

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: July 21, 2021

Findings Date: July 21, 2021

Project Analyst: Tanya M. Saporito

Team Leader: Gloria C. Hale

Project ID #: J-12067-21

Facility: University of North Carolina Hospitals-Hillsborough

FID #: 090274

County: Orange

Applicant: University of North Carolina Hospitals at Chapel Hill

Project: Expand an existing hospital-based oncology clinic

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

N.C. Gen. Stat. §131E-183(a) The Agency 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.

C

University of North Carolina Hospitals at Chapel Hill (hereinafter referred to as “the applicant”) proposes to expand an existing hospital-based oncology clinic and related hospital-based oncology services in an existing medical office building (MOB) on the University of North Carolina Hospitals-Hillsborough (UNC Hillsborough) campus.

Need Determination

The applicant does not propose to develop any beds or services for which there is a need determination in the 2021 State Medical Facilities Plan (SMFP). Further, the applicant does not propose to acquire any medical equipment for which there is a need determination in the 2021 SMFP.

Policies

There is one policy in the 2021 SMFP applicable to this review.

Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities, on page 29 of the 2021 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 is required to submit a plan for 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.”

The proposed capital expenditure for this project is greater than \$2 million but less than \$5 million. In Exhibit B.21 and Section K.3, pages 74-75, the applicant describes the project’s plan to improve energy efficiency and conserve water. The applicant adequately demonstrates that the application includes a written statement describing the project’s plan to assure improved energy efficiency and water conservation.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion because the applicant adequately demonstrates that the proposal is consistent with Policy GEN-4 in that it includes a written statement describing the project’s plan to assure improved energy efficiency and water conservation.

- (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.

C

The applicant proposes to expand an existing hospital-based oncology clinic and related hospital-based oncology services in a MOB on the UNC Hillsborough campus. In Section C, pages 26-27, the applicant states the project involves renovation of 8,162 square feet of existing space in the MOB to accommodate the following specifics:

- Develop seven additional infusion therapy bays (for a total of 18)
- Develop four additional exam rooms (for a total of 19)
- Develop additional provider workstations
- Develop a procurement lab (to accommodate on-site tissue sampling and evaluation)

Patient Origin

N.C.G.S. §131E-176(24a) states: “*Service area means the area of the State, as defined in the State Medical Facilities Plan or rules adopted by the Department, which receives services from a health service facility.*” The 2021 SMFP does not define a service area for a provider-based oncology care MOB that provides infusion therapy and related oncology services, nor are there any applicable rules adopted by the Department that define the service area for a provider-based cancer care center. Thus, the service area in this review is as defined by the applicant. In Section C, pages 30-35 the applicant explains the service area that has been served by UNC oncology services, both at the main campus and the Hillsborough campus. The applicant states the primary service area for oncology services at the Hillsborough location is Orange County. Facilities may also serve residents not included in their service area.

On pages 28-29, the applicant states that existing multiple myeloma patients currently seen on the main UNC Chapel Hill campus are projected to receive comprehensive care at the MOB following project completion; therefore, patient origin combines those multiple myeloma patients historically seen and treated at the main UNC Chapel Hill campus, as shown in the following tables:

UNC HOSPITALS HILLSBOROUGH CAMPUS HISTORICAL INFUSION THERAPY VISITS

COUNTY	LAST FULL FY (JULY 1, 2019 – JUNE 30, 2020)	
	NUMBER OF PATIENTS	% OF TOTAL
Orange	1,191	26.4%
Alamance	807	17.9%
Durham	457	10.1%
Chatham	276	6.1%
Wake	248	5.5%
Guilford	201	4.5%
Vance	181	4.0%
Person	150	3.3%
Caswell	136	3.0%
Danville City, Virginia	132	2.9%
Pittsylvania, Virginia	83	1.8%
Lee	63	1.4%
Cumberland	56	1.3%
Randolph	52	1.2%
Pitt	49	1.1%
Other*	422	9.4%
Total	4,505	100.0%

*The applicant states “other” includes Beaufort, Bertie, Brunswick, Burke, Carteret, Chowan, Davie, Duplin, Forsyth, Franklin, Granville, Halifax, Harnett, Hoke, Johnston, Lenoir, Mecklenburg, Mitchell, Montgomery, Moore, New Hanover, Northampton, Onslow, Pender, Perquimans, Richmond, Robeson, Rockingham, Rowan, Sampson, Wilson and Yancey counties in North Carolina and other states.

UNC HOSPITALS MAIN CAMPUS HISTORICAL MULTIPLE MYELOMA INFUSION THERAPY VISITS

COUNTY	LAST FULL FY (JULY 1, 2019 – JUNE 30, 2020)	
	NUMBER OF PATIENTS	% OF TOTAL
Wake	571	22.0%
Orange	394	15.2%
Chatham	342	13.2%
Durham	189	7.3%
Caswell	145	5.6%
Alamance	128	4.9%
Nash	123	4.7%
Moore	117	4.5%
Cumberland	113	4.4%
Edgecombe	74	2.8%
Guilford	50	1.9%
Lee	43	1.6%
Pender	41	1.6%
Danville City, Virginia	39	1.5%
Other*	224	8.6%
Total	2,592	100.0%

*The applicant states “other” includes Beaufort, Brunswick, Buncombe, Cabarrus, Caldwell, Carteret, Craven, Dare, Duplin, Forsyth, Gaston, Halifax, Harnett, Hoke, Johnston, Jones, Lenoir, Lincoln, Martin, Mecklenburg, Montgomery, New Hanover, Onslow, Person, Pitt, Randolph, Richmond,

Robeson, Rockingham, Rowan, Sampson, Scotland, Surry, Warren,
 Washington, Wayne and Wilson counties in North Carolina and other states.

In Section C, page 31, the applicant provides a table to illustrate projected patient origin for oncology infusion therapy visits which include those patients historically seen at the UNC Chapel Hill main campus, as shown in the following table:

UNC HOSPITALS HILLSBOROUGH CAMPUS MOB PROJECTED PATIENT ORIGIN

COUNTY	1 ST FULL FY 7/1/2023-6/30/2024		2 ND FULL FY 7/1/2024-6/30/2025		3 RD FULL FY 7/1/2025-6/30/3026	
	NUMBER OF PATIENTS	% OF TOTAL	NUMBER OF PATIENTS	% OF TOTAL	NUMBER OF PATIENTS	% OF TOTAL
Orange	1,626	22.3%	1,636	22.3%	1,647	22.3%
Alamance	959	13.2%	965	13.2%	972	13.2%
Wake	839	11.5%	845	11.5%	850	11.5%
Durham	663	9.1%	667	9.1%	672	9.1%
Chatham	634	8.7%	638	8.7%	642	8.7%
Caswell	287	3.9%	289	3.9%	291	3.9%
Guilford	258	3.5%	259	3.5%	261	3.5%
Vance	185	2.5%	187	2.5%	188	2.5%
Danville City, Virginia	175	2.4%	176	2.4%	178	2.4%
Cumberland	174	2.4%	175	2.4%	176	2.4%
Person	157	2.2%	158	2.2%	159	2.2%
Moore	134	1.8%	135	1.8%	136	1.8%
Nash	126	1.7%	126	1.7%	127	1.7%
Lee	109	1.5%	109	1.5%	110	1.5%
Pittsylvania, Virginia	85	1.2%	86	1.2%	86	1.2%
Edgecombe	76	1.0%	76	1.0%	77	1.0%
Randolph	71	1.0%	71	1.0%	72	1.0%
Other*	721	9.9%	726	9.9%	730	9.9%
Total	7,280	100.0%	7,326	100.0%	7,374	100.0%

*The applicant states "other" includes Beaufort, Bertie, Brunswick, Buncombe, Burke, Cabarrus, Caldwell, Carteret, Chowan, Craven, Dare, Davie, Duplin, Forsyth, Franklin, Gaston, Granville, Halifax, Harnett, Hoke, Johnston, Jones, Lenoir, Lincoln, Martin, Mecklenburg, Mitchell, Montgomery, New Hanover, Northampton, Onslow, Pender, Perquimans, Pitt, Richmond, Robeson, Rockingham, Rowan, Sampson, Scotland, Surry, Warren, Washington, Wayne, Wilson and Yancey counties in North Carolina and other states.

In Section Q, tab Form C, the applicant provides the assumptions and methodology used to project its patient origin. The applicant's assumptions are reasonable and adequately supported because they are based on historical patient origin of existing UNC patients receiving oncology clinic and outpatient infusion therapy services.

Analysis of Need

In Section C.4, pages 33-37, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services, as summarized below:

- Growth, aging and cancer incidence in the Orange County population – the applicant states the population of Orange County as a whole increased by 11.0% from 2011-

2021, according to data obtained from the North Carolina Office of State Budget and Management (NCOSBM) and is projected to continue to increase between 2021-2029. The applicant states the population growth in the counties that surround Orange County and contribute to UNC-Hillsborough’s patient population is also projected to increase during that same time (pages 33-34).

- Growth in the over 65 population in Orange County and surrounding counties – the applicant relies on additional NCOSBM data to show that the over-65 population in the service area is projected to increase by 33.0% from 2021-2029 and comprise more than 19% of the total county population, as shown in the following table:

COUNTY	2021		2029		TOTAL GROWTH 2021-2029
	TOTAL 65+	% OVER 65	TOTAL 65+	% OVER 65	
Orange	22,634	15.7%	31,426	19.4%	33.0%

Source: application page 34

The applicant states the over 65 population is the population group most likely to utilize healthcare services like the oncology services provided by the applicant (pages 34-35).

- Incidence of cancer in Orange County and surrounding counties served by UNC hospitals which will drive the demand for cancer services – the applicant provides data to show that the incidence of cancer in the service area and in the state as a whole is high, and the population of Orange County is projected to increase. Specifically, the applicant states Orange County and some of the contiguous counties report some of the highest cancer incidence rates in the state (pages 35-36).
- Need for expanded hospital-based oncology services at the UNC Hillsborough campus – the applicant states it needs to expand existing oncology and infusion therapy services, including adding a procurement lab at the Hillsborough MOB location, in direct response to patient demand and to support its research initiatives. The procurement lab will permit tissue sampling and testing on-site. The applicant states UNC Hospitals in the only hospital-based oncology provider in Orange County (pages 35-36).
- The proposed inclusion of the multiple myeloma patients – the applicant states the multiple myeloma patients who are currently treated at the main campus will be treated at the Hillsborough campus, which will allow for easier access for patients (page 37).

The information is reasonable and adequately supported based on the following:

- The applicant uses historical and demographic data to identify the population to be served, the projected growth, aging and cancer incidence within that population, and the need the identified population has for the proposed services;
- The applicant demonstrated the need for oncology clinic services and infusion therapy services for the projected population.

- The applicant demonstrated that the multiple myeloma patient population historically served at the main UNC campus would be better served at the Hillsborough MOB.

Projected Utilization

In Form C.4a and C.4b, Section Q, the applicant provides historical and projected utilization, as illustrated in the following tables:

UNC Hillsborough Historical and Interim Utilization

	LAST FULL FY	INTERIM FY	INTERIM FY	INTERIM FY
	7/1/19-6/30/20	7/1/20-6/30/21	7/1/21-6/30/22	7/1/22-6/30/23
# Infusion Therapy Chairs	11	11	11	18
Infusion Therapy Visits	4,505	4,550	4,595	6,801
E&M Physician Visits*	3,626	3,662	3,699	6,514
Total	8,131	8,212	8,294	13,315

*E&M is defined on application page 37 as *evaluation and management* visits, which are physician oncology visits

UNC Hillsborough Projected Utilization

	1 ST FULL FY	2 ND FULL FY	3 RD FULL FY
	7/1/23-6/30/24	7/1/24-6/30/25	7/1/25-6/30/26
# Infusion Therapy Chairs	18	18	18
Infusion Therapy Visits	7,280	7,326	7,374
E&M Physician Visits	7,107	7,145	7,183
Total	14,387	14,471	14,557

In Section Q, the applicant provides the assumptions and methodology used to project utilization, which are summarized below:

- The applicant states that the proposed project will begin operation September 1, 2022, and the applicant’s FY corresponds to the state FY as noted in the tables above.
- The applicant calculated the compound annual growth rate (CAGR) from FY 2017 to FY 2020 based on the historical utilization of infusion therapy services (involves one patient visit during which infusion chair therapy occurs) at UNC Hillsborough campus and the multiple myeloma patients at the UNC main campus, as shown in the following table:

Historical Infusion Therapy Visits – Hillsborough and Main Campus

	FY 2017	FY 2018	FY 2019	FY 2020	CAGR
Total Hillsborough Infusion Visits	2,941	3,829	4,518	4,505	15.3%
Main Campus MM* Infusion Visits	2,716	3,040	2,785	2,592	-2.1%
Total	5,702	6,869	7,303	7,097	7.6%

Source: Application Section Q

*multiple myeloma

The applicant states the total Hillsborough campus visits have increased, while the main campus multiple myeloma visits decreased slightly. Total combined visits increased by a CAGR of 7.6% from FY 2017 to FY 2020.

- The applicant analyzed the historical number of oncology evaluation and management (“E&M”) visits for the same time, as shown in the following table:

Historical Oncology E&M Visits at Hillsborough Campus

	FY 2017	FY 2018	FY 2019	FY 2020	CAGR
Total Hillsborough Campus E&M	2,101	3,123	3,255	3,626	20.0%
Main Campus MM E&M Visits	1,541	3,246	3,480	3,334	29.3%
Total	3,642	6,369	6,735	6,960	24.1%

Source: Application Section Q

The applicant states the total Hillsborough campus E&M visits increased by 20%, and the main campus multiple myeloma E&M visits increased by 29.3% from FY 2017 to FY 2020. Total combined visits increased by a CAGR of 24.1% during the same time.

- The applicant states the North Carolina Office of State Budget and Management (NC OSBM) data indicates the Orange County population is projected to increase by 1.0% annually through 2029, and the over 65 population is projected to increase by 3.6% during the same time, as shown in the following table:

	2021	2029	CAGR
Orange County Total Population	150,125	162,199	1.0%
Orange County 65+ Population	23,634	31,426	3.6%

Source: Application Section Q

- The applicant assumes the Hillsborough Campus infusion visits will increase at the same rate as the projected population growth, 1.0%, and that the multiple myeloma visits will remain constant, with no growth. Combined, that results in a 0.6% annual growth for the Hillsborough Campus. Given the historical growth shown in the tables above, the applicant states this projection is conservative. See the following table, from Section Q, to illustrate the projections:

Hillsborough Campus Projected Infusion Visits

	FY 2021	FY 2022	FY 2023	FY 2024	FY 2025	FY 2026	CAGR
Total Hillsborough Infusion Visits*	4,550	4,595	4,641	4,688	4,734	4,782	1.0%
Main Campus MM Infusion Visits	2,592	2,592	2,592	2,592	2,592	2,592	0.0%
Total Potential Infusion Visits	7,142	7,187	7,233	7,280	7,325	7,374	0.6%

*Includes total historical Hillsborough Campus infusion visits prior to adding Main Campus multiple myeloma visits

- The applicant states the project will become operational on September 1, 2022, which is FY 2023. Thus, the third FY is FY 2026. Beginning on September 1, 2022, the applicant assumes 83.3% of the multiple myeloma visits which have historically been performed on the Main Campus will shift to the Hillsborough Campus. To project growth in these visits, the applicant determined that the total projected Hillsborough

infusion visits will consist of 100% of the Hillsborough Campus infusion visits, and 83.3% of the Main Campus infusion visits as shown in the following table from Section Q:

Hillsborough Campus and Main Campus Multiple Myeloma Projected Infusion Visits

	FY 2020	FY 2021	FY 2022	FY 2023*	FY 2024	FY 2025	FY 2026
Hillsborough Campus Infusion Visits	4,505	4,550	4,595	6,801	7,280	7,326	7,374

*Beginning FY 2023, total Hillsborough visits includes 83.3% of Main Campus projected myeloma visits

- The applicant states its experience shows that the capacity of one infusion therapy bay is two patients per workday, and that each infusion therapy takes 240 minutes, or four hours. Each infusion bay is assumed to be available eight hours per workday; therefore, each infusion bay can accommodate two patients per workday.
- The applicant states the infusion therapy service on the Hillsborough Campus currently operates with an average of 1.6 patients per workday. The applicant states that, assuming two patients per infusion bay per workday and 250 workdays per year, the projected utilization of 7,374 infusion therapy visits will require 14.7 bays [7,374 infusion visits / 2 visits per day / 250 days per year = 14.748]. The applicant proposes a total of 18 infusion bays, which would mean those bays would operate at 81.9% capacity [14.748 / 18 = 0.81933]. The applicant states the Hillsborough Campus currently operates at the same capacity with 11 infusion therapy bays. See the following table from Section Q:

Hillsborough Campus Infusion Therapy Bays Projected Utilization

	FY 2020	FY 2021	FY 2022	FY 2023	FY 2024	FY 2025	FY 2026
Hillsborough Campus Infusion Visits	4,505	4,550	4,595	6,801	7,280	7,326	7,374
# Infusion Bays Needed	9.0	9.1	9.2	13.6	14.6	14.7	14.7
# Infusion Bays	11	11	11	18	18	18	18
% Capacity	81.9%	82.7%	83.6%	75.6%	80.9%	81.4%	81.9%

- The applicant also projects the E&M visits on the Hillsborough Campus to increase at 1.0%, consistent with the Orange County projected population growth for 2020-2029. Additionally, the E&M visits historically served on the Main Campus will be served on the Hillsborough Campus and the growth of those visits will remain constant, as shown in the following table from Section Q:

Potential E&M Visits for UNC Hillsborough Campus

	FY 2021	FY 2022	FY 2023	FY 2024	FY 2025	FY 2026
Hillsborough Campus E&M Visits*	3,662	3,699	3,763	3,773	3,811	3,849
Main Campus Multiple Myeloma E&M	3,334	3,334	3,334	3,334	3,334	3,334
Total Potential E&M Visits	6,996	7,033	7,070	7,107	7,145	7,183

*includes 83.3% of Main Campus projected myeloma visits

The applicant assumes that 83.3% of the Main Campus multiple myeloma E&M visits will be provided on the Hillsborough Campus, as with infusion therapy visits beginning in FY 2023, as shown in the following table from Section Q:

Hillsborough Campus E&M Visits

	FY 2021	FY 2022	FY 2023*	FY 2024	FY 2025	FY 2026
Hillsborough Campus E&M Visits	3,662	3,699	6,514	7,107	7,145	7,183

*Beginning FY 2023, total Hillsborough visits includes 83.3% of Main Campus projected myeloma visits

Projected utilization is reasonable and adequately supported based on the following reasons:

- The applicant uses NC OSBM population growth projections and its own historical utilization to project the number of infusion therapy visits and the number of E&M visits to be served on the Hillsborough Campus following project completion.
- The applicant conservatively projects growth in the Hillsborough Campus visits at a rate that is consistent with population growth projections.
- The applicant factored in capacity of the 18 proposed infusion therapy bays.

Access to Medically Underserved Groups

In Section C.6, page 44, the applicant states that, as North Carolina’s only state-owned full-service hospital system, UNC Healthcare System (including UNC Hospitals) is obligated to accept any North Carolina citizen who requires medical treatment; as such, UNC Hospitals will not deny access to any non-elective care because of race, creed, sex, age, handicap, financial status or lack of medical insurance.

On page 45 the applicant provides the estimated percentage for each medically underserved group during FY 2026, as shown in the following table:

MEDICALLY UNDERSERVED GROUPS	PERCENTAGE OF TOTAL PATIENTS
Low income persons	--
Racial and ethnic minorities	34.8%
Women	60.0%
Persons with Disabilities	--
The elderly	32.3%
Medicare beneficiaries	37.6%
Medicaid recipients	11.6%

The applicant states it does not maintain data that includes the number of low-income persons or persons with disabilities and thus has no basis to include that data; however, the applicant states it will not deny access to services to any person within those groups.

The applicant adequately describes the extent to which all residents of the service area, including underserved groups, are likely to have access to the proposed services based on the following:

- The applicant estimates the percentages of underserved groups it will serve based on historical percentages.
- The applicant states it will continue to provide services to persons in traditionally underserved groups at all of its UNC campuses.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for the following reasons:

- The applicant adequately identifies the population to be served.
- The applicant adequately explains why the population to be served needs the services proposed in this application.
- Projected utilization is reasonable and adequately supported.
- The applicant describes the extent to which all residents, including underserved groups, are likely to have access to the proposed services and adequately supports its assumptions.

- (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.

NA

The applicant does not propose to reduce a service, eliminate a service or relocate a facility or service. Therefore, Criterion (3a) is not applicable to this review.

- (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

The applicant proposes to expand an existing hospital-based oncology clinic and related hospital-based oncology services in a MOB on the UNC Hillsborough campus.

In Section E, pages 54-55, the applicant describes the alternatives it considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

- Maintain the Status Quo- The applicant states this alternative would not develop additional needed capacity for hospital-based oncology services at UNC Hillsborough and would result in treatment delays for patients due to lack of capacity. Additionally, the applicant states this alternative would not allow UNC to develop the procurement lab that will allow providers to collect and process tissue samples on-site to deliver timely care for patients. This alternative would also fail to address access and capacity issues for the multiple myeloma patients who currently must travel to the main campus for treatment. Thus, this is not an effective alternative.
- Expand existing hospital-based oncology services at the main UNC campus – The applicant states increasing capacity at the main UNC campus is not an effective alternative because that campus is already experiencing capacity constraints. Travel issues in the congested area create additional difficulties for patients. The applicant states expansion of these services at the main campus would not allow the applicant to consolidate comprehensive oncology services, including physician visits and infusion therapy services, for the patients it serves. Thus, this is not an effective alternative.
- Develop a different number of infusion therapy bays/exam rooms – The applicant states developing fewer infusion therapy bays and/or exam rooms would fail to address the existing capacity constraints at UNC hospitals and would not effectively serve increasing patient demand. Thus, this is not an effective alternative.

On pages 54-55, the applicant states that its proposal is the most effective alternative because it will offer a more accessible location for high quality oncology services, including infusion therapy and procurement lab services for patients in the service area.

The applicant adequately demonstrates that the alternative proposed in this application is the most effective alternative to meet the need based on the following reasons:

- The application is conforming to all statutory and regulatory review criteria.
- The applicant explains why it believes the proposed project is the most effective alternative to treat increasing demand for oncology services.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above. Therefore, the application is approved subject to the following conditions:

- 1. University of North Carolina Hospitals at Chapel Hill (hereinafter certificate holder) shall materially comply with all representations made in the certificate of need application.**
- 2. The certificate holder shall develop seven addition infusion therapy bays, four additional exam rooms and a procurement lab at the existing MOB on the UNC Hillsborough campus.**
- 3. Progress Reports:**
 - a. Pursuant to G.S. 131E-189(a), the certificate holder shall submit periodic reports on the progress being made to develop the project consistent with the timetable and representations made in the application on the Progress Report form provided by the Healthcare Planning and Certificate of Need Section. The form is available online at: <https://info.ncdhhs.gov/dhsr/coneed/progressreport.html>.**
 - b. The certificate holder shall complete all sections of the Progress Report form.**
 - c. The certificate holder shall describe in detail all steps taken to develop the project since the last progress report and should include documentation to substantiate each step taken as available.**
 - d. Progress reports shall be due on the first day of every third month. The first progress report shall be due on December 1, 2021. The second progress report shall be due on March 1, 2022 and so forth.**
- 4. The certificate holder shall not acquire as part of this project any equipment that is not included in the project's proposed capital expenditures in Section Q of the application and that would otherwise require a certificate of need.**
- 5. No later than three months after the last day of each of the first three full fiscal years of operation following initiation of the services authorized by this certificate of need, the certificate holder 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.**

6. The certificate holder 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.

C

The applicant proposes to expand an existing hospital-based oncology clinic and related hospital-based oncology services in a MOB on the UNC Hillsborough campus.

Capital and Working Capital Costs

In Form F.1a in Section Q, the applicant projects the total capital cost of the project, as shown in the table below:

Site Costs	\$0.00
Construction/ Renovation Costs	\$2,555,147
Miscellaneous Costs	\$1,006,591
Total	\$3,261,738

In Section Q, the applicant provides the assumptions used to project the capital cost. The applicant adequately demonstrates that the projected capital cost is based on reasonable and adequately supported assumptions based on the following:

- Construction and engineering costs are based on the project architect’s experience with similar projects for the applicant.
- Medical equipment costs are based on vendor quotes and the applicant’s experience with similar projects.
- Miscellaneous costs include project contingency and IT costs and are based on the applicant’s experience with similar projects.
- In Exhibit F.1 the applicant provides an architect’s certified cost estimate confirming the capital cost of the project.

In Section F.3, pages 59-60, the applicant projects there will be no start-up or initial operating expenses for the project.

Availability of Funds

In Section F.2, page 57, the applicant states that the capital cost will be funded as shown in the table below:

Sources of Capital Cost Financing

TYPE	TOTAL	TOTAL
Loans	\$0	\$0
Cash and Cash Equivalents, Accumulated reserves or OE *	\$3,261,738	\$3,261,738
Bonds	\$0	\$0
Other (Specify)	\$0	\$0
Total Financing	\$3,261,738	\$3,261,738

*OE = Owner’s Equity

In Section F, page 58, the applicant states that the capital costs for the project will be funded with accumulated reserves of UNC Hospitals.

In Exhibit F.2-1 the applicant provides an April 15, 2021 letter signed by the Chief Financial Officer of UNC Hospitals confirming the availability of funds and commitment of those funds to the project. Exhibit F.2-2 contains the audited financial statements for UNC Hospitals which shows \$431,681,827 in cash and cash equivalents and \$970 million in total current assets as of June 30, 2020.

The applicant adequately demonstrates the availability of sufficient funds for the capital needs of the proposed project.

Financial Feasibility

The applicant provided pro forma financial statements for the first three full fiscal years of operation following completion of the project. The applicant’s operating years (OY) are consistent with the state fiscal year (July 1-June 30). In Form F.2, the applicant projects that revenues will exceed operating expenses in each of the first three operating years of the project, as shown in the table below:

	1ST FULL FY (7/1/2023-6/30/2024)	2ND FULL FY (7/1/2023-6/30/2024)	3RD FULL FY (7/1/2023-6/30/2024)
Total Procedures*	14,387	14,471	14,557
Total Gross Revenues (Charges)	\$112,499,629	\$116,614,063	\$120,881,714
Total Net Revenue	\$27,304,558	\$28,303,361	\$29,339,365
Average Net Revenue per Procedure	\$1,897.86	\$1,955.87	\$2,015.48
Total Operating Expenses (Costs)	\$26,186,840	\$27,129,369	\$28,106,673
Average Operating Expense per Procedure	\$1,820.17	\$1,874.74	\$1,930.80
Net Income	\$1,117,718	\$1,173,992	\$1,232,692

*Total procedures includes infusion therapy visits and “Evaluation and Management” physician visits

The assumptions used by the applicant in preparation of the pro forma financial statements are provided in Section Q. The applicant adequately demonstrates that the financial feasibility of the proposal is reasonable and adequately supported because it is based on the applicant’s FY 2020 experience for UNC Hospitals Hillsborough campus.

Projected utilization is based on reasonable and adequately supported assumptions. See the discussion regarding projected utilization in Criterion (3) which is incorporated herein by reference.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for the following reasons:

- The applicant adequately demonstrates that the capital and working capital costs are based on reasonable and adequately supported assumptions for all the reasons described above.
- The applicant adequately demonstrates availability of sufficient funds for the capital and working capital needs of the proposal for all the reasons described above.
- 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 revenues and operating expenses for all the reasons described above.

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

C

The applicant proposes to expand an existing hospital-based oncology clinic and related hospital-based oncology services in a MOB on the UNC Hillsborough campus.

N.C.G.S. §131E-176(24a) states: “*Service area means the area of the State, as defined in the State Medical Facilities Plan or rules adopted by the Department, which receives services from a health service facility.*” The 2021 SMFP does not define a service area for a provider-based oncology care MOB that provides infusion therapy and related oncology services, nor are there any applicable rules adopted by the Department that define the service area for a provider-based cancer care center. Thus, the service area in this review is as defined by the applicant. In Section C, pages 30-35 the applicant explains the service area that has been served by UNC oncology services, both at the main campus and the Hillsborough campus. The applicant states the primary service area for oncology services at the Hillsborough location is Orange County. Additionally, in Section G, page 66 the applicant states that UNC is the only provider of hospital-based oncology services in Orange County. Facilities may also serve residents of counties not included in their service area.

In Section G.1, page 66, the applicant states there are no other providers of hospital-based oncology services in Orange County.

In Section G, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved hospital-based oncology services in the service area. The applicant states:

“The proposed project will not result in an unnecessary duplication of the existing or approved health service facilities located in the proposed service area that provide the same service components proposed in this application for several reasons. ... UNC Hospitals is the only existing provider of hospital-based oncology services in Orange County. Further, as the only State-owned teaching hospital in North Carolina which is consistently recognized as one of the highest quality healthcare institutions in the nation, it is imperative that UNC Hospitals provide sufficient capacity and convenient access to its hospital-based oncology services, including infusion therapy. In addition, ... patient demand for UNC Hospitals’ hospital-based oncology services is increasing at a significant rate and is expected to continue to grow, which will require additional capacity to ensure patients receive the care that they need in a timely and efficient manner.”

The applicant adequately demonstrates that the proposal would not result in an unnecessary duplication of existing or approved services in the service area because it is currently the only provider of hospital-based oncology services, including infusion therapy in Orange County.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion based on the reasons stated above.

- (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.

C

In Section Q, Form H, the applicant provides current and projected full-time equivalent (FTE) staffing for the proposed services, as illustrated in the following table:

POSITION	CURRENT STAFF	PROJECTED STAFF		
	AS OF 6/30/2020	1 ST FULL FY (7/1/23-6/30/24)	2 ND FULL FY (7/1/24-6/30/25)	3 RD FULL FY (7/1/25-6/30/26)
Registered Nurses	8	9	9	9
CNA / Nursing Assistant	1	4	4	4
Clerical	1	0	0	0
Navigator	0	1	1	1
Total	10	14	14	14

The assumptions and methodology used to project staffing are provided in Section Q. Adequate operating expenses for the health manpower and management positions proposed by the applicant are budgeted in Form F.3b. In Section H, pages 68-69, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs.

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services because the applicant bases its projections of needed FTE positions on its historical experience.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for all the reasons described above.

- (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.

C

The applicant proposes to expand an existing hospital-based oncology clinic and related hospital-based oncology services in a MOB on the UNC Hillsborough campus.

Ancillary and Support Services

In Section I.1, the applicant identifies the necessary ancillary and support services for the proposed services. On page 70, the applicant explains how each ancillary and support service is or will be made available and provides supporting documentation in Exhibit I.1. The applicant adequately demonstrates that the necessary ancillary and support services will be made available based on the following:

- The applicant identifies the existing ancillary and support services at UNC Hillsborough and explains how they are necessary for the oncology services.
- The applicant states all of the necessary ancillary and support services that will be required for the provision of the oncology and infusion therapy services will continue to be provided by UNC Hillsborough.

- The applicant provides a letter signed by the President of UNC Hospitals that confirms all the necessary ancillary and support services are currently in place and will continue to be provided following project completion.

Coordination

In Section I, page 71, the applicant describes its existing and proposed relationships with other local health care and social service providers and provides supporting documentation in Exhibit I.2. The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system based on the following:

- The applicant describes its existing relationships with local healthcare providers and social service providers that are currently provided at UNC Hillsborough.
- The applicant provides letters of support from area physicians and community members in Exhibit I.2.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for all the reasons described above.

- (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

The applicant does not project to provide the proposed services to a substantial number of persons residing in Health Service Areas (HSAs) that are not adjacent to the HSA in which the services will be offered. Furthermore, the applicant does not project to provide the proposed services to a substantial number of persons residing in other states that are not adjacent to the North Carolina county in which the services will be offered. Therefore, Criterion (9) is not applicable to this review.

- (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

The applicant is not an HMO. Therefore, Criterion (10) is not applicable to this review.

- (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.

C

The applicant proposes to expand an existing hospital-based oncology clinic and related hospital-based oncology services in a MOB on the UNC Hillsborough campus.

In Section K, page 74, the applicant states that the project involves renovating 8,162 square feet of existing space in the existing MOB. Line drawings are provided in Exhibit C.1.

On page 74, the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal because the applicant states the necessary renovation for the addition of treatment bays can be developed within the existing building footprint without new construction, thus conserving resources.

On page 75, the applicant adequately explains why the proposal will not unduly increase the costs to the applicant of providing the proposed services or the costs and charges to the public for the proposed services based on the following:

- The applicant states the project will provide additional capacity without requiring new construction, thereby lowering capital costs and not unduly increasing the costs of providing the service to the public.
- The applicant states the project will be funded through accumulated reserves; therefore, no increased costs will be passed on to the patients to fund the project.
- The applicant states it benefits from significant cost-saving measures that it can pass on to patients, because it is a member of the larger UNC Health System.

On page 75, the applicant identifies any applicable energy saving features that will be incorporated into the construction plans and provides supporting documentation in Exhibit B.21.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for all the reasons described above.

- (13) The applicant shall demonstrate the contribution of the proposed service in meeting the health-related 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;

C

In Section L, page 78, the applicant provides the historical payor mix during FY 2020 (July 1-June 30) for the entire UNC Hospitals Hillsborough campus, as shown in the table below:

Payor Category	Percent of Total
Self-Pay	12.5%
Charity Care*	--
Medicare**	37.6%
Medicaid**	11.6%
Insurance**	27.7%
Workers Compensation	--
TRICARE	--
Other (government, worker's comp)	10.6%
Total	100.0%

*The applicant states internal data does not include charity care as a payor source; the applicant provides charity care to any patient in any payor category.

**Includes managed care plans.

In Section L, page 79, the applicant provides the following comparison.

	PERCENTAGE OF TOTAL PATIENTS SERVED BY THE FACILITY OR CAMPUS DURING THE LAST FULL FY	PERCENTAGE OF THE POPULATION OF THE SERVICE AREA
Female	60.0%	52.3%
Male	40.0%	47.7%
Unknown	0.0%	0.0%
64 and Younger	67.7%	85.4%
65 and Older	32.3%	14.6%
American Indian	0.4%	0.6%
Asian	1.0%	8.1%
Black or African-American	24.3%	11.8%
Native Hawaiian or Pacific Islander	0.1%	0.1%
White or Caucasian	65.2%	69.5%
Other Race	7.0%	9.9%
Declined / Unavailable	2.0%	0.0%

The Agency reviewed the.

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the applicant adequately documents 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. 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 and handicapped persons to programs receiving federal assistance, including the existence of any civil rights access complaints against the applicant;

C

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L, page 80, the applicant states it is under no obligation to provide uncompensated care, community service, access by minorities or access by handicapped persons.

In Section L, page 81, the applicant states that during the 18 months immediately preceding the application deadline, no patient civil rights access complaints have been filed against the facility or any similar facilities owned by the applicant or a related entity and located in North Carolina.

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that 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

C

In Section L, page 82, the applicant projects the following payor mix for the proposed services during the third full fiscal year of operation following completion of the project, as shown in the table below:

Infusion Therapy Payor Mix

PAYOR CATEGORY	PERCENT OF TOTAL
Self-Pay	1.4%
Medicare*	63.9%
Medicaid*	6.2%
Insurance*	20.5%
Other (Gov't, Worker's Comp)	8.0%
Total	100.0%

Source: Table on page 82 of the application.

*Includes managed care plans.

As shown in the table above, during the third full fiscal year of operation, the applicant projects that 1.4% of total services will be provided to self-pay patients, 63.9% to Medicare patients, and 6.2% to Medicaid patients.

On page 82, the applicant provides the assumptions and methodology used to project payor mix during the third full fiscal year of operation following completion of the project. The projected payor mix is reasonable and adequately supported because it is based on the applicant's experience providing similar services.

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion based on the reasons stated above.

- (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.

C

In Section L, page 84, the applicant adequately describes the range of means by which patients will have access to the proposed services.

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming 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.

C

The applicant proposes to expand an existing hospital-based oncology clinic and related hospital-based oncology services in a MOB on the UNC Hillsborough campus.

In Section M, the applicant describes the extent to which health professional training programs in the area have access to the facility for training purposes. The applicant adequately demonstrates that health professional training programs in the area have access to the facility for training purposes because it documents the availability of the programs on pages 85 and 86. Additionally, UNC Hospitals is an Academic Medical Center Teaching Hospital and has many of these programs on campus.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for all the reasons described above.

- (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.

C

The applicant proposes to expand an existing hospital-based oncology clinic and related hospital-based oncology services in a MOB on the UNC Hillsborough campus.

N.C. Gen. Stat. §131E-176(24a) states: “*Service area means the area of the State, as defined in the State Medical Facilities Plan or rules adopted by the Department, which receives services from a health service facility.*” The 2021 SMFP does not define a service area for a provider-based oncology care MOB that provides infusion therapy and related oncology services, nor are there any applicable rules adopted by the Department that define the service area for a provider-based cancer care center. Thus, the service area in this review is as defined by the applicant. In Section C, pages 30-35 the applicant explains the service area that has been served by UNC oncology services, both at the main campus and the Hillsborough campus. The applicant states the primary service area for oncology services at the Hillsborough location is Orange County. Additionally, in Section G, page 66 the applicant states that UNC is the only provider of hospital-based oncology services in Orange County. Facilities may also serve residents of counties not included in their service area.

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 88, the applicant states:

“...the proposed project will enhance competition by expanding the capacity of hospital-based oncology services at UNC Hospitals Hillsborough Campus, which will improve its ability to compete with other providers state-wide. The proposed project will enhance the provision of timely, quality patient care, and will assist UNC Hospitals in meeting its four-fold mission of patient care, teaching, research, and community service.”

Regarding the impact of the proposal on cost effectiveness, in Section N, page 88, the applicant states:

“UNC Hospitals’ proposal aims to maximize value by renovating existing space that can accommodate the additional infusion therapy bays, exam rooms, provider workstations, and the new procurement lab instead of undergoing new construction, which will allow UNC Hospitals to be a good steward of existing resources and space.

Further, UNC Hospitals, as a member of the larger UNC Health, benefits from significant cost saving measures through the consolidation of multiple services and large economies of scale.”

See also Sections C, F, K and Q of the application and any exhibits

Regarding the impact of the proposal on quality, in Section N, page 89, the applicant states:

“UNC Hospitals believes that the proposed project will promote the provision of quality healthcare services to patients from all 100 North Carolina counties. UNC Hospitals is known for providing high quality services and expects the proposed project to expand its hospital-based oncology services while bolstering its high-quality reputation. The proposed project will add needed hospital-based oncology service capacity to UNC Hospitals Hillsborough Campus to support the increasing patient demand.”

See also Sections C and O of the application and any exhibits.

Regarding the impact of the proposal on access by medically underserved groups, in Section N, page 91, the applicant states:

“The proposed project will promote access to healthcare services in the service area. UNC Hospitals is a quaternary academic medical center, trauma center, and provider of specialty care of complex diseases for patients from all 100 North Carolina counties. As North Carolina’s only state-owned, comprehensive, full service hospital system, 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, creed, age, handicap, financial status or lack of medical insurance....”

See also Section L and C of the application and any exhibits.

The applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates the proposal would have a positive impact on cost-effectiveness, quality, and access because the applicant adequately demonstrates that:

- 1) The proposal is cost effective because the applicant adequately demonstrated: a) the need the population to be served has for the proposal; b) that the proposal would not result in an unnecessary duplication of existing and approved health services; and c) that projected revenues and operating costs are reasonable.
- 2) Quality care would be provided based on the applicant’s representations about how it will ensure the quality of the proposed services and the applicant’s record of providing quality care in the past.
- 3) Medically underserved groups will have access to the proposed services based on the applicant’s representations about access by medically underserved groups and the projected payor mix.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion based on the reasons stated above.

- (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.

C

In Section Q, Form O, the applicant identifies the hospitals located in North Carolina owned, operated or managed by the applicant or a related entity. The applicant identifies a total of 12 of this type of facility located in North Carolina.

In Section O, page 94, the applicant states that, during the 18 months immediately preceding the submittal of the application, incidents related to quality of care occurred in two of the 12 facilities. The applicant states that all the problems have been corrected. According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, during the 18 months immediately preceding submission of the application through the date of this decision, incidents related to quality of care occurred in two of these facilities. On page 94, the applicant states each of the incidents has been resolved and there are no compliance issues. 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 12 UNC facilities, the applicant provided sufficient evidence that quality care has been provided in the past. 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.

NA

The applicant proposes to expand an existing hospital-based oncology clinic and related hospital-based oncology services in a MOB on the UNC Hillsborough campus. There are no administrative rules that are applicable to the proposed project.