DUKE UNIVERSITY MEDICAL CENTER & HEALTH SYSTEM

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DFS Health Planning
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Medical Facilities
Planning Section

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Members of the State Health Coordinating Council
NC Division of Health Service Regulation
Medical Facilities Planning Section
2714 Mail Service Center
Raleigh, NC 27699-2714

Re: Novant Petition Regarding Policy AC-3

Members of the Council:

On behalf of the Duke University School of Medicine and Duke University Hospital, I urge your continued support for Policy AC-3 and the disapproval of Novant's "Petition to the North Carolina State Health Coordinating Council regarding State Medical Facilities Plan Policy AC-3."

As a preliminary matter, I would note that petitions for changes in the Plan's basic policies and methodologies are to be made during the first two months of the year (by March 3, 2010, in the review process for the 2011 SMFP) in order that the SHCC may consider such fundamental changes with appropriate deliberation while the plan is under development. Novant's petition regarding Policy AC-3 is not timely for consideration in development of the 2011 plan.

More important, regardless of their timeliness, careful examination of Novant's claims demonstrates that they are without merit, as the following paragraphs show. Novant first argues that "Policy AC-3 is no longer necessary" because:

"I. A. Healthcare has changed dramatically since 1983"

Novant argues that "the 'service gap' between Academic Medical Centers (AMC) and non-AMCs is much smaller today than it was in 1983." Non-AMCs offer sophisticated services, operate sophisticated equipment, and compete directly with AMCs.

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The 'service gap' may be reduced, but the fundamental difference between AMCs and non-AMCs remains. A large community hospital may host training for 10 or 50 residents and other clinical learners, but clinical service is primary and education is secondary, involving a fraction of the medical staff. At AMCs, education is primary. Duke, for example, educates 400 medical students and trains well over 1000 residents and fellows, as well as a wide range of nursing and allied health professionals. The training of clinical learners is woven into every clinical service that Duke provides.

As with education, so with research. Physicians at large community hospitals may participate in clinical trials, but the trials are an adjunct to the services that the non-AMC provides. At Duke, clinical service is the focus of research, whether into the development and application of new science and technologies or the evaluation of innovations in the organization and delivery of clinical services.

The difference between AMCs and non-AMCs is driven by the differences between their missions. The mission of the non-AMC is the provision of outstanding clinical service. Any involvement in education or research is necessarily secondary, and must support the service mission.

AMCs vary, with some devoted primarily to education and others more to research. None would put clinical service ahead of education or research because education and research are their reasons for being.

"I. B. The AMCs do not need Policy AC-3"

Novant claims that Policy AC-3 is not needed because "relatively few Policy AC-3 applications are filed." That is because Policy AC-3 includes stringent requirements. The AMC is required to show how and why the proposed project is essential to an increase in the number of faculty, residents, or students, to an expansion of funded research, or to satisfy the requirements of a residency review committee. And the Dean must certify the need.

Duke uses Policy AC-3 only in those instances where the involvement of research and teaching in the provision of clinical services creates a need not captured by the methodologies driving the need determinations in the State Medical Facilities Plan. But in those instances, the use of Policy AC-3 is essential to State approval of the proposed project.

For example, the use of Policy AC-3 allowed the inclusion of 16 additional ORs in the Duke Medicine Pavilion project approved in 2008. When the application was filed, the Plan showed no need for additional ORs in Durham County. But the Plan then (and now) assumed that inpatient procedures require an average of 180 minutes, that ambulatory procedures require an average of 90 minutes, and that ORs should be expected to provide no more than 1,872 hours of surgery each year.

At that time, Duke North's inpatient procedures required an average of 256 minutes, ambulatory procedures required an average of 157 minutes, and the ORs provided an average of 2,542 hours of surgery each year. The addition of the 16 ORs would simply reduce the average utilization to 1,872 hours per OR per year.

Similarly, in approving the development of the major hospital addition and the expansion of Duke's Cancer Center, the Section authorized the eventual acquisition of additional MRIs and LINACs, though the Plan found no need for either. In the case of the MRIs, the Section recognized that Duke's clinical MRIs are routinely used in research that adds imaging sequences to each clinical procedure and more than 20 minutes to the time required for each. (For example, outpatient scans involving neither contrast nor sedation are assumed to require 30 minutes in the Plan but actually required an average of 54.2 minutes at Duke.) In the case of the LINACs, the Section recognized that the Duke machines are used in clinical research, in the training of fellows, residents and other clinicians, and now in the training of Medical Physics learners mandated by the American College of Radiology.

Another Duke Policy AC-3 application is mentioned in the Novant petition: An application for a heart-lung bypass machine to be used for pediatric patients. That application was approved because Duke was able to demonstrate that its existing machines were in use or on standby in the OR more than 8 hours per day, to support a wide variety of procedures (including some oncologic surgery), and that none was designed or equipped to support cardiac surgery for pediatric patients, especially infants. In order for Duke to expand its faculty in pediatric cardiac surgery, its education of learners, and its NIH-funded research in pediatric cardiac surgery, it was essential that Duke acquire the appropriate equipment, even though the Plan did not show need for an additional bypass machine in Durham County.

Review of these applications and their processing shows that:

- No one commented in opposition to any of them
- No one appealed their approval
- The Certificate of Need Section approved them only after requiring additional data documenting in detail that Policy AC-3 requirements were met

Novant suggests that AMCs meet the needs of their academic missions through petitions for special need determinations in the Plan. Use of that alternative would add a year or more to the development of facilities and services essential to research and teaching projects for which only AMCs are eligible. Since the CON process allows ample opportunity for comment and for evaluation of an AMC's claim that the proposed project is essential to meet particular academic needs, there is no need or reason to require that the AMC apply to the State Health Coordinating Council for a special need determination before submitting a CON application for the very same project.

Novant similarly proposes that AMCs use exemptions from certificate of need review granted pursuant to Chapter 131 E-179 for projects involving research. In fact, basic science research projects are initiated under that provision: Duke's Department of Radiology, for example, has two MRI scanners devoted to brain imaging and analysis that were acquired pursuant to research exemptions, and they are used by neurologists, psychiatrists, neurobiologists and other basic scientists, and radiologists to analyze neural pathways, brain functions, etc. However, equipment acquired pursuant to the provision cannot be used for any procedures for which patients or payors are billed, which greatly limits the purposes for which they can be used. Therefore, such equipment is not usable for clinical research projects involving billed procedures.

On the other hand, most clinical research projects are funded only partly by research grants, with the remainder of the funding for these essential research activities derived from clinical use of the service to treat patients. Neither Duke nor any other AMC can afford to provide high volumes of clinical services without reimbursement from payers, even when those services are provided as part of Duke's clinical research activities. For example, as noted in Table 9L (1) in the 2010 Plan, the CON Section approved the development of cardiac MRIs at Duke for cardiovascular clinical research pursuant to Policy AC-3 application. The machines were purchased with funds provided by the School of Medicine and the Hospital, and they are used to perform animal and human studies. The human studies are funded by payers and patients, and the animal studies are funded by grants. Without the reimbursement of the clinical services that the machine provides, Duke could not afford to operate either machine.

"II. Policy AC-3 Gives Academic Medical Centers an unfair advantage"

Novant argues that the exemption from the need determinations possible for AMC projects that are essential to education, research, or the requirements of residency review committees gives the AMCs an "unfair advantage".

This contention is contradicted by a fact that Novant acknowledges: In most instances, AMCs pursue new institutional health services through the regular need determinations applicable to all providers. That is, when the AMCs are simply seeking to expand clinical services similar to those provided by their competitors without a research or teaching component, the AMCs generally pursue those applications under the same constraints as other providers. However, AMCs are more than community hospitals by another name. As the Council first determined 27 years ago, certain of their proposals need to be judged by different standards, appropriate to their missions and needs. Duke would note that, in all of its recent applications filed under Policy AC-3, there have been no negative comments filed and no challenges to the applications' approvals made by any competitors or other third parties.

It is striking and significant, moreover, that Novant's entire claim of the unfairness of Policy AC-3 rests on the approval of a single Policy AC-3 application now under appeal. Since Novant has appealed the approval of that application, Novant will have ample opportunity to demonstrate any alleged error in approving the application and to seek the reversal of the Section's decision. Wholesale modification of the policy itself is unnecessary, and inappropriate as a remedy for Novant's dissatisfaction with a particular application.

Certainly Novant would be hard put to demonstrate that it has been historically disadvantaged by the long-standing existence of Policy AC-3. As the petition shows, Novant has been able to develop a large tertiary care hospital providing a wide range of clinical services in direct competition with North Carolina Baptist Hospital in Forsyth County and to develop a health care system far larger than any of those operated by the academic medical centers benefitted by Policy AC-3.

"III. Policy AC-3 is inconsistent with North Carolina's Health Planning Process"

Novant argues that Policy AC-3 undermines the state's health planning process and its CON program, which "are designed to assure that only new institutional health services that are actually *needed* are built."

In fact, the law recognizes that North Carolina <u>needs</u> and must support the clinical services of the state's academic medical centers and the education and research missions those services support, even if that entails approval of the development of services and facilities that might not otherwise meet the plan's need methodology. Section 131E-183(b) of the Certificate of Need Statute specifically includes the following:

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

In enacting this provision, the Legislature recognized the special circumstances that may lead to a need for new institutional health services at an academic medical center that is distinct from the need in the community at large.

Moreover, Policy AC-3 is entirely consistent with the health planning process: applications filed pursuant to Policy AC-3 must meet specific criteria for approval, must demonstrate that the services are, in fact, needed for the AMC's educational and research missions, and are subject to the certificate of need decision-making process. As Novant's petition demonstrates in the case of the Baptist application, the public has the right and opportunity to comment on any Policy AC-3 application, as with any other kind of CON application, and affected persons have the right to initiate a contested case to challenge any approval.

Novant's primary argument is that the application recently filed by North Carolina Baptist Hospital is not a judicious use of Policy AC-3. If it believes that to be so, it has already taken the appropriate step: it filed a petition to challenge the CON Section's decision in the Office of Administrative Hearings. In that hearing, it can raise all of its arguments regarding the suitability of and need for Baptist's project. In its petition now to the SHCC, it appears to be trying to litigate that single project in this forum as well.

Clinical services provide both the essential context for clinical education and research programs and the financial support they require. It goes without saying that the tuition and grants supporting medical education fund no more than a small fraction of its cost. Not so well known is the fact that the largest, best funded, and most successful research programs require substantial subsidy. At Duke, which sponsors the nation's largest academic clinical research organization and hundreds of projects funded by the NIH, foundations, and industry, the expenditures essential to support Medical Center research exceed the external funding for such research by about 15%.

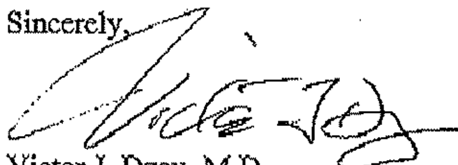
In short, Policy AC-3 reflects the considered conclusion of the legislature and the Council that, in certain circumstances, the unique and important missions of the state's academic medical centers require the possibility of an exception to the Plan's need determinations. That conclusion remains as sound today as when the Policy was first implemented.

Alternative Proposals

Finally, Novant proposes certain alternatives to a complete repeal of Policy AC-3, which include allowing other providers what amounts to a veto of applications – a veto that non-AMCs would never face – or requiring the modification of information to be provided to the CON Section. As set forth above, both academic medical centers and community hospitals have operated successfully with Policy AC-3 or its predecessor in place for more than 25 years. Changes to the CON application and review process for particular kinds of applications are therefore are not necessary; moreover, they are properly the subject of CON rulemaking, not petitions to the SHCC.

For all the reasons set forth in this letter, Policy AC-3 continues to serve a valuable purpose for the continued success of North Carolina's academic medical centers. Novant's petition should be rejected.

Sincerely,



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