serving as a critical tool for evaluating the full range of Federal health care efforts.

The Affordable Care Act calls on the National Quality Strategy to include HHS agency-specific plans, goals, benchmarks, and standardized quality metrics where available. By design, this first-year Strategy does not include these elements, in order to allow them to be developed with additional collaboration and engagement of the participating agencies along with private sector consultation. We believe nation-wide support and subsequent impact is optimized when those needed to implement strategic plans participate fully in their development. We have begun implementation planning across HHS and have established a mechanism to obtain additional private sector input on specific goals, benchmarks, and quality metrics in 2011. The Agency for Healthcare Research and Quality is tasked with supporting and coordinating the implementation planning and further development and updating of the Strategy.

As implementation of the National Quality Strategy proceeds, it will be periodically refined, based on lessons learned in the public and private sectors, emerging best practices, new research findings, and the changing needs of the Nation. Updates on the Strategy and the Nation's progress in meeting the three aims of better care, improved health, and making quality care more affordable will be delivered annually to Congress and the American people.

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Section II. Aims, Priorities, and Goals for Improving Quality

As noted earlier, the National Quality Strategy is guided by three broad aims: better care, healthier people and communities, and affordable quality care for all. These aims are not separate, but are interrelated and mutually reinforcing. For example, by reducing gaps in patient support that raise the risk of avoidable complications or readmissions, better care coordination leads to better patient outcomes. In addition, care coordination can also make care more affordable by reducing duplication and preventing costly hospital admissions or readmissions and avoidable emergency department visits. Because of these connections, national priorities should contribute to the achievement of all three aims.

As the National Quality Strategy is implemented in 2011, the priorities and initiatives listed in this report will be refined, additional goals will be identified, and quality metrics and benchmarks will be

applied to ensure accountability for performance. (The Appendix to this report lists examples of measures that may be useful for monitoring the Nation's progress in achieving the Strategy's priorities. Actual targets and measures will be identified later in 2011. And the first update on the National Quality Strategy provided to Congress and the Nation in 2012 will include additional detail on how Federal agencies are addressing the priorities and goals in agency-specific strategic plans.)

In this first report to Congress and the Nation, we describe initiatives that are currently underway within HHS for each priority area. The initiatives described are not intended to be an exhaustive catalogue, but rather a sample of initiatives that are already addressing the priorities identified in this plan.

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1. Making Care Safer

Health care-related errors harm millions of American patients each year and needlessly add billions of dollars to health care costs. The Centers for Disease Control and Prevention (CDC) estimate that at least 1.7 million healthcare-associated infections occur each year and lead to 99,000 deaths. Adverse medication events cause more than 770,000 injuries and deaths each year—and the cost of treating patients who are harmed by these events is estimated to be as high as $5 billion annually.

Health care providers should be relentless in their efforts to reduce the risk for injury from care, aiming for zero harm whenever possible and striving to create a system that reliably provides high-quality health care for everyone. This isn't easy. Such a system requires, for example, the design of standard operating procedures, a workforce with diverse yet complementary skills, workloads that allow enough time for errors to be corrected or mitigated and leadership that promotes continuous improvement. But this kind of system can also make a big difference in improving care, whether it's by preventing serious medication events or eliminating healthcare associated infections and other preventable conditions.

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Examples of Federal Initiatives Making Care Safer

1. **Michigan Keystone Intensive Care Unit Project:** Nearly one in every 20 hospitalized patients in the United States each year acquires a healthcare-associated infection while receiving medical care. Central intravenous line associated blood-stream infections are one of the most deadly types, with a mortality rate of 12 to 25 percent. In this AHRQ-funded project, a research team at Johns Hopkins University partnered with the Michigan Health and Hospital Association to implement CDC recommendations to reduce central line blood stream infections in 100 intensive care units throughout the State. The initiative, known as the "Keystone Project," reduced the rate of these central line bloodstream infections by two-thirds within 3 months. Over 18 months, the program saved more than 1,500 lives and nearly $200 million. These dramatic improvements have been sustained for 5 years and the approach used is now being spread to all 50 States and the District of Columbia. For more information, go to www.ahrq.gov/about/annualmtg07/0928slides/goeschel/Goeschel.ppt.
2. **Safe Use Initiative:** Today, tens of millions of people in the United States depend on prescription and over-the-counter medications to sustain their health—with as many as 3 billion prescriptions written annually. Too many people, however, suffer unnecessary injuries, and even death, as a result of preventable medication errors. The U.S. Food and Drug Administration (FDA) has launched the Safe Use Initiative to create and facilitate public and private collaborations within the health care community with the goal of reducing this preventable harm. The Safe Use

Initiative will identify specific, preventable medication risks and then develop, implement, and evaluate cross-sector interventions to reduce these risks.For more information, go to http://www.fda.gov/Drugs/DrugSafety/ucm187806.htm.

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2. Ensuring Person- and Family-Centered Care

Health care delivery in the United States is often not designed around meeting the needs of the patient. Instead, clinical services are often organized around specific clinical conditions and designed with little input or direction from the patient. We need to change that.

Health care should give each individual patient and family an active role in their care. Care should adapt readily to individual and family circumstances, as well as differing cultures, languages, disabilities, health literacy levels, and social backgrounds.

This kind of person-centered care, which sees a person as a multifaceted individual rather than the carrier of a particular symptom or illness, requires a partnership between the provider and the patient with shared power and responsibility in decision making and care management. It also requires giving the patient access to understandable information and decision support tools that help patients manage their health and navigate the health care delivery system. Person-centered care means defining success not just by the resolution of clinical syndromes but also by whether patients achieve their desired outcomes.

Some examples of person-centered care could be assuring that patients' feedback on their preferences, desired outcomes, and experiences of care is integrated into care delivery, integrating patient-generated data in electronic health records, and finding additional ways to involve patients and families in managing their care effectively.

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Examples of Federal Initiatives Fostering Person- and Family-Centered Care

1. **Building Patients' Perspectives Into All Performance Assessments:** The Federal government has taken the lead in assuring that the patient's perspective of care is a core measure of performance for providers and health plans. Starting with the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS), Medicare has used its purchasing power to get virtually all hospitals to publicly report standardized information on the perspective of all patients (including Medicare beneficiaries, Medicaid beneficiaries, and those with private insurance). This was the first large-scale initiative to include patient experience as a factor in quality reporting. In addition, the Affordable Care Act uses HCAHPS as one of the measures to calculate value-based incentive payments to hospitals beginning in 2012, and also calls on CMS to expand the use of patient experience information to assess physicians and other facilities, including nursing homes. For more information, go to https://www.cms.gov/HospitalQualityInits/30_HospitalHCAHPS.asp.
2. **Establishing the Patient-Centered Outcomes Research Institute:** Established as an independent, nonprofit organization under the Affordable Care Act, the Patient-Centered Outcomes Research Institute (PCORI) will build on the current work of AHRQ and NIH to assist patients, clinicians, and policymakers in making informed health decisions. To do this, PCORI will identify research projects that provide quality, relevant evidence on how diseases and health conditions can be effectively diagnosed, prevented, treated, and managed. The Act requires that

initial priorities for PCORI be informed by the National Quality Strategy, and that consumer input influence all phases of sponsored research, starting with developing the questions researchers will try to answer. The 21 members of the PCORI Board of Governors are made up of 19 members appointed by the Comptroller General and the Directors of AHRQ and NIH. For more information, go to http://pcori.org/.

3. **AHRQ's Patient-Centered Care Improvement Guide:** AHRQ has developed a guide to help hospitals become more patient-centered. It outlines best practices and addresses common barriers to implementing patient-centered care. For more information, go to http://www.innovations.ahrq.gov/content.aspx?id=2383.

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3. Promoting Effective Communication and Coordination of Care

When all of a patient's health care providers coordinate their efforts, it helps ensure that the patient gets the care and support he needs and wants, when and how he needs and wants it. Effective care coordination models have begun to show that they can deliver better quality and lower costs in settings that range from small physician practices to large hospital centers.

Health care systems need to encourage coordination and help providers care for patients with chronic diseases so they get the kind of seamless care that is most effective. Gaps and duplication in patient care delivery can be reduced or eliminated through proven technologies such as electronic health records, e-prescribing, and telemedicine. Hospitals and long-term care and rehabilitation facilities, along with physicians, nurses, and other clinicians working together, are helping recently discharged patients avoid unnecessary rehospitalization. All too often, however, the way health care is paid for does not foster coordination but instead pays more to providers for doing more instead of working together. Policies advanced by the National Quality Strategy will help change that.

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Examples of Federal Initiatives Promoting More Effective Care Coordination

1. **Advancing Primary Care Services and Medical Homes:** The Federal government is promoting better care coordination through multiple programs. In November 2010, CMS announced: (1) the participation of eight States in the Multi-Payer Advanced Primary Care Practice Demonstration to evaluate the effectiveness of health professionals across care systems working in a more integrated fashion and receiving more coordinated payment from Medicare, Medicaid, and private health plans. Ultimately this will provide advanced practice primary care for up to 1 million Medicare beneficiaries; (2) support to help States establish "health homes" to provide care to Medicaid beneficiaries with at least two chronic conditions; (3) the participation of up to 500 Federally Qualified Health Centers to test the effectiveness of health professionals working in teams to treat low-income patients at community health centers; and (4) the opportunity for States to apply for contracts to support development of new integrated care models aimed at improving care quality, care coordination, cost-effectiveness, and overall experiences of beneficiaries who are eligible for both Medicare and Medicaid, also known as "dual eligibles." For more information, go to http://innovations.cms.gov/news/pressreleases/pr110910.shtml.
2. **Developing Accountable Care Organizations:** As part of the Affordable Care Act, Congress directed CMS to establish a "shared savings program" to bring together groups of providers and

suppliers to deliver better quality and more cost-effective care for Medicare beneficiaries. CMS is currently engaging with physicians, hospitals, employers, and consumer groups to help plan this program, which the statute requires be established no later than January 2012. For more information, go to https://www.cms.gov/OfficeofLegislation/Downloads/AccountableCareOrganization.pdf.

3. **Improving Care Coordination Through Health Information Technology:** The Health Information Technology for Economic and Clinical Health (HITECH) Act allows HHS to establish programs to improve health care quality, safety, and efficiency through the adoption of health information technology, including electronic health records (EHRs) and private and secure electronic health information exchange. Eligible health care professionals and hospitals can qualify for Medicare and Medicaid incentive payments when they adopt certified EHR technology and use it to achieve specified objectives for improving care. Altogether, more than $27 billion in incentive payments is available to eligible providers and hospitals that meet these "meaningful use" objectives. A Federal regulation defining the first stage of meaningful use objectives was released in 2010. For more information, go to https://www.cms.gov/ehrincentiveprograms/. Meaningful use of health information technology improves quality by making needed clinical information accessible to all appropriate providers and in a more complete and timely fashion than paper records.

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4. Promoting the Most Effective Prevention and Treatment of the Leading Causes of Mortality, Starting With Cardiovascular Disease

More than 133 million Americans have at least one chronic illness, and many have several. As individuals and health systems feel the strain of this growing trend, we need to do a better job preventing and treating a number of leading causes of mortality and illness in adults and children including cardiovascular disease, cancer, diabetes, HIV/AIDS, premature births, and behavioral health conditions.

Among these, cardiovascular disease is the most deadly, accounting for one of every three deaths in the United States. Over $503 billion is spent annually on cardiovascular disease. And approximately 75 million Americans have high blood pressure, 18 million have a history of heart attack or angina, 6 million have a history of heart failure, and 6 million have a history of stroke. While mortality from cardiovascular disease has declined dramatically over the past forty years, current quality initiatives can help us do even better. For example, health plans with the best performance in managing cardiac risk factors (90th percentile) still only report effective care for 71 percent of patients.

Decades of research and practice have demonstrated that public health and clinical strategies can greatly reduce the risk of cardiovascular disease. The key interventions are referred to as the "ABCS": aspirin, blood pressure control, cholesterol reduction, and smoking cessation. Under this umbrella, activities that can improve heart health include reducing uncontrolled blood pressure and cholesterol, decreasing sodium and trans-fat intake, eliminating smoking and exposure to secondhand smoke, increasing aspirin use to prevent and reduce the severity of heart attacks and strokes, and lifestyle interventions to modify risk factors such as obesity.

By focusing on cardiovascular disease, we'll provide a model for how the Nation can make a dramatic and immediate impact on the health and health care of millions of Americans. And the lessons from this effort will inform complementary efforts addressing other conditions, including HIV/AIDS and other

chronic illnesses. Future initiatives will address a broad range of diseases and age ranges.

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Examples of Federal Initiatives Addressing the Leading Causes of Mortality

1. **CDC Community Transformation and Self Management Grants:** In 2011, the Affordable Care Act provides $750 million in prevention and public health funding to support a variety of activities to promote healthy living These grants represent a major commitment to promoting health in local communities, including reducing heart disease. Funding from CDC will support programs that reduce risk factors for chronic illnesses and discourage behaviors that increase risk.
2. **Focusing on Priority Conditions:** The National Quality Strategy highlights cardiovascular disease as a place to start, partially out of recognition of other important efforts already under way. For example:

- **The National HIV/AIDS Strategy:** On July 13, 2010, the White House released the National HIV/AIDS Strategy (NHAS). This ambitious plan is the Nation's first-ever comprehensive coordinated HIV/AIDS roadmap with clear and measurable targets to be achieved by 2015. In December 2010, HHS and five other lead agencies submitted NHAS operational plans to the White House, which were made public in February 2011. HHS is committed to NHAS priorities of preventing HIV infections, making more people aware of their HIV status, and giving people greater access to HIV care and treatment, using innovative, culturally appropriate means. For more information, go to http://www.aids.gov/federal-resources/policies/national-hiv-aids-strategy/.
- **The Strategic Framework on Multiple Chronic Conditions:** In December 2010, HHS issued its new Strategic Framework on Multiple Chronic Conditions—an innovative, private-public sector collaboration. The new strategic framework will improve the overall health of individuals with multiple chronic conditions and reduce their risk of complications by providing more information and better tools to help health professionals—as well as patients—learn how to better coordinate and manage care and by facilitating research to improve care. For more information, go to http://www.hhs.gov/ash/initiatives/mcc/.

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5. Working With Communities to Promote Wide Use of Best Practices to Enable Healthy Living

Health is a state of physical, mental and social well-being and not merely the absence of disease or infirmity. Our health is affected by a range of factors such as individual behavior, access to health services, and the environment in which we live, in addition to biology and genetics.

The broad goal of promoting better health is one that is shared across the country, whether it's promoting healthy behaviors such as not using tobacco or fostering healthy environments that make it easier to exercise and get access to healthy foods. For that reason, successful efforts to improve these health factors rely on deploying evidence-based interventions through strong partnerships between local health care providers, public health professionals, and individuals.

One specific opportunity to improve health is by increasing the adoption of clinical preventive services for children and adults. When used correctly, these services can prevent illnesses and also identify them

at an earlier and more treatable stage. Clinical preventive services include such things as tobacco cessation services, screening for hypertension, high cholesterol, and depression and screening and counseling for risky alcohol behavior and other drug use. Another specific opportunity is to increase the adoption of evidence-based interventions to improve population health, such as those recommended by the CDC's Task Force on Community Preventive Services. The forthcoming National Prevention and Health Promotion Strategy will also align with the National Quality Strategy and will provide a more specific plan for improving population health.

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Examples of Federal Initiatives Supporting Better Health in Communities

1. **Putting Prevention to Work in Communities:** The American Recovery and Reinvestment Act of 2009 provided $650 million to carry out evidence-based clinical and community-based programs to prevent or delay chronic diseases and promote wellness in children and adults. Some of those funds went to "Communities Putting Prevention to Work," a program which supports policy and environmental changes at the local and State level that aim to increase levels of physical activity; improve nutrition; decrease obesity rates; and decrease smoking prevalence, teen smoking, and exposure to second-hand smoke. For more information, go to http://www.cdc.gov/CommunitiesPuttingPreventiontoWork/about/index.htm.
2. **First Lady's Let's Move! Campaign:** The Let's Move! campaign, started by First Lady Michelle Obama, has an ambitious national goal of addressing the challenge of childhood obesity within a generation so that children born today will reach adulthood at a healthy weight. Let's Move! is combating the epidemic of childhood obesity through a comprehensive approach that is engaging all the parties that affect the health of children, and providing schools, families, and communities with simple tools to help kids be more active, eat better, and get healthy. At the launch of the campaign, President Barack Obama signed a Presidential Memorandum creating the first-ever Task Force on Childhood Obesity to conduct a review of every single program and policy relating to child nutrition and physical activity, develop a national action plan to make the most of Federal resources, and set concrete benchmarks toward the First Lady's national goal. For more information, go to http://www.letsmove.gov/.
3. **Preventing Substance Abuse and Mental Illness in Tribal Communities:** Helping communities promote emotional health and reduce the likelihood of mental illness, substance abuse, and suicide is the goal of the Substance Abuse and Mental Health Services Administration's "Circles of Care" initiative. This initiative focuses on providing grants to Tribal communities to develop models of care, create new partnerships, and help community members to obtain comprehensive behavioral health services. Circles of Care currently support eight tribes and urban Indian organizations across the country. For more information, go to http://www.samhsa.gov/samhsaNewsletter/Volume_18_Number_6/CirclesOfCare.aspx.

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6. Making Quality Care More Affordable

For the past 30 years, health care spending has risen at a faster rate than the economy nearly every year. These rising costs have put a burden on America's families as patients, taxpayers, business owners, and employees who have seen a growing share of their paychecks go to pay for health care.

Yet there is good evidence that health care costs can be reduced while quality is improved. Making sure the right care is delivered to the right person at the right time every time can also make care more

affordable. The National Quality Strategy recognizes that while this will be a challenge, the goal of reducing costs is important to all because of the impact of increasing costs on families, employers, and State and Federal governments. Reducing costs must be considered hand-in-hand with the aims of expanding access, providing better care, and promoting population health.

For that reason, the National Quality Strategy will foster care strategies that reduce redundant and harmful care, for example, by reducing health care-acquired conditions; establish common measures that will help assess the cost impact of new programs and payment systems on families, employers, and the public sector, along with how well these programs support innovation and effective care; build measurement of cost and resource use—along with patient experience and outcomes—into the full range of public and private sector efforts to reform payment; reduce waste from undue administrative burdens; and make health care costs and quality more transparent to consumers and providers, so they can make better choices and decisions.

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Initiatives Making Care More Affordable

1. **Establishing Health Insurance Exchanges:** Today, individuals and small businesses looking to buy health insurance are often on their own, forced to choose between several undesirable options. Starting in 2014, State-based health insurance exchanges will lower costs and improve health care quality for individuals and small business owners by creating a more transparent and competitive marketplace. Exchanges will offer information on price and quality, so that insurers will compete on offering the best providers and services for the most affordable premium. By pooling people together, exchanges will also give individuals and small business owners purchasing power similar to that of large businesses. For more information, go to http://www.hhs.gov/news/press/2011pres/01/20110120b.html
2. **Fostering Innovations to Promote Quality and Reduce Cost:** The Affordable Care Act established a new Center for Medicare and Medicaid Innovation in CMS, charged with testing innovative payment and service delivery models in Medicare, Medicaid, and the Children's Health Insurance Program (CHIP) that improve care and save money. In 2011, the Innovation Center will begin testing additional models and engage clinicians, consumers, employers, and other stakeholders around the common pursuit of creating a health care system that delivers high-quality care while keeping costs down for Medicare, Medicaid, and CHIP beneficiaries. For more information, go to http://innovations.cms.gov/.
3. **Administrative Simplification:** The Affordable Care Act includes provisions to foster "administrative simplification." Under those provisions, new tools will be adopted to help doctors and other providers focus on patients instead of paperwork, such as a standard unique identifier for health plans, a new standard for electronic funds transfer, and operating rules that provide more specificity to existing transaction standards. These provisions are expected to generate significant savings. As electronic transactions become easier, more providers will use them in place of costly paper or telephone communication. As a result, providers and plans will save from reduced phone calls, reduced postage and check printing costs, fewer rejected transactions, and more automated processes.

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Section III. Policies and Infrastructure Needed to Support Priorities

The National Quality Strategy sets forth broad aims, initial priorities and goals, and maps out early initiatives. Reaching these goals will be the product of the actions of many individuals and groups across the Nation. At the forefront, are the millions of committed clinicians and health professionals seeking to partner with their patients in providing the best possible care. States, licensing organizations, health care professional specialty organizations, accrediting organizations, consumer advocates, and private sector purchasers will also contribute. A national strategy must build on and support these efforts and create a common path forward that results in high quality, affordable care everywhere.

To achieve its objective of improving health and health care for all Americans, the National Quality Strategy promotes collaboration among stakeholders in the Nation's health system around several initiatives, including the Healthcare Associated Infection Prevention Initiative, Accountable Care Organizations, and Communities Putting Prevention to Work. The strategy counts on the actions taken by doctors, nurses and other clinicians; better informed choices made by patients and family members; and systems of care put in place by health care providers and institutions to ensure high quality and reliable care.

The Federal government plays a vital role in supporting the delivery of safe, high quality care, including paying for care, monitoring quality, addressing disparities, providing technical assistance, supporting research, and directly providing care to veterans, members of the military, Native Americans, and others. Similarly, State, local, and tribal governments can support better care delivery in their communities.

At the same time the strategy provides an ongoing opportunity to identify and learn from those providers and communities that are ahead of the quality care curve. It is our hope that this National Quality Strategy launches a new level of cooperation that reflects the Nation's highest aspirations for health and health care for all Americans. With the appropriate modifications and enhancements, the current "building blocks" of the U.S. health care system can become a foundation for a system that provides better care, a healthier population, and lower health costs

This National Quality Strategy—and all efforts to improve health and health care delivery—must be guided by a core set of principles. We identify 10 principles (available at www.ahrq.gov/workingforquality) that can be used when designing specific initiatives to achieve the National Quality Strategy's three aims.

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1. Payment

Payment arrangements should offer incentives that foster better health; promote quality improvement and greater value while creating an environment that fosters innovation. Health care systems should be rewarded for working collaboratively to improve efficiency and adopt evidence-based practices across the spectrum of inpatient and outpatient services. Medicare, State Medicaid programs, and many private sector health plans and purchasers are moving rapidly to change payment systems to reward coordination and better outcomes. New payment incentives and delivery models that will be launched under the auspices of the Medicare, Medicaid, and private sector partnerships will provide the opportunity to evaluate and bring successful models to scale.

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2. Public Reporting

Public reporting initiatives offer consumers and payers vehicles to compare costs, review treatment outcomes, assess patient satisfaction, and hold providers accountable. This is done while ensuring the protection of personal health information and adjusting for factors beyond providers' control. Reporting also provides important resources and motivation for clinicians and other providers to improve performance. You can see examples of these initiatives—sponsored by health plans, States, nonprofit groups and community consortiums, employer coalitions, and individual firms—on a variety of scales. Many provide information that can help guide patients' decisions about their health care providers. This reporting should be further refined and expanded with broader use of commonly endorsed measures of performance. The new consumer focused web site, healthcare.gov will also improve transparency. The site allows all consumers to view the insurance plans in their area, compare them by price and benefits and pick the one that is best for them and their families. There will also be hospital pricing information, in addition to performance data, available online to help inform consumer decisions about where to obtain care.

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3. Quality Improvement/Technical Assistance

Public and private efforts to support providers' desire to deliver higher quality care are critically important. These include programs sponsored by provider organizations and clinical specialty groups and quality improvement organizations (QIOs) that work cooperatively with physicians, hospitals, nursing homes, home health agencies, and others to disseminate research evidence to the point of care, share best practices and technical assistance. HHS is contracting with QIOs to drive quality improvement through collaboratives at the State level. Collaborative efforts at the local level are also a vital resource for measuring, monitoring, and improving quality of care.

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4. Certification, Accreditation, and Regulation

State and Federal regulations create public standards for safe, reliable care. Certification by State, Federal, or federally-approved accrediting organizations lets public and private payers, consumers, and other stakeholders know that a clinician or organization meets certain quality standards for health services. Standards applied by accrediting entities should continue to draw on the expertise of provider organizations, clinicians, purchasers, health plans, consumers, and measurement experts and be mindful of the burden placed on providers. Through their regulatory authority, State and Federal agencies overseeing provider organizations and facilities should continue to monitor providers, ensure feedback and accountability, and strengthen patient safety and quality improvement. For example, provider participation in public programs will be conditioned on more rigorous screening to ensure providers meet appropriate standards.

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5. Consumer Incentives and Benefit Designs

Consumer incentives, such as financial assistance for tobacco cessation programs, can help turn good

intentions into action. Some employers and private health plans already use the evidence-based programs to promote better health. Similar approaches can improve adherence to recommended medications, which many Americans fail to take, often due to cost. At the Federal level, HHS is promoting value-based insurance models. Value-based insurance provides incentives for consumers to choose high quality, efficient providers. In addition, clinicians and patients need information on the evidence supporting the care they give and receive.

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6. Measurement of Care Processes and Outcomes

Public and private stakeholders have worked hard to create accurate measurements for health care services quality. However, those efforts have relied largely on incomplete data generated from claims or patients' charts after an encounter with the health care system. Valid, reliable measures are the cornerstone of monitoring quality improvement efforts. In order to achieve the quality improvements envisioned by the National Quality Strategy, data on care delivery and outcomes should be measured using consistent, nationally-endorsed measures in order to provide information that is timely, actionable, and meaningful to both providers and patients. Across the country, there are efforts based in States and regional collaboratives that are at the cutting edge of measuring performance.

At the national level, HHS continues to help coordinate quality measurement efforts that address the National Quality Strategy's six priorities. The department will also develop national consensus on specific measures, data sources, and data collection procedures. Efforts will focus on aligning measurement efforts within value-based purchasing programs and will move toward measuring outcomes and patient experience. HHS will promote effective measurement while minimizing the burden of data collection by aligning measures across its programs, coordinating measurement with the private sector and developing a plan to integrate reporting on quality measures with the reporting requirements for meaningful use of electronic health records.

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7. Health Information Technology

Increased adoption of EHRs has the power to cut health care costs, reduce paperwork, improve outcomes, and give patients more control over their health care, while maintaining full protections on the privacy of individual health information. To promote adoption and improve the performance of the health care system, the HITECH Act was signed into law in 2009. The Act addresses obstacles to the adoption of EHRs and provides substantial financial incentives for the adoption and meaningful use of certified EHR technology. Meaningful use criteria include quality measurements that will be built on over the next several years. The goal is to build a system that supports clinical practice, research, public health, and the health of individual patients. The Office of the National Coordinator for Health Information Technology is focusing its efforts on engaging the private sector, including vendors, service companies, and insurers, to make health information exchange a reality. It is also working with health care providers through Beacon Community Programs, State Health Information Exchange Programs, and Regional Extension Centers to help expand the use of EHRs. At the same time, it builds on State and local efforts to promote better use of health information technology by engaging clinicians, employers, consumers, and others.

An increasing number of case studies demonstrate that health information technology improves quality.

A recent review published by AHRQ contained numerous examples of how health information technology can, for example, increase the likelihood that patients received life-saving treatment, or lower the frequency of a common type of hospital-acquired infection. (See *Using Health IT: Eight Quality Improvement Stories*, available at http://healthit.ahrq.gov/SuccessStoriesTHQIT.)

In one case, 15 nursing homes implemented an electronic documentation and clinical decision support system and subsequently observed a 34 percent decrease in high-risk pressure ulcers. In another case, a clinical decision support for emergency medical responders resulted in lower time-to-treatment for patients experiencing heart attacks. This increased the likelihood that patients received timely life-saving treatment. In a third example, use of clinical decision support through an EHR system in rural Iowa helped to reduce the rate of urinary tract infections after surgery. Using health information technology can also lead to improved efficiencies in health care delivery. One example from the AHRQ report is a continuity of care record that helped decrease the number of emergency room visits made by children who had experienced barriers to care. Another involved using formulary decision support to identify prescription drug savings for insurers and patients.

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8. Evaluation and Feedback

Clinicians and other providers need timely and actionable feedback in order to improve. Similarly, new innovations in delivery and payment need robust and rapid evaluation to support potential widespread implementation. One example of this can be found in patient safety organizations (PSOs). PSOs were created to provide feedback to health care organizations, on a voluntary basis, to improve patient safety and quality of care. These private organizations have expertise in identifying and analyzing confidential data reported to them by hospitals and physicians. They then provide feedback on ways to reduce or eliminate risks. Another example of useful feedback is the information provided to clinicians as part of their professional certification. Health plans also provide feedback to their contracted providers to identify gaps in care.

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9. Training, Professional Certification, and Workforce and Capacity Development

To achieve the aims and goals of the National Quality Strategy, health care professionals should be encouraged to maximize their training and skills through life-long learning that includes the application of quality improvement principles and patient safety systems concepts such as teamwork. At the same time, there is a need for a new generation of health care professionals. The Affordable Care Act provides $1.5 billion over 5 years to expand the National Health Service Corps (NHSC). This follows a $300 million investment that the American Recovery and Reinvestment Act of 2009 made in the program. As of September 30, 2010, the NHSC is a network of 7,500 primary health care professionals and 10,000 sites in underserved communities across the country providing valuable services to persons who would otherwise lack access to primary care. To support their service, the NHSC provides physicians, nurse practitioners, physician assistants, and other health professionals with financial support in the form of loan repayment and scholarships. The Health Resources and Services Administration's National Center for Health Workforce Analysis is working to identify workforce shortages and advise where resources might be best placed. At the same time, boards of medicine, nursing, and other providers enhance the quality of care that patients receive by requiring that practitioners continually demonstrate skills and

knowledge critical to their field. Promisingly, board policies are increasingly promoting a lifelong commitment to learning and the adoption of new evidence-based practices. Certification programs can also serve as a valuable tool for consumers to use as they choose a health care provider.

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10. Promoting Innovation and Rapid-Cycle Learning

Thanks to innovations in care, collaboration, and communication our health care system has made major strides in the detection and treatment of diseases and care delivery. But too often, these improved models are not known outside of the organization that created them. The Center for Medicare and Medicaid Innovation is part of a broad array of public and private sector efforts seeking to fix that problem. The Innovation Center is supporting new models of care and innovative practices for Medicare, Medicaid, and CHIP beneficiaries, with the goal, for example, of improving transitions from various health settings within a patient's community.

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Section IV. Next Steps

The National Quality Strategy is designed to adapt with the evolving health needs of the Nation. It is a broad roadmap that will require the ongoing development of specific goals and agreed-upon metrics. It will depend on initiatives launched through a public and private sector collaboration that builds on the successes already under way and respects the needs and priorities of local communities. This approach reflects the direction and support provided to the Secretary by the Affordable Care Act.

The National Quality Strategy will be shaped by recommendations and feedback from the private sector and with State engagement. Consumers, hospitals, clinicians, insurers, businesses, drug and device manufacturers, representatives of the health information technology industry, and other key stakeholders will be engaged to participate in improvement initiatives, identify the practical impact of public and private sector policies to improve quality, and guide public and private sector policymakers to expand or modify those policies as needed.

From the perspective of the Federal government, the National Quality Strategy will serve as a guide for HHS agencies as they develop programs, regulations, and new initiatives, as well as a vital tool in evaluating the full range of Federal health care efforts.

The Affordable Care Act calls on the National Quality Strategy to include HHS agency-specific plans, goals, benchmarks, and standardized quality metrics where available. By design, this first-year Strategy does not include these elements, in order to allow them to be developed with additional collaboration and engagement of the participating agencies along with private sector consultation. We believe nation-wide support and subsequent impact is optimized when those needed to implement strategic plans participate fully in their development. We have begun implementation planning across HHS and have established a mechanism to obtain additional private sector input on specific goals, benchmarks, and quality metrics in 2011. The Agency for Healthcare Research and Quality is tasked with supporting and coordinating the implementation planning and further development and updating of the Strategy.

In addition, a Federal Interagency Working Group on Health Care Quality will begin working in 2011. It will be composed of senior-level members of Federal departments and agencies with jurisdiction over

health care quality and quality improvement. Their mission will be to collaborate, cooperate, and consult with departments and agencies that develop and disseminate the strategies, goals, models, and timetables that will advance the national priorities outlined in the National Quality Strategy. The main goals of this effort are to avoid duplication of efforts, assure accountability, and, where possible, develop a streamlined approach for quality reporting.

The National Quality Strategy will continue to be refined based on public and private sector experiences, best practices, research findings, and emerging health needs. Updates on the Strategy and the nation's progress in meeting the three aims of better care, improved health, and making care more affordable for all Americans will be reported annually to Congress and the public.

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APPENDIX: National Quality Strategy Priorities and Goals, With Illustrative Measures

The goals and illustrative measures described here are designed to begin a dialogue that will continue throughout 2011. The next version of the National Quality Strategy will reflect specific measures and include short-term and long-term goals. HHS will promote effective measurement while minimizing the burden of data collection by aligning measures across its programs, coordinating measurement with the private sector and developing a plan to integrate reporting on quality measures with the reporting requirements for meaningful use of electronic health records. All measures will be specifically assessed with the goal of making sure they can be included in electronic collection systems.

Appendix Table: National Quality Strategy Priorities and Goals, With Illustrative Measures

Priority	Initial Goals, Opportunities for Success, and Illustrative Measures
#1 Safer Care	**Goal:** Eliminate preventable health care-acquired conditions **Opportunities for success:** • Eliminate hospital-acquired infections • Reduce the number of serious adverse medication events **Illustrative measures:** • Standardized infection ratio for central line-associated blood stream infection as reported by CDC's National Healthcare Safety Network • Incidence of serious adverse medication events
#2 Effective Care Coordination	**Goal:** Create a delivery system that is less fragmented and more coordinated, where handoffs are clear, and patients and clinicians have the information they need to optimize the patient-clinician partnership **Opportunities for success:** • Reduce preventable hospital admissions and readmissions

	• Prevent and manage chronic illness and disability • Ensure secure information exchange to facilitate efficient care delivery **Illustrative measures:** • All-cause readmissions within 30 days of discharge • Percentage of providers who provide a summary record of care for transitions and referrals
#3 Person- and Family-Centered Care	**Goal:** Build a system that has the capacity to capture and act on patient-reported information, including preferences, desired outcomes, and experiences with health care **Opportunities for success:** • Integrate patient feedback on preferences, functional outcomes, and experiences of care into all care settings and care delivery • Increase use of EHRs that capture the voice of the patient by integrating patient-generated data in EHRs • Routinely measure patient engagement and self-management, shared decision-making, and patient-reported outcomes **Illustrative measures:** • Percentage of patients asked for feedback
#4 Prevention and Treatment of Leading Causes of Mortality	**Goal:** Prevent and reduce the harm caused by cardiovascular disease **Opportunities for success:** • Increase blood pressure control in adults • Reduce high cholesterol levels in adults • Increase the use of aspirin to prevent cardiovascular disease • Decrease smoking among adults and adolescents **Illustrative measures:** • Percentage of patients ages 18 years and older with ischemic vascular disease whose most recent blood pressure during the measurement year is <140/90 mm Hg • Percentage of patients with ischemic vascular disease whose most recent low-density cholesterol is <100 • Percentage of patients with ischemic vascular disease who have documentation of use of aspirin or other antithrombotic during the 12-month measurement period • Percentage of patients who received evidence-based smoking cessation services (e.g., medications)
#5 Supporting Better Health in	**Goal:** Support every U.S. community as it pursues its local health priorities

Communities	**Opportunities for success:** • Increase the provision of clinical preventive services for children and adults • Increase the adoption of evidence-based interventions to improve health **Illustrative measures:** • Percentage of children and adults screened for depression and receiving a documented follow-up plan • Percentage of adults screened for risky alcohol use and if positive, received brief counseling • Percentage of children and adults who use the oral health care system each year • Proportion of U.S. population served by community water systems with optimally fluoridated water
#6 **Making Care More Affordable**	**Goal:** Identify and apply measures that can serve as effective indicators of progress in reducing costs **Opportunities for success:** • Build cost and resource use measurement into payment reforms • Establish common measures to assess the cost impacts of new programs and payment systems • Reduce amount of health care spending that goes to administrative burden • Make costs and quality more transparent to consumers **Illustrative measures:** • To be developed

U.S. Department of
Health and Human Services
March 2011