DUKE UNIVERSITY MEDICAL CENTER & HEALTH SYSTEM

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Via Facsimile and Electronic Mail

Elizabeth Brown, Section Chief
North Carolina Division of Health Service Regulation
Medical Facilities Planning Section
2714 Mail Service Center
Raleigh, NC 27699-2714

Re: Novant Health, Inc. Petition to State Health Coordinating Council regarding Policy AC-3

Dear Ms. Brown:

Duke University Health System, Inc., which owns and operates Duke University Hospital as the teaching site of Duke University School of Medicine, submits these comments in response to the Petition to the State Health Coordinating Council filed by Novant Health, Inc. regarding Policy AC-3. As you are aware, academic medical centers have complex missions of training, research and clinical care that are demanding even under normal economic times. The changes proposed by Novant would make it much more difficult for Duke and other academic medical center teaching hospitals to pursue the academic missions critical to the ongoing provision of quality health care to North Carolina citizens. As set forth in the petition filed by Duke, UNC Hospitals-Chapel Hill, North Carolina Baptist Hospital, and Pitt County Memorial Hospital regarding Policy AC-3, the policy is an important part of the state's health planning process.

Responses to Novant's Arguments against the Policy

Novant first argues that Policy AC-3 should be eliminated. In response to Novant's arguments, Duke would say that:

1) **Policy AC-3 does not violate the CON Law and North Carolina's health planning policy.**

As set forth more fully in the joint petition filed by the academic medical center teaching hospitals currently eligible to file applications pursuant to Policy AC-3 (the "AMCTHs"), the Policy is entirely consistent with the CON Law and the state's health planning process. In enacting North Carolina General Statutes Section 131E-183(b), the General Assembly has explicitly recognized that AMCTHs should not be required to document that any facility or service at another hospital is being appropriately utilized for

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approval of a certificate of need for the AMCTH to develop any similar facility or service. In fact, this provision, which applies to all AMCTH applications, is even broader than Policy AC-3, which is limited only to those projects pursued to expand academic teaching or research activities or to meet accreditation requirements.

Novant also overlooks the fact that Section 131E-183(a)(1) ("Criterion 1") only makes outcome determinative those need determinations which are "applicable" to the project, leaving to the SHCC to define when those need determinations are applicable. The SHCC may therefore appropriately conclude that those need determinations are not applicable to projects necessary for academic purposes.

2) Policy AC-3 has not "outlived its useful life."

Novant also argues that, because the services that AMCTHs used to provide exclusively have now spread to other hospitals, the Policy is no longer needed. This conclusion is completely backwards. AMCTHs are in the vanguard of developing new technologies and treatments because they invest in the research and teaching activities necessary to support that progress even when existing clinical demand alone would not call for it; other hospitals then reap the benefits of that investment. And while hospitals across the state may now offer services previously developed at AMCTHs, AMCTHs continue to lead the way in developing new technologies that may, 10 and 20 years from now, similarly be widespread. However, if AMCTHs' ability to pursue their academic missions is hindered, progress will similarly be stymied. The AMCTHs' teaching and research missions and the needs arising from them continue, and indeed, given the impending shortage of physicians and other health care providers, the fulfillment of their academic missions is more critical and essential to the state than ever.

3) Policy AC-3 is limited in scope.

Novant claims, paradoxically, that the AMCTHs' limited use of Policy AC-3 demonstrates that it is not needed. In fact, the limited use highlights both 1) the AMCTHs' good faith in adhering to the requirements and 2) the limitations on the Policy itself. If anything, the Policy provides only limited support to AMCTHs in furtherance of their academic missions. By limiting use to expansions of numbers of students or faculty or expansions of research activities as documented by grants (or to meet accreditation requirements), the Policy is not available for an academic medical center that simply finds itself with capacity needs as a result of its existing academic activities. That is, as set forth in the AMCTHs' petition, the time it takes for an AMCTH to complete surgeries or diagnostic procedures is often much greater than the average assumed by the state medical facilities plan, as a result of the incorporation of teaching and research activities as well as the higher complexity of cases; AMCTHs may have their ORs or equipment fully utilized as a function of time in operation, even if the resulting volumes may not create a need under the standard plan methodology. In such cases, Policy AC-3 provides no relief from the need determinations, and AMCTHs may have no option other than simply scheduling their facilities for longer and longer hours to meet existing clinical

demand and academic needs. It is only when the AMCTHs' research and teaching programs are expanded that Policy AC-3 becomes available.

4) Policy AC-3 has not been abused.

It is clear that Novant's essential complaint with Policy AC-3 arises out of a single case in the past 27 years in which it claims Policy AC-3 was not properly applied or enforced. If Novant believes that the CON Section is not properly interpreting and applying the Policy, it can – and did – challenge the Section's decision. In the case of North Carolina Baptist's AC-3 application, discussed at length in Novant's Petition, Novant has filed a petition for contested case hearing and was provided a full evidentiary hearing before an administrative law judge pursuant to the Administrative Procedures Act. Novant will also have the right of appeal from any resulting final agency decision. If Novant is correct that Baptist's application should not have been approved or that Policy AC-3 was not properly applied, it should prevail in its challenge. If it is not correct, it won't. Either way, Novant's concern with the CON Section's decision on a single application is not grounds for a wholesale policy change.

5) Policy AC-3 does not create an unfair advantage for AMCTHs.

Novant claims that Policy AC-3 creates an unfair advantage for AMCTHs. As set forth in the AMCTHs' joint petition, the Policy is available only in those instances where AMCTHs are acting in their unique roles which cannot be filled by other providers, namely, the expansion of significant research and teaching activities or meeting accreditation requirements, and no unfair advantage results.

One concern Novant raises about a possible unfair advantage created by Policy AC-3 is particularly without foundation. Novant claims that an AMCTH could create a new hospital using Policy AC-3, by applying to develop operating rooms under a need determination and to develop beds under Policy AC-3, for example. This misunderstands the requirements of the Policy. It would be impossible to create a new licensed facility under Policy AC-3. Facilities must first seek and establish designation as academic medical center teaching hospitals before they may become eligible to apply for projects under the Policy; the Policy attaches to the teaching hospital itself, not a medical school. Moreover, it would not be feasible for a medical school to establish multiple "primary" teaching sites for a single medical school campus. The Policy is therefore only available to expand a designated teaching hospital to meet academic needs, not to create new facilities out of whole cloth. Novant's concern is therefore baseless.

6) The AMCTHs' petition addresses the treatment of Policy AC-3 projects in the plan inventories to protect the health planning process and other providers.

Novant identifies a concern with how Policy AC-3 projects may affect need determinations. Although Novant cannot point to any example of any provider disadvantaged by this current treatment of AC-3 projects, the AMCTHs have already

petitioned for a modification to Policy AC-3 that would eliminate even the risk of distortion to the need determinations to ensure fairness to all providers.

Responses to Novant's proposed modifications to Policy AC-3

As an alternative to eliminating the Policy, Novant proposes modifications to Policy AC-3. Those modifications would make it much more difficult for Duke and the state's other AMCTHs' to protect and pursue their academic missions, which are critical to the ongoing provision of quality health care to the people of North Carolina. The proposed modifications are neither appropriate nor reasonable, and would undermine the "unique needs that merit special consideration in the health planning process" that even Novant recognizes. To be specific:

1) **Requiring special need determination for all academic projects would be inefficient and duplicative.**

Novant first proposes that when AMCTHs need to develop projects to fulfill their academic missions but no need determination for the services exists, the AMCTHs should first be required seek special need determinations in the Plan, for which any provider could then apply. This proposed process is inefficient and duplicative. If an AMCTH identifies a need to accommodate an expansion of faculty, students, or research, or an accreditation requirement, it will not generally be feasible for another provider to fill that need. And if a need exists for the clinical services without the academic component, then any provider may file a petition for a special need determination under existing policies and procedures.

Moreover, the CON Section is already required to evaluate the need for any proposed AC-3 projects, to evaluate conformity with the requirements of the Policy as well as with all other statutory criteria. Requiring AMCTHs first to file special need petitions for academic projects with the SHCC would require the SHCC to perform a duplicative exercise in evaluating the same project, with the practical effect of delaying by a year the CON Section's own review and the resulting implementation of any successful project.

2) **Requiring consent of all providers in the area to an application would be anticompetitive.**

Novant also proposes that AMCTHs could file AC-3 applications only if they could provide the express representation of all other providers within 20 miles that those providers cannot fill the identified need. This requirement would allow the CON process to be manipulated in an inappropriate, anticompetitive way by other providers.

The CON process is designed to allow the state to review projects to determine whether there is need for them, not to allow other providers to veto projects. As a result, the CON Process does not, and should not, require any applicant (AMCTH or other) to demonstrate affirmative consent by other providers to the proposed project. Allowing

such a veto in the realm of academic projects would create the opportunity for other providers to stymie academic projects for no reason at all, or to hold them up in an attempt to extract unrelated concessions. Certainly the CON Law is not intended to provide this kind of leverage by existing providers against new projects.

The current procedure allows providers to participate in public comments and hearing on an application, and further allows any provider of the same or similar services in the service area to initiate a contested case proceeding to challenge the approval of a project. This affords other providers ample opportunity and any necessary due process to voice their opinions without giving them a veto or other impermissible anticompetitive leverage over the pursuit of academic projects.

3) Requiring reporting of payor and patient origin information for AC-3 Projects is not warranted.

Novant proposes certain reporting requirements on Policy AC-3 projects. In their petition, the AMCTHs have collectively proposed changes that would include certain reporting requirements. The AMCTHs have proposed reporting the volumes of procedures on Policy AC-3 projects separately on license renewal applications and equipment forms (so that they may be properly excluded from the need determination process). In addition, the hospital license renewal applications require reporting of patient origin by county for several different services.

The additional information Novant seeks, however, would place unfair and unnecessary additional obligations on AMCTHs that would not further the goals of Policy AC-3. Specifically, Novant seeks to impose additional obligations like those that the SHCC created for demonstration projects for single-specialty ambulatory surgery centers and for prostate cancer linear accelerators. Those demonstration projects raised special concerns regarding the provision of care to underserved patients, especially since they were going to be physician-owned projects with self-referral opportunities. See, e.g., July 31, 2009 Comments of North Carolina Hospital Association on Single Specialty Ambulatory Surgery Demonstration Project ("Establishing a surgery center demonstration project without a requirement to serve the uninsured will increase the mal-distribution of non-paying patients referred to hospitals for their surgery."); May 7, 2008 Comments of North Carolina Council of Affiliated Regional Radiation Oncology Societies ("NC-CARROS also shares the concerns raised by investigations quoted by the American College of Radiology, American College of Radiation Oncology, and the American Society for Therapeutic Radiology and Oncology about the powerful financial incentive for self-referral by referring urologists with ownership in linear accelerators.") Requiring additional information regarding the payor mix of patients served and other operational information therefore was appropriate to evaluate whether such projects would adversely affect access to care. Moreover, those demonstration projects were necessarily going to involve new providers without a track record regarding their care and payment patterns.

AMCTHs raise none of those concerns. In fact, Association of American Medical Colleges data show that while AAMCTH Council of Teaching Hospitals and Health Systems members (including Duke, UNC, Pitt, and Baptist) constitute only 6% of hospitals and provide 23% of inpatient admissions nationwide, they bear 59% of total charity care costs. During fiscal year 2010, for example, Duke University Health System provided over $184 million in Community Benefit, defined by the IRS as Charity Care, Medicaid program losses, support to community healthcare organizations and to the education of healthcare professionals. In addition, the system absorbed nearly $74 million in Medicare uncompensated care and patient bad debt. In all, the value of the Duke University Health System's commitment in fiscal year 2010 was $258 million. Other AMCTHs bear similar charity care costs. Accordingly, AMCTHs do not create the same risk of diminishing access to underserved patients that was raised in comments regarding demonstrations projects.

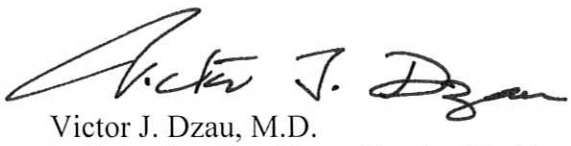
Novant also seeks to impose a requirement that AMCTHs report the service of patients by county of origin for each Policy AC-3 project. The Hospital License Renewal Application form already requires reporting of county of origin for patients for many services. AMCTHs can generally keep records of the number of procedures provided on machines; they can keep records patient origin data by service line, but it is not feasible to require them to keep patient origin data for particular machines. Nor is such information necessary. As set forth in their joint petition, AMCTHs have a documented track record of treating patients from wide service areas.

The entire point of a demonstration project is to determine if such facilities are in the best interest of the state. There can be no serious debate that academic medical centers are in the state's best interests. Novant's proposal is simply designed to increase the burdens on AMCTHs and deter them from seeking to use Policy AC-3.

Conclusion

Not even Novant argues that the AMCTHs' training and research programs should be eliminated or cut back. But adoption of Novant's proposals to abolish Policy AC-3 or to obstruct its use would have a destructive impact on those programs. Duke urges the State Health Coordinating Council to accept the AMCTHs' recommendations in their petition, and to reject Novant's proposals as contrary to the best interests of North Carolina citizens.

Very truly yours,



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