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PETITION TO THE NORTH CAROLINA STATE HEALTH COORDINATING COUNCIL REGARDING STATE MEDICAL FACILITIES PLAN POLICY AC-3

Novant Health, Inc. (Novant) hereby petitions the North Carolina State Health Coordinating Council (SHCC) to repeal or revise State Medical Facilities Plan (SMFP) Policy AC-3 in the 2012 SMFP (hereafter referred to as Policy AC-3).

This Petition was originally filed on August 2, 2010 (the 2010 Petition). The Staff of the Medical Facilities Planning Section recommended, and the SHCC agreed, that the 2010 Petition was filed untimely because it addressed an issue that has a statewide effect. Novant was invited to re-submit its Petition in 2011. This Petition incorporates information from the 2010 Petition and also presents updated information.

EXECUTIVE SUMMARY

There are four academic medical centers (AMCs) in North Carolina: North Carolina Baptist Hospital, Duke University Medical Center, University of North Carolina Hospitals at Chapel Hill and Pitt County Memorial Hospital. Policy AC-3 exempts the four AMCs from the need determinations in the SMFP, provided the AMCs meet certain conditions.

There are significant legal and health policy issues associated with Policy AC-3 as it is presently written. While eliminating all aspects of this Policy would be the surest way of protecting North Carolinians from unnecessary duplication of health services that drive up health care costs, Novant recognizes that AMCs may have some unique needs that merit special consideration in the health planning process. For that reason, Novant has proposed a list of proposed modifications to Policy AC-3 in the event the SHCC is not inclined to

eliminate this policy entirely. These modifications will bridge the gap between the legal and policy problems associated with Policy AC-3 and the AMCs' legitimate needs. Following is a summary of the legal and health policy problems associated with Policy AC-3:

1. **Policy AC-3 violates the CON Law:** From a legal perspective, there is an irreconcilable conflict between Policy AC-3, which creates an exemption from the need determinations in the SMFP for four providers, and the Certificate of Need (CON) Law, N.C. Gen. Stat. § 131E-175 *et seq.*, which makes the need determinations in the SMFP binding on *all* providers. Novant has filed a Declaratory Ruling Request with the Department asking it to declare that Policy AC-3 in the 2011 SMFP is invalid.[1]

2. **Policy AC-3 conflicts with North Carolina's Health Policy:** North Carolina's stated health policy is to limit the development of health care services to those that are actually needed. *See* N.C. Gen. Stat. § 131E-175(4), (6), (7). North Carolina has therefore chosen a careful and deliberate health planning process. The purpose of the health planning process is to control cost, ensure access for all North Carolinians and avoid unnecessary duplication of services. *See* N.C. Gen. Stat. § 131E-175. The CON Law and the need determinations in SMFP are the bedrock of the health planning process in North Carolina. Novant strongly supports the work that the SHCC and the Medical Facilities Planning staff do every year in developing the SMFP, and believes that the need determinations reflect the additional facilities and services that are needed in North Carolina. Policy AC-3 undermines North

[1]Novant does not intend to reargue the Declaratory Ruling Request in this Petition. This Petition focuses on the health policy problems associated with Policy AC-3, and how those problems can be solved by adopting the modifications suggested in this Petition.

Carolina's health policy and its health planning process by allowing the four AMCs to avoid the need determinations in the SMFP and develop services even when the SMFP expressly states that there is no need for these services, and even when the services at issue are routinely provided by non-AMCs. Of all the States with health planning processes, only North Carolina gives a special exemption for AMCs.

3. **Policy AC-3 has outlived its useful life:** Policy AC-3 was first enacted (under a different title) in the 1983 SMFP, at a time when AMCs offered services far different from those offered by tertiary hospitals in the community. Given the vast changes that have occurred in health care since 1983, it is appropriate for the SHCC to consider whether it is still necessary, almost thirty years later, to "protect" AMCs and exempt them from the need determinations in the Plan.

4. **Policy AC-3 has been abused:** Rather than meeting the legitimate needs of AMCs, Policy AC-3 can be used, and has been used as a vehicle to thwart health planning and give an unfair competitive advantage to AMCs. As discussed below, North Carolina Baptist Hospital (NCBH) filed an AC-3 application in 2010 proposing to add seven new operating rooms in Forsyth County, when there is a surplus of 5.52 operating rooms in that county, and all adjacent counties in the area likewise show a surplus of operating rooms. Additionally, in 2009, NCBH's associated medical school, Wake Forest University Health Sciences, acquired three severely underutilized operating rooms at Plastic Surgery Center of North Carolina. The NCBH Policy AC-3 application gives no consideration as to how those operating rooms might have been used to meet NCBH's purported needs. The proposed ASC will perform garden variety ambulatory procedures like cataracts removal and

tonsillectomies. There was no clear "academic" reason for this project. The decision on that CON application, which has been appealed, shows that the CON Section did not properly apply Policy AC-3, and has therefore not only allowed NCBH to increase the surplus of operating rooms, but also allowed NCBH and WFUHS to hold on to three severely underutilized operating rooms for other purposes.[2]

5. **Policy AC-3 is not in the public interest:** North Carolina's health policy is to limit the development of additional health care facilities and services to only those that are actually needed. North Carolina has determined that allowing providers to unnecessarily duplicate existing services drives up cost and ultimately harms the public welfare. For this reason, need determinations are placed in the SMFP to regulate the addition of new health care facilities and services. Policy AC-3, which allows AMCs to avoid these need determinations, is directly contrary to the public interest.

6. **Policy AC-3 gives AMCs an unfair advantage:** By allowing the AMCs to avoid the need determinations in the SMFP, Policy AC-3 allows four providers in this state to propose facilities and services that their non-AMC competitors cannot propose, unless and until a need determination appears in the SMFP. This gives the AMCs a tremendous competitive advantage over their non-AMC competitors.

As noted above, Novant recognizes that there may be limited and legitimate circumstances that may prompt an AMC to seek to add services or facilities for which the

[2]Four months after the Agency decided the AC-3 application, NCBH's affiliate, Wake Forest Ambulatory Ventures, LLC, filed a CON application proposing to move the PSCNC operating rooms to an outpatient site in Clemmons.

SMFP does not contain a need, such as a demand from a graduate medical education accreditation body or a desire to acquire esoteric technology that is used mainly in the academic setting.

Novant has therefore proposed in this Petition several modifications to current Policy AC-3 that would make it more consistent with North Carolina's health policy and planning process, while also accommodating the AMCs' unique situations. Under Novant's proposal, there would be no more AC-3 exemptions from the need determinations in the SMFP. Rather, a special needs petition would be filed by the AMC, and if approved, a special need determination would be placed in the SMFP, similar to what has been done recently with regard to linear accelerator and operating room demonstration projects. Novant's recommendations are as follows:

1. AMCs that wish to add services, facilities or equipment to accommodate the expansion of faculty, students or residents, teaching or research activities, or requirements of specialty education accrediting bodies must first file a special needs petition with the SHCC. This would apply to the range of assets (beds, operating rooms, equipment, etc.) limited by the SMFP. The special needs petition shall utilize the factors contained in current Policy AC-3, as herein modified. Special emphasis must be placed on why existing non-AMCs that are within 20 miles of the AMC that offer the service the AMC proposes to offer cannot effectively meet the proposed need. For example, if an AMC proposes to add operating rooms when there is no need in the SMFP for operating rooms, it must demonstrate clearly and convincingly why other non-AMCs that have operating rooms within 20 miles of the AMC cannot meet this need. Requiring

the AMC to file a special needs petition harmonizes the Policy AC-3 process with the CON Law (and in particular, Criterion 1 of the CON Law, N.C Gen. Stat. § 131E-183(a)(1), which says that the need determinations in the SMFP are determinative). At the present time, Policy AC-3 applications ignore the need determinations in the SMFP, and for that reason, the present Policy AC-3 process violates the CON Law. It is not unduly burdensome for AMCs to file petitions. Most Policy AC-3 applications are filed because an AMC voluntarily decides to do something, not because of exigent circumstances. Moreover, one AMC, Pitt, successfully used the petitioning process in 2007 to satisfy its need for additional operating rooms.

2. AMCs seeking to add beds, operating rooms or equipment when the then-current SMFP shows a surplus of these assets in the county where the assets are proposed to be located, or in any county within twenty miles of where these assets are proposed to be located, must demonstrate by clear and convincing evidence in the special needs petition why the SHCC should permit an increase in the inventory of these assets and why the proposed increase does not conflict with the CON Law.

3. If the special needs petition is granted, the need shall be placed in the next year's SMFP, and anyone may apply to meet the need.

4. AMCs who are approved for these special needs projects (hereafter referred to as Academic Projects) must report all Academic Project assets (beds, operating rooms and equipment) on the appropriate annual license renewal application or registration form for the asset. The information to be reported for the Academic

Project assets should include: (1) inventory or number of units of Academic Project CON approved beds, operating rooms or equipment; (2) the annual volume of days, cases or procedures performed for the reporting year on the Academic Project approved asset; and (3) the patient origin by county. This would allow providers who are not AMCs to keep better track of the Academic Project assets that compete with them. It would also provide a more complete picture of the total CON-approved assets available to serve patients in North Carolina, and may also be useful in determining future health care needs in North Carolina.

5. All Academic Project CON applications must contain written statements from all providers of comparable services in the 20 mile radius of the AMC indicating they cannot meet the need described in the Academic Project CON application.

6. An AMC that is awarded a CON pursuant to an Academic Project application must submit annual reports to the Medical Facilities Planning Section and the CON Section for each of the first five operating years of the project that shall include:

a. the number of persons treated by the new institutional health service for which the Academic Project CON was approved;

b. the number of insured, underinsured and uninsured patients served by type of payment categories;

c. a detailed description of how the new institutional health service is operating in compliance with the representations the applicant made in its application;

d. a detailed description of how the new institutional health service promoted the three basic principles of the SMFP: safety and quality, access and value;

e. a detailed description of how the new institutional health service complemented a specified and approved expansion of the number or types of students, residents or faculty; or

f. a detailed description of how the new institutional health service accommodated 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

g. a detailed description of how the new institutional health service accommodated changes in requirements of specialty education accrediting bodies, as evidenced by copies of documents issued by such bodies.

These reporting requirements, which are modeled after the rules that were adopted for the 2009 linear accelerator demonstration project, for development of a multidisciplinary prostate health center, and the 2010 single specialty ambulatory surgery center demonstration projects, serve two purposes: (1) the Medical Facilities Planning Section receives data that can be used for further study and analysis; and (2) the CON Section receives information so that it can determine whether the applicant is in material compliance with the representations made in its application. Presently, there is no way to verify whether Policy AC-3 assets are actually being used for teaching or research, or have directly furthered the AMC's academic mission, as opposed to its competitive interests, because the CON progress report forms do not capture this information. Given the considerable economic benefits associated with the CON approvals that may flow from these special need petitions, this should not be viewed as unduly burdensome to the AMCs.

7. Special rules should also be adopted by the Department for the review of Academic Project applications which are designed to ask specific questions concerning how the project accommodates the purported teaching and research

need or the requirement of the specialty education accrediting bodies. The NCBH AC-3 application, discussed later in this document, shows that the CON Section does not always rigorously apply the Policy AC-3 requirements and that further guidance in the form of rules is needed. Novant realizes the SHCC does not implement CON regulations, but this factor is on the list of modifications so that a complete picture is presented concerning how the Policy AC-3 regime could be overhauled to ensure that the stated purpose of the CON Law is being met.

Identification of Petitioner

Novant is a non-profit corporation that operates the following hospitals in North Carolina: Forsyth Medical Center, Medical Park Hospital, Thomasville Medical Center, The Presbyterian Hospital, Presbyterian Hospital Huntersville, Presbyterian Hospital Matthews, Presbyterian Orthopaedic Hospital, Rowan Regional Medical Center, Brunswick Community Hospital and Franklin Regional Medical Center. In March 2011, Novant will open Kernersville Medical Center, a 50-bed community hospital in Kernersville. In the summer of 2011, Novant will open Brunswick Novant Medical Center to replace the existing Brunswick Community Hospital. Two of Novant's hospitals, Forsyth Medical Center and The Presbyterian Hospital, are full-service, tertiary hospitals that offer many of the same services that are found in the state's four AMCs: Duke University Medical Center, North Carolina Baptist Hospital, UNC Hospitals, and Pitt County Memorial Hospital.

Novant may be contacted about this Petition through its counsel, at the following addresses:

Denise M. Gunter
Nelson Mullins Riley & Scarborough LLP
380 Knollwood Street
Suite 530
Winston-Salem, NC 27103
(336) 774-3322
denise.gunter@nelsonmullins.com

POLICY AC-3: EXEMPTION FROM PLAN PROVISIONS FOR CERTAIN ACADEMIC MEDICAL CENTER TEACHING HOSPITAL PROJECTS[3]

Policy AC-3 provides in pertinent part:

> *Exemption from the provisions of need determinations of the North Carolina State Medical Facilities Plan shall be granted to projects submitted by Academic Medical Center Teaching Hospitals designated prior to January 1, 1990 provided the projects comply with one of the following conditions:*
>
> 1. *Necessary to complement a specified and approved expansion of the number or types of students, residents or faculty, as certified by the head of the relevant associated professional school; or*
>
> 2. *Necessary to accommodate patients, staff or equipment for a specified and approved expansion of research activities, as certified by the head of the entity sponsoring the research; or*
>
> 3. *Necessary to accommodate changes in requirements of specialty education accrediting bodies, as evidenced by copies of documents issued by such bodies.*

[3] *See* 2011 SMFP, Chapter 4, at pages 22-23.

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

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

In the State of North Carolina, only four facilities are permitted to use Policy AC-3: Duke University Medical Center, Pitt County Memorial Hospital, UNC Hospitals and North Carolina Baptist Hospital (collectively referred to in this Petition as the AMCs). The State of North Carolina is the only State in the country with a health planning process that gives AMCs an exemption from the health planning process.

As the plain language of the policy shows, these four hospitals receive a substantial benefit not available to any other healthcare provider in North Carolina because they are the only ones allowed to deviate from the need determinations in the SMFP. Simply because of their AMC status, they can apply to add services even where the SMFP expressly states that there is no need for additional services and even when the services in question are routinely provided by non-AMCs. This benefit extends to all kinds of SMFP-limited services such as beds (acute beds, ICU beds, psychiatric beds, rehabilitation beds, SNF beds, adult care home beds and hospice beds), operating rooms and medical equipment (such as PET scanners, MRI scanners, linear accelerators and cardiac catheterization units) regardless of capital cost. Thus, all the work that the SHCC does in developing the need determinations in the SMFP,

which is in turn presented to the Governor for her signature, is undone on an ad-hoc, case-by-case basis via Policy AC-3. As explained below, North Carolina's health policy does not support this unpredictable deviation from the health planning process.

Reasons for Proposed Adjustment

I. POLICY AC-3 CONFLICTS WITH NORTH CAROLINA'S HEALTH POLICY.[4]

A. The CON Law Clearly Articulates North Carolina's Health Policy.

The findings of fact in the CON Law, N.C. Gen. Stat. § 131E-175, clearly set forth North Carolina's health policy.

> (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 care 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 as patients, health insurance subscribers, health plan contributors, and taxpayers.
>
> (7) That the general welfare and protection of lives, health, and property of the people of this State require that new institutional health services to be offered within this State be subject to review and evaluation as to need, cost of service, accessibility to services, quality of care, feasibility, and other criteria as determined by provisions of this Article or by the North Carolina Department of Health and Human Services pursuant to provisions of this Article prior to such services being offered or developed in order that only appropriate and needed institutional health services are made available in the area to be served.

N.C. Gen. Stat. § 131E-175(4), (6), (7).

[4]In response to the 2010 Petition, the AMCs argued that N.C. Gen. Stat. § 131E-183(b) provides evidence that Policy AC-3 is consistent with North Carolina's health planning process. They are wrong. N.C. Gen. Stat. § 131E-183(b) has nothing to do with Policy AC-3. It only says that the Department cannot adopt rules requiring an AMC to demonstrate that any facility or service at another hospital is being appropriately utilized in order for the AMC to be approved for a CON. Neither Policy AC-3, the SMFP nor the CON Law is a rule.

These findings make crystal clear the Legislature's concern over the development of costly, unneeded facilities. To ensure that only those services that are actually needed are developed, North Carolina adheres to a rigorous health planning process, which requires the development of an annual SMFP. *See* N.C. Gen. Stat. § 131E-177(4). The SMFP is subject to multiple public hearings, ensuring that all who have an interest in the topic have the opportunity to express their views about the additional health care services and facilities needed in North Carolina.

To determine which new institutional health services are actually needed, the SHCC and the Staff of the Medical Facilities Planning Section of DHSR spend countless hours each year developing the SMFP. Based on a thorough analysis of data and input from providers, the SMFP sets forth the need for new beds, operating rooms and certain types of medical equipment such as PET scanners, MRI units, linear accelerators, and cardiac catheterization units. The general rule is that a provider who files a CON application proposing to develop an SMFP-limited service cannot be approved *unless* there is a need for the service explicitly specified in the annual SMFP. *See, e.g.*, N.C. Gen. Stat. § 131E-183(a)(1)("The proposed project shall be consistent with applicable policies and need determinations in the State Medical Facilities Plan, the 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 office that may be approved.").

Policy AC-3 turns North Carolina's careful health planning process upside down and inside out. For example, in a county where there is a significant surplus of SMFP-regulated assets such as beds and operating rooms, and zero need in the SMFP for more of these assets,

an AMC can propose to spend millions of dollars adding more of these assets simply by having the Dean of its associated medical school sign a letter.

Thus, at the present time, there are two sets of health planning "rules" in North Carolina: one for the AMCs, and another set for everyone else. The AMCs may propose to add whatever they want, but all other providers remain subject to the SMFP. Yet the CON Law makes it clear there is only one set of rules, and everyone must abide by them. The CON Law does not allow anyone to "opt out" of the need determinations and invent their own need.

Therefore, Novant's recommendations for modification to Policy AC-3 attempt to harmonize the AMCs' legitimate teaching and research needs with the health policy mandate in the CON Law.[5]

B. Policy AC-3 Has Outlived Its Useful Life.

The origins of Policy AC-3 can be traced back to the 1983 SMFP and Policy B.5.:

> A hospital that has been designated an Academic Medical Center Teaching Hospital may receive a special exemption from the State Medical Facilities Plan, if justified. Requests for additional resources made by a formally designated Academic Medical Center Teaching Hospital which are subject to Certificate of Need review will be evaluated in the context of the overall requirements of the academic medical center and in the context of the special characteristics which distinguish the academic medical center teaching hospital from other acute care facilities.

See Exhibit A.

Since 1983, only the four AMCs have been designated as academic medical center teaching hospitals and therefore only these four AMCs have received this "special exemption" from the SMFP. With some wording and numbering changes,

[5]As noted above, North Carolina is the only state in the country that has this bifurcated approach to health planning.

Policy AC-3 and its predecessors have been in existence for twenty-eight years. As explained below, the evidence suggests that the policy has become outmoded.

In 1983, when the "special exemption" for AMCs was born, healthcare was obviously radically different from what we know today. Technology and pharmaceuticals (including medicines, contrast agents and chemotherapy mixtures), healthcare delivery systems, payment mechanisms and competition have all evolved dramatically over the last twenty-eight years.

For example, in the early 1980s, more care was provided in the hospital instead of in an outpatient setting. The AMCs were normally the first facilities to obtain the latest medical technology (*e.g.*, MRI scanners) and the first ones to perform medically-complex procedures such as open heart surgery. Over time, those circumstances have changed. Much more care is provided on an outpatient basis As shown in recent equipment and asset inventories included in the annual SMFPs, the "service gap" between AMCs and non-AMCs is much smaller today than it was in 1983. Many non-AMCs in this State provide open heart surgery and own technology such as MRI scanners, cardiac catheterization units, linear accelerators, PET scanners, and robotic surgical devices. Physicians own MRI scanners, CT scanners and ASCs. Services such as PET and MRI are provided on a mobile basis to a variety of host sites, such as hospitals, physician offices, and diagnostic centers. Cardiac catheterization services are also offered at outpatient sites and at a variety of smaller or rural hospitals to improve local access to this important diagnostic service. Lithotripsy, which was once believed to be the province of AMCs, is routinely performed in mobile lithotripters.

Geographically, healthcare services have become much more widely distributed throughout North Carolina. For example, a patient is no longer required to travel to a major metropolitan area for radiation therapy, as many smaller communities in North Carolina now have linear accelerators. *See* Exhibit B (Table 9E of the 2011 SMFP). This benefits cancer patients and their families by allowing them to seek care closer to home. Through SMFP Policy Gen-3, healthcare providers are also required to demonstrate that their services are economically accessible as well. While the future of health care reform is unknown, no one doubts that further changes in health care delivery will happen.

AMCs have also changed over time. While AMCs may have once been perceived as devoted solely to teaching and research and the treatment of the most complex cases, this is no longer the case. AMCs compete directly with non-AMCs (and this includes tertiary hospitals, community hospitals, ASCs, physician offices and diagnostic centers) for all kinds of patients. The NCBH AC-3 application discussed in this petition is a prime example of this phenomenon: NCBH is proposing to add seven new operating rooms to perform low-intensity procedures like tonsillectomies and cataracts removal. These procedures are done routinely in non-academic settings.

In the Triangle market of North Carolina, two AMCs, Duke University Medical Center and UNC Hospitals, compete vigorously not only with each other, but also with non-AMC providers such as WakeMed Hospitals, and imaging centers, and surgery centers owned by non-AMC providers and physicians. UNC Hospitals has recently been approved for a new imaging center in Orange County, as well as a new community hospital in Orange County. Duke has executed its competitive moves in the Triangle market by operating two community

hospitals, Durham Regional Medical Center in Durham and Duke Raleigh Hospital in north Raleigh, among other projects.

Comparing a hospital like Forsyth Medical Center with an AMC such as North Carolina Baptist Hospital (NCBH) is especially revealing, as it shows that the "service gap" at that level is indeed very small. Forsyth Medical Center, which is just three miles away from NCBH, provides nearly every service that NCBH provides.[6] The two hospitals have large, multi-county service areas and compete vigorously for patients. Forsyth and NCBH both have large and growing medical staffs. Both hospitals have large cancer programs. Both offer open heart and cardiac catheterization services. Forsyth provides one of the state's largest Neonatal Intensive Care programs. Forsyth also serves as a teaching site for many of NCBH's residency programs.[7] In fact, the vast majority of NCBH's OB/GYN residency program is conducted at Forsyth. According to the time period covered by the 2011 SMFP, Forsyth and its affiliates in Forsyth County provided significantly more acute days of care, outpatient surgeries, adult open heart surgeries, radiation oncology treatments, MRI scans, PET scans and cardiac catheterizations than did NCBH. Yet Forsyth *always* remains subject to the need determinations in the SMFP while NCBH does not.

While it is true that the case mix index (CMI) of the AMCs is higher than the CMI of the tertiary hospitals, the case mix differential does not, standing alone, justify treating AMCs differently from other providers. In fact, Policy AC-3 does not discuss CMI at all. If higher CMI alone were relevant, then Presbyterian Orthopaedic Hospital (POH), which has a

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[6]The major difference is that Forsyth does not have a trauma center designation and Forsyth does not provide burn intensive care services, gamma knife treatments, and transplant services. Due to the evolution of linear accelerator technology, FMC's cancer center does offer stereotactic radiotherapies on one of its linear accelerators.

[7]Other tertiary, non-AMC hospitals in North Carolina such as Carolinas Medical Center, Mission, New Hanover and Moses Cone, have residency programs.

significantly higher CMI than Duke, UNC, Pitt and NCBH, should be singled out for special treatment in the SMFP.[8] Yet POH does not receive special treatment in the SMFP because of its high CMI.

Given all of the changes in healthcare since the 1980s, given that the distinctions between certain tertiary hospitals and AMCs are becoming less apparent, and given that sophisticated health care services are increasingly available throughout North Carolina, it is appropriate to question whether a policy designed specifically for AMCs in 1983 needs to remain in the SMFP twenty-nine years later in 2012. It is also appropriate to ask why North Carolina is the only state in the country with a health planning process that "protects" its AMCs in this fashion. And from what exactly are the AMCs being "protected?"

Possibly the best evidence that Policy AC-3 has outlived its useful life is the fact that AMCs do not regularly use Policy AC-3 for their CON applications. In 2010, more than one hundred CON applications were filed; of these, only four were noted on the CON Monthly Reports as Policy AC-3 applications.

The hallmarks of an AMC are teaching and research. *See* page 22 of the 2011 SMFP. If Policy AC-3 were so important for teaching and research, one would expect to see many more AC-3 applications filed so that the AMCs could fulfill their teaching and research missions. The paucity of Policy AC-3 applications suggests that the AMCs are able to satisfy their teaching and research missions in other ways, such as through the need determinations in the SMFP, as well as the annual petitioning process to add need determinations – a process that

[8]According to Solucient data for CY 2009, Presbyterian Orthopaedic Hospital's weighted CMI is 2.3038. Duke's weighted average CMI was 1.8988 with normal newborns and 1.9934 without. UNC's weighted average CMI was 1.5924 with normal newborns and 1.7043 without. Pitt's weighted average CMI was 1.6838 with normal newborns and 1.7912 without. NCBH's weighted average CMI was 1.8424 with normal newborns and 1.8432 without.

is open to everyone, including the AMCs. In fact, Pitt used the petitioning process in 2007 to propose new operating rooms in 2008. *See* Exhibit C. Pitt's actions show how the health planning process can work effectively, even for AMCs. Instead of deviating from the health planning process by using Policy AC-3, Pitt adhered to the process, filed a petition and later a CON application and was ultimately approved. Using Pitt's example, one of Novant's recommendations includes a requirement that the AMCs file special needs petitions if they wish to propose a facility, service or equipment for which there is no need in the SMFP.

It should also be noted that N.C. Gen. Stat. § 131E-179 specifically exempts from CON review the offering of a new institutional health service to be used solely for research. N.C. Gen. Stat. § 131E-179(c) even allows the new institutional health service to be used for patient care provided on an occasional and irregular basis and not as part of the research program. For example, if an AMC needs a PET scanner for research, the AMC could seek an exemption under N.C. Gen. Stat. § 131E-179, and could even use the PET scanner for occasional patient care. Thus, elimination or modification of Policy AC-3 will not unduly hamper the research or patient care activities of the AMCs.

There is also no evidence that Policy AC-3 has actually benefitted teaching or research in any meaningful way. That is because the AMCs are not required to report how, if at all, their AC-3 projects, *as actually implemented,* benefitted teaching or research. If Policy AC-3 is allowed to remain part of the SMFP, one of the suggested modifications at the end of this petition is that the AMCs report actual results so that the SHCC can measure whether Policy AC-3 actually benefits teaching or research.

Policy AC-3 may have been appropriate in the early 1980s, but times have changed greatly. The different and special treatment afforded AMCs can no longer be justified in today's environment.

C. Policy AC-3 Has Been Abused.

The AMCs may suggest that because Policy AC-3 is used relatively infrequently, there is little potential for abuse. They are wrong. Policy AC-3 has been abused, and the potential for even greater abuse looms.

The process by which an AMC receives an exemption under Policy AC-3 is simple. The AMC needs to demonstrate conformance with one of the three conditions in Policy AC-3 and comply with the 20-Mile Provision. The easiest way for the AMC to satisfy the conditions is to obtain a letter from the Dean of its associated Medical School. The Dean of the Medical School wants the CON application approved, so he or she is acting in obvious self-interest. The CON Section will typically accept the Dean's representations at face value and will not do any investigation to determine if these representations are actually correct.

The CON application filed by NCBH for an 8-operating room ambulatory surgery center project, Project I.D. G-8460-10 (the NCBH Project)[9] illustrates just how easy it is for an AMC to abuse Policy AC-3. The NCBH Project, with an estimated capital cost of approximately $39 million, was filed in January 2010 pursuant to Policy AC-3. The CON Section issued its decision on this application on June 10, 2010 and made its decision in less than the allotted 150 days for CON application review. Seven of the eight operating rooms in the NCBH Project are new operating rooms for Forsyth County; the eighth room is a relocation of an existing operating room. In addition, NCBH's Policy AC-3 CON Application

[9]Novant has appealed the Agency's decision on the NCBH Project.

proposed two more operating rooms, with one for simulation training and one for robotics and micro-surgery training. In Forsyth County, Novant also offers robotic surgery, as does Moses Cone Hospital and High Point Regional Health System in nearby Guilford County.

The 2010 SMFP contained no need for additional operating rooms in Forsyth County; in fact, there is a surplus of 5.52 operating rooms in Forsyth County. There is also a surplus of operating rooms in each of the adjacent counties.

To satisfy the requirements of Policy AC-3 for the NCBH Project, NCBH simply provided a letter from the Dean of its affiliated medical school stating that the Project is *'necessary to complement a specified and approved expansion of the number of types of students, residents, or faculty.'* No recruitment plan for students, residents or faculty was filed with the CON application, so there was no way for the CON Section to verify the statements in the letter. Rather, the letter purported to give an estimate of surgeons that would be recruited over a 10-year time frame. No specific information was given about when the physicians would arrive over the 10-year horizon. No estimate was given concerning how many cases the surgeons would perform when and if they arrived in Winston-Salem. The CON Section accepted the letter at face value and did not question anything in it. The letter appears to have been copied over from a previously-approved Duke Policy AC-3 application.

With respect to the 20-Mile Rule, NCBH simply reported:

> *Given the combination of facilities and services required to provide the surgical services, simulation operating rooms, training facilities, equipment, and the fact that the resources are already in place at NCBH, the clinical model the Surgical Services department has developed, and the deep involvement of Wake Forest University reasearchers [sic], NCBH has concluded that expanding the campus to accommodate the outpatient surgery center on the NCBH campus would benefit our patients and their families, our clinicians, and our researchers far more than establishing the expanded OR and training capacity at another off-*

> *campus location. Since all Wake Forest University Faculty provide clinics and have their offices housed on the NCBH campus it would not make sense to relocate services off campus away from where faculty currently practice.*

See Exhibit D.

This answer does not address the specific requirement of Policy AC-3 that the AMC demonstrate that no non-AMC within 20 miles could meet the need. The answer reflects only NCBH's preference for keeping everything on its campus, which is not what the 20-Mile Rule requires. As reflected on page 4 of the Agency Findings, the Agency accepted this representation without question, even though NCBH did not answer the specific mandatory[10] requirement of Policy AC-3. *See* Exhibit E.

In comments that Novant filed against the NCBH Project, Novant pointed out not only that there are several Novant facilities with operating rooms within 20 miles of NCBH, but also stated that in 2009, NCBH's affiliate, Wake Forest University Health Sciences, had acquired Plastic Surgery Center of North Carolina, a facility in Winston-Salem with three underutilized operating rooms. *See* Exhibit F. According to the 2010 SMFP, in the time period October 1, 2007 through September 30, 2008, Plastic Surgery Center of North Carolina performed only 411 cases. The SMFP therefore classified Plastic Surgery Center as "underutilized." *See* Exhibit G. The Agency appeared not to have considered these comments because it approved the NCBH Project anyway, even though NCBH did not answer the 20-Mile Rule.

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[10]This provision of Policy AC-states, in part: "A project submitted by an Academic Medical Center Teaching Hospital under this Policy... *shall* also demonstrate that the Academic Medical Center Teaching Hospital's teaching or research need for the proposed project cannot be achieved effectively at any non-Academic Medical Center Teaching Hospital provider which currently offers the service for which the exemption is requested and which is within 20 miles of the Academic Center Teaching Hospital." (emphasis added).

According to the 2011 SMFP, Table 6A, Plastic Surgery Center of North Carolina performed significantly fewer cases (only 148) in FFY 2009 (Oct. 1, 2008 – Sept. 30, 2009) than in the prior year. The 2011 SMFP again identifies Plastic Surgery Center of North Carolina as an "underutilized facility." *See* Exhibit H. Applying the SMFP Operating Room Need Method formula and based on the FFY 2009 data, Plastic Surgery Center of North Carolina needs 0.12 operating rooms[11] and thus has a surplus of 2.88 operating rooms. The three operating rooms at Plastic Surgery Center of North Carolina were also identified as "chronically underutilized in the 2009 SMFP (page 72) and the 2008 SMFP (page 56). *See* Exhibits I and J. There is no evidence in the Agency's findings on the NCBH Project that the CON Section considered the chronic underutilization of the three operating rooms at Plastic Surgery Center of North Carolina. *See* Exhibit E. There is no explanation in the NCBH CON Application that it considered the alternative of relocating any of the Plastic Surgery Center operating rooms to the new proposed 8-operating room surgery center or otherwise using these rooms to satisfy a need. Finally, there was no discussion in the application about Novant's involvement over the last three decades training NCBH residents (including surgical residents) and medical students.

Despite these facts, NCBH was conditionally approved to develop seven new operating rooms in a county that has a surplus of 5.52 operating rooms. The 2011 SMFP, Table 6B (based on FFY 2009 data) shows that Forsyth County still has a surplus of 4.95, or almost five operating rooms. *See* Exhibit H. Had Forsyth Medical Center filed an application in 2010 proposing to develop seven new operating rooms, its application would have been summarily disapproved because it failed to comply with the SMFP. The CON Section testified that it

[11]Calculation: (148 cases X 1.5 hours per case) = 222 weighted OR case hours/1872 hours per OR per year = 0.12 ORs needed.

reviewed the NCBH application "differently" because it was a Policy AC-3 application. Yet there is nothing in the CON review criteria that allows for different treatment based on whether or not an application is filed under Policy AC-3.

The NCBH Project proposes to serve mainly patients from Forsyth County and other North Carolina counties in Health Service Area II and North Carolina counties near or adjacent to Health Service Area II. All of these counties have surplus operating rooms. At its new ASC, NCBH projects to perform only outpatient surgical procedures such as cataract surgery, arthroscopic knee surgery, tonsillectomy, ear drum openings and cystoscopy. *See* Exhibit D. These are routine outpatient surgical procedures that are performed at existing non-AMCs and ambulatory surgery centers within 20 miles of NCBH, such as Forsyth Medical Center, FMC's Hawthorne Surgery Center, and Medical Park Hospital. Furthermore, when FMC's Kernersville Medical Center, a new community hospital in eastern Forsyth County with 50 beds and 4 operating rooms opens in March, 2011, it will offer outpatient surgical procedures such as those proposed by NCBH for its new 8-operating room surgery center. There is nothing in the Policy AC-3 surgery center application to suggest that NCBH's seven new operating rooms will be used to accommodate a teaching or a research need that is unique to AMCs.

There is no need in the 2011 SMFP for additional operating rooms in Forsyth County, because there is a surplus of operating rooms in Forsyth County as discussed above. Since the physician recruitment discussed in the application was supposed to occur over a ten-year time frame, there were no exigent circumstances mandating that the NCBH application be filed in 2010. NCBH certainly could have filed a petition with the SHCC at the time it began planning for the project, just like its fellow AMC, Pitt, did in 2007. But following the "traditional"

planning process that everyone else is required to follow meant that others, including Forsyth, could have applied for those additional operating rooms. Using Policy AC-3 ensured that there would be no competition for those operating rooms.

Novant estimates that the NCBH Project could take away approximately one third to one half of Medical Park Hospital's outpatient surgical cases. Using 2009 outpatient surgical volumes for Medical Park Hospital, the estimated range of lost cases is 3,497 to 5,298 cases. The NCBH Project will also take patients away from Kernersville Medical Center. At this time, Novant estimates that the lost revenue attributable to the NCBH Project ranges from $7.8 million to $11.9 million.

The advantage that NCBH receives as a result of its AMC status is not the result of ordinary competition. Rather, Policy AC-3 has given NCBH an unfair advantage that allows NCBH to add substantial and unnecessary operating room capacity in Forsyth County solely because NCBH is an AMC.

The NCBH application is a prime example of how Policy AC-3 can be abused, but it is not the only example. Given that Policy AC-3 removes the constraints imposed by the SMFP, an AMC can propose to add beds, operating rooms, MRI scanners, PET scanners, lithotripters, dialysis units and any other SMFP-regulated assets anywhere in North Carolina at any time. Policy AC-3 does not require that the AMC seek approval for new CON assets only in the county that is home to the AMC. The probability that a Policy AC-3 CON application will be approved, either initially or in settlement, is high. As the decision on the NCBH application shows, the SHCC cannot count on the CON Section to "police" the use of Policy AC-3.

For this reason, Novant has proposed significant modifications to Policy AC-3 to ensure that the health planning process in North Carolina functions as the legislature intended.

D. Policy AC-3 Is Not In the Public Interest.

Based on the legislative intent of the CON Law as set forth in N.C. Gen. Stat. § 131E-175, our Legislature has decided that is in the public interest to specifically regulate the addition of new institutional health services, and to strictly limit the addition of certain facilities, services and equipment by imposing determinative limitations in the annual SMFP. The development of the SMFP is a public process in which all interested parties, including the AMCs, participate. Policy AC-3, which allows AMCs to bypass this public process to add facilities, services and equipment that have not been found to be needed, is directly contrary to the public interest as articulated by the Legislature.

The vast majority of AC-3 applications are filed because the AMC voluntarily decides to embark on an expansion of some kind (*e.g.*, faculty recruitment), not because an accreditation body such as the Accreditation Council for Graduate Medical Education threatened to revoke the AMC's accreditation unless it immediately added more beds, operating rooms or MRI scanners to handle teaching or research needs. There usually are not exigent circumstances associated with these applications, and the applications themselves do not usually happen overnight. As many of these projects are capital intensive, the planning process is done over a multi-month (sometimes multi-year) horizon, so the time it takes to go through the SHCC petitioning process can be factored in. That is what Pitt did in 2007 when it filed a petition to add more operating rooms in Pitt County.

Because AMCs are not required to report how much teaching and research they do with their Policy AC-3 assets, it is impossible for the Department or the SHCC to know the extent

to which Policy AC-3 is really used for teaching and research, as opposed to furthering an AMC's competitive interests.

Finally, the SHCC should not be persuaded by any suggestion that Policy AC-3 must remain intact because Policy AC-3 and its predecessors have been in place for many years. A policy cannot remain in place simply for the sake of history. As far as Novant is aware, this Petition (and its 2010 predecessor) is the first time anyone has asked the SHCC to undertake a thorough review of Policy AC-3.

E. Policy AC-3 Gives Academic Medical Centers an Unfair Advantage.

Policy AC-3 gives AMCs several unfair advantages not available to their non-AMC competitors.[12] First, Policy AC-3 allows the AMC to avoid the need determinations in the SMFP and thwart the beneficial aspects of competition.[13] Since multiple competing CON applications typically are filed for healthcare assets that are the subject of SMFP need determinations, Policy AC-3 allows AMCs to choose to avoid this type of competitive review, to the detriment of the AMCs' competitors in the service area. If an AMC wants additional beds or operating rooms, for example, it *always* has the ability to apply for them, even if the county in which the AMC is located has a significant surplus of these assets. Using Policy AC-3, an AMC could build an ASC in a county that has a surplus of operating rooms. The AMC can use its new ASC to draw patients from competitors. The competitors' option for responding to the competition created by the new ASC is limited when there is no need for additional operating rooms in the county where the AMC proposes to build the new surgery center.

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[12] In response to the 2010 Petition, Duke argued that its competitors' failure to appeal Duke's Policy AC-3 applications meant that Policy AC-3 was not problematic. Silence should not be confused with acquiescence.

[13] *See* N.C. Gen. Stat. § 131E-183(a)(18a), which pertains to the requirement that the applicant must "demonstrate the expected effects of the proposed services on competition in the proposed service area."

Second, Policy AC-3 allows "double dipping." For example, an AMC can apply for operating rooms under Policy AC-3 *and* under a need determination if a county shows a need in the SMFP for more operating rooms. Thus, the AMC has doubled its chances of getting approved. The non-AMC competitor is limited to filing an application only when there is a need determination in the SMFP for more operating rooms.

Third, Policy AC-3 creates a strategic advantage for AMCs that is not available to non-AMCs. For example, in the case of a need determination for operating rooms in a county, the AMC could apply for the operating rooms under the SMFP *and* also use Policy AC-3 to propose additional acute care beds to develop a hospital. The non-AMC would not have the ability to develop a hospital unless it already had beds and was in a position to relocate them to build a hospital.

Fourth, any health service facility or health service facility bed that results from an AC-3 CON application is not included in the inventory in the SMFP. However, the volumes generated from the AC-3 project will be counted in the SMFP. Using the ASC example above, the operating rooms themselves will not be counted in the inventory of operating rooms, but the volume of cases performed in those rooms will be counted. This makes it appear that the AMC is "doing more with less" which gives the AMC an advantage in a subsequent CON review, based on the established SMFP operating room need formulas and the performance standards in the CON OR regulations, which are applicable to all operating room CON reviews. Further, when a need is generated under the SMFP for a new institutional health service, the AMC also has the opportunity to apply in that review. Alternatively, the AMC can forego the SMFP-scheduled review and argue that its Policy AC-3

created capacity makes additional services by other providers an unnecessary duplication of existing services.

Fifth, Policy AC-3 can be used for *any* SMFP-limited service such as beds, operating rooms and linear accelerators. Policy AC-3 projects are not limited to teaching or research activities; they can be used for *anything*. For example, there is no requirement that the ASC in the above example ever be used for the training of any medical students or residents.

IV. Further Reasons for the Proposed Adjustment

A. A statement of the adverse effects on providers or consumers of health services that are likely to ensue if the change is not made.

As illustrated above, Policy AC-3 violates the CON Law. Thus, it directly and adversely affects the consumers who are supposed to benefit from CON, and the non-AMC providers who are required to abide by the CON and health planning processes. As illustrated by the NCBH Project, Policy AC-3 allows AMCs to develop new institutional health services even in cases where there is a surplus. This creation of unnecessary duplication harms providers, consumers and the health planning process, as recognized by N.C. Gen. Stat. § 131E-175(4).

B. A statement of the alternatives to the proposed change that were considered and not found feasible.

As explained in this Petition, Novant has proposed two alternatives: repealing Policy AC-3 entirely or modifying it. The modifications are suggested above, beginning on page 5. Novant does not believe that maintaining the status quo is a feasible option for the reasons explained in this Petition.

V. Evidence that the proposed change would not result in unnecessary duplication of health resources in the area.

This Petition does not request any additional health resources; rather, it is intended to prevent unnecessary duplication of services.

VI. Evidence that the requested change is consistent with the three Basic Principles governing the development of the N.C. State Medical Facilities Plan: Safety and Quality, Access and Value.

This Petition is consistent with the three basic principles governing development of the SMFP.

First, the modification of Policy AC-3 will not diminish safety and quality, and it will not harm the research activities of AMCs. As noted above, research activities are exempt from CON review under N.C. Gen. Stat. § 131E-179.

Second, modification of Policy AC-3 will not diminish geographic or economic access to healthcare. The purpose of Policy AC-3 is to promote teaching and research, not improve geographic or economic access to healthcare. There is no reason to believe that any AMC will be less able to meet the needs of those facing geographic or economic barriers to healthcare if Policy AC-3 is eliminated. If, however, an AMC believes that specific geographic and economic barriers exist such that an SMFP-limited service such as beds or operating rooms needs to be added to the SMFP, it can always petition the SHCC to add the need in the annual SMFP, and then all interested providers would be given the opportunity to comment on that petition at the SHCC and draft SMFP hearings, and later to compete to serve the need.

Third, modification of Policy AC-3 will not hamper an AMC's ability to deliver value-driven healthcare. If anything, modification of Policy AC-3 may reduce the unnecessary duplication of healthcare resources.

If the SHCC decides to modify Policy AC-3, the annual reporting requirement discussed in Novant's proposed modifications specifically requires the AMC to demonstrate that its project is consistent with the three basic principles.

Proposed Adjustment

For all of the foregoing reasons, Novant respectfully requests that the SHCC repeal or modify Policy AC-3. The list of proposed modifications is found beginning on page 5 of this Petition.

Novant appreciates the opportunity to present its views on Policy AC-3 and thanks the SHCC and Medical Facilities Planning staff in advance for their careful consideration of the information presented in this Petition.

Respectfully submitted this 2d of March, 2011.

Denise M. Gunter
Nelson Mullins Riley & Scarborough LLP
380 Knollwood Street, Suite 530
Winston-Salem, North Carolina 27103
Telephone: (336) 774-3322
Facsimile: (336) 774-3372
denise.gunter@nelsonmullins.com

EXHIBITS FOR NOVANT HEALTH, INC.'S
PETITION TO THE STATE HEALTH COORDINATING COUNCIL
REGARDING POLICY AC-3

Exhibit	Name
A	Policy B.5 from 1983 SMFP
B	Table 9E from 2011 SMFP
C	Pitt County Memorial Hospital's 2007 Operating Room Petition
D	Excerpts from NCBH Application, Project I.D. No. G-8460-10
E	Agency Findings on Project I.D. No. G-8460-10
F	Comments in Opposition to Project I.D. No. G-8460-10
G	Excerpts from 2010 SMFP
H	Excerpts from 2011 SMFP
I	Excerpts from 2009 SMFP
J	Excerpts from 2008 SMFP