

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: March 18, 2019

Findings Date: March 18, 2019

Project Analyst: Tanya M. Saporito

Assistant Chief: Lisa Pittman

Project ID #: J-11613-18

Facility: Duke North Pavilion

FID #: 956937

County: Durham

Applicant: Duke University Health System, Inc.

Project: Renovate and upfit space in North Pavilion to accommodate relocation of Duke Compounding Facility, Clinical Pharmacy, and Hematologic Malignancies clinical services. In addition, renovate space for Adult Bone Marrow Transplant (ABMT) services.

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

Duke University Health System, Inc. (the applicant) proposes to renovate and upfit space in the North Pavilion building located at 2400 Pratt Street in Durham to accommodate the relocation of the following services:

1. The Duke Compounding Facility – currently operated in Duke South – relocating to the terrace level of North Pavilion.
2. The clinical pharmacy – currently operated in the Duke North Pavilion building – relocating to new space on the second level.

3. The applicant proposes to combine Adult Bone Marrow Transplant (ABMT) services – currently provided in the Duke North Pavilion building and the Hematologic Malignancies clinical services – currently provided in the Duke Cancer Center into a Hematological Malignancies and Cellular Therapy (HMCT) program on the plaza level (Level 1) of the Duke North Pavilion building. The combined new clinical space will include five treatment rooms, 28 exam rooms and 60 infusion chairs. The relocation and combination of these services will involve renovation on the plaza level, and will include relocated and expanded space for laboratory services to support HMCT patients.

Need Determination

There are no need determinations in the 2018 State Medical Facilities Plan (SMFP) applicable to the development of hospital outpatient clinics. Therefore, this criterion is not applicable to this review.

Policies

There is one policy in the 2018 SMFP which is applicable to this review: Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities.

Policy GEN-4

On page 33 of the 2018 SMFP, Policy GEN-4 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 \$5 million. In Exhibit B.11, the applicant documents its plan to ensure energy efficiency and water conservation. The applicant adequately demonstrates that the application includes a written statement describing the project's plans to assure improved energy efficiency and water conservation. Therefore, the application is consistent with Policy GEN-4.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Remarks made at the public hearing

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

- The applicant does not propose the addition of any new health service beds, services or equipment for which there is a need determination in the 2018 SMFP.
- The applicant adequately demonstrates that the proposal is consistent with Policy GEN-4 in the 2018 SMFP.

- (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

Duke University Health System, Inc. (the applicant) proposes to renovate and upfit space in the North Pavilion building located at 2400 Pratt Street in Durham to accommodate the relocation of the following services:

1. The Duke Compounding Facility – currently operated in Duke South – relocating to the terrace level of North Pavilion.
2. The clinical pharmacy – currently operated in the Duke North Pavilion building – relocating to new space on the second level.
3. The applicant proposes to combine Adult Bone Marrow Transplant (ABMT) services – currently provided in the Duke North Pavilion building and the Hematologic Malignancies clinical services – currently provided in the Duke Cancer Center into a Hematological Malignancies and Cellular Therapy (HMCT) program on the plaza level (Level 1) of the Duke North Pavilion building. The combined new clinical space will include five treatment rooms, 28 exam rooms and 60 infusion chairs. The relocation and combination of these services will involve

renovation on the plaza level, and will include relocated and expanded space for laboratory services to support HMCT patients.

Patient Origin

The 2018 SMFP does not define a service area for Bone Marrow Transplant Services, Compounding Services or Clinical Pharmacy Services nor are there any applicable rules adopted by the Department that define the service area for those services. Thus, the service area in this review is as defined by the applicant.

In Section C.3, pages 23 - 24, the applicant provides a table showing its projected patient origin for the proposed physician clinics for the first three operating years (FY 2022 - FY 2024) of the proposed project, as summarized in the following table:

Projected Patient Origin, HMCT Services

COUNTY OF ORIGIN	FY 2022 (7/1/2021 – 6/30/2022)		FY 2023 (7/1/2022– 6/30/2023)		FY 2024 (7/1/2023 – 6/30/2024)	
	# PATIENTS	% OF TOTAL	# PATIENTS	% OF TOTAL	# PATIENTS	% OF TOTAL
Wake	6,193	18.1%	6,379	18.1%	6,567*	18.1%
Durham	5,928	17.3%	6,105	17.3%	6,277*	17.3%
Orange	1,309	3.8%	1,348	3.8%	1,379*	3.8%
Alamance	935	2.7%	963	2.7%	980	2.7%
Guilford	903	2.6%	930	2.6%	943	2.6%
Person	735	2.1%	757	2.1%	762	2.1%
Granville	692	2.0%	712	2.0%	726	2.0%
Cumberland	712	2.1%	733	2.1%	762	2.1%
Johnston	437	1.3%	450	1.3%	472	1.3%
Vance	393	1.1%	405	1.1%	399	1.1%
Harnett	309	0.9%	318	0.9%	327	0.9%
Chatham	266	0.8%	274	0.8%	290	0.8%
Franklin	200	0.6%	206	0.6%	218*	0.6%
Other NC Counties	8,961	26.2%	9,229	26.2%	9,506*	26.2%
Other States	6,219	18.2%	6,379	18.2%	6,603*	18.2%
Other Countries	8	0.0%	9	0.0%	9	0.0%
Total	34,199	100.0%	35,225	100.0%	36,282	100.0%

*The numbers provided in the application in this column appeared to have been shifted by a spreadsheet error; the Project Analyst calculated those totals which were “off” to reflect the percentages provided by the applicant.

Projected Patient Origin, Clinical Pharmacy Services

COUNTY OF ORIGIN	FY 2022 (7/1/2021 – 6/30/2022)		FY 2023 (7/1/2022 – 6/30/2023)		FY 2024 (7/1/2023 – 6/30/2024)	
	# PATIENTS	% OF TOTAL	# PATIENTS	% OF TOTAL	# PATIENTS	% OF TOTAL
Durham	3,555	21.3%	3,661	21.3%	3,771	21.3%
Wake	2,793	16.8%	2,877	16.8%	2,963	16.8%
Orange	868	5.2%	894	5.2%	920	5.2%
Alamance	526	3.2%	542	3.2%	558	3.2%
Guilford	485	2.9%	499	2.9%	514	2.9%
Person	388	2.1%	400	2.1%	412	2.1%
Granville	379	2.3%	390	2.3%	402	2.3%
Cumberland	302	2.3%	311	2.3%	320	2.3%
Johnston	175	1.8%	180	1.8%	186	1.8%
Vance	158	1.0%	163	1.0%	168	1.0%
Harnett	151	0.9%	155	0.9%	160	0.9%
Chatham	101	0.6%	104	0.6%	107	0.6%
Franklin	88	0.5%	91	0.5%	93	0.5%
Other NC Counties	3,904	23.4%	4,021	23.4%	4,142	23.4%
Other States	2,805	16.8%	2,889	16.8%	2,976	16.8%
Total	16,677	100.0%	17,177	100.0%	17,692	100.0%

The applicant provides patient origin for the two services listed, as HMCT services include the ABMT services and other clinical malignancies services. Additionally, the applicant does not track patient origin for the Compounding Facility services.

In Section C.3, page 25, the applicant states projected patient origin is not projected to change from the historical patient origin. The applicant’s assumptions are reasonable and adequately supported.

Analysis of Need

In Section C.4, pages 25 - 31, the applicant explains why it believes the population projected to utilize the proposed services needs those services. On page 25, the applicant explains the proposed renovation and expansion of the North Pavilion building. The applicant states there are significant safety benefits to relocating the services proposed in this application simultaneously with the renovation. Specifically, construction projects raise infection control issues which are particularly important to immunocompromised patients such as those who utilize the services in the Duke Cancer Center. To combine the renovation with the relocation of these services reduces the potentially negative impact on patients who utilize the services. The applicant address each of the services proposed in this project, which are summarized as follows:

Compounding Facility Services

The applicant states the existing Compounding Facility (CF) serves the entire Duke University Health System and is located in the main Duke University Hospital building,

approximately one-half mile from the Duke North Pavilion building. The applicant states this application is a response to the existing CF space constraints, and proposes to relocate CF services to 7,514 square feet of space which the applicant will upfit to accommodate evolving compliance and care standards to more effectively serve patients in the Duke University Health System. In addition, relocating CF services will allow the applicant to meet the needs of its existing and future patients' needs for custom compounded medication that is not commercially available and is needed for the types of cancer treatments provided by the applicant (page 26).

On page 26, the applicant shows the increase in production volumes from FY 2016 through FY 2018, as shown in the following table:

**Duke University Compounding Facility
Historical Production**

YEAR	TOTAL UNITS PRODUCED
FY 2016	535,700
FY 2017	624,180
FY 2018	658,819
Growth*	23.0%

*Growth was calculated by the Project Analyst

Clinical Pharmacy

The Duke University Hospital Clinical Pharmacy (CP) is currently located in the Duke North Pavilion, and primarily serves ambulatory surgical patients and ABMT services. It is not a retail pharmacy, as it only serves Duke University Health System patients in the course of their procedures or treatments. The applicant proposes to upfit 1,750 square feet of space to modernize the CP and improve its efficiency and operation (pages 26 – 27).

On page 27, the applicant shows the increase in medication volumes (which it refers to as “units” from FY 2017 to FY 2018, as shown in the following table, noting that this data was not collected prior to FY 2017:

**Duke University Clinical Pharmacy
Historical Production**

YEAR	TOTAL UNITS PRODUCED
FY 2017	19,429
FY 2018	22,539
Growth	16.0%

*Growth was calculated by the Project Analyst

Hematological Malignancies and Adult Bone Marrow Treatment Co-Location

Hematological Malignancies services are currently located in the Duke Cancer Center, in the main Duke University Hospital building, approximately one-half mile from the Duke North Pavilion building. ABMT services are located in the Duke North Pavilion building. The applicant proposes to combine the two services into one Hematological Malignancies and Cellular Therapy (HMCT) program to provide stem-cell transplants and treatment primarily

to blood cancer patients, while continuing critical research and improving patient care in the Duke University Health System. As part of the project, the applicant proposes to upfit 10,825 square feet of space and renovate 16,391 square feet of space on Level 1 of the North Pavilion building. The applicant proposes to increase the number of infusion chairs from 41 to 60, and add five treatment rooms and 28 examination rooms. None of those services are governed or regulated by certificate of need law. The applicant states the renovation and upfit will allow the combined HMCT program to more effectively treat blood cancer patients, and will also include:

- Create a single patient-centered program focused on treating blood cancers,
- Provide improved continuum of care for these patients as they transition through the treatment regimes,
- Promote clinical quality, patient safety and multi-disciplinary care,
- Improve operational efficiencies, thus improving patient throughput and access to services,
- Provide additional patient, family and caregiver support services,
- Provide seven-day outpatient access for hematologic malignancy patients (currently available only to ABMT patients), and
- Provide expanded space to accommodate growing patient volumes.

The applicant states the Hematologic Malignancies and ABMT programs at Duke University Hospital provide care to patients with over 70 different medical diagnoses, 95% of which are blood cancers. The program has experienced growth since 2011, and the applicant examined both population growth data from Truven Health and its own experience in the provision of these services, stating that both have increased. Additionally, the applicant describes the current limitations of the existing space to effectively treat the growing patient population (pages 27 – 30).

On page 28, relying on data from its internal tumor registry data, the applicant shows the increase in cancers treated in the combined HMCT program from 2011 to 2015, as shown in the following table:

Duke University Tumor Registry Data, Growth in Cancers 2011 - 2015

CANCER TYPE	2011	2012	2013	2014	2015	CAGR
Multiple Myeloma	184	224	151	215	254	6%
Leukemias	281	259	242	303	381	8%
Lymphomas	492	464	462	460	537	2%

On page 29 the applicant shows the increase in visits to the Duke Cancer Center from 2016 to 2018, as shown in the following table:

Duke Cancer Center Services, 2016 - 2018

	2016	2017	2018
EVALUATION AND MANAGEMENT (E&M) VISITS			
Cancer Center E&M visits	11,563	10,691	10,871
North Pavilion ABMT E&M visits	7,522	7,812	8,329
INFUSIONS			
North Pavilion Infusions			
Chemo infusion	993	1,175	1,583
Injections	445	1,174	1,559
Non Chemo infusions	8,760	8,626	9,079
Total	10,198	10,975	12,221
Cancer Center Infusions			
Chemo infusion	3,198	2,570	2,482
Injections	1,683	1,398	1,019
Non Chemo infusions	2,363	2,117	2,254
Total	7,243	6,085	5,755
North Pavilion Services			
North Pavilion Photopheresis	660	1,051	844
North Pavilion stem cell harvest	303	335	366
North Pavilion stem cell infusion	179	226	224
Treatment visits	94	2,165	2,138
Grand Total	37,762	39,340	40,748

The applicant states on page 29 that the numbers in the table above do not correspond exactly with the projected volumes in Form C, because individual patient encounters (from Form C) may include multiple services.

The information provided by the applicant in the pages referenced above is reasonable and adequately supported for the following reasons:

- The applicant provides information regarding the current capacity constraints at Duke North for the services provided to its patients.
- The applicant provides information regarding the improved patient access and convenience of the proposed location of the services.
- The applicant provides historical data regarding its existing Hematologic Malignancies and ABMT services, Compounding Facility services and Clinical Pharmacy services such that it demonstrates that the existing location and configuration of the Duke North Pavilion building does not allow for the provision of the quality of services the applicant proposes in the renovation.

Projected Utilization

In Section Q, Form C, the applicant provides projected utilization for the proposed services through the first three full fiscal years (FY 2022 – FY 2024) as summarized in the following table:

DUKE NORTH PAVILION			
	FY 2022	FY 2023	FY 2024
Compounding Facility Units	658,819	658,819	658,819
Clinical Pharmacy Units	23,621	24,330	25,060
Outpatient Encounters	37,565	38,692	39,853

The applicant provides its assumptions and methodology for projecting utilization for its proposed services in Section Q, Form C.

Projected utilization is reasonable and adequately supported for the following reasons:

- The applicant’s utilization projections for the HMCT program are supported by the historical utilization of ABMT and Hematological Malignancy services at the Duke Cancer Center and the main Duke University Hospital.
- The applicant’s utilization projections for the Compounding Facility and Clinical Pharmacy are based on its historical experience on the same services currently located at the Duke Cancer Center and the main Duke University Hospital.

Access

In Section C.11, page 34, the applicant states that the services provided by Duke University Hospital are open to *“all area and non-area residents for inpatient, outpatient and other healthcare services, on a walk-in, emergency, appointment or referral basis depending on the particular service. There is no discrimination on the basis of race, ethnicity, age, gender, or disability.”* In Section L.3, page 65, the applicant projects the following payor mix for UNC Hospitals and the proposed services during the second year of operation (FY 2023) following completion of the project, as shown in the following table:

The projected payor mix is reasonable and adequately supported.

Duke North Pavilion Projected Payor Mix, Second Fiscal Year

PAYOR SOURCE	ENTIRE FACILITY	HMCT SERVICES	NP CLINICAL PHARMACY
Self Pay / Charity	2.5%	0.7%	0.1%
Medicare	45.1%	51.3%	48.1%
Medicaid	13.3%	3.3%	3.7%
Insurance	33.3%	41.6%	44.8%
Other*	4.7%	3.1%	3.2%
Total	100.0%	100.0%	100.0%

Note: numbers may not sum due to rounding.

*The applicant states *“other”* includes out-of-state Medicaid, other governmental and non-governmental payors, Tricare/Champus, and Workers Compensation.

Conclusion

The Agency reviewed the:

- Application

- Exhibits to the application
- Information publicly available during the review and used by the Agency

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 projects the extent to which all residents, including underserved groups, will have access to the proposed services (payer mix) 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.

C

The applicant proposes to renovate existing space in the Duke North Pavilion building to accommodate the relocation of services from a different location in the same building, and the relocation of services from the Duke Cancer Center, which is approximately ½ mile from the North Pavilion. In Section D.2, page 38, the applicant states:

“Due to the geographic proximity [of certain hematological malignancy clinical services], the Hematological Malignancy services that will be relocated will be equally accessible in their new location to their current location.

Duke will also be developing capacity for infusion and other services for hematological malignancy patients in North Pavilion, but will not decrease existing capacity in the Cancer Center available for other oncology patients who need those services.”

On page 38, the applicant explains that this project seeks to develop 60 infusion chairs at the Duke North building for the combined HMCT services; however, the 68 infusion chairs that are currently located at the Duke Cancer center will remain there. The applicant states current capacity constraints at the Duke Cancer Center forces evening scheduling in the infusion chairs; thus, developing the chairs with the relocation of certain hematological malignancy services at Duke North will ease those capacity constraints for existing and future patients.

On page 39, the applicant states it proposes to develop all necessary support and laboratory services at the Duke North building and will not reduce those services at the Cancer Center.

In Section Q, the applicant provides historical utilization of the compounding services and HMCT services to be relocated to the Duke North building, as illustrated in the following tables:

Historical Utilization, Compounding Facility OP Encounters

	FY 2015	FY 2016	FY 2017	FY 2018
# Compounding Facility Units	535,700	624,180	658,819	658,819
# Procedures (Clinical Pharmacy Units)	--	19,429	22,539	22,539
# Procedures (OP Encounters)	15,896	18,087	19,672	19,672

Source: Section Q, Form C.

Historical Utilization, Cancer Center HMCT Services

	FY 2015	FY 2016	FY 2017	FY 2018
# OP Encounters in Cancer Center	65,332	60,538	64,447	64,447

Source: Section Q, Form C.

In Section Q, the applicant provides projected utilization of the compounding services and HMCT services to be relocated to the Duke North building, as illustrated in the following tables:

Projected Utilization, Compounding Facility OP Encounters

	FY 2019	FY 2020	FY 2021	FY 2022	FY 2023
# Compounding Facility Units	658,819	658,819	658,819	658,819	658,819
# Procedures (Clinical Pharmacy Units)	22,539	22,933	23,621	24,330	25,060
# Procedures (OP Encounters)	19,672	29,987	37,565	38,692	39,853

Source: Section Q, Form C.

Projected Utilization, Cancer Center HMCT Services

	FY 2019	FY 2020	FY 2021	FY 2022	FY 2023
# OP Encounters in Cancer Center	64,447	55,634	49,108	50,581	52,098

Source: Section Q, Form C.

In Section Q, the applicant provides the assumptions and methodology for the projected utilization of the compounding facility, clinical pharmacy and HMCT services, stating that the projections are based on the historical experience of Duke Cancer Center in providing these services, summarized as follows:

Compounding Pharmacy - The applicant states that projected volumes reflect actual production in the existing compounding facility at the Duke Cancer Center. The applicant projects FY 2018 volumes to remain constant through the third project year, as the facility serves the entire Duke system, and the proposed relocation is based on operational needs unique to the system to meet existing demand.

Clinical Pharmacy - The applicant states that projected utilization of clinical pharmacy services at the Duke North building are projected to remain flat through FY 2020 due to space constraints for HMCT services, which are the primary users of pharmacy services. Upon completion of the relocation in FY 2021, the applicant states clinical pharmacy services are projected to grow at the same rate as the HMCT encounters (3% annually), based on market analysis.

HMCT Procedures - The applicant states the term “*procedures*” is not specifically defined for the purposes of hospital clinical visits; the applicant provides historical and projected patient “*encounters*” for the North Pavilion. The applicant states “*encounters*” include clinic visits, chemotherapy and non-chemotherapy infusions and BMT-specific services such as stem cell collections, stem cell infusions and photopheresis. The applicant states the projected volumes are based on the historical experience of Duke.

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

- Utilization projections for all services proposed to be relocated are based on the historical experience of the applicant at the Duke Cancer Center

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Information publicly available during the review and used by the Agency
- Remarks made at the public hearing

Based on that review, the Agency concludes that the applicant adequately demonstrates that:

- The needs of the population currently using the services to be reduced, eliminated or relocated will be adequately met following project completion.
- The project will not adversely impact the ability of underserved groups to access these services following project completion.

- (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 renovate existing space in the Duke North Pavilion building to accommodate the relocation of services from a different location in the same building, and the relocation of services from the Duke Cancer Center.

In Section E.3, page 43, the applicant states the only alternative considered was the project as proposed. Space constraints make effectively treating existing and projected cancer patients extremely difficult. Additionally, the services proposed to be relocated are currently in two different locations despite being closely related in terms of service to patients. This project, according to the applicant, allows for the continued provision of these essential services on the Duke University campus in new and renovated space that is in close proximity to the main hospital building.

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

- This alternative will meet the need for additional space and improved access to clinical pharmacy, compounding, and HMCT services.
- This alternative meets the need to consolidate the HM and ABMT services into one program to more effectively meet the needs of existing and projected patients.

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. Duke University Health System, Inc. shall materially comply with all representations made in the certificate of need application.**
- 2. Duke University Health System, Inc. shall relocate the Duke Compounding Facility and Hematologic Malignancies clinical service to the Duke North Pavilion, and shall renovate existing space for Adult Bone Marrow Transplant services and the Clinical Pharmacy at the Duke North Pavilion.**
- 3. Duke University Health System, Inc. 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.**
- 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, Duke University Health System, Inc. 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. Duke University Health System, Inc. shall 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.
6. Duke University Health System, Inc. shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to insurance 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 renovate existing space in the Duke North Pavilion building to accommodate the relocation of services from a different location in the same building, and the relocation of services from the Duke Cancer Center.

Capital and Working Capital Costs

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

	COMPOUNDING FACILITY	CLINICAL PHARMACY	HMCT SERVICES	TOTAL CAPITAL COSTS
Construction Costs	\$2,521,274	\$662,961	\$6,019,769	\$9,204,004
Miscellaneous Costs	\$3,478,726	\$837,039	\$4,630,231	\$8,945,996
Application Fee	0	0	0	\$50,000
Total	\$6,000,000	\$1,500,000	\$10,650,000	\$18,200,000

In Form F.1a, the applicant includes \$50,000 for the application fee in its total capital cost, which brings the total to \$18,200,000. In Section Q, the applicant provides the assumptions used to project the capital cost.

In Section F.3, page 45, the applicant states Duke University Hospital is an existing hospital and therefore there will be no start-up costs or initial operating expenses associated with this project.

Availability of Funds

In Section F, page 44, the applicant states that the capital cost will be funded as shown in the table below.

Sources of Capital Cost Financing

TYPE	DUKE UNIVERSITY HEALTH SYSTEM	TOTAL
Loans	\$0	\$0
Accumulated reserves or OE *	\$18,150,000	\$18,200,000
Bonds	\$0	\$0
Other (Specify)	\$0	\$0
Total Financing	\$18,150,000	\$18,200,000

* OE = Owner's Equity

Exhibit F.2 contains a letter dated October 9, 2018 from the Chief Financial Officer of Duke University Health System documenting its intention to provide accumulated reserves for the capital needs of the proposed project. Exhibit F.2 contains the audited financial statements of Duke University Health System which show that at the end of FY 2018, the applicant had \$277,957,000 million in cash and cash equivalents, \$6.2 billion in total assets, and \$3.6 billion in net assets (total assets less total liabilities).

Financial Feasibility

The applicant provided pro forma financial statements for Duke University Health System for the first three full fiscal years of operation following completion of the project. In Form F.3, the applicant projects that revenues will exceed operating expenses for the entire healthcare system in the each of the first three operating years of the project, as shown in the table below.

REVENUES/EXPENSE (IN 000'S)	YEAR 1 FY 2022	YEAR 2 FY 2023	YEAR 3 FY 2024
Gross Patient Revenue	\$12,357,236	\$12,780,852	\$13,112,526
Total Net Revenue	\$3,966,388	\$4,134,355	\$4,276,620
Operating Expenses (Costs)	\$3,764,354	\$3,923,925	\$4,059,076
Operating Income (Loss)	\$202,034	\$210,430	\$217,544

The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs and charges. See the Pro Forma Section 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

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.
 - The applicant adequately demonstrates availability of sufficient funds for the capital and working capital needs of the proposal.
 - 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.
- (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

Duke University Health System, Inc. (the applicant) proposes to renovate and upfit space in the North Pavilion building located at 2400 Pratt Street in Durham to accommodate the relocation of the following services:

1. The Duke Compounding Facility – currently operated in Duke South – relocating to the terrace level of North Pavilion.
2. The clinical pharmacy – currently operated in the Duke North Pavilion building – relocating to new space on the second level.

The applicant proposes to combine Adult Bone Marrow Transplant (ABMT) services – currently provided in the Duke North Pavilion building, and the Hematologic Malignancies clinical services – currently provided in the Duke Cancer Center, into a Hematological Malignancies and Cellular Therapy (HMCT) program on the plaza level (Level 1) of the Duke North Pavilion building. The combined new clinical space will include five treatment rooms, 28 exam rooms and 60 infusion chairs.

The 2018 SMFP does not define a service area for Bone Marrow Transplant Services, Compounding Services or Clinical Pharmacy Services nor are there any applicable rules adopted by the Department that define the service area for those services. Thus, the service area in this review is as defined by the applicant.

In Section G.1, page 50, the applicant lists the other providers of ABMT services in the state (also listed on pages 99 and 100 of the 2018 SMFP), which total five, as follows:

- Carolinas Medical Center
- Duke University Hospital
- North Carolina Baptist Hospital
- Vidant Medical Center
- University of North Carolina Hospitals

In Section G.3, page 50, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved services in the service area. The applicant states:

“This project entails the renovation or upfit of space to accommodate existing clinical services operated by Duke University Hospital, which is the largest provider of bone marrow transplant services in the state. This will not create any new provider or duplicate any existing services; it will instead make Duke’s existing services more accessible and efficient.”

There is no publicly available information with regard to clinical pharmacy services or compounding facilities in the service area.

The applicant adequately demonstrates that the proposal would not result in an unnecessary duplication of existing or approved services in the service area because the applicant adequately demonstrates that the proposed physician clinics and hospital-based services are needed in addition to the existing or approved services.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Information which was publicly available during the review and used by the Agency

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

SERVICE / POSITION	CURRENT FTE STAFF AS OF JUNE 30, 2018	PROJECTED FTE STAFF 2ND FY (2023)
Compounding Facility		
Pharmacist	4.7	5.81
Pharmacy Technician	12.7	13.81
Clinical Pharmacy		
Pharmacist	2.4	3.5
Pharmacy Technician	2.2	3.7
HMCT Services		
Physician Assistants	0.18	0.19
RNs	31.71	34.23
Aides / Orderlies	8.07	8.71
Nurse Practitioner	0.18	0.19
Nurse Manager	1.53	1.65
Clerical	1.52	1.64
TOTAL All Positions	65.19	73.43

The assumptions and methodology used to project staffing are provided in Section Q. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form A, which is found in Section Q. In Section H.2 and H.4, pages 52 and 53, respectively, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs. In Section H.4, page 53, the applicant identifies the current medical director for each service.

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Information which was publicly available during the review and used by the Agency

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

In Section I, page 55, the applicant states that the following ancillary and support services are necessary for the proposed services:

- Business office / registration (HMCT)
- Medical Records (HMCT)
- Laboratory (HMCT)
- Administration
- Materials Management
- Quality Control
- Clinical Engineering
- Laundry / Housekeeping

On page 55, the applicant adequately explains how each ancillary and support service is or will be made available.

In Section I, page 55, the applicant describes its existing and proposed relationships with other local health care and social service providers.

The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Information which was publicly available during the review and used by the Agency

Based on that review, the Agency concludes that 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

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 HSA IV where 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

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

In Sections K.2 and K.3, page 58, the applicant states the project involves renovating 18,605 square feet of space and up fitting 17,875 square feet of existing space in the Duke North Pavilion. Line drawings are provided in Exhibit K.3.

In Section K.4, page 59, the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal.

In Section K.4. pages 59 - 60, 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.

In Exhibit B.11, the applicant identifies any applicable energy saving features that will be incorporated into the construction plans.

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.

- (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.1(b), page 64, the applicant provides the historical payor mix during FY 2018 for the proposed services, as shown in the table below.

PAYOR CATEGORY	ENTIRE CAMPUS	HMCT	CLINICAL PHARMACY
Self-Pay / Charity	2.5%	0.7%	0.1%
Medicare	42.0%	47.7%	44.3%
Medicaid	13.3%	3.3%	3.7%
Insurance	36.3%	44.4%	48.7%
Other	4.7%	3.1%	3.2%
Total	100.0%	100.0%	100.0%

*The applicant states on page 64 that "other" includes out-of-state Medicaid, other governmental and non-governmental payors, Tricare / Champus and Worker's Compensation

In Section L.1, page 63, the applicant provides the following comparison.

	Percentage of Total Patients Served by the Facility or Campus during the FY 2018	Percentage of the Population of the Service Area
Female	57.1%	51.6%
Male	42.8%	48.4%
Unknown	NA	NA
64 and Younger	72.8%	87.3%
65 and Older	27.8%	12.7%
American Indian	0.5%	0.5%
Asian	2.9%	5.9%
Black or African-American	25.5%	23.9%
Native Hawaiian or Pacific Islander	0.1%	--
White or Caucasian	61.1%	61.4%
Other Race	5.1%	8.2%
Declined / Unavailable	4.7%	0.0%

The Agency reviewed the:

- Application
- Exhibits to the application
- Information which was publicly available during the review and used by the Agency

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

In Section L.2, page 64, the applicant states Duke University Health System has satisfied the requirements of applicable federal regulations to provide a certain amount of uncompensated care on an annual basis, and that Duke University Health System complies with all the relevant regulatory requirements with regard to uncompensated care, community service and access by minorities and handicapped persons.

The applicant did not respond to question number L.2 in Section L.2, page 67. However, the applicant filed another application, Project ID #J-11631-18, one month after this application was filed. On page 88 of that application, in response to the

same question, the applicant states that during the last five years, no patient civil rights access complaints have been filed against Duke University Health System. Since the applicant in both applications is Duke University Health System, and since Project ID #J-11631-18 was filed one month after this application was filed, the Agency will use the information contained in the second application.

The Agency reviewed the:

- Application
- Exhibits to the application
- Information which was publicly available during the review and used by the Agency

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.3, page 65, the applicant projects the following payor mix for proposed services at the Duke North Pavilion during the second year of operation (FY 2023) following completion of the project, as shown in the following table.

PAYOR CATEGORY	ENTIRE CAMPUS	HMCT	CLINICAL PHARMACY
Self-Pay / Charity	2.5%	0.7%	0.1%
Medicare	45.1%	51.3%	48.1%
Medicaid	13.3%	3.3%	3.7%
Insurance	33.3%	41.6%	44.8%
Other	4.7%	3.1%	3.2%
Total	100.0%	100.0%	100.0%

*The applicant states on page 64 that "other" includes out-of-state Medicaid, other governmental and non-governmental payors, Tricare / Champus and Worker's Compensation

In Section L.3(b), page 65, the applicant provides the assumptions and methodology used to project payor mix during the first three full fiscal years of operation following completion of the project. The projected payor mix is reasonable and adequately supported because it is based on the applicant's historical experience providing the services proposed in this application.

The Agency reviewed the:

- Application

- Exhibits to the application
- Information which was publicly available during the review and used by the Agency

Based on that review, the Agency concludes that 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.

C

In Section L.5, page 66, 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
- Information which was publicly available during the review and used by the Agency

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

In Section M.1, page 67, the applicant describes the extent to which health professional training programs in the area will have access to the facility for training purposes.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Information which was publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the applicant adequately demonstrates that the proposed services will accommodate the clinical needs of area health professional training programs, and therefore, the application is conforming 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.

C

Duke University Health System, Inc. (the applicant) proposes to renovate and upfit space in the North Pavilion building located at 2400 Pratt Street in Durham to accommodate the relocation of the following services:

1. The Duke Compounding Facility – currently operated in Duke South – relocating to the terrace level of North Pavilion.
2. The clinical pharmacy – currently operated in the Duke North Pavilion building – relocating to new space on the second level.

The applicant proposes to combine Adult Bone Marrow Transplant (ABMT) services – currently provided in the Duke North Pavilion building and Hematologic Malignancies clinical services – currently provided in the Duke Cancer Center into a Hematological Malignancies and Cellular Therapy (HMCT) program on the plaza level (Level 1) of the Duke North Pavilion building. The combined new clinical space will include five treatment rooms, 28 exam rooms and 60 infusion chairs.

The 2018 SMFP does not define a service area for Bone Marrow Transplant Services, Compounding Services or Clinical Pharmacy Services nor are there any applicable rules adopted by the Department that define the service area for those services. Thus, the service area in this review is as defined by the applicant.

In Section N.2, page 68, the applicant describes the expected effects of the proposed services on competition in the service area and discusses how any enhanced competition in the service area will promote the cost-effectiveness, quality and access to the proposed services. The applicant states:

“This project will not directly affect the cost effectiveness of services, as it is an expansion and relocation of existing services for which charges will not change. Although this project will not affect the cost to patients or payors for the services provided by Duke, this project will enhance Duke’s ability to continue to provide cost-effective and high quality services to patients.”

The applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates:

- The cost-effectiveness of the proposal (see Sections F and Q of the application and any exhibits)
- Quality services will be provided (see Section O of the application and any exhibits)
- Access will be provided to underserved groups (see Section L of the application and any exhibits)

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for 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 O.3, page 70, the applicant states that it owns or manages three licensed healthcare facilities in North Carolina.

In Section O, page 71, the applicant states that, during the 18 months immediately preceding the submittal of the application, no Duke hospital has been determined to be out of compliance with any Medicare Conditions of Participation. The applicant states it does not include in the response, “*standard deficiencies that may have been identified and immediately addressed in the course of inspections or surveys....*” According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, all of the facilities are back in compliance with all Medicare Conditions of Participation. 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 Duke University Health Service facilities, the applicant provides 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 renovate existing space in the Duke North Pavilion building to accommodate the relocation of services from a different location in the same building, and the relocation of services from the Duke Cancer Center, which is approximately ½ mile from the North Pavilion. There are no administrative rules that are applicable to proposals to develop hospital-based outpatient clinics.