NORTH CAROLINA STATE HEALTH COORDINATING COUNCIL

PETITION

FOR CHANGE IN POLICY AC-3

Petitioners 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") hereby submit this petition for modification to Policy AC-3 of the State Medical Facilities Plan.

Petitioner Identification

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Statement of the Requested Change

Petitioners propose that Policy AC-3 be amended as set forth in Exhibit A hereto.

Reasons for the Proposed Change

As set forth in greater detail below, the fundamental policy embodied by Policy AC-3 is crucial to the ongoing teaching and research missions of the state's medical schools, and by extension, the health care system in the state as a whole. However, there are modifications that would allow the Policy to better address the needs of the state going forward, to facilitate and support the education of more North Carolina physicians, and to ensure fairness to other providers in the health planning process.

I. Specific Proposed Changes

A. Refinement of the definition of those AMCs to which Policy AC-3 applies.

Currently, Policy AC-3 is limited to those academic medical center teaching hospitals ("AMCs") designated before 1990. As a practical matter, the Policy therefore applies to the four primary teaching hospitals affiliated with the state's four accredited medical schools (University of North Carolina-Chapel Hill School of Medicine, Duke University School of Medicine, Wake Forest University School of Medicine, and Brody School of Medicine at East Carolina University).

As discussed in greater depth below, however, the state needs to be prepared to train more physicians to address a foreseeable physician shortage nationwide. It is therefore likely that either a new medical school will become accredited in North Carolina, or that an existing medical school will expand to another campus in another part of the state, or both. For example, UNC has received Board of Governors' approval to develop campuses in Asheville and Charlotte. The proposed modification would therefore allow for the application of the Policy to any other designated AMC which is closely integrated with a medical school, as evidenced by common ownership or having the majority of the hospital's chiefs of service serving as the medical school clinical department chairs.¹ In addition, the Policy would apply to the sole designated teaching sites for separate campuses determined to have adequate resources by the Liaison Committee on Medical Education ("LCME"), the national accrediting organization for medical schools, where such campuses provide the entire two-year clinical education portion of a medical student's experience and therefore incorporate medical students into the full range of clinical services offered by the AMC. This would allow the Policy to be available to separate campuses that may be approved for existing medical schools, as well as to new medical schools. This change allows the Policy to accommodate and respond to a changing academic landscape.

Petitioners also propose that applicants for AMC designation petition the SHCC, rather than the Planning Section; this was the procedure followed the last time a provider sought AMC designation and would provide for public comment and hearing on the application.

¹ This standard is derived from the definition of "integrated academic medical center hospitals" used by the Association of American Medical Colleges.

B. Amendment to the Requirement Regarding the Feasibility of Pursuing a Project at an Alternative Site.

The current policy states that the applicant must demonstrate that the teaching or research needs driving the project "cannot be achieved effectively" at a non-AMC within 20 miles. The proposed alternative substitutes the words "met in a cost effective and clinically efficient manner" for the words "achieved effectively". This revision allows consideration of both the operational issues of pursuing the project at a different site as well as the cost/revenue issues that could affect the feasibility of the project.

C. Effect of Policy AC-3 Projects on the Inventory Used for Need Determinations.

The current policy states that beds and facilities developed pursuant to Policy AC-3 shall be excluded from the inventory used in the SMFP's need determinations, but it is silent as to the services provided by those beds or facilities. The current policy also does not address equipment or operating rooms, which implies that equipment or operating rooms developed pursuant to Policy AC-3 will be included in the inventory, along with the services provided.

The modifications proposed by Petitioners would exclude from the need determination all Policy AC-3 projects and the resulting services. Excluding both the projects and the resulting services eliminates the risk of any distortion of the resulting need determination.

Excluding all projects and the services they provide, rather than including all, reflects that the projects are developed separate from the need determinations. It 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, which the Plan otherwise routinely includes in the inventories. Finally, it reflects the fact that, as documented below, the AMCs

serve a much wider patient population and service area than even the largest community hospitals.

D. Reporting of Data

The proposed modification would require that certificates of need issued pursuant to the approval of a Policy AC-3 application include the condition that the applicant report each year, in an addendum to the Hospital License Renewal Application, the utilization of the facility, service, beds, operating rooms, and equipment acquired pursuant to the award of the certificate of need. This would allow careful tracking of Policy AC-3 projects.

II. Background of Policy AC-3.

As set forth below, Policy AC-3 has effectively served the needs of the state's medical schools, and by extension, the state's citizens since its inception.

A. Policy AC-3 furthers the legislative intent of the CON Law.

Policy AC-3 appropriately recognizes that the state's population may have needs for services that are not addressed in standard need determinations, which cannot take into account the research and teaching activities that are central to the state's AMCs.

The North Carolina legislature expressly recognized the unique attributes and contributions of those providers 20 years ago. North Carolina General Statutes Section 183(b) provides that the Department may not promulgate rules that would "require an academic medical center teaching hospital, <u>as defined by the State Medical Facilities Plan</u>, 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" (emphasis added). This provision was added to the existing CON Law by Session Law 1991 Ch. 692, Section 6 (ratified July 15, 1991). This

amendment documents the legislature's awareness and approval of the SMFP's long-standing policy of exempting certain AMC projects from need determinations.

This Policy, as endorsed by the legislature, reflects that the AMCs must be able to develop projects to further their academic missions, regardless of the utilization of the other facilities in their service areas.

B. The Policy reflects the unique nature of AMCs.

Policy AC-3 recognizes that while every hospital has a mission to provide clinical services to patients – that is, to meet a need quantified by the State Medical Facilities Plan in the need determinations – AMCs serve additional unique needs arising from their academic missions.

AMCs are more than simply full-service tertiary and quaternary hospitals, and the differences extend beyond a higher case mix index than non-academic hospitals.² Clinical services provide the essential context for the AMCs' clinical education and research programs. The four hospitals that serve as the primary training sites for the state's four medical schools host significant numbers of learners in all areas of clinical service:

- Duke has 403 medical students, as well as 956 trainees (residents and fellows) in 75 accredited programs and 66 non-accredited advanced specialty programs, which include 6-24 month fellowships available to practitioners wishing to return to the academic setting to ensure that their skills are current. Duke also has 147 physician assistant trainees and approximately 1800 nursing students.
- UNC has 640 medical students plus 738 additional interns, residents, and fellows, as well as learners in pharmacy, dentistry, nursing, laboratory, radiology, physical therapy, occupational therapy, and many other allied health programs.
- Brody School of Medicine has 309 medical students who are trained at Pitt. Pitt currently has 344 residents and fellows in 29 programs, and is projected to

² In FY 2009, North Carolina Hospital Association Patient Data System data demonstrates that the average case mix index for inpatient discharges at the four AMCs eligible to use Policy AC-3 was 1.7, compared to 1.23 for non-AMCs.

increase the number of residents and fellows to 372 in 31 programs effective July 1, 2011.

• Baptist is the training site for 479 Wake Forest University School of Medical students, 350 PhD students, 175 postdoctoral students and 106 PA program students, plus 494 medical residents and 120 fellows in 54 programs.

This is in addition to any educational activities that AMCs undertake as training sites for many other schools' health profession training programs. The 2010 National Resident Matching Program Main Residency Match demonstrates the distinction between these AMCs and other hospitals in terms of their educational obligations: of the 649 residents matched to North Carolina, 531 were at the four AMCs currently eligible to file Policy AC-3 petitions. At AMCs, residents do not simply provide services in a few service lines; rather, learners and researchers in medicine, nursing, and the allied health professions are incorporated at every level of service, usually in every clinical department. Inserting teaching into the provision of these clinical services necessarily adds time and costs to the AMCs' operations.³

Not only are they integral to the AMCs clinical services, these teaching activities are critical to the education of the state's healthcare providers. A 2005 Sheps Center report documented that 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. See "Trends in Physician Supply in North Carolina" (Sheps Center, December 2005). For example, at last count, more than 4,397 UNC – Chapel Hill School of Medicine alumni or former residents

³ It is notable that, while Medicare and Medicaid provide some reimbursement for graduate medical education programs, such reimbursement is capped at a fixed number of trainees per institution, and training programs exceeding that cap (such as Duke, which hosts significantly more residents than its reimbursement cap of 514, and UNC, which exceeds its reimbursement cap by 63%) do not get reimbursed for the excess. Moreover, the reimbursement level per resident even within the cap does not cover the full costs of supporting those residents. AMCs must bear the costs for its additional trainees through other sources, including its regular clinical services revenue.

practice in the state of North Carolina. Similarly, 59% percent of Brody's graduates over the past 25 years practice in North Carolina, with 28% of graduates practicing in rural North Carolina. In order to continue educating health care providers for the future, North Carolina's medical schools need to remain competitive in attracting and training medical students, residents, and other trainees, and to do so, need to be able to accommodate learners' needs and support the faculty to train them.

Further, recent federal healthcare reform includes provisions to increase the number of health care professionals to address current and future workforce needs, and it authorizes new or expanded health professional training programs to expand the number of primary care professionals, nurses, public health workers, allied health, mental health and substance abuse, and dental health professionals, as well as direct care workers. As a result, State agencies as well as various schools and medical centers applied for grants from HRSA. The following is a summary of grants to increase the health professional workforce awarded to entities in North Carolina, as of November 19, 2010:

• *Primary Care Residency Expansion.* The UNC-Chapel Hill Department of Pediatrics/UNC Hospitals received a five-year grant of \$3.7 million to fund an increase of four residents per year with a focus on training general pediatricians for communities in North Carolina. In addition, New Hanover Regional Medical Center/South East AHEC received a five-year grant of \$1.8 million to fund an expansion of the family medicine residency in Wilmington from the current four residents per year to six.

• *Expansion of Physician Assistant Training.* Duke's Physician Assistant Program (PA) received a five-year grant of \$1,320,000 to expand its entering class size from the current level of 72 per class to 80 per class. A total of 34 PA students will receive financial aid as part of this grant. In addition, Methodist University Physician Assistant Program received a five-year grant of \$1,888,000 to both increase class size and to provide support to students to strengthen the likelihood they will enter primary care practice.

• Advanced Nursing Education Expansion. Duke University School of Nursing received a grant of \$1,276,000 to fund a five-year project to increase the number of Adult Nurse Practitioners and Family Nurse Practitioners.

• *Personal and Home Care Aide Training.* With this three-year \$578,745 personal and home care aide training grant, two pilot projects will be developed to train between 190-230 personal and home care aides, with 60-80 trained via allied health programs in community colleges or high schools, and another 120-150 participating in training through home care agencies and adult care homes.

• *State Health Workforce Development*. The North Carolina Commission on Workforce Development was the recipient of a one year grant of \$144,595 to increase primary care supply. The grant was submitted by the Commission on behalf of UNC's Cecil G. Sheps Center for Health Services Research. The Sheps Center will be working with a panel of experts to identify strategies the State can employ to increase the per capita primary care workforce by 10% to 25% in the next ten years.

Like teaching, research also affects all of an AMC's operations, increasing the time and costs incurred in providing clinical services. Clinical facilities are used not only for regular clinical service but also for clinical research. An example of the effect on operations can be seen in the realm of diagnostic imaging. Scans performed for clinical trials require specific protocols, and often require that patients be scanned on the same machine each time. This decreases scheduling flexibility – a patient cannot simply be scanned on the next available machine but must be scheduled on a particular piece of equipment – and it also increases the time between scans, as the equipment must be recalibrated to accommodate particular research needs.

Even when they are not responding to particular grants, moreover, AMCs also work to develop new and better diagnostic and therapeutic tools. For example, Duke has recently developed a protocol for whole body PET imaging, particularly for legs, which will decrease the time that it takes to conduct such procedures, and it is publishing its findings this month. While that protocol will eventually reduce time not only for Duke but for any hospital that wants to take advantage of Duke's research in this area, developing the protocol itself required an investment in research resources and time on Duke's clinical equipment.

As a result of these complexities, accommodating the same number of procedures often takes significantly longer than it would at a non-academic hospital, reflecting not only the higher acuity of patients and the complexity of procedures, but also the research and teaching overlay on all of an AMC's clinical activities. In FY 2010, for example, Duke's inpatient surgery cases required an average of 276 minutes (excluding cases performed at the Duke Eye Center), and Baptist's required an average of 250 minutes, compared to the state's assumed average of 180 minutes. UNC's and Pitt's inpatient case times also routinely exceed the state's assumed average of 180 minutes. Similarly, Duke must allow one hour or more per MRI procedure to ensure that it can meet the research needs that accompany the clinical services, and makes up for it by scheduling all of its regular clinical machines an average of more than 80 hours per week to accommodate the clinical demand. Similarly, Duke schedules CT scans for half-hour appointments, when such appointments might typically be completed in 15-20 minutes at hospitals or facilities without research activities.

Moreover, in many cases AMCs are the only providers of some of the most complex services in the state. North Carolina's AMCs are the only facilities that provide solid organ or bone marrow transplantation services. Similarly, the state's only burn intensive care services are offered at two AMCs and at no community hospital, and the state's only comprehensive burn center is an AMC. AMCs also often use equipment that would otherwise be regulated by the State Medical Facilities Plan for general use, but are dedicated to particular uses specific to the AMC. For example, Duke has two MRIs dedicated to heart use that are unavailable for other purposes. It was also approved to acquire an MRI dedicated to intra-operative use to meet the needs of particular neurosurgery patients. Similarly, UNC was approved to acquire a linear accelerator solely dedicated to intra-operative use to meet the needs of particular oncology patients. Baptist has an MRI and PET/CT simulator obtained through Policy AC-3 for the exclusive use of radiation oncology treatment planning and related research and education.

Activities like these are specific to AMCs, and reflect the ways in which AMCs differ from other providers.

As a result of these specialized services, AMCs also demonstrate a patient base dramatically different from even the most sophisticated non-academic facilities. The need determinations in the state medical facilities plan are based on assumed service areas for particular services, which in most cases are generally a single county – for linear accelerators, cardiac catheterization equipment, MRIs, operating rooms, and beds, for example. In practice, however, the AMCs generally serve much wider service areas.

For example, 2009 inpatient discharge data reflect the following patient origin for the four hospitals to which Policy AC-3 currently applies, as well as to other large hospitals:⁴

Hospital	Total Discharges	Home County	Outside Home County	% from Home County	% from Outside Home County
UNC	36,301	6,919	29,382	19.1%	80.9%
Duke	38,943	11,812	27,131	30.3%	69.7%
Pitt	37,445	15,198	22,247	40.6%	59.4%
Baptist	33,557	11,360	22,197	33.9%	66.1%
CMC	45,988	25,711	20,277	55.9%	44.1%
Mission	40,718	21,392	19,326	52.5%	47.5%
New Hanover	36,287	18,152	18,135	50.0%	50.0%
Forsyth	40,238	23,406	16,832	58.2%	41.8%
WakeMed	37,214	24,102	13,112	64.8%	35.2%
Moses Cone	46,581	34,298	12,283	73.6%	26.4%
Presbyterian	33,566	23,519	10,047	70.1%	29.9%
Cape Fear	32,056	24,849	7,207	77.5%	22.5%

Similarly, as reflected in its 2011 license renewal application, UNC drew only 11% of inpatient surgery patients, 15% of ambulatory surgery patients, 16% of MRI patients, 15% of

⁴ CY 2009 Patient Origin for AMCs and Large Community Hospitals, Inpatient Discharges Source: Thomson (formerly Solucient); HPM

Note: Includes Behavioral Health, Rehab; Presbyterian Hospital includes Presbyterian Orthopaedic Hospital

linear accelerator patients, 12% of positron emission tomography patients and 23% of endoscopy patients from Orange County. Baptist drew only 23.7% of inpatient surgery patients, 33.4% of ambulatory patients, 34.8% of MRI patients and 32.7% of linear accelerator patients from Forsyth County. County residents also made up less than half of surgery patients at Pitt and Duke also. The remainder came from other counties, states, and countries.

C. Other CON Procedures Do Not Fulfill The Academic Need.

Policy AC-3 is necessary for AMCs to meet the research and academic needs of the state. Other tools in the state planning process are insufficient to provide access to the types of equipment or facilities that learners need to be educated to operate, use, and interpret results therefrom.

1. Research exemption

The AMCs can, and do, pursue certain research projects under the research exemption created by N.C. Gen. Stat. Section 131E-184. However, while this research exemption reflects the legislature's understanding that some projects may be appropriate without a demonstration of clinical need, it is limited to those projects where no billable patient service is provided. Therefore, the exemption is unavailable for projects necessary to accommodate clinical education of students and residents, as opposed to research. It is also unavailable for projects where the research component is clinical research done in conjunction with reimbursed care. Nothing in Medicare or Medicaid is inconsistent with such a research overlay on patient care, and such research is critical to improving clinical services for citizens of this state. Large capital investments in clinical equipment that cannot provide reimburseable services are frequently infeasible.

2. Modification to need determinations on an annual basis

The CON process allows would-be applicants to petition for adjustments to need determinations, but they are frequently inadequate to meet academic needs. While it is possible for AMCs to seek adjustments, the process adds a full year to project development by requiring that a petition be filed to adjust the need in the following year, and therefore delays an AMC's efforts. That can make it impossible for AMCs to pursue research grants, recruit faculty, or meet accreditation standards. Second, the process requires the SHCC to assume the role of the CON Section in evaluating the need for individual projects by individual applicants, since the academic need identified would not be met by any other provider in the service area, but rather is specific to a particular academic provider.

In fact, AMCs have used this tool, and their experience demonstrates why it is not wellsuited to advance the state's medical schools. For example, Duke's Department of Radiation Oncology has an MRI scanner acquired to perform non-invasive thermometry of tumors for patients undergoing radiation therapy. Because the machine was needed for clinical service as well as for research, the research exemption was unavailable. However, the equipment was not needed for a documented "expansion" of research or of education, and Duke was not eligible to apply pursuant to Policy AC-3. Therefore, its only option was to seek an adjustment to the need determination in 1999 for the following year's SMFP (rather than filing an application in the year the need was identified). The 2000 SMFP accordingly included a need for an MRI "for use as a therapeutic device in hospitals or radiation oncology treatment centers to plan radiation oncology treatments" in Duke's service area. Not surprisingly, Duke was the only applicant for the equipment. Using the SMFP adjustment process was ultimately successful, but delayed implementation by at least one year. In many cases, delays of an additional year arising from pursuing the need determination adjustment may preclude an AMC from being eligible to pursue a research grant or from meeting faculty recruits' needs for facilities to support their work. Requiring 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.

D. History Supports the Use of Policy AC-3.

In the years since it was incorporated into the Plan, Policy AC-3 has been sparingly used. Because Policy AC-3 is available only to support the expansion of specified teaching or research purposes or to meet accreditation standards, when an AMC simply seeks to expand a clinical service, it must compete with all other providers pursuant to the standard need determinations. In fact, this is true even where the need for additional capacity is generated by the AMC's longer procedure times due to the incorporation of existing teaching and research activities, as set forth above, often putting AMCs at a disadvantage to other providers who can use their facilities more efficiently because they do not have to fulfill research and clinical missions. But Policy AC-3 is important for the very reason that it is used sparingly: it reflects a very distinct need that cannot be met by other providers.

E. Policy AC-3 applications remain subject to all CON criteria.

Criterion 1 provides that an application must conform to applicable SMFP policies or need determinations; if the need determinations are not applicable because the application is subject to Policy AC-3, then the requirements of Policy AC-3 apply. Moreover, the application must meet all other statutory criteria as well. Policy AC-3 does not, and should not, provide a free pass to AMCs. In fact, AC-3 applications are not uniformly approved. When Duke submitted a hospital expansion project for review under Policy AC-3 to support a major increase in faculty

recruitment, the CON Section approved the application on the condition that Duke could not acquire all of the equipment it proposed – despite the fact that there was no opposition to the project during the public hearing process.

Any person can participate in the public comment and hearing process, and affected persons can initiate contested case proceedings to challenge agency decisions on the application. While opposition to Policy AC-3 applications has historically been very rare, another provider that feels that an application is not needed to meet research and education requirements or otherwise does not satisfy Policy AC-3 is free to oppose the application and challenge its approval. The application and appeal process is the appropriate venue for evaluation of AMC Policy AC-3 projects. In most cases in the past, AMCs have faced no opposition from other providers to their Policy AC-3 projects. The AMCs are aware of only two recent cases in which such applications were challenged; one, for a linear accelerator at UNC, was quickly resolved and the project was able to proceed. The other, for ambulatory operating rooms at Baptist, is still underway. This latter litigation demonstrates the sufficiency of the existing legal process; a competitor believed that the application was an improper use of Policy AC-3, and is pursuing its challenge accordingly. There is full recourse to the administrative appeal process in which those issues can be addressed.

F. Changes in the health care environment make Policy AC-3 more, not less, critical.

Since the time that Policy AC-3 has been part of the state's planning process, AMCs have been in the vanguard of developing new treatments and using new technology. The research that AMC perform allows the spread of those treatments and technology to other providers. Thus, while MRIs, PET scanners, open heart surgery, and robotic surgery devices were once the purview of the AMCs, the work that AMCs did with those technologies has enabled their safe and efficient use at other hospitals as well. The work that AMCs do continues to lead the way for the diagnosis and treatment of medical conditions, including expanding transplant technology, developing gene therapy, and developing new and better tests for life-threatening illnesses. (See "American's Teaching Hospitals – Discovering Tomorrow's Cures," at <u>https://www.aamc.org/download/70246/data/thfirsts.pdf</u>.) For example, Baptist is home to the Institute for Regenerative Medicine. The Institute for Regenerative Medicine was the first in the world to successfully implant a laboratory grown organ into humans and today is working to grow more than 22 different organs and tissues. Baptist, UNC, and Duke are also the only facilities designated by the National Cancer Institute as Comprehensive Cancer Centers in North Carolina. This designation recognizes excellence in cancer research, teaching and clinical care. Through their comprehensive programs, these AMCs are able to offer innovative procedures not offered elsewhere. If AMCs cannot pursue similar activities going forward, 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.

In fact, the pace of medical research makes ensuring the competitiveness of the state's medical schools even more critical. Research grant money is limited, and medical researchers must be able to move quickly to apply for it. Qualified faculty are heavily recruited by medical schools across the country, and they require state-of-the-art facilities to support their research and teaching. Schools that are unable to provide those facilities have a more difficult time attracting and retaining the best faculty to the state.

G. The State Needs To Be Able To Address Any Physician Shortage.

Finally, the country faces a pending shortage of physicians and other health care providers that will require the potential development and/or of medical training programs to meet the needs

of tomorrow's patients. AMA President Cecil B. Wilson recently identified a potential deficiency least 125,000 physicians by 2025. (See https://www.amaof at anns.org/amednews/2011/01/10/edca0110.htm). To address this potential shortage, the American Association of Medical Colleges has proposed increasing enrollment in medical schools by 30 percent by 2015. (See June 2006 AAMC Statement on the Physician Workforce at https://www.aamc.org/download/55458/data/workforceposition.pdf.)

The state can reasonably anticipate that the state's medical schools will need to expand, and/or new medical schools may be developed, to meet those needs, and those schools will need to have access to sufficient clinical facilities to train them and support their education. The UNC Board of Governors has already approved the development of UNC-Chapel Hill based medical campuses in Charlotte and Asheville as a first step to address this issue.

III. Adverse Effects on Providers or Consumers without the Proposed Changes

Without the proposed changes, Policy AC-3 would not be as optimally designed to meet the state's needs in the future. For example, if another medical school were to be developed in the future, a change to Policy AC-3 is appropriate to allow a teaching hospital integrated with that school to pursue academic projects as necessary; without the change, it would not currently be eligible to file projects under the Policy. The proposed changes to the treatment of Policy AC-3 projects in the inventory would also minimize the effect of such projects on the need determinations applicable to all providers.

IV. Alternatives Considered and Found not Feasible

Alternatives to the proposed changes include retaining Policy AC-3 in its current form. This alternative would not support the academic mission of any new medical school or program.

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Petitioners also considered alternatives regarding eligibility to file applications pursuant to Policy AC-3. Each of these alternatives would still incorporate the existing requirement that the provider achieve designation as an AMC based on teaching, research, and clinical activities as a prerequisite to eligibility for the Policy, but would differ in other respects:

• One alternative would extend eligibility only to designated AMCs under common ownership with a medical school or having the majority of the hospital's chiefs of service serving as the medical school clinical department chairs. This standard is derived from the definition used by the Association of American Medical Colleges for "integrated academic medical center teaching hospitals," and would encompass any AMCs that have the kind of relationship with a medical school that the state's current medical schools have with their teaching hospitals (Duke and UNC are under common ownership with the schools of medicine; Baptist and Pitt have the integration of chiefs of service and chairs of medical school departments). This standard would therefore appropriately allow a provider integrated with a new medical school to demonstrate conformity with the AMC designation requirements and to become eligible to use the Policy. However, it would not necessarily extend to AMCs which are the primary teaching sites for branch medical school campuses of an existing medical school, because those AMCs might not be able to demonstrate the same level of integration with the medical school.

• Another alternative would extend eligibility to AMCs that are the sole designated primary teaching sites for LCME accredited campuses only if those campuses provide all four years of their students' medical education, rather than the two clinical rotation years. While it is possible for an existing medical school to establish a separate campus that provides all four years, it would be more cost effective not to duplicate the basic science education programs which make up the first two years of a typical medical school curriculum. And given that the Policy applies to the development of clinical facilities, it is appropriate to require the separate campus to accommodate the clinical education portion of a graduate medical education program.

• A third alternative would extend eligibility to all AMCs that are the sole designated primary teaching sites when, based on the evidence provided by the school, the LCME makes a determination that the resources currently available to support the branch campus appear to be adequate, even if those campuses only provide one year of graduate medical education, rather than both clinical rotation years. However, such campuses that do not accommodate students through the full complement of clinical rotations which comprise the two clinical education years do not have to incorporate medical students into all clinical areas, and therefore do not either bear the costs of pursuing the comprehensive academic mission that Policy AC-3 reflects or face the need for the teaching and research support that Policy AC-3 can provide.

• A fourth alternative would extend eligibility to AMCs that are the sole designated primary teaching sites for LCME accredited campuses only if those campuses hosted a

specified number of enrolled medical students. However, that might create an artificial constraint unrelated to the most effective provision of medical education at a branch campus.

Finally, any alternative that would hinder an AMC's ability to develop the projects necessary to pursue its research and education missions by limiting the availability or use of this Policy would adversely affect the education of North Carolina physicians and the advancement of health care treatment in the state.

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

For almost three decades, Policy AC-3 or its predecessor has served the state's needs well by allowing the state's medical schools' teaching hospitals to provide the best possible teaching and research facilities for medical education. The changes proposed by Petitioners simply refine the Policy to meet the needs of the state going forward, and would not result in any unnecessary duplication of health resources. In addition to having to satisfy all the statutory criteria for CON applications (including a demonstration of need), Policy AC-3 applicants must demonstrate that the projects are specifically needed for academic or research purposes that cannot be met in a cost effective or clinically efficient manner at any non-AMC within 20 miles.

VI. Evidence that the requested change is consistent with the Basic Principles of Safety and Quality, Access, and Value.

The Policy is essential to the Basic Principles represented by the Plan. The state's AMCs are in the vanguard of developing tools to improve safety and quality, access, and value. Those tools can then be used by medical centers around the state for the benefit of all patients.

The changes proposed by Petitioners would specifically improve access by supporting the academic missions of additional or expanded medical schools and school and academic medical

center teaching hospital programs which may be needed to train physicians to meet the state's health care needs.

EXHIBIT A

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

The State Health Coordinating Council shall designate as an Academic Medical Center Teaching Hospital any facility whose petition for such designation demonstrates the following characteristics of the hospital:

1. Serves as a primary teaching site for a school of medicine and at least one other health professional school, providing undergraduate, graduate and postgraduate education.

2. Houses extensive basic medical science and clinical research programs, patients and equipment.

3. Serves the treatment needs of patients from a broad geographic area through multiple medical specialties.

Exemption from the provisions of need determinations of the North Carolina State Medical Facilities Plan shall be granted to projects submitted by any designated Academic Medical Center Teaching Hospital which either 1) is under common ownership with a school of medicine, or 2) which has the majority of the hospital's chiefs of service serving as medical school clinical department chairs, 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.

Only those projects that comply with one or more of the following conditions shall be eligible for exemption from the relevant need determinations:

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.

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 met in a cost effective and clinically efficient manner 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.

Certificates of need issued pursuant to the approval of a Policy AC-3 application will include the condition that the applicant report each year, in an addendum to the Hospital License Renewal Application, the utilization of the facility, service, beds, operating rooms, and equipment acquired pursuant to the award of the certificate of need.

The facilities, services, beds, operating rooms, and equipment developed pursuant to the approval of Policy AC-3 projects claiming exemptions from need determinations shall not be included in the inventories of the State Medical Facilities Plan, and their utilization shall not be included in the utilization data tables in the Plan.