ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming CA = Conditional NC = Nonconforming NA = Not Applicable

Decision Date: September 20, 2017 Findings Date: September 20, 2017

Project Analyst: Celia C. Inman Team Leader: Fatimah Wilson

Project ID #: J-11364-17

Facility: University of North Carolina Hospitals-Hillsborough

FID #: 090274 County: Orange

Applicant: University of North Carolina Hospitals at Chapel Hill

Project: Develop a vascular interventional radiology suite on the Hillsborough Campus

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

N.C. Gen. Stat. §131E-183(a) The Department shall review all applications utilizing the criteria outlined in this subsection and shall determine that an application is either consistent with or not in conflict with these criteria before a certificate of need for the proposed project shall be issued.

(1) The proposed project shall be consistent with applicable policies and need determinations in the State Medical Facilities Plan, the need determination of which constitutes a determinative limitation on the provision of any health service, health service facility, health service facility beds, dialysis stations, operating rooms, or home health offices that may be approved.

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The University of North Carolina Hospitals at Chapel Hill (UNC Hospitals), the applicant, proposes to purchase one unit of vascular interventional radiology (VIR) equipment and develop a VIR suite at UNC Hospitals Hillsborough Campus (UNC Hillsborough).

Need Determination

Chapter 9 of the 2017 State Medical Facilities Plan (SMFP) provides need determinations for the following technologies and equipment:

- Lithotripsy
- Gamma Knife

- Linear Accelerator
- Positron Emission Tomography Scanner
- Magnetic Resonance Imaging
- Cardiac Catheterization Equipment

As indicated by the list above, the 2017 SMFP does not provide a need determination for interventional radiology or angiography equipment; therefore, there are no need determinations in the 2017 SMFP which apply to this review.

Policies

UNC Hospitals proposes to acquire one unit of VIR equipment and renovate existing space to create a VIR suite at UNC Hillsborough. The proposed capital expenditure is greater than \$2 million and less than \$5 million; therefore Policy GEN-4 is applicable to this review.

Policy GEN-4: ENERGY EFFICIENCY AND SUSTAINABILITY FOR HEALTH SERVICE FACILITIES, on page 33 of the 2017 SMFP, states:

"Any person proposing a capital expenditure greater than \$2 million to develop, replace, renovate or add to a health service facility pursuant to G.S. 131E-178 shall include in its certificate of need application a written statement describing the project's plan to assure improved energy efficiency and water conservation.

In approving a certificate of need proposing an expenditure greater than \$5 million to develop, replace, renovate or add to a health service facility pursuant to G.S. 131E-178, Certificate of Need shall impose a condition requiring the applicant to develop and implement an Energy Efficiency and Sustainability Plan for the project that conforms to or exceeds energy efficiency and water conservation standards incorporated in the latest editions of the North Carolina State Building Codes. The plan must be consistent with the applicant's representation in the written statement as described in paragraph one of Policy GEN-4.

Any person awarded a certificate of need for a project or an exemption from review pursuant to G.S. 131E-184 are required to submit a plan of energy efficiency and water conservation that conforms to the rules, codes and standards implemented by the Construction Section of the Division of Health Service Regulation. The plan must be consistent with the applicant's representation in the written statement as described in paragraph one of Policy GEN-4. The plan shall not adversely affect patient or resident health, safety or infection control."

In Section B.10-11, pages 27-28, the applicant addresses Policy GEN-4, stating:

"UNC Hospitals will develop and implement an Energy Efficiency and Sustainability Plan for the proposed project that conforms to or exceeds the energy efficiency and water conservation standards incorporated in the latest editions of the NC State Building Codes. The Plan shall not adversely affect patient or resident health, safety or infection control."

The applicant states that UNC Hospitals Energy Efficiency and Sustainability Plan for the proposed project will address the following systems and features:

- 1. Lighting Systems Lighting systems will provide higher energy efficiency in accordance with energy efficiency and water conservation standards incorporated in the latest editions of the North Carolina State Building Codes. The lighting systems shall not adversely affect patient or resident health, safety or infection control.
- 2. Water Systems Water systems, hand wash facilities, and toilets will provide higher energy efficiency ...
- 3. Heating, Ventilation, and Air-conditioning (HVAC) Systems HVAC systems will provide higher energy efficiency ...
- 4. Minor Equipment will be evaluated prior to purchase and implementation based on energy efficiency and water conservation. ...
- 5. Other potential energy conservation measures for the project will be researched and evaluated by the project engineer and architect as well as UNCH administration.

The applicant adequately demonstrates the proposal includes a plan to assure improved energy efficiency and water conservation. Therefore, the application is consistent with Policy GEN-4.

Conclusion

In summary, the applicant adequately demonstrates that the proposal to acquire VIR equipment and develop a VIR suite at UNC Hillsborough is consistent with Policy GEN-4. Therefore, the application is conforming to this criterion.

- (2) Repealed effective July 1, 1987.
- (3) The applicant shall identify the population to be served by the proposed project, and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and, in particular, low income persons, racial and ethnic minorities, women, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.

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The applicant proposes to acquire VIR equipment, specifically, a Siemens Artis Q ceiling-mounted C-arm, and develop a VIR suite by renovating 1,100 square feet of existing UNC Hillsborough hospital space, including adding lead lining to the walls, medical gases and additional ventilation.

In Section C.1, pages 29-30, the applicant discusses VIR and UNC Hospitals' existing VIR services. VIR utilizes image guidance to perform a variety of minimally invasive, vascular and non-vascular procedures to treat a wide range of diseases. Procedures are performed in VIR suites using ultrasound, fluoroscopy or X-ray, and CT scanning for guidance. Instead of large incisions required for open surgeries, these procedures are performed through small incisions, allowing catheters, needles, and other devices to be guided to the treatment site. Examples of such interventions include image-guided biopsies, insertion of venous ports and catheters, thermal ablation of tumors through heating or freezing, treatment of liver tumors using catheters to inject chemotherapeutic agents or radioactive particles into the tumors, vertebroplasty and kyphoplasty for spine fractures, uterine artery embolization to treat fibroids, prostate artery embolization to treat benign prostatic hypertrophy, and endovenous laser ablation to treat varicose veins.

UNC Hospitals provides comprehensive, full-service VIR services at UNC Hospitals Chapel Hill (UNC Chapel Hill), with nine state-of-the-art procedure rooms and a 10-bed holding area to care for patients before and after their procedures. The applicant states that the service is highly utilized and consistently operates at practical capacity.

The applicant states that UNC Hospitals also offers very limited outpatient VIR services at its off-site UNC Vascular Interventional Radiology at Meadowmont (Meadowmont) facility utilizing portable imaging equipment, and only performing central venous access procedures, which are basic procedures requiring less intensive imaging guidance.

The applicant further states that historically, VIR services have not been available at UNC Hillsborough; inpatients at UNC Hillsborough who required VIR procedures had to be transported to UNC Chapel Hill for the service and then back to UNC Hillsborough following the procedure. UNC Hospitals recently operationalized limited VIR services within UNC Hillsborough by utilizing portable imaging equipment from its radiology department and scheduling time on a limited basis (two days per month) in one of the two existing unlicensed procedure rooms at the hospital.

Patient Origin

On page 39, the 2017 SMFP defines the service area for acute care services as the planning area in which the bed is located. "An acute care bed's service area is the acute care bed planning area in which the bed is located. The acute care bed planning areas are the single

and multicounty groupings shown in Figure 5.1." Figure 5.1 on page 42 of the SMFP shows Orange County as a single county acute care bed planning area. UNC Hospitals is located in Orange County. Thus, the service area for this facility consists of Orange County. Facilities may also serve residents of counties not included in their service area.

In Section C.2(a), pages 33-36, the applicant identifies the patient origin for UNC Hospitals VIR services during FY2016, as summarized below.

Historical Patient Origin VIR Services 7/1/15-6/30/16

County of Residence	Percent of Total Patients
Wake	15.6%
Orange	9.6%
Cumberland	7.0%
Alamance	6.9%
Chatham	4.4%
Durham	4.3%
Lee	3.6%
Harnett	2.7%
Johnston	2.3%
Moore	2.2%
Robeson	2.2%
Guilford	2.2%
New Hanover	2.0%
Other NC Counties	31.1%
Total NC	96.1%
Other US States	3.9%
Total	100.0%

Totals may not sum due to rounding

Source: UNC Hospitals internal data. Other NC Counties includes patients from NC counties as listed on pages 33-35. Other US includes the states listed on page 36.

As illustrated in the table above, residents of Wake, Orange, Cumberland, Alamance, Chatham, Durham, Lee, Harnett, Johnston, Moore, Robeson, Guilford and New Hanover counties represent 2% or more each of the total number of patients receiving VIR services and together represent approximately 65% of UNC Hospitals' total VIR services. The table on pages 33-36 of the application shows that UNC Hospitals provided VIR services to patients from 95 counties across North Carolina and 33 other states.

In Section C.3, page 40, the applicant states that the proposed project is not expected to impact patient origin; therefore, patient origin for the proposed project will remain consistent with its FY2016 UNC Hospitals patient origin. On pages 37-40, the applicant provides a table showing projected patient origin percentages for the first three full fiscal years, consistent with historical patient origin, as summarized in the table above.

The applicant adequately identifies the population it proposes to serve.

Analysis of Need

The applicant proposes to acquire VIR equipment and develop a VIR suite at UNC Hillsborough. In Section C.4, the applicant discusses the need for the project. On page 41, the applicant states:

"The overall need for the proposed project is based on the following factors:

- The need for comprehensive VIR services at UNC Hospitals Hillsborough Campus;
- The need for additional VIR capacity across UNC Hospitals;
- The need for enhanced quality, access, and value; and
- The projected growth and aging of the population in Orange County."

The applicant discusses each of the above factors on pages 41-46 of the application, as summarized below.

Need for Comprehensive VIR Services at UNC Hospitals Hillsborough Campus

In Section C.4(a), page 41, the applicant states:

"As a full-service acute care hospital, the Hillsborough Campus needs to have the ability to provide comprehensive VIR services in order to best meet the needs of its patients. In particular, UNC Hospitals Hillsborough Campus has a significant geriatric patient population and also a significant oncology patient population ..., both of which are patient populations with a recognized need for VIR services."

The applicant further states that VIR services have historically not been available at UNC Hillsborough, have only recently been operationalized on a very limited basis, and the service is not sufficient to address the full need for comprehensive VIR services on that campus. The limited service, two days per month, results in the frequent need to transport patients (five to seven cases per week) to UNC Chapel Hill for VIR procedures. Following the required VIR procedure and recovery at UNC Chapel Hill, the patient is then transported back to UNC Hillsborough for the remainder of his or her inpatient hospital stay. In addition, oncology patients commonly have the need to schedule multiple related appointments on a single visit,

including a clinic visit, chemotherapy/infusion, and/or VIR procedures, such as line or port insertion or replacement. The applicant states that UNC Hillsborough represents the most convenient location for many patients to receive comprehensive oncology care. However, absent the availability of comprehensive VIR services, these patients must be scheduled at UNC Chapel Hill in order to allow them to receive all of the services in one single visit rather than multiple visits to two different locations.

Need for Additional VIR Capacity across UNC Hospitals

The applicant discusses the need for additional VIR services throughout the UNC Hospitals System in Section C.4(a), pages 42-43. The applicant states that all nine VIR rooms at UNC Chapel Hill are staffed at least five days per week for 10 hours per day. Additionally, two of the rooms are staffed for 10 hours each Saturday, and one is staffed each Sunday. In addition to accommodating a high volume of both inpatient and outpatient VIR procedures through its regularly scheduled hours of operation, the VIR service at UNC Chapel Hill must be available at all times for aortic aneurysm and stroke-related emergencies. As such, the highly utilized UNC Chapel Hill VIR service is staffed Monday through Friday 24 hours per day with back-up teams and on-call staff available 24 hours per day on weekends.

The applicant further states that despite the extensive hours of operation, the existing VIR service at UNC Chapel Hill consistently operates at practical capacity and often results in delays in scheduled inpatient VIR procedures, which in turn results in longer lengths of stay for patients awaiting scheduled VIR procedures. The applicant states that during the first quarter of Calendar Year 2017, January through March, UNC Hospitals delayed a total of 41 VIR procedures due to capacity constraints, which in turn resulted in a total of 147 avoidable patient days of care. The applicant states that the transport of patients from UNC Hillsborough further strains the capacity of VIR services at UNC Chapel Hill; therefore, the addition of comprehensive VIR services at UNC Hillsborough will not only provide needed access to the service for patients at UNC Hillsborough, but will also provide additional capacity to the UNC System overall and allow UNC Hospitals to shift appropriate VIR volume to UNC Hillsborough to alleviate capacity constraints at UNC Chapel Hill.

On page 43, the applicant states:

"Further, given the limitations of the VIR service at Meadowmont attributable to the limitations of the portable imaging equipment there and the lack of a full-service hospital setting, the proposed project will also increase capacity with the system by replacing the limited service at Meadowmont with a full-service VIR program at UNC Hospitals Hillsborough Campus that is capable of providing expanded VIR services."

Enhanced Quality, Access, and Value

In Section C, pages 43 and 44, the applicant discusses how the addition of comprehensive, full-service VIR capabilities at UNC Hillsborough will have a positive impact on quality care delivery, access and value, stating that the proposed advanced equipment will enhance the quality of service at UNC Hillsborough and obviate the need to transport UNC Hillsborough patients; thereby having a positive impact on quality, patient safety, and access.

Population Growth and Aging

In Section C.4, pages 44-46, the applicant provides population data for Orange County. According to data from the North Carolina Office of State Budget and Management (NC OSBM), Orange County is the 19th fastest growing county in North Carolina based on numerical growth and the 25th fastest growing county based on percentage growth (Exhibit C.4). The NC OSBM projects Orange County's population to grow by 10.4% between 2010 and 2020 (Exhibit C.4), adding over 13,000 people within the decade. The applicant also provides a map on page 45 that shows that the county populations east, west and south of Orange County are growing at a medium to high rate, while the two counties north of Orange County are growing at a lower rate.

In discussing the aging of the population, the applicant states that by 2020, 15 percent of the total population in Orange County will be over the age of 65 (more than 22,000 people), up from 9.7% in 2010 (Exhibit C.4). Further, between 2010 and 2020, Orange County's population over the age of 65 is projected to grow by 72.4 percent. The applicant further states on page 46, that the aging is significant, "because, typically, older residents utilize healthcare services at a higher rate than those who are younger".

The applicant states that the improvement in access to healthcare services, including VIR services, will support the expected higher utilization of this population group. The applicant further states:

"Additionally, given that UNC Hospitals also serves patients residing outside of Orange County, the higher growth projected in other surrounding areas, such as Wake, Durham, and Chatham counties, will influence the utilization of UNC Hospitals."

The applicant adequately demonstrates the need to develop a vascular interventional radiology suite on the Hillsborough campus.

Projected Utilization

UNC Hospitals proposes to develop a full-service VIR suite at UNC Hillsborough. UNC Hospitals operates on a July 1 to June 30 fiscal year (FY). The proposed project is expected to

begin operations on July 1, 2018; thus, the first operating year (PY1) is FY2019, begins July 1, 2018, and runs through June 30, 2019. The second operating year (PY2) is FY2020, begins July 1, 2019, and runs through June 30, 2020. The applicant provides its assumptions and methodology for projecting UNC Hospitals VIR utilization through FY2021 in Section Q, Form C–Assumptions and Methodology, pages 1-4, as summarized below:

• VIR patient volume has increased at UNC Chapel Hill and Meadowmont over the past three years, growing at a compound annual growth rate (CAGR) of 11.3% and 5.5%, respectively, from FY2015 to FY2017. This results in a combined VIR CAGR of 11.0% for the time period. The table on Form C–Assumptions and Methodology, page 1, provides the historical utilization for UNC Hospitals total VIR utilization.

UNC Hospitals Historical VIR Utilization

	FY2015	FY2016	FY2017 Annualized*	CAGR
UNC Chapel Hill Patients	9,517	10,150	11,792	11.3%
Meadowmont Patients	565	622	629	5.5%
Total Patients	10,082	10,772	12,421	11.0%

Source: UNC Hospitals internal data

• The applicant states that it applied one quarter of the historical 11.0% CAGR (2.7%) to its annualized FY2017 volume for projecting VIR utilization forward and believes it to be reasonable and conservative based on the historical CAGR for overall VIR services across UNC Hospitals. The following table summarizes the projected VIR total utilization at UNC Hospitals.

UNC Hospitals Projected VIR Utilization

	Interim FY2018	PY1 FY2019	PY2 FY2020	PY3 FY2021	CAGR
Total VIR Patients	12,763	13,114	13,474	13,845	2.7%

Totals may not foot due to rounding

• UNC Hillsborough, with its current limited VIR service two days per month, with five patients per day, can accommodate only 10 patients per month or 120 patients annually. With the implementation of the proposed project, UNC Hillsborough is projected to accommodate 1,250 patients per year (five patients per day x 250 days per year = 1,250 patients per year), resulting in the following projection.

^{*}Annualized based on nine months' data

UNC Hillsborough Projected VIR Utilization

	Interim	PY1	PY2	PY3
	FY2018	FY2019	FY2020	FY2021
Total VIR Patients	120	1,250	1,250	1,250

Totals may not foot due to rounding

 Once the proposed project is implemented, the patients receiving VIR services at Meadowmont will be redirected to UNC Hillsborough. Until that time, the applicant expects services at Meadowmont to increase by one quarter of the historical 11% CAGR (2.7%) through FY2018, as shown below.

Meadowmont Projected VIR Utilization

	FY2017	FY2018
UNC Main Total Acute Care Patients	629	647

Totals may not foot due to rounding

• The applicant expects UNC Chapel Hill to provide VIR services to all patients not served at UNC Meadowmont and UNC Hillsborough.

UNC Hospitals Projected VIR Utilization

	Interim FY2018	PY1 FY2019	PY2 FY2020	PY3 FY2021
Total Patients Projected	12,763	13,114	13,474	13,845
UNC Hillsborough Patients	120	1,250	1,250	1,250
Meadowmont Patients	647	0	0	0
UNC Chapel Hill Patients	11,996	11,864	12,224	12,595

- The applicant states that capacity of UNC Hospitals VIR services is dependent upon each location's number of VIR rooms and hours of operation as well as the estimated length of time needed to treat a patient, including room turnover.
 - UNC Hillsborough the proposed full-service VIR begins in FY2019 and is expected to have a capacity of 1,333 patients based on one room staffed 250 days per year for eight hours per day and an assumed patient case time of 1.5 hours (250 days x 8 hours / 1.5 hours per patient).
 - Meadowmont the annual capacity for Meadowmont's limited VIR services prior to development of the project is estimated at 998 patients based on one room staffed 156 days per year for eight hours per day and an assumed patient case time of 1.25 hours (156 days x 8 hours / 1.25 hours per patient).

O UNC Chapel Hill – the applicant states that estimating maximum annual capacity at UNC Chapel Hill is more difficult due to complexity and range of procedures provided. Nine rooms staffed 250 weekdays per year for ten hours per day (2,250 days per year), plus two rooms staffed each Saturday (104 additional days per year) for 10 hours per day, and one room staffed on Sundays (52 additional days per year) for ten hours per day results in a total of 24,060 staffed hours. Assuming the minimum patient case time of 100 minutes, an annual capacity of 14,436 patients (24,060 staffed hours / 1.67 hours per patient) is projected. Longer case times would result in lower annual capacity.

The following table shows UNC Hospitals' capacity as outlined above.

UNC Hospitals Projected VIR Capacity

	UNC Chapel Hill	Meadowmont	UNC Hillsborough
Total Patients	14,436	998	1,333

The applicant provides the projected percent of utilization at each campus based upon capacity, as shown below.

UNC Hospitals Projected VIR Utilization and Capacity

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	FY2019	FY2020	FY2021		
UNC Chapel Hill Patients	11,864	12,224	12,595		
UNC Chapel Hill Capacity	14,436	14,436	14,436		
UNC Chapel Hill % Utilization	82.2%	84.7%	87.2%		
UNC Hillsborough Patients	1,250	1,250	1,250		
UNC Hillsborough Capacity	1,333	1,333	1,333		
UNC Hillsborough % Utilization	93.8%	93.8%	93.8%		

The applicant states that UNC Hospitals has shown a clear need for full-service VIR services at UNC Hillsborough to increase patient access to VIR services at UNC Hillsborough and across UNC Hospitals, and to help relieve capacity constraints at UNC Chapel Hill.

Projected utilization is based on reasonable and adequately supported assumptions.

Access

In Section C.10, pages 49-50, the applicant discusses how the proposed project will promote equitable access. The applicant states:

"As North Carolina's only state-owned comprehensive, full service hospital-based program, UNC Hospitals has the obligation to accept any North Carolina citizen requiring medically necessary treatment. No North Carolina citizen is presently denied access to non-elective care because of race, sex, creed, age, handicap, financial status or lack of medical insurance as demonstrated in Section C."

The applicant states that the document "Assuring Access at UNC Health Care" found in Exhibit C.10-1, highlights UNC Hospitals System's effort to provide adequate financial assistance and expand its overall capacity in order to meet the health care needs of North Carolinians.

In Section L.1, page 80, the applicant provides the following information on the percentage of patients served by UNC Hospitals, based on FY2016 data.

	Percentage Served by UNC Hospitals	Percentage for Orange County
Women	58.7%	52.1%
65 and Older	26.4%	12.0%
Racial Minorities	36.2%	27.6%

Source: UNC Hospitals internal data and ESRI population reports

In Section C.10, page 50, and Section L.2(b), page 82, the applicant states that UNC Hospitals has traditionally provided services to a wide variety of patient groups, as evidenced by the information as summarized below.

	Low Income	Racial & Ethnic Minorities	Women	Elderly	Other Underserved
UNC Hospitals Total	16.1%	36.2%	58.7%	26.4%	9.2%
VIR Services*	14.7%	36.0%	31.3%	49.7%	5.7%

^{*}Includes VIR services provided at UNC Chapel Hill and Meadowmont

Low Income = Medicaid and ½ of Medicaid Pending; Other Underserved = Self Pay and ½ of Medicaid Pending. "Low income" is based on Federal poverty guidelines as outlined in the Patient Financial Assistance Policy contained in Exhibit C.10. "Elderly" is defined as patients age 65 and over.

In Section L.3(a), page 83, the applicant provides the projected payor mix for the entire facility, and UNC Hospitals VIR services for FY2020 (July 1, 2019 – June 30, 2020), the second full fiscal year following completion of the project, as illustrated in the table below:

Projected FY2020 Payor Mix Patients as a Percent of Total Utilization

Payor Source	Entire Facility	UNC Hospitals VIR Services
Self-Pay / Indigent / Charity	5.9%	6.1%
Medicare	33.3%	44.0%
Medicaid	28.5%	13.7%
Commercial Insurance/ Managed Care	27.3%	29.7%
Other (Other Gov't)	4.9%	6.4%
Total	100.0%	100.0%

Totals may not sum due to rounding

In Section L.4, pages 83-84, the applicant discusses charity care, stating that the UNC Hospitals charity program ensures that all eligible individuals receive medically necessary care at UNC Hospitals regardless of their ability to pay. Exhibit C.10 contains UNC Hospitals' current policies on access to services.

In Section Q, Form F.3, the applicant shows that UNC Hospitals will provide approximately \$285,526,000 and \$300,416,000 in charity care in project years one and two, respectively; and approximately \$119,199,000 and \$125,415,000 in bad debt in project years one and two, respectively, based on FY2016 experience.

The applicant adequately demonstrates the extent to which residents of the area, including underserved groups, are likely to have access to the proposed services.

Conclusion

In summary, the applicant adequately identifies the population to be served, demonstrates the need the population to be served has for the proposed project and the extent to which all residents of the area, including underserved groups, are likely to have access to the proposed services. Therefore, the application is conforming to this criterion.

(3a) In the case of a reduction or elimination of a service, including the relocation of a facility or a service, the applicant shall demonstrate that the needs of the population presently served will be met adequately by the proposed relocation or by alternative arrangements, and the effect of the reduction, elimination or relocation of the service on the ability of low income persons, racial and ethnic minorities, women, handicapped persons, and other underserved groups and the elderly to obtain needed health care.

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UNC Hospitals proposes to shift all VIR patients from Meadowmont to the proposed VIR service at UNC Hillsborough; therefore the same patients that might have been treated at

Meadowmont will now receive the service at UNC Hillsborough. The outpatient VIR services at Meadowmont are located in downtown Chapel Hill, about 10 miles from UNC Hillsborough. In Section D.2, page 54, the applicant states:

"With the proposed project, existing outpatient VIR services currently provided at Meadowmont will be relocated to the proposed comprehensive full-service VIR program at UNC Hospitals Hillsborough Campus."

The applicant further states that the existing VIR service at Meadowmont is very limited given the absence of advanced imaging capabilities and the lack of a full-service hospital setting. Due to these limitations, Meadowmont is restricted to only performing line and port procedures, which are basic VIR procedures that do not require intensive imaging services. With the proposed project, UNC Hospitals will develop a comprehensive, full-service VIR program at UNC Hillsborough that is capable of providing the same level of services as those currently available at UNC Chapel Hill, with the exception of very complex cases such as aortic aneurysm and neurology procedures. On page 55, the applicant further states:

"Relocating outpatient VIR procedures from Meadowmont to the Hillsborough Campus will enable UNC Hospitals to provide comprehensive, full-service VIR services in two different locations, which will provide patients with a geographic choice of location and improved access."

The applicant adequately demonstrates that the needs of the population presently served will be met adequately by the proposed relocation of the service and that the proposed relocation of the service will not have a negative impact on the ability of low income persons, racial and ethnic minorities, women, handicapped persons, and other underserved groups and the elderly to obtain needed health care; therefore the application is conforming to this criterion.

(4) Where alternative methods of meeting the needs for the proposed project exist, the applicant shall demonstrate that the least costly or most effective alternative has been proposed.

CA

In Section E.2, pages 57-58, the applicant describes the alternatives considered, which include the following:

1) Maintain Status Quo – UNC Hospitals considered maintaining the status quo; however, the applicant concluded this alternative would not meet the needs of the patients at UNC Hillsborough. Patients would still be required to schedule outpatient VIR procedures at UNC Chapel Hill and UNC Hillsborough inpatients would be transported to UNC Chapel Hill when in need of inpatient VIR procedures. Therefore, the applicant determined maintaining the status quo was not in the best interest of its patients and rejected this alternative.

- 2) Develop Additional VIR Capacity at UNC Chapel Hill the applicant evaluated this alternative and determined it would not remedy the lack of access to comprehensive VIR services at UNC Hillsborough and would still require those inpatients to be transported to UNC Chapel Hill for VIR procedures. Therefore, the applicant rejected this alternative.
- 3) Acquire Siemens Artis Q Equipment for Use at Meadowmont the applicant determined that even with the advanced imaging capabilities of the Artis Q, VIR services at Meadowmont would continue to be limited given the lack of a full-service acute care hospital setting. Further, this alternative would not meet the need to provide comprehensive VIR services at UNC Hillsborough; therefore this alternative was rejected.
- 4) Develop the Project as Proposed The applicant states on page 58 that UNC Hospitals' project as proposed will remedy the lack of access to comprehensive VIR service at UNC Hillsborough, which is critical to support the inpatient services of a full-service acute care hospital. It will also provide convenient access to outpatient VIR patients who prefer to schedule services at UNC Hillsborough, will obviate the need to transport patients from one campus to another and back again, and will alleviate some of the capacity constraints at UNC Chapel Hill.

For the above reasons, the applicant determined that the project as proposed is the most reasonable and cost-effective alternative for meeting UNC Hospitals' need for comprehensive VIR services at UNC Hillsborough and relieving capacity constraints at UNC Chapel Hill.

The applicant adequately demonstrates that the proposed project to develop a VIR suite at UNC Hillsborough is the most effective alternative to meet UNC Hospitals' identified need.

Furthermore, the application is conforming to all other applicable statutory and regulatory review criteria, and thus, is approvable. A project that cannot be approved cannot be an effective alternative.

In summary, the applicant adequately demonstrates that its proposal is the least costly or most effective alternative to meet the identified need. Therefore, the application is conforming to this criterion and approved subject to the following conditions.

- 1. University of North Carolina Hospitals at Chapel Hill shall materially comply with all representations made in the certificate of need application.
- 2. University of North Carolina Hospitals at Chapel Hill shall purchase one unit of vascular interventional radiology equipment and develop a vascular interventional radiology suite at UNC Hospitals Hillsborough Campus.

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- 3. University of North Carolina Hospitals at Chapel Hill shall not acquire, as part of this project, any equipment that is not included in the project's proposed capital expenditure in Section Q, Form F.1a of the application and that would otherwise require a certificate of need.
- 4. No later than three months after the last day of each of the first three full years of operation following initiation of the services authorized by this certificate of need, University of North Carolina Hospitals at Chapel Hill shall submit, on the form provided by the Healthcare Planning and Certificate of Need Section, an annual report containing the:
 - a. Payor mix for the services authorized in this certificate of need.
 - b. Utilization of the services authorized in this certificate of need.
 - c. Revenues and operating costs for the services authorized in this certificate of need.
 - d. Average gross revenue per unit of service.
 - e. Average net revenue per unit of service.
 - f. Average operating cost per unit of service.
- 5. University of North Carolina Hospitals at Chapel Hill shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

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The applicant proposes to purchase one unit of VIR equipment and develop a VIR suite at UNC Hillsborough. The project will require the renovation of 1,100 square feet at the UNC Hillsborough facility.

Capital and Working Capital Costs

In Section F.1 and Section Q, Form F.1a, the applicant states that the total capital cost of the project will be \$3,083,656, as summarized in the table below.

Project Capital Cost

Construction / Renovation	\$1,016,000
Medical Equipment	\$1,811,256
Architect & Engineering Fees	\$152,400
Contingency and IT Costs	\$104,000
Total Capital Cost	\$3,083,656

Exhibit F.1 contains a May 10, 2017 cost estimate by a licensed architect.

In Section F.3, pages 61-62, the applicant states there will be no start-up or initial operating expenses associated with the proposed project.

Availability of Funds

In Section F.2, page 60, the applicant states that the project will be funded with accumulated reserves or owner's equity of UNC Hospitals. Exhibit F.2-1 contains a June 15, 2017 letter signed by the Executive Vice President and CFO for UNC Hospitals, which states:

"The total capital expenditure for this project is estimated to be \$3,083,656. There are no start-up costs related to this project.

UNC Hospitals will fund the capital cost from existing accumulated cash reserves. This expenditure will not impact any other capital projects currently underway or planned for at this time. For verification of the availability of these funds and our ability to finance these projects internally, please refer to the "Cash and Cash Equivalents" line item in the audited financial statements included with this Certificate of Need application."

Exhibit F.2-2 contains the audited financial statements for UNC Hospitals for the year ending June 30, 2016. As of June 30, 2016, UNC Hospitals had \$190,080,877 in cash and cash equivalents and \$1,311,716,613 in net assets. The applicant adequately demonstrates the availability of sufficient funds for the capital needs of the project.

Financial Feasibility

The information provided by the applicant in Section Q, Form F.4 shows that UNC Hospitals VIR services revenues will exceed expenses in each of the first three fiscal years following completion of the proposed project, as shown below.

UNC Hospitals VIR Services	FY2019	FY 2020	FY 2021
Projected # of VIR Patients	13,114	13,474	13,845
Projected Average Charge	\$6,601.26	\$6,799.57	\$7,003.27
Gross Patient Revenue	\$86,568,984	\$91,617,424	\$96,960,274
Deductions from Gross Patient Revenue	\$54,028,734	\$57,179,526	\$60,514,062
Net Patient Revenue	\$32,540,250	\$34,437,898	\$36,446,212
Total Expenses	\$31,684,007	\$33,275,993	\$34,953,674
Net Income	\$856,242	\$1,161,905	\$1,492,538

Totals may not sum due to rounding

The applicant projects that VIR services revenues will exceed operating expenses in each of the first three operating years of the project for UNC Hospitals. Furthermore, Form F.3, Statement of Revenues and Expenses for the entire facility, also shows revenues exceeding operating expenses in each of the first three years of the project.

The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs and charges. See Section Q of the application for the assumptions used regarding costs and charges. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference. The applicant adequately demonstrates sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.

Conclusion

In summary, the applicant adequately demonstrates the financial feasibility of the project is based upon reasonable and adequately supported assumptions regarding projected utilization, revenues (charges) and operating costs. Therefore, the application is conforming to this criterion.

(6) The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

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On page 39, the 2017 SMFP defines the service area for acute care services as the planning area in which the bed is located. "An acute care bed's service area is the acute care bed planning area in which the bed is located. The acute care bed planning areas are the single and multicounty groupings shown in Figure 5.1." Figure 5.1 on page 42 of the SMFP shows Orange County as a single county acute care bed planning area. UNC Hospitals is located in Orange County. Thus, the service area for this facility consists of Orange County. Facilities may also serve residents of counties not included in their service area.

UNC Hospitals is the only provider of acute care hospital services located in Orange County. UNC Hillsborough, a full-service acute care hospital, providing geriatric and oncology services does not currently offer comprehensive VIR services and therefore proposes to acquire VIR equipment and develop a VIR suite to provide those services at UNC Hillsborough and to alleviate VIR capacity constraints at UNC Chapel Hill. The applicant adequately demonstrates the need the population proposed to be served has for the proposed VIR services at UNC Hillsborough. The discussions regarding analysis of need, including projected utilization, and access, found in Criteria (3) and (4), respectively, are incorporated herein by reference.

Therefore, the applicant adequately demonstrates the project would not result in unnecessary duplication of existing or approved health services in the Orange County service area. Consequently, the application is conforming to this criterion.

(7) The applicant shall show evidence of the availability of resources, including health manpower and management personnel, for the provision of the services proposed to be provided.

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In Section Q, Form H, the applicant provides the projected staffing for UNC Hospitals VIR services, during the second full fiscal year following the completion of the project, as summarized in the following table.

Proposed Staffing FY2020

	Total # of FTE Position	Average Annual Salary	Total Projected Salary
Patient Services Manager	1.23	\$96,583	\$119,127
Clinical Nurse I	0.00	\$66,118	\$128
Clinical Nurse II	16.74	\$80,808	\$1,352,499
Clinical Nurse III	1.34	\$119,009	\$158,884
Clinical Nurse IV	0.77	\$90,465	\$70,063
Clinical Nurse II-OR	2.19	\$75,398	\$165,471
Clinical Nurse III-OR	0.00	\$420,149	\$267
Surgical Tech	0.18	49152	\$8,795
Senior Surgical Tech	0.00	\$69,430	\$179
Radiology Intervention Tech	21.65	\$80,686	\$1,746,634
Radiology Intervention Supervisor	0.80	\$120,209	\$95,844
Cardiac Cath Spec-N	0.00	\$151,499	\$351
Administrative Support Supervisor	0.01	\$52,623	\$597
Administrative Associate	0.00	\$38,137	\$0
Clinical Nurse-PD	0.18	\$79,243	\$14,028
Radiology Intervention Tech -PD	0.68	\$68,606	\$46,629
Temporary Nurse	0.02	\$81,071	\$1,871
Radiology Imaging Manager	0.23	\$123,758	\$28,560
Clinical Nurse Manager	0.00	\$89,234	\$0
Nuclear Medicine Tech	0.00	\$70,221	\$0
Totals	46.03		\$3,809,927

Totals may not sum due to rounding

As illustrated in the table above, the applicant projects 46.03 full-time equivalent (FTE) positions in FY2020, the second full fiscal year following completion of the proposed project. Form F.4, provides adequate salary allowances to cover the projected staffing.

In Section H.3, page 69, the applicant states that the project will not involve the addition of any new positions because the staff positions for the services are already in place, as the services are existing services provided by UNC Chapel Hill. In Section Q, Form H, the table and the assumptions show the incremental staff increase (40.54 FTE positions in 2018 to 46.03 FTE positions) with the expansion of the VIR service to include UNC Hillsborough.

In Section H.2, page 68, the applicant discusses UNC Hospitals' recruitment and staff retention plans. In Section H.4, pages 69-70, the applicant states Dr. Thomas Ivester serves as the Chief Medical Officer for UNC Hospitals and Dr. Charles Burke, a board certified radiologist serves as

Division Chief of Vascular Interventional Radiology and will provide medical direction for the VIR services at UNC Hillsborough. Exhibit H.4 contains copies of letters of support from the above referenced physicians. The applicant demonstrates the availability of adequate health manpower and management personnel to provide the proposed services, and therefore, the application is conforming to this criterion.

(8) The applicant shall demonstrate that the provider of the proposed services will make available, or otherwise make arrangements for, the provision of the necessary ancillary and support services. The applicant shall also demonstrate that the proposed service will be coordinated with the existing health care system.

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The applicant currently provides comprehensive VIR services at UNC Chapel Hill. UNC Hospitals has the necessary ancillary and support services currently available to provide comprehensive VIR services at UNC Hillsborough. In Section I.1 (a), page 71, the applicant states:

"UNC Hospitals currently has all ancillary and support services in place necessary to support hospital operations. These existing ancillary and support services will also support the VIR suite to be developed as proposed in this application. Patients utilizing the VIR suite may require the use of any of UNC Hospitals' existing ancillary and support services, including laboratory, radiology, pharmacy, housekeeping, maintenance, and administration, among others. Ancillary and support services will continue to be provided at the Hillsborough Campus upon completion of the proposed project."

Exhibit I.1 contains a letter from the President of UNC Hospitals attesting to the availability of the necessary ancillary and support services.

In Section I.2, page 71, the applicant states that UNC Hospitals has established relationships with area healthcare and social service providers. The applicant further states that the relationships will continue following completion of the proposed project. Exhibit I.2 contains letters of support from area healthcare providers.

The applicant adequately demonstrates the availability of the necessary ancillary and support services and that the proposed services will be coordinated with the existing health care system. Therefore, the application is conforming to this criterion.

(9) An applicant proposing to provide a substantial portion of the project's services to individuals not residing in the health service area in which the project is located, or in adjacent health service areas, shall document the special needs and circumstances that warrant service to these individuals.

NA

- (10) When applicable, the applicant shall show that the special needs of health maintenance organizations will be fulfilled by the project. Specifically, the applicant shall show that the project accommodates: (a) The needs of enrolled members and reasonably anticipated new members of the HMO for the health service to be provided by the organization; and (b) The availability of new health services from non-HMO providers or other HMOs in a reasonable and cost-effective manner which is consistent with the basic method of operation of the HMO. In assessing the availability of these health services from these providers, the applicant shall consider only whether the services from these providers:
 - (i) would be available under a contract of at least 5 years duration;
 - (ii) would be available and conveniently accessible through physicians and other health professionals associated with the HMO;
 - (iii) would cost no more than if the services were provided by the HMO; and
 - (iv) would be available in a manner which is administratively feasible to the HMO.

NA

- (11) Repealed effective July 1, 1987.
- (12) Applications involving construction shall demonstrate that the cost, design, and means of construction proposed represent the most reasonable alternative, and that the construction project will not unduly increase the costs of providing health services by the person proposing the construction project or the costs and charges to the public of providing health services by other persons, and that applicable energy saving features have been incorporated into the construction plans.

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In Section K.1, pages 74-75, the applicant states that the proposed project does not involve construction of new space; the proposed VIR Suite can be developed in existing space and will require only minor renovations. Exhibit C.1 contains the line drawings. Exhibit F.1 contains a certified cost estimate projecting renovation, equipment, and miscellaneous costs totaling \$3,083,656, which corresponds to the capital cost projections provided by the applicant in Section Q, Form F.1a. In Section K.4(c), pages 75-76, the applicant describes the methods that will be used by the facility to maintain efficient energy operations and contain the costs of utilities. The discussion regarding costs and charges found in Criterion (5) is incorporated herein by reference. The applicant adequately demonstrates that the proposed cost, design and means of construction represent the most reasonable alternative, and that the construction cost will not unduly increase costs and charges for health services. Therefore, the application is conforming to this criterion.

- (13) The applicant shall demonstrate the contribution of the proposed service in meeting the healthrelated needs of the elderly and of members of medically underserved groups, such as
 medically indigent or low income persons, Medicaid and Medicare recipients, racial and
 ethnic minorities, women, and handicapped persons, which have traditionally experienced
 difficulties in obtaining equal access to the proposed services, particularly those needs
 identified in the State Health Plan as deserving of priority. For the purpose of determining the
 extent to which the proposed service will be accessible, the applicant shall show:
 - (a) The extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved;

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In Section L.1(b), page 81, the applicant reports the following payor mix for UNC Hospitals' entire facility and its VIR services for FY2016, as illustrated in the table below:

Last Full FY 7/1/15-6/30/16
Patients as a Percent of Total Utilization

Payor Source	Entire Facility	UNC Hospitals VIR Services
Self-Pay / Indigent / Charity	5.9%	6.1%
Medicare	33.3%	44.0%
Medicaid	28.5%	13.7%
Commercial Insurance/ Managed Care	27.3%	29.7%
Other (Other Gov't)	4.9%	6.4%
Total	100.0%	100.0%

Totals may not sum due to rounding

As shown in the table above, the applicant states that 44% of its VIR services were reimbursed by Medicare and 13.7% were reimbursed by Medicaid during FY2016.

In Section L.2(b), pages 81-82, the applicant states:

"As North Carolina's only state-owned comprehensive, full service hospital-based program, UNC Hospitals has the obligation to accept any North Carolina citizen requiring medically necessary treatment. No North Carolina citizen is presently denied access to non-elective care because of race, sex, creed, age, handicap, financial status or lack of medical insurance. Charity care provided by UNC Hospitals for Fiscal Year 2019 is estimated to be \$245 million.

The proposed project will be designed in accordance with the latest State of North Carolina and Federal guidelines for handicapped accessibility. The project incorporates all applicable provisions of the Americans with Disabilities Act."

The applicant further states that UNC Hospitals has traditionally provided services to a wide variety of patient groups, as shown in the following table providing utilization percentages for UNC Hospitals as a whole and VIR services in FY2016.

	Low	Low Racial & Ethnic			Other
	Income	Minorities	Women	Elderly	Underserved
UNC Hospitals Total	16.1%	36.2%	58.7%	26.4%	9.2%
VIR Services*	14.7%	36.0%	31.3%	49.7%	5.7%

^{*}Includes VIR services provided at UNC Hospital Chapel Hills and at Vascular Interventional Radiology at Meadowmont Low Income = Medicaid and ½ of Medicaid Pending; Other Underserved = Self Pay and ½ of Medicaid Pending. "Low income" is based on Federal poverty guidelines as outlined in the Patient Financial Assistance Policy contained in Exhibit C.10. "Elderly" is defined as patients age 65 and over.

The United States Census Bureau provides demographic data for North Carolina and all counties in North Carolina. The following table contains relevant demographic statistics for the applicant's service area.

Percent of Population						
County	% 65+	% Female	% Racial and Ethnic Minority*	% Persons in Poverty**	% < Age 65 with a Disability	% < Age 65 without Health Insurance**
	2016 Estimate	2016 Estimate	2016 Estimate	2015 Estimate	2011-2015	2015 Estimate
Orange	12%	52%	31%	14%	6%	10%
Statewide	16%	51%	37%	16%	10%	13%

http://www.census.gov/quickfacts/table

Latest Data 7/1/16 as of 8/22/17

However, a direct comparison to the applicant's current payor mix would be of little value. The population data by age, race or gender does not include information on the number of elderly, minorities, women or handicapped persons utilizing health services.

The applicant demonstrates that it currently provides adequate access to medically underserved populations. Therefore, the application is conforming to this criterion.

(b) Its past performance in meeting its obligation, if any, under any applicable regulations requiring provision of uncompensated care, community service, or access by minorities

^{*}Excludes "White alone" who are "not Hispanic or Latino"

^{**&}quot;This geographic level of poverty and health estimates are not comparable to other geographic levels of these estimates. Some estimates presented here come from sample data, and thus have sampling errors that may render some apparent differences between geographies statistically indistinguishable...The vintage year (e.g., V2016) refers to the final year of the series (2010 thru 2016). Different vintage years of estimates are not comparable."

and handicapped persons to programs receiving federal assistance, including the existence of any civil rights access complaints against the applicant;

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Recipients of Hill-Burton funds were required to provide uncompensated care, community service and access by minorities and handicapped persons. In Section L.2(b), page 81, the applicant states:

"UNC Hospitals has long since satisfied its "free care" obligation under the Hill-Burton Act. UNC Hospitals has no obligations under federal regulations to provide uncompensated care, community services, or access to care by medically underserved, minorities, or handicapped persons."

However, as stated by the applicant in Section L.2,(b), pages 81-82:

"As North Carolina's only state-owned comprehensive, full service hospital-based program, UNC Hospitals has the obligation to accept any North Carolina citizen requiring medically necessary treatment. No North Carolina citizen is presently denied access to non-elective care because of race, sex, creed, age, handicap, financial status or lack of medical insurance. Charity care provided by UNC Hospitals for Fiscal Year 2019 is estimated to be \$245 million.

The proposed project will be designed in accordance with the latest State of North Carolina and Federal guidelines for handicapped accessibility. The project incorporates all applicable provisions of the Americans with Disabilities Act."

See Exhibit C.10 for copies of the applicant's "Assuring Access at UNC Health Care" and financial assistance policies.

In Section L.2(c), page 82, the applicant states that it has not been notified of any civil rights equal access complaints being filed against the hospital and/or any facilities or services owned by the hospital within the past five years. Therefore, the application is conforming to this criterion.

(c) That the elderly and the medically underserved groups identified in this subdivision will be served by the applicant's proposed services and the extent to which each of these groups is expected to utilize the proposed services; and

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 \mathbf{C}

In Section L.3(a), page 83, the applicant provides the projected payor mix for the entire facility, and UNC Hospitals VIR services for FY2020 (July 1, 2019 – June 30, 2020), the second full fiscal year following completion of the project, as illustrated in the table below:

Projected FY2020 Payor Mix Patients as a Percent of Total Utilization

Payor Source	Entire Facility	UNC Hospitals VIR Services
Self-Pay / Indigent / Charity	5.9%	6.1%
Medicare	33.3%	44.0%
Medicaid	28.5%	13.7%
Commercial Insurance/ Managed Care	27.3%	29.7%
Other (Other Gov't)	4.9%	6.4%
Total	100.0%	100.0%

Totals may not sum due to rounding

On page 83, the applicant states:

"UNC Hospitals does not expect that the proposed project will change payor mix. Thus, UNC Hospitals assumed payor mix will remain consistent with its historical payor mix through the third project year."

The applicant adequately demonstrates the extent to which medically underserved populations will have access to the proposed services. Therefore, the application is conforming to this criterion.

(d) That the applicant offers a range of means by which a person will have access to its services. Examples of a range of means are outpatient services, admission by house staff, and admission by personal physicians.

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In Section L.5, page 84, the applicant describes the range of means by which a person will have access to its services, including by self-referral and physician referral. The applicant adequately demonstrates that the facility will offer a range of means by which patients will have access to the proposed services. The information provided in Section L.5 is reasonable and credible and supports a finding of conformity to this criterion.

(14) The applicant shall demonstrate that the proposed health services accommodate the clinical needs of health professional training programs in the area, as applicable.

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In Section M.1, pages 85-86, the applicant states that UNC Hospitals serves as a clinical site for a broad range of healthcare disciplines including medical, dental, public health, pharmacy, and nursing students, as well as students in medical technology, medical therapies and many others. The applicant also states that vascular interventional radiology is a unique specialty that interfaces with virtually every medical discipline, as it provides minimally invasive procedures for diagnosis and treatment of a wide range of pathology across all ages. As a result, this affects a variety of learners and training programs, such as surgery, urology, internal medicine, oncology, family practice and pediatrics, in addition to radiology and will enhance the clinical experience of those clinical training programs. In addition, the Department of Radiology provides electives for medical students and residents, including international learners. The applicant states that educational development is strongly supported by UNC Hospitals; therefore, the proposed VIR suite at UNC Hillsborough will be available as a clinical site for training programs. The information provided in Section M.1 is reasonable and credible and supports a finding of conformity to this criterion.

- (15) Repealed effective July 1, 1987.
- (16) Repealed effective July 1, 1987.
- (17) Repealed effective July 1, 1987.
- (18) Repealed effective July 1, 1987.
- (18a) The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact upon the cost effectiveness, quality, and access to the services proposed; and in the case of applications for services where competition between providers will not have a favorable impact on cost-effectiveness, quality, and access to the services proposed, the applicant shall demonstrate that its application is for a service on which competition will not have a favorable impact.

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On page 39, the 2017 SMFP defines the service area for acute care services as the planning area in which the bed is located. "An acute care bed's service area is the acute care bed planning area in which the bed is located. The acute care bed planning areas are the single and multicounty groupings shown in Figure 5.1." Figure 5.1 on page 42 of the SMFP shows Orange County as a single county acute care bed planning area. UNC Hospitals is located in Orange County. Thus, the service area for this facility consists of Orange County. Facilities may also serve residents of counties not included in their service area.

UNC Hospitals is the only provider of acute care hospital services located in Orange County. UNC Hillsborough, a full-service acute care hospital, providing geriatric and oncology services does not currently offer comprehensive VIR services; therefore, UNC Hospitals proposes to acquire VIR equipment and develop a VIR suite to provide comprehensive VIR services at UNC Hillsborough and to alleviate VIR capacity constraints at UNC Chapel Hill.

In Section N, pages 87-89, the applicant discusses how any enhanced competition in the service area will promote cost-effectiveness, quality and access to the proposed services. The applicant states:

"UNC Hospitals believes that the proposed project may foster some competition in the proposed service area, particularly as the only provider of acute care services in the service area. However, the proposed project is not specifically being developed to foster competition per se, but rather to enhance the provision of timely, quality patient care and to assist UNC Hospitals in meeting its four-fold mission of patient care, teaching, research, and community service. UNC Hospitals maintains that the development of a full-service VIR suite on its Hillsborough Campus will promote cost-effectiveness, quality, and access to services in the service area and will thus be in compliance with the spirit and legislative intent of the Certificate of Need Law."

See also Sections B, C, E, F and H where the applicant discusses the impact of the project on cost-effectiveness, quality and access.

The information in the application is reasonable and credible and adequately demonstrates that any enhanced competition in the service area includes a positive impact on cost-effectiveness, quality and access to the proposed services. This determination is based on the information in the application and the following analysis:

- The applicant adequately demonstrates the need to develop comprehensive VIR services at UNC Hillsborough and that the project is a cost-effective alternative. The discussions regarding analysis of need and alternatives found in Criteria (3) and (4), respectively, are incorporated herein by reference.
- The applicant adequately demonstrates that UNC Hospitals has and will continue to provide quality services. The discussion regarding quality found in Criterion (20) is incorporated herein by reference.
- The applicant adequately demonstrates UNC Hospitals will continue to provide adequate access to medically underserved populations. The discussions regarding access found in Criteria (3), (3a), and (13) are incorporated herein by reference.

The application is conforming to this criterion.

(19) Repealed effective July 1, 1987.

(20) An applicant already involved in the provision of health services shall provide evidence that quality care has been provided in the past.

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In Section O.1, page 92, the applicant describes the methods used by UNC Hospitals to insure and maintain quality care, including its Performance Improvement Program and each department's own Quality Assurance program. Exhibit N.2 contains copies of UNC Hospitals Performance Improvement Program, Utilization Management Review Plan and Risk Management Program.

In Section O.2, page 92, the applicant documents that UNC Hospitals meets all licensure requirements, is certified for participation in the Medicare and Medicaid programs and currently meets all requirements for certification, and is accredited by The Joint Commission.

In Section O.3(a), pages 92-93, the applicant states that in addition to the two UNC Hospitals academic medical campuses, other entities under the UNC Health Care System include UNC REX Healthcare, Chatham Hospital, High Point Regional Health, Caldwell Memorial Hospital, and the UNC Physicians Network (formerly TPN). The applicant states that the UNC Health Care System also has partial ownership of Johnston Health Services Corporation, which oversees Johnston Health's hospital operations; and manages Pardee Hospital, Nash Health Care, Wayne Memorial Hospital, and UNC Lenoir Health Care. In Section O.3(c), page 93, the applicant further states:

"None of the facilities identified in response to Section O, Question 3(a) was determined by the Division of Health Service Regulation or the Centers for Medicare and Medicaid Services to have operated out of compliance with any Medical Conditions of Participation during the 18 month look-back period.

... None of the facilities in response to Section O, Question 3(a) had any deficiencies."

After reviewing and considering information provided by the applicant and by the Acute and Home Care Licensure and Certification Section and considering the quality of care provided at all nine facilities, the applicant provided sufficient evidence that quality care has been provided in the past and adequately demonstrated that there is no pattern of substandard quality of care. Therefore, the application is conforming to this criterion.

- (21) Repealed effective July 1, 1987.
- (b) The Department is authorized to adopt rules for the review of particular types of applications that will be used in addition to those criteria outlined in subsection (a) of this section and may vary according to the purpose for which a particular review is being conducted or the type of

health service reviewed. No such rule adopted by the Department shall require an academic medical center teaching hospital, as defined by the State Medical Facilities Plan, to demonstrate that any facility or service at another hospital is being appropriately utilized in order for that academic medical center teaching hospital to be approved for the issuance of a certificate of need to develop any similar facility or service.