

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: April 23, 2020

Findings Date: April 23, 2020

Project Analyst: Julie M. Faenza

Team Leader: Gloria C. Hale

Project ID #: J-11865-20

Facility: UNC Health Care Panther Creek Diagnostic Center

FID #: 200142

County: Wake

Applicant: University of North Carolina Health Care System

Project: Develop a new diagnostic center in an existing medical office building in Cary

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.

NA

University of North Carolina Health Care System (hereinafter referred to as UNC-HCS or “the applicant”) proposes to develop a new diagnostic center, UNC Health Care Panther Creek Diagnostic Center (UNC Panther Creek), in an existing medical office building (MOB) in the Panther Creek area of Cary, in Wake County. The combined value of the medical diagnostic equipment costing \$10,000 or more exceeds the statutory threshold of \$500,000 and therefore qualifies as a diagnostic center, which is a new institutional health service, and which requires a certificate of need.

The applicant does not propose to:

- Acquire any medical equipment for which there is a need determination in the 2020 State Medical Facilities Plan (SMFP).

- Offer a new institutional health service for which there are any applicable policies in the 2020 SMFP.

Therefore, Criterion (1) is not applicable to this review.

- (2) Repealed effective July 1, 1987.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 develop a new diagnostic center in an existing MOB in the Panther Creek area of Cary, in Wake County.

In Section C, pages 24-25, the applicant provides background about the development of the MOB, services included in this application, and other tenants of the MOB.

Project I.D. #J-8263-08 authorized Rex Hospital, Inc. to develop a hospital-based outpatient care center, to include urgent care and diagnostic imaging modalities, in a MOB that would be developed by an outside third party. The certificate of need for the project was issued July 27, 2010. On February 1, 2019, a transfer for good cause and material compliance request was filed by Rex Hospital, Inc., seeking to have WR Imaging, LLC develop the diagnostic imaging services portion of the approved outpatient care center. WR Imaging, LLC is an entity owned jointly by Rex Hospital, Inc. and Wake Radiology Services, LLC.

Also, on February 1, 2019, UNC-HCS filed an exemption request, seeking to develop the MOB that was part of Project I.D. #J-8263-08, and Rex Hospital, Inc. filed two requests for a determination of no review, seeking to develop the urgent care and laboratory components that had previously been included in the certificate of need for Project I.D. #J-8263-08. The Agency approved all requests on February 12, 2019. A related material compliance request, seeking to clarify the scope of the certificate of need, was approved by the Agency on November 4, 2019. The certificate of need for Project I.D. #J-8263-08 is now held by WR Imaging, LLC and authorizes the development of a freestanding diagnostic imaging center.

Comments submitted during the public comment period suggest that UNC-HCS is the owner of the freestanding diagnostic imaging center on the first floor of the MOB. The Agency notes that the owner and certificate holder is WR Imaging, LLC. WR Imaging, LLC is owned jointly by Rex Hospital, Inc. and Wake Radiology Services, LLC. A parent company of an entity involved in a joint venture with at least one other unaffiliated entity does not necessarily have controlling authority over the operations of the joint venture. Thus, UNC-HCS, as the parent company of one of the joint venture entities, does not necessarily have any controlling authority over the operation of WR Imaging, LLC. There is no information provided in the comments to

substantiate the allegation that UNC-HCS does have controlling authority over WR Imaging, LLC.

The exempt MOB developed by UNC-HCS became operational in January 2020. WR Imaging, LLC operates an independent diagnostic testing facility on the first floor of the MOB. Also on the first floor of the MOB is Raleigh Orthopaedic Surgery Center – West Cary, a single specialty freestanding ambulatory surgical facility (ASF). The second and third floors of UNC Health Care Panther Creek are occupied by the urgent care center and laboratory previously discussed, along with numerous physician office practices, most of which are affiliated with UNC-HCS.

UNC-HCS states that the diagnostic center proposal will cover all of the second and third floors of the Panther Creek MOB, with the exception of space on the second floor occupied by Raleigh Orthopaedic Clinic, an unrelated tenant. The applicant also states the first floor of the MOB is not part of the proposed project.

Designation as a Diagnostic Center

In Section C, pages 25-28, the applicant states the proposed diagnostic center will be comprised of the qualifying diagnostic imaging equipment in physician offices of wholly-owned subsidiaries of UNC-HCS. The applicant states the proposed diagnostic center will include the following pieces of new and existing medical diagnostic equipment, each of which is worth \$10,000 or more:

UNC Panther Creek Type and Location of Medical Diagnostic Equipment		
Equipment	Number of Units	New or Existing
URGENT CARE – SECOND FLOOR		
Electrocardiogram (EKG)	1	Existing
ORTHOPEDIC CLINIC – SECOND FLOOR		
Diagnostic X-Ray*	1	Existing
Ultrasound	1	Existing
OB/GYN CLINIC – SECOND FLOOR		
Fetal Ultrasound	1	Existing
SPECIALTY CLINIC – THIRD FLOOR		
Electrocardiogram (EKG)	2	Existing
Echocardiography**	1	Existing
Pulmonary Function Test (PFT)	1	Existing
Nuclear Camera***	1	New
Ultrasound	1	Existing

Source: Section C, page 26

*Also used by the Urgent Care Center

**Includes stress treadmill

***Includes hot lab and stress treadmill

The applicant states all the existing and proposed equipment will be used in support of physician office practices and billed as such, and none of the proposed services will be billed as an independent diagnostic testing facility. The applicant also states that out of an abundance

of caution, the applicant included the original price for each of the existing pieces of diagnostic imaging equipment and which will be part of the proposed diagnostic imaging center. On Form F.1a, the applicant lists the cost of medical equipment as \$832,707.

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 2020 SMFP does not define a service area for diagnostic centers, nor are there any applicable rules adopted by the Department that define the service area for diagnostic centers. Thus, the service area in this review is as defined by the applicant. In Section C, pages 28-31, and Section G, pages 65-66, the applicant defines the service area as Wake, Durham, and Chatham counties. Facilities may also serve residents of counties not included in their service area.

UNC Panther Creek is not an existing facility. The following table illustrates projected patient origin during the first three full fiscal years following project completion.

UNC Panther Creek Projected Patient Origin – FYs 1-3 (CYs 2022-2024)						
County	FY 1 – SFY* 2022		FY 2 – SFY* 2023		FY 3 – SFY* 2024	
	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total
27519 (Wake)	9,535	53.6%	11,918	53.6%	12,142	53.6%
Wake (Other)	6,273	35.3%	7,841	35.3%	7,988	35.3%
Durham	710	4.0%	887	4.0%	904	4.0%
Chatham	430	2.4%	538	2.4%	548	2.4%
Other**	827	4.7%	1,033	4.7%	1,053	4.7%
Total	17,774	100.0%	22,218	100.0%	22,634	100.0%

Source: Section C, page 31

*SFY = State Fiscal Year, which runs from July 1 to June 30 of the following year. For example, State Fiscal Year 2020 runs from July 1, 2019 through June 30, 2020.

**Other includes Harnett, Johnston, and Orange counties.

In Section C, page 32, the applicant provides the assumptions and methodology used to project its patient origin. The applicant’s assumptions are reasonable and adequately supported.

Analysis of Need

In Section C, pages 32-38, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. The applicant states:

- There has been tremendous growth in the Panther Creek area of Wake County in the last 10 years – approximately double the growth rate as the rest of the county. The applicant began locating healthcare services in the area ten years ago, and states this venture, along with the existing physician practices in place, will allow access to services not currently offered in Panther Creek in a more convenient setting.

- By ensuring physician offices have the medical diagnostic equipment needed to diagnose patients, along with the available capacity to use that equipment as needed for patients, UNC Panther Creek will allow patients to receive medical diagnostic services at the same location they see their providers much more quickly than if they had to be referred to an outside clinic with different scheduling.
- Providing the medical diagnostic equipment necessary for physicians at the physician offices allows physicians to avoid referring patients needing medical diagnostic services to a different location with potentially higher charges. Additionally, as a physician-based practice, UNC Panther Creek will provide patients with an opportunity to lower their out-of-pocket medical costs.
- According to the North Carolina Office of State Budget and Management (NC OSBM), the Wake County population is projected to grow at a Compound Annual Growth Rate (CAGR) of 1.9 percent between 2019 and 2024, and the population of Wake County residents age 65 and older will increase from 12 percent in 2019 to more than 14 percent in 2024. The applicant states the increase in the percent of the population age 65 and older is significant because older residents utilize healthcare services at a higher rate than younger residents. The applicant states that the Panther Creek area (defined by the applicant as ZIP code 27519) is projected to have the second highest numerical population growth of any ZIP code in Wake County between 2019 and 2024.

The information is reasonable and adequately supported for the following reasons:

- The applicant provides reasonable and adequately supported information to support its assertion that acquisition of additional medical diagnostic equipment for physicians utilizing UNC Panther Creek will better serve patients.
- Reliable data sources are used to support assertions about population growth.

Projected Utilization

In Section Q, Form C, the applicant provides projected utilization, as illustrated in the following table.

UNC Panther Creek Projected Utilization – FYs 1-3 (SFYs 2022-2024)			
Component	FY 1 (SFY 2022)	FY 2 (SFY 2023)	FY 3 (SFY 2024)
Urgent Care EKG – Units	1	1	1
Urgent Care EKG – Tests	347	434	442
Urgent Care/Orthopedics X-Ray – Units	1	1	1
Urgent Care/Orthopedics X-Ray – Tests	9,478	11,847	12,069
Orthopedic Ultrasound – Units	1	1	1
Orthopedic Ultrasound – Tests	2,982	3,728	3,798
Fetal Ultrasound – Units	1	1	1
Fetal Ultrasound – Tests	52	65	66
Specialty Clinic EKG – Units	2	2	2
Specialty Clinic EKG – Tests	1,716	2,145	2,185
Specialty Clinic Echocardiography - Units	1	1	1
Specialty Clinic Echocardiography - Tests	1,266	1,582	1,612
PFT Machines – Units	1	1	1
PFT Machines – Tests	1,353	1,691	1,723
Nuclear Camera – Units	1	1	1
Nuclear Camera – Tests	101	126	128
Surgery Ultrasound – Units	1	1	1
Surgery Ultrasound – Tests	480	600	611
Total Tests	17,775	22,218	22,634

In Section C, pages 39-42, and in the Form C Utilization – Assumptions and Methodology subsection of Section Q, the applicant provides the annual maximum capacity per unit for each type of medical diagnostic equipment proposed in this application, as well as the assumptions and methodology used to project the annual maximum capacities. The annual maximum capacity for each type of medical diagnostic equipment proposed in this application is shown in the table below.

Annual Maximum Capacity for Each Type of Medical Diagnostic Equipment Proposed					
Equipment Type	# Units	Tests/Hour	Hours/Day	Days/Year	Maximum Annual Capacity*
Urgent Care EKG	1	4.00	NA	365	NA
Urgent Care/Orthopedics X-Ray	1	4.00	12	365	17,520
Orthopedic Ultrasound	1	2.00	NA	302	NA
Fetal Ultrasound	1	2.00	NA	250	NA
Specialty Clinic EKG	2	4.0	NA	250	NA
Specialty Clinic Echocardiography**	1	2.00	7	250	3,500
PFT Machine	1	1.50	7	250	2,625
Nuclear Camera***	1	0.75	7	250	1,313
Surgery Ultrasound	1	4.00	NA	250	NA

Source: Section C, page 39; Form C Utilization – Assumptions and Methodology subsection of Section Q

*Maximum Annual Capacity = (Units X Patients X Hours X Days)

**Includes stress treadmill

***Includes hot lab and stress treadmill

Note: The applicant states there is no dedicated staff for the urgent care EKG, orthopedic ultrasound, fetal ultrasound, specialty clinic EKGs, and specialty clinic surgery ultrasound, and no assumed hours – so no annual capacity is calculated for that equipment.

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

The applicant states that, since physician clinics at the Panther Creek MOB only began offering services in January 2020, the applicant relied on historical utilization of UNC-HCS clinics of a similar size and offering similar services as the physician clinics at UNC Panther Creek to project future utilization at UNC Panther Creek. The applicant states it projects its utilization will “ramp-up” over a three-year period. The applicant states it assumes 60 percent of the full projected volume will be served in SFY 2021, 80 percent of the full projected volume will be served in SFY 2022, and 100 percent of the projected volume will be served in SFY 2023. The applicant then projects growth of the services through SFY 2024 by using the projected growth rate of the population of Wake County for CY 2019-2024, 1.9 percent, as published by NC OSBM.

The applicant further states that the urgent care EKG machine, orthopedic ultrasound machine, fetal ultrasound machine, specialty clinic EKG machine, and specialty clinic ultrasound machine have no dedicated staff and are used by physicians as needed for their diagnostic requirements. The applicant states the equipment proposed is intended to maximize the efficiency of the physicians using the equipment and efficiency of care to patients rather than to maximize utilization of the equipment.

Urgent Care EKG

- The applicant projects that, based on historical utilization at similarly sized clinics offering similar services, UNC Panther Creek will perform 434 urgent care EKGs in SFY 2023, and that number will grow by 1.9 percent between SFY 2023 and SFY 2024. The table below shows the projected utilization, including ramp-up, between SFYs 2021-2024.

UNC Panther Creek Urgent Care EKG Projected Utilization				
	SFY 2021	FY 1 – SFY 2022	FY 2 – SFY 2023	FY 3 – SFY 2024
Procedures	210	347	434	442
Ramp-up/Growth	60%	80%	100%	+1.9%

- The applicant projects to perform 442 urgent care EKG procedures at UNC Panther Creek in SFY 2024. The applicant states the urgent care EKG machine does not have dedicated staff and is utilized based on physician need; therefore, there is no maximum annual utilization calculated for the urgent care EKG machine. While there is no maximum annual utilization calculated, the applicant states that if the urgent care EKG machine was fully staffed by dedicated providers every day, the maximum annual capacity of the urgent care EKG machine would be 17,520 EKGs.
- The applicant states the urgent care EKG machine is necessary to avoid urgent care providers and patients at the urgent care clinic having to wait unnecessarily for this diagnostic imaging equipment.

Urgent Care/Orthopedic X-Ray

- The applicant projects that, based on historical utilization at similarly sized clinics offering similar services, UNC Panther Creek will perform 2,575 urgent care x-rays and 9,272 orthopedic x-rays for a combined total of 11,847 diagnostic x-rays in SFY 2023, and that number will grow by 1.9 percent between SFY 2023 and SFY 2024. The table below shows the projected utilization, including ramp-up, between SFYs 2021-2024.

UNC Panther Creek Urgent Care/Orthopedic X-Ray Projected Utilization				
	SFY 2021	FY 1 – SFY 2022	FY 2 – SFY 2023	FY 3 – SFY 2024
Urgent Care	1,545	2,060	2,575	2,623
Orthopedic	5,563	7,418	9,272	9,446
Total	7,108	9,478	11,847	12,069
Ramp-up/Growth	60%	80%	100%	+1.9%

- The table below shows the projected utilization of the x-ray in SFY 2024 based on the maximum capacity defined by the applicant.

UNC Panther Creek Urgent Care/Orthopedic X-Ray Capacity				
	# of Units	Maximum Capacity	SFY 2024 Projected Utilization	% Capacity
X-Ray	1	17,250	12,069	68.9%

- The applicant states the urgent care/orthopedic x-ray is necessary for urgent care and orthopedic patients to have immediate access to x-ray services and results and that requiring patients to go elsewhere will result in unnecessary delay and create disruption in patient flow through clinics.

Orthopedic Ultrasound

- The applicant projects that, based on historical utilization at similarly sized clinics offering similar services, UNC Panther Creek will perform 3,728 orthopedic ultrasounds in SFY 2023, and that number will grow by 1.9 percent between SFY 2023 and SFY 2024. The table below shows the projected utilization, including ramp-up, between SFYs 2021-2024.

UNC Panther Creek Orthopedic Ultrasound Projected Utilization				
	SFY 2021	FY 1 – SFY 2022	FY 2 – SFY 2023	FY 3 – SFY 2024
Procedures	2,237	2,982	3,728	3,798
Ramp-up/Growth	60%	80%	100%	+1.9%

- The applicant projects to perform 3,798 orthopedic ultrasounds at UNC Panther Creek in SFY 2024. The applicant states the orthopedic ultrasound machine does not have dedicated staff and is utilized based on physician need; therefore, there is no maximum annual utilization calculated for the orthopedic ultrasound machine. While there is no maximum annual utilization calculated, the applicant states that if the orthopedic ultrasound machine was fully staffed by dedicated providers every day, the maximum annual capacity of the orthopedic ultrasound machine would be 7,248 ultrasounds.

- The applicant states the orthopedic ultrasound machine is necessary to provide patients with access to this diagnostic imaging service in a convenient setting at a physician-based clinic.

Fetal Ultrasound

- The applicant projects that, based on historical utilization at similarly sized clinics offering similar services, UNC Panther Creek will perform 65 fetal ultrasounds in SFY 2023, and that number will grow by 1.9 percent between SFY 2023 and SFY 2024. The table below shows the projected utilization, including ramp-up, between SFYs 2021-2024.

UNC Panther Creek Fetal Ultrasound Projected Utilization				
	SFY 2021	FY 1 – SFY 2022	FY 2 – SFY 2023	FY 3 – SFY 2024
Procedures	39	52	65	66
Ramp-up/Growth	60%	80%	100%	+1.9%

- The applicant projects to perform 66 fetal ultrasounds at UNC Panther Creek in SFY 2024. The applicant states the fetal ultrasound machine does not have dedicated staff and is utilized based on physician need; therefore, there is no maximum annual utilization calculated for the fetal ultrasound machine. While there is no maximum annual utilization calculated, the applicant states that if the fetal ultrasound machine was fully staffed by dedicated providers every day, the maximum annual capacity of the fetal ultrasound machine would be 3,500 fetal ultrasounds.
- The applicant states the fetal ultrasound machine is necessary to provide pregnant patients with vital diagnostic information about the health of the fetus and to have those results interpreted immediately by the patient’s regular provider.

Specialty Clinic EKGs

- The applicant projects that, based on historical utilization at similarly sized clinics offering similar services, UNC Panther Creek will perform 500 cardiology EKGs and 1,645 Department of Medicine EKGs for a combined total of 2,145 EKGs on the two specialty clinic EKGs in SFY 2023, and that number will grow by 1.9 percent between SFY 2023 and SFY 2024. The table below shows the projected utilization, including ramp-up, between SFYs 2021-2024.

UNC Panther Creek Specialty Clinic EKG Projected Utilization				
	SFY 2021	FY 1 – SFY 2022	FY 2 – SFY 2023	FY 3 – SFY 2024
Cardiology	300	400	500	509
Dept. of Medicine	987	1,316	1,645	1,675
Total	1,287	1,716	2,145	2,185
Ramp-up/Growth	60%	80%	100%	+1.9%

- The applicant projects to perform 509 cardiology EKGs and 1,675 Department of Medicine EKGs for a combined total of 2,185 EKGs on the specialty clinic EKG machines at UNC

Panther Creek in SFY 2024. The applicant states the specialty clinic EKG machines do not have dedicated staff and are utilized based on physician need; therefore, there is no maximum annual utilization calculated for the specialty clinic EKG machines. While there is no maximum annual utilization calculated, the applicant states that if the two specialty clinic EKG machines were fully staffed by dedicated providers every day, the maximum annual capacity of the two specialty clinic EKG machines would be 14,000 EKGs.

- The applicant states the specialty clinic EKG machines are necessary to avoid disruptions to patient flow and for patients to avoid an unnecessary wait for this diagnostic imaging service.

Specialty Clinic Echocardiography

- The applicant projects that, based on historical utilization at similarly sized clinics offering similar services, UNC Panther Creek will perform 485 cardiology echocardiograms and 1,097 Department of Medicine echocardiograms for a combined total of 1,582 echocardiograms in SFY 2023, and that number will grow by 1.9 percent between SFY 2023 and SFY 2024. The table below shows the projected utilization, including ramp-up, between SFYs 2021-2024.

UNC Panther Creek Specialty Clinic Echocardiography Projected Utilization				
	SFY 2021	FY 1 – SFY 2022	FY 2 – SFY 2023	FY 3 – SFY 2024
Cardiology	291	388	485	495
Dept. of Medicine	658	877	1,097	1,117
Total	949	1,266	1,582	1,612
Ramp-up/Growth	60%	80%	100%	+1.9%

- The table below shows the projected utilization of the echocardiography machine in SFY 2024 based on the capacity defined by the applicant.

UNC Panther Creek Specialty Clinic Echocardiography Machine Capacity				
	# of Units	Maximum Capacity	SFY 2024 Projected Utilization	% Capacity
Echocardiography Machine	1	3,500	1,612	46.1%

- The applicant states the specialty clinic echocardiography machine is necessary to avoid unnecessary delay in access to this diagnostic imaging service for patients and disruption to patient flow.

PFT Machine

- The applicant projects that, based on historical utilization at similarly sized clinics offering similar services, UNC Panther Creek will perform 1,691 tests on the PFT machine in SFY 2023, and that number will grow by 1.9 percent between SFY 2023 and SFY 2024. The table below shows the projected utilization, including ramp-up, between SFYs 2021-2024.

UNC Panther Creek PFT Machine Projected Utilization				
	SFY 2021	FY 1 – SFY 2022	FY 2 – SFY 2023	FY 3 – SFY 2024
Procedures	1,015	1,353	1,691	1,723
Ramp-up/Growth	60%	80%	100%	+1.9%

- The table below shows the projected utilization of the PFT machine in SFY 2024 based on the capacity defined by the applicant.

UNC Panther Creek PFT Machine Capacity				
	# of Units	Maximum Capacity	SFY 2024 Projected Utilization	% Capacity
PFT Machine	1	2,625	1,723	65.6%

- The applicant states the PFT machine is necessary to avoid unnecessary delay in access to this diagnostic imaging service for patients and disruption to patient flow.

Nuclear Camera

- The applicant projects that, based on historical utilization at similarly sized clinics offering similar services, UNC Panther Creek will perform 126 nuclear camera studies in SFY 2023, and that number will grow by 1.9 percent between SFY 2023 and SFY 2024. The table below shows the projected utilization, including ramp-up, between SFYs 2021-2024.

UNC Panther Creek Nuclear Camera Projected Utilization				
	SFY 2021	FY 1 – SFY 2022	FY 2 – SFY 2023	FY 3 – SFY 2024
Studies	76	101	126	128
Ramp-up/Growth	60%	80%	100%	+1.9%

- The table below shows the projected utilization of the nuclear camera in SFY 2024 based on the capacity defined by the applicant.

UNC Panther Creek PFT Machine Capacity				
	# of Units	Maximum Capacity	SFY 2024 Projected Utilization	% Capacity
Nuclear Camera	1	1,313	128	9.8%

- The applicant states the nuclear camera is necessary to avoid unnecessary delay in access to this diagnostic imaging service for patients and disruption to patient flow.

Surgery Ultrasound

- The applicant projects that, based on historical utilization at similarly sized clinics offering similar services, UNC Panther Creek will perform 600 surgery ultrasounds in SFY 2023, and that number will grow by 1.9 percent between SFY 2023 and SFY 2024. The table below shows the projected utilization, including ramp-up, between SFY 2021-2024.

UNC Panther Creek Surgery Ultrasound Machine Projected Utilization				
	SFY 2021	FY 1 – SFY 2022	FY 2 – SFY 2023	FY 3 – SFY 2024
Procedures	360	480	600	611
Ramp-up/Growth	60%	80%	100%	+1.9%

- The applicant projects to perform 611 surgery ultrasounds at UNC Panther Creek in SFY 2024. The applicant states the surgery ultrasound machine does not have dedicated staff and is utilized based on physician need; therefore, there is no maximum annual utilization calculated for the surgery ultrasound machine. While there is no maximum annual utilization calculated, the applicant states that if the surgery ultrasound machine was staffed by dedicated providers every day, the maximum annual capacity of the surgery ultrasound machine would be 7,000 ultrasounds.
- In Section C, page 27, the applicant states this ultrasound machine will be used for surgical procedures in the specialty clinic. The applicant states the surgery ultrasound machine is necessary because, while there are other ultrasound machines available, there are challenges involved in using the same ultrasound machine in a sterile environment and a nonsterile environment.

A summary of the applicant’s historical utilization, details of assumptions and methodology, and projected utilization for each type of equipment is shown in the table below.

UNC Panther Creek Utilization Assumptions, Methodology, and Projections – SFY 2021-2024						
Component	SFY 2021	FY 1 (SFY 2022)	FY 2 (SFY 2023)	FY 3 (SFY 2024)	Max. Capacity	% of Max. Capacity
Ramp-up/Growth	60%	80%	100%	1.9%	--	--
Urgent Care EKG (1 unit)	210	347	434	442	NA	NA
Urgent Care/Orthopedics X-Ray (1 unit)	7,108	9,478	11,847	12,069	17,250	68.9%
Orthopedic Ultrasound (1 unit)	2,237	2,982	3,728	3,798	NA	NA
Fetal Ultrasound (1 unit)	39	52	65	66	NA	NA
Specialty Clinic EKG (2 units)	1,287	1,716	2,145	2,185	NA	NA
Specialty Clinic Echocardiography (1 unit)	949	1,266	1,582	1,612	3,500	46.1%
PFT Machine (1 unit)	1,015	1,353	1,691	1,723	2,625	65.6%
Nuclear Camera (1 unit)	76	101	126	128	1,313	9.8%
Surgery Ultrasound (1 unit)	360	480	600	611	NA	NA
Total Tests		17,775	22,218	22,634		

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

- There was not sufficient existing utilization at UNC Panther Creek to use in projecting utilization, because services were first offered in January 2020.
- Because of the lack of historical utilization at UNC Panther Creek, the applicant used historical data from existing physician clinics offering similar services and of similar size to the proposed diagnostic imaging center to project utilization.

- The applicant uses a projected annual growth rate of 1.9 percent, equivalent to the projected annual growth rate for the population of all of Wake County, which is more conservative than the 3.2 percent projected annual growth rate for the Panther Creek area of Cary where the proposed facility is located.
- The applicant provided projected utilization for medical equipment which already exists and is in use at UNC Panther Creek and which will continue to exist and be utilized at UNC Panther Creek regardless of the outcome of this application.
- There are no performance standards applicable for any of the pieces of existing or proposed diagnostic imaging equipment at UNC Panther Creek.
- For equipment which is not proposed to have dedicated staff, and for which there is no projected annual capacity because of the lack of dedicated staff, the applicant still provides information about potential annual capacity of the equipment.
- The applicant provides reasonable and adequately supported information to demonstrate the need for diagnostic imaging equipment based on providing efficient care to patients and maximizing efficiency for providers versus maximizing utilization of the existing and proposed diagnostic imaging equipment.

Access

In Section C, page 46, the applicant states:

“As North Carolina’s only state-owned, comprehensive, full-service hospital system, UNCHCS has the obligation to accept any North Carolina citizen requiring medically necessary treatment. No North Carolina citizen is presently denied access to non-elective care because of race, sex, creed, age, handicap, financial status, or lack of medical insurance.”

In Section L, page 81, the applicant projects the following payor mix during the third full fiscal year of operation following completion of the project, as illustrated in the following table.

UNC Panther Creek Payor Mix – FY 3 (SFY 2024)	
Payor Source	Percent of Services
Self-Pay	7.9%
Medicare*	26.8%
Medicaid*	8.3%
Insurance*	56.0%
Other**	0.9%
Total	100.0%

Note: The applicant states that it does not have charity care as a payor source, and that patients in every payor category receive charity care.

*Including any managed care plans

**"Other" includes Worker's Compensation, TRICARE, Department of Corrections, and other payors

The projected payor mix is reasonable and adequately supported.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- 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 (payor 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.

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 develop a new diagnostic center in an existing MOB in the Panther Creek area of Cary, in Wake County.

In Section E, page 56, 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 option would not allow enhanced and more convenient access to care by patients and would force patients to receive diagnostic services elsewhere; therefore, this is not an effective alternative.

Develop the Diagnostic Center in a Smaller Space: The applicant states developing the diagnostic center in a smaller space, such as the specialty clinic only, would be too narrow in scope and would not allow the other physician clinics in the MOB the necessary flexibility to meet patient demand and practice need; therefore, this is not an effective alternative.

On page 56, the applicant states its proposal is the most effective alternative because it provides enhanced and more convenient access to patients, provides the necessary diagnostic imaging equipment for providers and patients, and allows the appropriate flexibility necessary for the physician clinics at UNC Panther Creek.

Comments submitted during the public comment period suggest the least costly or most effective alternative would be to locate the nuclear camera component of the proposed diagnostic imaging center on the first floor of the MOB, based on a floor plan submitted with a material compliance request on February 1, 2019. The comments suggest that since the floor plan indicates there is unoccupied space on the first floor of the MOB, the least costly or most effective alternative would be to locate the nuclear camera in that space, rather than in the physician clinic where it would be used.

The Agency notes that, according to that referenced floor plan, there are two areas of space on the first floor of the MOB that the comments may be referring to. Both areas are labeled as "Building Support." Even if those two areas were truly unoccupied, one of the areas is located inside an unaffiliated ambulatory surgical center and the other is outside of the freestanding diagnostic imaging center on the first floor of the MOB. The Agency has no reason to believe that renovating a storage space inside an unaffiliated ambulatory surgical facility to accommodate radioactive testing would be the least costly or most effective alternative.

Further, the comments provide no information to suggest that developing the nuclear camera and the associated space on the first floor of the MOB would be less costly than developing it where proposed, or that requiring a patient and provider on a different floor of the MOB to leave the physician clinic to travel to the first floor of the MOB and then returning to the physician clinic would be the most effective alternative. Additionally, the Agency notes the drawings referenced were submitted with correspondence more than a year prior to the submission of the application under review; the comments do not provide any information to suggest the spaces referenced are still either unoccupied or serving as “Building Storage” as of the date of the submission of this application.

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

- The application is conforming to all statutory and regulatory criteria.
- The applicant provides credible information to explain why it believes the proposed project is the most effective alternative.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- 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. Therefore, the application is approved subject to the following conditions:

- 1. University of North Carolina Health Care System shall materially comply with all representations made in the certificate of need application.**
- 2. University of North Carolina Health Care System shall develop a diagnostic center in the existing UNC Health Care Panther Creek Medical Office Building by adding a nuclear camera to existing diagnostic imaging equipment located in UNC Health Care Panther Creek Medical Office Building.**
- 3. University of North Carolina Health Care System, as part of this project, shall not acquire any equipment that is not included in the project’s proposed capital expenditures in Sections F and Q of the application or that would otherwise require a certificate of need.**
- 4. No later than three months after the last day of each of the first three full years of operation following initiation of the services authorized by this certificate of need,**

University of North Carolina Health Care System shall submit, on the form provided by the Healthcare Planning and Certificate of Need Section, an annual report containing the:

- a. Payor mix for the services authorized in this certificate of need.**
- b. Utilization of the services authorized in this certificate of need.**
- c. Revenues and operating costs for the services authorized in this certificate of need.**
- d. Average gross revenue per unit of service.**
- e. Average net revenue per unit of service.**
- f. Average operating cost per unit of service.**

5. University of North Carolina Health Care System 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 develop a new diagnostic center in an existing MOB in the Panther Creek area of Cary, in Wake County.

Capital and Working Capital Costs

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

Construction Costs	\$194,438
Medical Equipment Costs	\$832,707
Consultant/A&E Fees	\$48,948
Total	\$1,076,093

In Section Q, the applicant provides the assumptions used to project the capital cost.

In Section F, page 60, the applicant states the project does not involve any working capital costs.

Availability of Funds

In Section F, pages 58-59, the applicant states the capital cost of the project will be funded via accumulated reserves of UNC-HCS. Exhibit F.2-1 contains a letter from the Associate Chief Financial Officer of UNC-HCS, stating UNC-HCS will fund the capital cost of \$1,076,093 to develop the proposed project.

In Section F, page 59, the applicant states it does not have audited financials of UNC-HCS itself to demonstrate the availability of accumulated reserves but provides in Exhibits F.2-2 and F.2-3 the audited financial statements for UNC Hospitals and Rex Healthcare, Inc. and Subsidiaries, respectively, for the state fiscal years ending June 30, 2019 and 2018. UNC Hospitals and Rex Healthcare, Inc. and Subsidiaries are both components of UNC-HCS. As of June 30, 2019, UNC Hospitals and Rex Healthcare, Inc. and Subsidiaries had adequate cash and cash equivalents to fund 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. In Form F.2, the applicant projects that revenues will exceed operating expenses in the first three full fiscal years of the project, as shown in the table below.

UNC Panther Creek Revenue and Expenses – FYs 1-3 (SFYs 2022-2024)			
	FY 1 (SFY 2022)	FY 2 (SFY 2023)	FY 3 (SFY 2024)
Total Tests/Procedures	17,775	22,218	22,634
Total Gross Revenues (Charges)	\$1,741,277	\$2,241,894	\$2,352,455
Total Net Revenue	\$855,375	\$1,101,295	\$1,155,606
Average Net Revenue per Test	\$48	\$50	\$51
Total Operating Expenses (Costs)	\$686,590	\$748,812	\$771,410
Average Operating Expense per Test	\$39	\$34	\$34
Net Income / (Loss)	\$168,784	\$352,483	\$384,196

The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs, and charges. See Section Q of the application for the assumptions used regarding costs and charges. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

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 cost is based on reasonable and adequately supported assumptions.
- The applicant adequately demonstrates availability of sufficient funds for the 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

The applicant proposes to develop a new diagnostic center in an existing MOB in the Panther Creek area of Cary, in Wake County.

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 2020 SMFP does not define a service area for diagnostic centers, nor are there any applicable rules adopted by the Department that define the service area for diagnostic centers. Thus, the service area in this review is as defined by the applicant.

In Section C, pages 28-31, and Section G, pages 65-66, the applicant defines the service area as Wake, Durham, and Chatham counties. Facilities may also serve residents of counties not included in their service area.

In Section G, page 65, the applicant lists all hospital facilities offering diagnostic imaging services in its defined service area, and states it is unaware of any publicly available data to show inventory and utilization of existing and approved non-hospital-based facilities and equipment providing services like those proposed in this application. In Exhibit G.2, the applicant provides copies of pages from 2019 License Renewal Applications (LRAs) for the hospitals in Wake, Durham, and Chatham counties with equipment and services like those proposed in this application. On page 66, the applicant lists all the existing and approved diagnostic centers owned or operated by UNC-HCS or an affiliated entity.

In Section G, page 66, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved diagnostic center services in Wake, Durham, and Chatham counties. The applicant states:

“The need for the proposed project is based on the need for UNCHCS to provide convenient access to diagnostic services to support the physician clinics in the existing MOB. The proposed diagnostic center will serve to optimize UNCHCS’s ability to provide patient-centered care in a cost-effective manner. No other provider can meet the identified need. Further, though other imaging and diagnostic services may be available in the service area, they are not reasonably available to the patients of the UNCHCS physicians located at its Panther Creek MOB. Specifically, use of such equipment would require leaving the physician office building, registering as a patient at another facility, waiting hours, days, or weeks for an available appointment, then having to return to the UNCHCS practice. Compared to the availability of the service

within the same building, typically during the same visit, the use of other capacity in the service area is ineffective at providing sufficient access to patients.”

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 diagnostic center is needed in addition to the existing or approved diagnostic centers.

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.

- (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 projected staffing for the proposed services as illustrated in the following table. Also, in Section Q, in its assumptions and methodology for projecting utilization of the proposed facility, the applicant states that there are no dedicated staff for the urgent care EKG machine, orthopedic ultrasound machine, fetal ultrasound machine, specialty clinic EKG machines, and specialty clinic surgery ultrasound machine.

UNC Panther Creek Projected Staffing – All FYs (SFYs 2022-2024)	
Position	FTEs
Radiology Technologists	3.4
Aides/Orderlies*	0.2
Respiratory Therapists	1.0
Nuclear Camera Technician	0.4
Total	5.0

Source: Form H in Section Q of the application.

*In FY 1 (SFY 2022), the applicant projects 0.1 FTEs for Aides/Orderlies in the Specialty Clinic; for FYs 2 and 3 (SFYs 2023-2024), the applicant projects 0.2 FTEs.

Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form F.3, which is found in Section Q. In Section H, pages 68-69, the applicant describes the methods to be used to recruit or fill new positions and its proposed training and continuing education programs. In Exhibit I.2, the applicant provides letters of support from local physicians.

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

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 70, the applicant states the following ancillary and support services are necessary for the proposed diagnostic center:

- Housekeeping
- Security
- Maintenance
- Registration
- Administration
- Other Ancillary and Support Services

On page 70, the applicant adequately explains how each ancillary and support service will be made available.

Comments submitted during the public comment period suggest the applicant did not include all necessary ancillary and support services necessary, such as information about providers who will interpret imaging or information about the handling and disposal of radioactive material associated with the acquisition of the nuclear camera. The Agency notes that provider interpretations of imaging and handling of necessary radioactive material would be integral to the provision of the proposed diagnostic imaging services and would not be considered ancillary and support services.

In Section I, pages 70-71, the applicant describes its existing 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.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments

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 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

In Section K, page 73, the applicant states that the project involves renovating 512 square feet of existing space in the UNC Health Care Panther Creek MOB. Line drawings are provided in Exhibit C.1-3.

In Section K, pages 73-74, the applicant adequately explains how the cost, design, and means of construction represent the most reasonable alternative for the proposal.

Comments submitted during the public comment period suggest the applicant failed to include critical information regarding the company performing renovations, the architect or engineering company providing estimates, or a specific renovation contract. The comments also suggested it was necessary to include information regarding construction specifications for a single component of the proposed diagnostic imaging center. The Agency notes that nothing in the statutory language of this criterion requires the type of information suggested and nothing in the comments submitted provide the Agency with any reason to require that type of information in this review.

In Section K, page 74, 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. The applicant states physician-based services have lower out-of-pocket insurance costs, and consolidation of services allows for economies of scale.

In Section K, pages 74-75, 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
- Written comments

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;

NA

UNC Health Care Panther Creek Diagnostic Center is not an existing facility. Therefore, Criterion (13a) is not applicable to this review.

- (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

UNC Health Care Panther Creek Diagnostic Center is not an existing facility. However, UNC-HCS previously had Hill-Burton Act obligations. 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 that it fulfilled its prior Hill-Burton Act obligations and currently has no such obligations.

In Section L, page 80, the applicant states that during the last five years 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.

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.

- (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 81, the applicant projects the following payor mix during the third full fiscal year of operation following completion of the project, as illustrated in the following table.

UNC Panther Creek Payor Mix – FY 3 (SFY 2024)	
Payor Source	Percent of Services
Self-Pay	7.9%
Medicare*	26.8%
Medicaid*	8.3%
Insurance*	56.0%
Other**	0.9%
Total	100.0%

Note: The applicant states that it does not have charity care as a payor source, and that patients in every payor category receive charity care.

*Including any managed care plans

**"Other" includes Worker's Compensation, TRICARE, Department of Corrections, and other payors

As shown in the table above, during the third full fiscal year of operation, the applicant projects that 7.9 percent of total services will be provided to self-pay patients, 26.8 percent to Medicare patients, and 8.3 percent to Medicaid patients.

In Section L, page 81, 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 for the following reasons:

- Projected payor mix is based on the historical experience of other UNC-HCS physician clinics of similar size and which offer similar services.
- The applicant provides reasonable and adequately supported information to explain why there are no changes to the projected payor mix in future years.

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.

- (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 82, the applicant adequately describes the range of means by which patients will have access to the proposed 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.

- (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, pages 83-84, 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

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

The applicant proposes to develop a new diagnostic center in an existing MOB in the Panther Creek area of Cary, in Wake County.

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 2020 SMFP does not define a service area for diagnostic centers, nor are there any applicable rules adopted by the Department that define the service area for diagnostic centers. Thus, the service area in this review is as defined by the applicant.

In Section C, pages 28-31, and Section G, pages 65-66, the applicant defines the service area as Wake, Durham, and Chatham counties. 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 85, the applicant states:

“The proposed project is expected to enhance competition in the service area by promoting cost effectiveness, quality, and access to diagnostic services.”

Regarding the impact of the proposal on cost effectiveness, in Section N, page 85, the applicant states:

“The proposed project will enable UNCHCS to continue to provide its patient population with the best care possible, while also being responsive in a healthcare environment that emphasizes cost containment and efficient utilization of existing resources.”

Regarding the impact of the proposal on quality, in Section N, page 85, the applicant states:

“UNCHCS believes that the proposed project will promote the provision of quality healthcare services to its patients. UNCHCS is known for providing high quality services and expects the proposed project to expand convenient access to its physician-based diagnostic medical services while bolstering its high-quality reputation.”

Regarding the impact of the proposal on access by medically underserved groups, in Section N, pages 88-89, the applicant states:

“The proposed project will promote access to diagnostic services in the service area. UNCHCS is a not-for-profit integrated healthcare system owned by the state of North

Carolina and based in Chapel Hill. Currently, UNCHCS comprises UNC Hospitals and its provider network, the clinical programs of the UNC School of Medicine, and eleven affiliate hospitals and hospital systems across the state. As North Carolina's only state-owned, comprehensive, full service hospital system, UNCHCS has the obligation to accept any North Carolina citizen requiring medically necessary treatment. No North Carolina citizen is presently denied access to non-elective care because of race, sex, creed, age, handicap, financial status, or lack of medical insurance as demonstrated in Section C.

...[UNCHCS] strives to provide adequate financial assistance and expand its overall capacity in order to meet the healthcare needs of North Carolinians. UNCHCS's commitment to treating all patients regardless of their ability to pay is evidenced by its payor mix. UNCHCS has a long and proud history of serving patients who require care, regardless of their ability to pay. UNCHCS expects that patients with limited financial resources will continue to access its services upon completion of the proposed project."

Considering all the information in the application, 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 (see Sections C, F, K, N, and Q of the application and any exhibits)
- Quality (see Sections C, N, and O of the application and any exhibits)
- Access to medically underserved groups (see Sections C, L, and N 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

On Form A in Section Q, the applicant identifies all other diagnostic centers in North Carolina owned, operated, or managed by the applicant or a related entity. The applicant identifies a total of 16 diagnostic centers located in North Carolina.

In Section O, page 90, the applicant states:

“Each of the facilities identified...has continually maintained all relevant licensure, certification, and accreditation for the 18 months preceding the submission of this application.”

After reviewing and considering information provided by the applicant regarding the quality of care provided at all 16 diagnostic centers, 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 develop a new diagnostic center. There are no administrative rules that are applicable to proposals to develop new diagnostic centers.