

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: January 29, 2018

Findings Date: January 29, 2018

Project Analyst: Jane Rhoe-Jones

Team Leader: Fatimah Wilson

Project ID #: P-11423-17

Facility: UNC Orthopedics at Goldsboro

FID #: 170471

County: Wayne

Applicant: UNC Physicians Network, LLC

Project: Develop a new diagnostic center

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

UNC Physicians Network, LLC (UNCPN - “the applicant”) proposes to develop a new diagnostic center in Wayne County at an existing physician orthopedic practice located at 2820 McLamb Place in Goldsboro. The combined value of the existing medical diagnostic equipment exceeds the statutory threshold for a diagnostic center of \$500,000; therefore, the equipment qualifies as a new institutional health service facility and requires a certificate of need (CON).

Need Determination and Policies

There are no need determinations or policies in the 2017 State Medical Facilities Plan (SMFP) applicable to the acquisition of existing equipment or to the establishment of a diagnostic center. Therefore, this criterion is not applicable to this review.

Conclusion

The applicant does not propose to:

- develop any services for which there is a need determination in the 2017 State Medical Facilities Plan (SMFP)
- acquire any medical equipment for which there is a need determination in the 2017 State Medical Facilities Plan (SMFP)
- offer a new institutional health service for which there are any policies in the 2017 State Medical Facilities Plan (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- (2) Repealed effective July 1, 1987.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 Wayne County as defined in N.C. Gen. Stat. §131E-176(7a) resulting from the acquisition of an existing physician's orthopedic practice, UNC Orthopedics at Goldsboro (formerly known as Goldsboro Orthopaedic Associates, P.A.) that has existing diagnostic equipment exceeding the \$500,000 statutory threshold for a diagnostic center. The following is a summary of that transition:

- 1976 - Goldsboro Orthopaedics Associates began serving the Goldsboro area
- 2012 - the practice became affiliated with Wayne Health Physicians, a 501(c)(3) organization owned by Wayne Health Corporation, the parent of Wayne Memorial Hospital
- 2017 - UNCPN acquired Wayne Health Physicians, which includes Goldsboro Orthopaedics Associates; hereby known as UNC Orthopedics at Goldsboro.
- 2017 – The GE Discovery XR 656 X-ray unit was replaced in March 2017. The cost of this unit caused the total value of medical diagnostic imaging equipment to exceed the \$500,000 statutory threshold for a diagnostic center.
- 2017 - Prior to acquiring Goldsboro Orthopaedics Associates, UNCPN became aware that all the medical diagnostic equipment which cost more than \$10,000 at Goldsboro Orthopaedics Associates exceed \$500,000, thereby requiring a CON.
- 2017 UNCPN took the new X-ray equipment out of service that resulted in exceeding total equipment cost of \$500,000 and requiring a CON as a diagnostic center per N.C. Gen. Stat. §131E-176(7a).

The proposed diagnostic center, is located in an existing medical office building located at 2808 McLamb place where outpatient diagnostic imaging services are currently being

provided. UNCPN, LLC leases approximately 29,868 square feet of space in the office building from Goldsboro Orthopaedic Properties, LLP. See Exhibit K.5 for a copy of the lease agreement between Goldsboro Orthopaedic Properties, LLP and UNCPN, LLC.

Designation as a Diagnostic Center

The applicant provides the following table in Section C.1, page listing the purchase price of the existing diagnostic equipment.

UNC ORTHOPEDICS AT GOLDSBORO		
Service	Equipment	Original Purchase Price
X-ray	Digital X-ray Room	\$296,867
X-ray*	GE Discovery XR 656 X-ray Machine	\$262,779
Bone Density	Bone Density Machine	\$31,575
Sub-total Existing Medical Diagnostic Equipment		\$591,218
Existing Essential Non-Medical Equipment Assets **		\$47,240
Total		\$638,462

*March 2017, taken out of service until CON approved. **Includes renovations necessary to accommodate the equipment.

As illustrated above, the applicant states that the existing diagnostic equipment is valued at \$591,218. The applicant states on pages 31-32 that when UNCPN became aware of the total value of the equipment, the GE Discovery XR 656 X-ray machine was removed from service until a CON could be approved. The total combined value of the existing diagnostic equipment is \$591,218. Without the GE Discovery XR 656 X-ray machine (\$591,218 - \$262,779 for the GE Discovery XR 656 X-ray machine = \$328,439), the total equipment value is \$328,439. The combined value of the existing medical diagnostic equipment exceeds the statutory threshold of \$500,000; therefore, it meets the definition of a diagnostic center as defined in N.C. Gen. Stat. §131E-176(7a).

On page 32, the applicant states that the new x-ray machine will be brought back into service once the CON is approved; thereby creating the diagnostic center. The applicant also states that no construction, renovation or additional equipment is required to create the diagnostic center.

Patient Origin

§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 2017 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, page 33, the applicant defines its service area as Wayne, Lenoir, Johnston, Duplin, Greene, and Sampson counties. The applicant lists 19 other counties that comprise approximately 1.9% of its patient origin.

X-ray and Bone Density

In Section C.2(a), page 33, the applicant provides the historical X-ray patient origin and provides the historical bone density patient origin on page 34 for calendar year (CY) 2016-2017. In Section C.3(a), page 35 the applicant provides the projected X-ray patient origin and on page 36, provides the projected bone density patient origin for the first three years of the proposed project CY2019-CY2021.

The historical and projected patient origin is illustrated below:

UNC ORTHOPEDICS AT GOLDSBORO		
Historical and Projected		
Patient Origin		
X-RAY & BONE DENSITY		
COUNTY	HISTORICAL PATIENT ORIGIN FY2016-2017	PROJECTED PATIENT ORIGIN FY2019-FY2021
Wayne	78.9%	78.9%
Lenoir	9.9%	9.9%
Johnston	3.8%	3.8%
Duplin	2.6%	2.6%
Greene	1.6%	1.6%
Sampson	1.3%	1.3%
Other*	1.9%	1.9%
Total	100.0%	100.0%

*Other includes patient origin from Beaufort, Bladen, Camden, Carteret, Columbus, Craven, Cumberland, Durham, Edgecombe, Halifax, Harnett, Mecklenburg, Nash, New Hanover, Onslow, Pitt, Wake, & Wilson counties in North Carolina, and other states

The applicant states on page 33,

“In order to estimate patient origin, UNC Orthopedics at Goldsboro analyzed FY 2017 patient origin data for orthopedics patients at UNC Wayne Memorial Hospital is believed to be a reasonable proxy for UNC Orthopedics at Goldsboro’s patient origin as many of the same patients were treated at both sites of care by the same orthopedic physicians during the same time period.”

Based on the applicant’s historical patient origin for X-ray and bone density services as shown in the table above, the projected patient origin for the proposed diagnostic center seems reasonable.

The applicant adequately identified the population to be served.

Analysis of Need

The applicant proposes a new diagnostic center by utilizing existing equipment and placing back into service equipment that was taken out of service in March 2017 at UNC Orthopedics at Goldsboro. The applicant provides a table in Section C.1, page 32, that lists the three units of medical diagnostic equipment in this proposed new diagnostic center (see above in these findings).

In Section C.4(a), pages 37-39, the applicant describes the factors which it states support the need for the proposed project.

- The total cost of the medical diagnostic imaging equipment exceeds \$500,000.
- When UNCPN discovered the existing equipment plus the equipment acquired in March 2017 exceeded the \$500,000 threshold, the newest acquired X-ray unit was taken out of service.
- Thus, UNC Orthopedics at Goldsboro is operating with only one X-ray machine since March 2017.
- Annual capacity of one X-ray unit is 8,000 scans and two is 16,000 scans (16,000 scans = 2.0 units x 8 hours/day x 250 days/year x 4 procedures/hour). Based on that capacity, utilization has been approximately 93%. See table below.

UNC ORTHOPEDICS AT GOLDSBORO			
X-ray Utilization			
	FY15	FY16	FY17
X-ray Procedures	14,849	14,913	14,828
Total Annual Capacity	16,000	16,000	16,000
% Utilization	92.8%	93.2%	92.7%

- As shown below, if the applicant continues to operate only one X-ray unit, the facility would exceed capacity as utilization would be at 185%.

UNC ORTHOPEDICS AT GOLDSBORO			
X-ray Utilization (assuming one X-ray Unit)			
	FY15	FY16	FY17
X-ray Procedures	14,849	14,913	14,828
Total Annual Capacity	8,000	8,000	8,000
% Utilization	185.6%	186.4%	185.4%

- Without the proposed project, UNC Orthopedics at Goldsboro will not be able to bring the second X-ray unit back into operation.
- Without the proposed project, access and convenience for the patients of UNC Orthopedics at Goldsboro will be compromised due to increased wait times and not being able to get scans on the same day as appointments.
- Without the proposed project, there would be increased costs if patients are referred to a hospital for scans.
- Insufficient capacity of only one X-ray unit would likely impede diagnosis of injury and disease, as well as the subsequent treatment and recovery for patients of UNC Orthopedics at Goldsboro.

The applicant adequately demonstrates the need to develop a new diagnostic center at UNC Orthopedics at Goldsboro in Wayne County.

Projected Utilization

In Section C.3, pages 35-36 and Section Q (pro formas), the applicant provides the historical and projected utilization for the diagnostic equipment at UNC Orthopedics at Goldsboro, as illustrated below.

UNC ORTHOPEDICS at GOLDSBORO							
Historical and Projected Utilization for							
X-ray Units and Bone Density Equipment							
	Historical			Interim	Projected		
	FY2015	FY2016	FY2017	FY2018	Project Year 1 FY2019	Project Year 2 FY2020	Project Year 3 FY2021
X-RAY							
# of Units (including fluoroscopy)	2	2	2 - 1*	1	2	2	2
# of Procedures	14,849	14,913	14,828	10,380	14,828	14,828	14,828
BONE DENSITY							
# of Units	1	1	1	1	1	1	1
# of Procedures	831	803	846	846	846	846	846

*UNCPN proposes to bring the second X-ray unit back into operation at the start of the proposed project in May 2018.

The applicant provides its assumptions and methodology for projecting utilization for its X-ray and bone density equipment in Section Q, Form C, pages 1-2. The applicant states that projected utilization is based on the applicant’s historical experience in providing the service. The applicant states that it is being conservative as its utilization is based on a 0.8 percent annual population growth/compound annual growth rate (CAGR) for Wayne County (see pages 1-2 of Section Q, Form C). Therefore, the applicant is projecting consistent utilization at 0% CAGR for the first three project years.

The Criteria and Standards for Diagnostic Centers were repealed. Therefore, there are no performance standards applicable and required for review of any of the existing equipment (in operation or taken out of service awaiting the review of and decision regarding this application).

Projected utilization is based on reasonable and adequately supported assumptions regarding continued growth. The applicant adequately demonstrates the need to develop a new diagnostic center by placing the second X-ray unit back into operation.

Access

In Section C.10, page 42-43, the applicant states that UNCPN follows the policies and procedures related to access and financial assistance of its parent entity, the University of North Carolina Health Care System (UNCHCS). The applicant states:

“... As North Carolina’s only state-owned comprehensive, full service hospital provider, UNCHCS has the obligation to accept any North Carolina citizen requiring medically necessary treatment. No North Carolina citizen is presently denied access by UNCHCS

to non-elective care because of race, sex, creed, age, handicap, financial status, or lack of medical insurance. ...”

In Section L.3(a), page 74, the applicant provides the projected payor mix for the second full fiscal year (2019-2020) of the proposed project by service component, as illustrated below.

UNC Orthopedics at Goldsboro Service Components FY 2019-2020			
Payor Source	Total Facility	X-ray	Bone Density
Medicare	36.5%	35.8%	49.8%
Medicaid	8.3%	9.5%	1.5%
Commercial/Managed Care	40.4%	41.1%	45.6%
Other	13.0%	10.8%	2.7%
Self-Pay	1.7%	2.8%	0.4%
Total	100.0%	100.0%	100.0%

*Includes worker's compensation and other payors.

The applicant states that the proposed project will not change the existing payor mix based on its historical FY2017 payor mix for the entire facility or the two service modalities. Further, the applicant states it will hold that assumption until there is greater clarity regarding health care reform.

Conclusion

The information in the application, including any exhibits, is reasonable and adequately supported for the following reasons:

- The applicant uses historical data that is clearly cited and is reasonable to use to make the assumptions used by the applicant with regard to identifying the population to be served and with regard to demonstrating the need the population projected to be served has for the proposed services.
- The applicant uses assumptions which are reasonable to demonstrate the need the population projected to be served has for the proposed services.
- The applicant uses historical data to project future access to the services it provides for all residents, including underserved groups.

This determination is based on a review of the:

- Information in the application, including any exhibits.
- Information which was publicly available during the review and used by the Agency.

Therefore, the applicant adequately demonstrates that the application is conforming to this criterion.

- (3a) In the case of a reduction or elimination of a service, including the relocation of a facility or a service, the applicant shall demonstrate that the needs of the population presently served will be met adequately by the proposed relocation or by alternative arrangements, and the effect of

the reduction, elimination or relocation of the service on the ability of low income persons, racial and ethnic minorities, women, handicapped persons, and other underserved groups and the elderly to obtain needed health care.

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

In Section E.3, page 49, the applicant states there is no alternative but to pursue the diagnostic center:

“... UNC Orthopedics at Goldsboro needs to obtain a certificate of need to be designated a diagnostic center in order to operate all of its medical diagnostic imaging equipment, which includes one bone density machine and two X-ray machines. Until that time the practice is only able to operate one of its X-ray machines. ... UNC Orthopedics at Goldsboro has a need for both of its existing X-ray units based on its historical and projected utilization. ... Without a second X-ray unit, UNC Orthopedics at Goldsboro may need to refer patients elsewhere or increase wait times, which results in unnecessary costs and delays in care. Thus there is no method of meeting the need for the project.”

The applicant concludes that development of the project as proposed in this application is its most cost-effective alternative to meet the need of residents in Wayne County.

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

The information in the application, including any exhibits, is reasonable and adequately supported for the following reasons:

- The applicant uses reasonable and adequately supported assumptions to project utilization.
- The data cited is reasonable to use to support the assumptions of the applicant with regard to the least costly or most effective alternative for development of the proposed project.

This determination is based on a review of the:

- Information in the application, including any exhibits.
- Information which was publicly available during the review and used by the Agency.

Therefore, the application is conforming to this criterion and approved subject to the following conditions.

1. **UNC Physicians Network, LLC shall materially comply with all representations made in the certificate of need application.**
 2. **UNC Physicians Network, LLC, as part of this project, shall not acquire any equipment that is not included in the project's proposed capital expenditures in Section F of the application or that would otherwise require a certificate of need.**
 3. **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, UNC Physicians Network, LLC 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.**
 4. **UNC Physicians Network, LLC 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 with two X-ray units and one bone density unit.

Capital and Working Capital Costs

In Form F.1a in Section Q, the applicant projects the total capital cost of the proposed project to be \$5,000, which is designated as a contingency. The medical diagnostic equipment and the medical office space already exist.

In Section F.3(a) and (b), pages 52-53, the applicant projects no start-up expenses and no initial operating expenses because UNC Orthopedics at Goldsboro is an existing facility. The applicant provides a copy of its lease agreement with Goldsboro Orthopaedic Properties, LLP in Exhibit K-5.

Availability of Funds

In Section F.2, page 51, the applicant states that the capital cost of the project will be funded with accumulated reserves or owner’s equity. Exhibit F.2-1 contains a letter dated October 16, 2017 from the Chief Financial Officer of UNC Physicians Network, LLC committing \$5,000 in cash reserves for capital cost of the proposed project. Exhibit F.2-2 contains the June 2016 financial statements for UNC Physicians Network verifying that UNCPN has significant funds to cover the capital costs of the proposed project.

Financial Feasibility

The applicant provides pro forma financial statements for the first three full fiscal years of operation following completion of the project. In the pro forma financial statement (Form F.3), the applicant projects that **for imaging only** [Agency Emphasis], operating expenses will exceed revenues in the first three operating years of the project, as shown below in the table.

UNC Orthopedics at Goldsboro Imaging Only			
	1st Full Fiscal Year	2nd Full Fiscal Year	3rd Full Fiscal Year
Total Scans (X-ray and Bone Density)	15,674	15,674	15,674
Total Gross Revenues (Charges)	\$1,215,407	\$1,251,870	\$1,289,426
Total Net Revenue	\$5,972,968	\$6,152,157	\$6,336,721
Average Net Revenue per Scan	\$381	\$393	\$404
Total Operating Expenses (Costs)	\$8,120,596	\$8,364,209	\$8,615,130
Average Operating Expense per Scan	\$518	\$534	\$550
Net Income / (Loss)	(\$2,147,628)	(\$2,212,052)	(\$2,278,409)

However, in Section Q, Form F.3 for UNC Wayne Health Care (the hospital), revenues exceed expenses in all three project years; shown in the following table.

UNC Wayne Health Care			
	1st Full Fiscal Year	2nd Full Fiscal Year	3rd Full Fiscal Year
Total Scans (X-ray and Bone Density)	NA	NA	NA
Total Gross Revenues (Charges)	\$620,342,195	\$640,739,373	\$664,494,661
Total Net Revenue	\$262,888,612	\$271,854,260	\$281,611,594
Average Net Revenue per Scan	NA	NA	NA
Total Operating Expenses (Costs)	\$248,842,182	\$256,363,363	\$264,973,170
Average Operating Expense per Scan	NA	NA	NA
Net Income	\$14,046,430	\$15,490,897	\$16,638,424

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

Conclusion

The information in the application, including any exhibits, is reasonable and adequately supported for the following reasons:

- The applicant uses reasonable and adequately supported assumptions to project utilization.
- Historical data is used to provide future projections of costs and charges and demonstrate financial feasibility of the project.

This determination is based on a review of the:

- Information in the application, including any exhibits.
- Information which was publicly available during the review and used by the Agency.

Therefore, the applicant adequately demonstrates that the application is conforming to this criterion.

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

C

The applicant proposes a new diagnostic center with two x-ray units and one bone density unit.

§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 2017 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, page 33, the applicant defines its service area as Wayne, Lenoir, Johnston, Duplin, Greene, and Sampson counties. The applicant lists 19 other counties that comprise approximately 1.9% of its patient origin.

In Section G, page 58, the applicant provides a list of existing X-ray and bone density providers in Wayne County, as listed below. There are no existing diagnostic centers in its Wayne County.

Wayne County X-ray and Bone Density Providers
X-ray Providers
Cherry Hospital
Family Medicine & Rehab Center, PA
Fastmed of Goldsboro
Goldsboro Skin Center, PA
Goshen Medical Center - Goldsboro
Goshen Medical Center - Fremont
Goshen Medical Center - Rosewood
Immediate Care of Goldsboro
Medical Care, Inc.
Medstat Centre
Mount Olive Medicine Center
Wayne Heart & Internal Medicine Associates, PA
UNC Wayne Memorial Hospital
Wayne Radiologists, PA
Bone Density Providers
Celestine Amaefule, MD, PC
Mount Olive Family Medicine Center
Wayne Family Medicine Center
Wayne Heart & Internal Medicine Associates, PA

Source: NC Division of Health Service Regulation:Radiation Protection Section.

In Section G.3(a), page 59, the applicant states that the development of a new diagnostic center will not result in the unnecessary duplication of services because UNC Orthopedics at Goldsboro will be bringing back into service an existing X-ray machine in order to provide necessary capacity for its patients. The applicant states,

“The second X-ray machine is existing medical equipment that has historically been well utilized ... Moreover, as demonstrated in the assumptions and methodology for Form C, the X-ray machine will be well utilized in the future. The availability of X-ray services at other physician practices or in hospital-based settings cannot meet the need for UNC Orthopedics at Goldsboro’s patients to receive timely care in coordination with their office visit.”

The information in the application, including any exhibits, is reasonable and adequately supported for the following reasons:

- The applicant uses assumptions which are reasonable to demonstrate the need for the proposed services.
- The applicant provides adequate documentation that the proposed services will not result in the unnecessary duplication of existing or approved health service capabilities or facilities.

This determination is based on a review of the:

- Information in the application, including any exhibits.
- Information which was publicly available during the review and used by the Agency.

Therefore, the applicant adequately demonstrates that the application is conforming to this criterion.

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

C

In Section H.2 and H.3, page 60, the applicant states that it uses a variety of social media and job boards to recruit its radiologic technology (Tech) staff. The applicant states that its radiologic tech staff receive formal training from appropriate diploma/certification programs and are required to receive continuing education.

In Section Q, Form H, the applicant provides a table which illustrates the current and projected staff for UNC Orthopedics at Goldsboro. The applicant currently employs 3.0 X-ray tech (2.0 registered and 1.0 unregistered) and does not project to add any additional staff in OY1 or OY2. In Section H.4(a), page 61, the applicant states that the UNC Orthopedics at Goldsboro medical practice is comprised of six orthopedists (one additional physician is being recruited) and that approximately 12 primary care physicians refer patients to the practice. The applicant further states on page 61 that Lynn Fiscus, MD will continue to serve as the Executive Medical Director of UNCPN's practice locations, including UNC Orthopedics at Goldsboro. Exhibit H.4 contains a letter from Dr. Fiscus documenting her support for the proposed project and her willingness to continue to serve as Medical Director.

The information in the application, including any exhibits, is reasonable and adequately supported for the following reasons:

- The applicant provides appropriate documentation of the availability of adequate health manpower and management personnel for the provision of the proposed dialysis services.
- The applicant provides appropriate and credible documentation of support from the current and continuing Medical Director of UNCPN.
- The applicant provides appropriate and credible documentation of the availability of other resources, including methods of recruitment and documentation of staff training, necessary for the provision of the proposed dialysis services.

This determination is based on a review of the:

- Information in the application, including any exhibits.
- Information which was publicly available during the review and used by the Agency.

Therefore, the applicant adequately demonstrates that the application is conforming to this criterion.

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

C

In Section I, pages 63-64, the applicant states that although UNC Orthopedics at Goldsboro is not a proposed new health service facility as defined in N.C. Gen. Stat. §131E-176(9b), the facility already offers medical diagnostic services in Wayne County. Further, the applicant states that all necessary ancillary and support services already exist and are provided by UNCPN and provides a letter from the Chief Financial and Operating Officer in Exhibit I.1 which documents those services. These services are listed as (but not limited to) diagnostic imaging interpretation, management, billing and collections, quality improvement, radiation safety services, annual physicist reviews and radiology equipment servicing.

The information in the application, including any exhibits, is reasonable and adequately supported for the following reasons:

- The applicant provides appropriate and credible documentation of the availability of necessary ancillary and support services for the provision of the proposed services.
- The applicant provides credible documentation of ongoing coordination with the existing health care system.

This determination is based on a review of the:

- Information in the application, including any exhibits.
- Information which was publicly available during the review and used by the Agency.

Therefore, the applicant adequately demonstrates 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 VI 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

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.

NA

The applicant proposes to develop a new diagnostic center in Wayne County by placing back in service an existing X-ray unit that is part of other existing X-ray equipment and a bone density machine that is located in UNC Orthopedics at Goldsboro. The new diagnostic center, is located in an existing orthopedic medical office building at 2820 McLamb Place in Goldsboro. UNCPN is leasing approximately 29,868 square feet of space that houses the existing medical office practice. The applicant does not propose to construct any new space or renovate any existing space. Therefore, Criterion (12) is not applicable to this review.

- (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

The proposed UNC Orthopedics at Goldsboro diagnostic center is not an existing health service facility as defined in N.C. Gen. Stat. §131E-176(9b), however, the facility already offers medical diagnostic services in Wayne County. In Section 13.1(a), pages 72-73, the applicant states that the data base of UNC Orthopedics at Goldsboro is not structured to collect data specific to medically underserved populations. Therefore, the applicant has chosen to report data collected from the UNC Wayne Health Care (related entity) because the patient demographics for both facilities are reasonably similar. On page 73, the applicant provides a table which illustrates the percentage of the medically underserved population served, including women, those age 65 and older and racial minorities served at the UNC Orthopedics at Goldsboro, UNC Wayne Health Care and throughout Wayne County, as illustrated below.

	% Served by UNC Orthopedics at Goldsboro FY2017*	% Served in Wayne County
Women	62.2%	50.9%
65+	37.2%	15.6%
Racial Minorities	27.8%	43.0%

*The applicant reports on page 72, that UNC Orthopedics at Goldsboro does not track racial and ethnic minority data on its patients; however UNC Wayne Memorial Hospital does.

Also on page 73, the applicant provides the payor mix for UNC Orthopedics at Goldsboro by modality for FY2017, as illustrated in the table below.

UNC ORTHOPEDICS at GOLDSBORO			
Payor Source	Entire Facility	X-ray	Bone Density
Medicare	36.5%	35.8%	49.8%
Medicaid	8.3%	9.5%	1.5%
Commercial/Managed Care	40.4%	41.1%	45.6%
Other*	13.0%	10.8%	2.7%
Self-Pay	1.7%	2.8%	0.4%
Total	100.0%	100.0%	100.0%

*Includes worker's comp and other payors.

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

Percent of Population						
County	% 65+	% Female	% Racial & Ethnic Minority*	% Persons in Poverty**	% < Age 65 with a Disability	% < Age 65 without Health Insurance**
	2016 Estimate	2016 Estimate	2016 Estimate	2015 Estimate	2011-2015	2015 Estimate
Wayne	15%	51%	46%	18%	12%	14%
Statewide	16%	51%	37%	16%	10%	13%

Source: <http://www.census.gov/quickfacts/table> Latest Data 7/1/16 as of 8/22/17

*Excludes "White alone" who are "not Hispanic or Latino"

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

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

The information in the application, including any exhibits, is reasonable and adequately supported for the following reasons:

- The applicant's historical payor mix is adequate documentation that it currently provides services to medically underserved populations.
- The applicant's historical payor mix is adequate documentation of the extent to which medically underserved populations utilize the applicant's existing services.

This determination is based on a review of the:

- Information in the application, including any exhibits.
- Information which was publicly available during the review and used by the Agency.

Therefore, the applicant adequately demonstrates that 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(a), page 73, the applicant states that it is not obligated under any applicable federal regulations to provide uncompensated care, community service, or access by minorities and handicapped persons. In Section L.4(a), page 75, the applicant states, "... No North Carolina citizen is presently denied access by UNCHCS to non-elective care because of race, sex, creed, age, handicap, financial status, or lack

of medical insurance. ...” The applicant provides a copy of its financial assistance policy in Exhibit C.10.

In Section L.2(c), page 74, the applicant states no civil rights equal access complaints have been filed against it or any related entities in the last five years.

The information in the application, including any exhibits, is reasonable and adequately supported for the following reasons:

- The applicant provides credible information about its lack of obligation to provide any uncompensated care or community service under any federal regulations.
- The applicant states it has not had any civil rights access complaints filed against it within the last five years.

This determination is based on a review of the:

- Information in the application, including any exhibits.
- Information which was publicly available during the review and used by the Agency.

Therefore, the applicant adequately demonstrates 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 74, the applicant projects its payor mix for the second operating year following project completion (FY2020) for the proposed UNC Orthopedics at Goldsboro, as shown below.

UNC ORTHOPEDICS at GOLDSBORO Projected Payor Mix OY2 (7/2019-6/2020)			
Payor Source	Entire Facility	X-ray	Bone Density
Medicare	36.5%	35.8%	49.8%
Medicaid	8.3%	9.5%	1.5%
Commercial/Managed Care	40.4%	41.1%	45.6%
Other*	13.0%	10.8%	2.7%
Self-Pay	1.7%	2.8%	0.4%
Total	100.0%	100.0%	100.0%

*Includes worker's compensation and other payors.

The applicant also states on page 74, that it does not project a change in its payor mix from its historical payor mix at UNC Orthopedics at Goldsboro given that healthcare reform is in a state of flux. The applicant demonstrates that medically underserved populations will continue to have adequate access to the services offered at UNC Orthopedics at Goldsboro. Concerning charity care, the applicant states on page 75, that UNCPN follows the financial assistance determinations made by UNCHCS. Exhibit C.10 contains UNCHCS' Financial Assistance Policy.

The information in the application, including any exhibits, is reasonable and adequately supported because the applicant's projected payor mix adequately demonstrates that medically underserved populations will have adequate access to the proposed services.

This determination is based on a review of the:

- Information in the application, including any exhibits.
- Information which was publicly available during the review and used by the Agency.

Therefore, the applicant adequately demonstrates 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 75, the applicant states that patients are referred for services by orthopedic and primary care physicians. The applicant adequately demonstrates that the facility will offer a range of means by which patients will have access to the proposed services. See Exhibit I.2 for physicians' letters of support.

The information in the application, including any exhibits, is reasonable and adequately supported because the applicant adequately demonstrates that the facility will provide a range of means by which a person can access the services.

This determination is based on a review of the:

- Information in the application, including any exhibits.
- Information which was publicly available during the review and used by the Agency.

Therefore, the applicant adequately demonstrates 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, page, page 76, the applicant states as existing providers of healthcare services, UNC Orthopedics at Goldsboro and UNCPN have established agreements with clinical training programs. UNC Orthopedics at Goldsboro (formerly Goldsboro Orthopaedic Associates) has several agreements including Campbell University School of Osteopathic Medicine, nursing and allied health programs at East Carolina University and University of North Carolina at Wilmington. UNCPN has continued those agreements and UNC Orthopedics at Goldsboro will continue to serve as a training site.

The information in the application, including any exhibits, is reasonable and adequately supported because the applicant adequately documents that the proposed health services will accommodate the clinical needs of health professional training programs in the area.

This determination is based on a review of the:

- Information in the application, including any exhibits.
- Information which was publicly available during the review and used by the Agency.

Therefore, the applicant adequately demonstrates that 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 a new diagnostic center with two X-ray units and one bone density unit.

§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 2017 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, page 33, the applicant defines its service area as Wayne, Lenoir, Johnston, Duplin, Greene, and Sampson counties. The applicant lists 19 other counties that comprise approximately 1.9% of its patient origin.

In Section N, page 77, the applicant discusses how any enhanced competition in the service area will promote cost-effectiveness, quality and access to the proposed services. The applicant states that its patients could be referred to the hospital within one-half mile of its office; however, hospital based diagnostic imaging usually means higher costs for patients. On page 78, the applicant states that it provides timely X-rays for its patients thereby reducing delays in diagnosis, treatment and recovery. Also on page 78, the applicant states that it follows the policies of UNCHCS related to patient access and financial assistance; which includes that no North Carolina citizen is denied access to non-elective health care because of a status as medically underserved.

See also Sections C, E, F, G, H, I, L, and O, where the applicant discusses the impact of the project on cost-effectiveness, quality, and access. The applicant discusses how any enhanced competition in the service area, including how the proposed project will have a positive impact on cost-effectiveness, quality, and access to the proposed services in Section N, pages 77-78. The information in the application is reasonable and adequately supported for the following reasons:

- The applicant adequately demonstrates the need for the proposed project and that it is an effective alternative.
- The applicant adequately demonstrates that UNC Orthopedics at Goldsboro/UNCPN will continue to provide quality diagnostic services.
- The applicant demonstrates that UNC Orthopedics at Goldsboro/UNCPN will continue to provide adequate access to medically underserved populations.

This determination is based on a review of the:

- Information in the application, including any exhibits.
- Information which was publicly available during the review and used by the Agency.

Therefore, the applicant adequately demonstrates that the application is conforming to this criterion.

- (19) Repealed effective July 1, 1987.
- (20) An applicant already involved in the provision of health services shall provide evidence that quality care has been provided in the past.

C

In Section O, pages 80-82, the applicant, UNCPN discusses quality and states that it does not currently own, operate or manage any other diagnostic centers. As diagnostic centers are not licensed facilities, there are no Division of Health Service Regulations requirements. The applicant states on page 81-82, that UNCPN will continue to provide quality care as part of the UNC Health Care System which is nationally recognized and certified for patient safety and quality of care. After reviewing and considering information provided by the applicant, 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 Criteria and Standards for Diagnostic Centers were repealed. Therefore, there are no performance standards required.