

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: September 27, 2018

Findings Date: September 27, 2018

Project Analyst: Gregory F. Yakaboski

Team Leader: Gloria C. Hale

Project ID #: A-11503-18

Facility: Graham County Urgent Care Center and Family Medicine

FID #: 180208

County: Graham

Applicant: Graham County Government

Project: Develop a new freestanding 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

Graham County Government, the applicant, proposes to develop a new diagnostic center, Graham County Urgent Care Center and Family Medicine d/b/a Smoky Mountain Urgent Care Center and Family Medicine (GCUCFM), in Graham County at an existing urgent care center at 21 South Main Street in Robbinsville. The applicant is proposing to acquire a: CT Scanner, 3D mammography unit, x-ray unit and ultrasound unit, which, combined with the value of the existing medical diagnostic equipment will exceed the statutory threshold for a diagnostic center of \$500,000; therefore, the proposal is a new institutional health service and requires a certificate of need (CON).

The applicant does not propose to:

- develop any beds or services for which there is a need determination in the 2018 State Medical Facilities Plan (SMFP)
- acquire any medical equipment for which there is a need determination in the 2018 SMFP
- offer a new institutional health service for which there are any policies in the 2018 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- (2) Repealed effective July 1, 1987.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

Graham County Government proposes to develop a new diagnostic center in Graham County at an existing urgent care center at 21 South Main Street in Robbinsville.

Patient Origin

On page 421 of the 2018 SMFP the North Carolina Certificate of Need Statute §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 2018 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. Facilities may also serve residents of counties not included in their service area.

The proposed service area is depicted in Figure C.4 on page 44 of the application and further defined in Table C.9 on page 45. In Section C, pages 43-44, the applicant defines its service area as a “*30-mile drive distance from the proposed diagnostic center address*”. The proposed service area consists of all of Graham County even though parts of Graham County are outside the 30-mile drive parameters because much of that portion of the county is owned by the federal government and is not available for residential or commercial development. In addition, portions of Cherokee, Clay, Macon and Swain Counties, defined by some or all of certain census tracts, are also part of the proposed service area.

The following table illustrates projected patient origin.

County	First Full FY of Operation following Project Completion (1/1/19 to 12/31/19)		Second Full FY of Operation following Project Completion (1/1/20 to 2/20/20)	
	Patients	% of Total	Patients	% of Total
Graham	2,899	45%	2,978	44%
Cherokee	1,683	26%	1,736	26%
Clay	537	8%	558	8%
Macon	429	7%	445	7%
Swain	261	4%	271	4%
Other*	683	11%	704	11%
Total	6,492	100%	6,693	100%

Source: Table C.7, page 34 of the application.

*Other includes tourists/visitors from other non-North Carolina counties, states, and countries.

In Section C, pages 35-36 and pages 43-46, 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 37-55, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. On page 42, the applicant states:

“The lack of vital diagnostic capacity in Graham County has ripple effects that extend beyond individual patients. With limited diagnostic capacity in the county emergency services are continuously under stress. EMS staff and vehicles are often called upon to transport individuals from Graham County to neighboring county facilities for non-life-threatening events. ... This creates a difficult situation when the only emergency responders in town are transporting people on 60-mile round trips. It often leaves the entire county without emergency transportation until at least one of those round trips is completed. Neighboring counties do fill in, but the mountain climate and circuitous roads can make travel difficult, even in milder weather months. Depending on out-of-county EMS can mean increased wait time or a decision to call for air evacuation when a true life-threatening emergency occurs.

Having the diagnostic center in an urgent care center that is open weekday evenings and on weekend days will reduce out-of-county transports for non-life threatening events, and provide more care options for life-threatening emergencies.”

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

- The proposed project is based on information from the 2015 Graham County Community Health Assessment and a 2016 market feasibility study for an urgent care center as well as first-hand accounts of hardships received by the Graham County Board of Commissioners for the last decade.
- Graham County, based on 2018 County Health Rankings, is in the lowest health status quartile in the state.

- The total cost of the medical diagnostic imaging equipment proposed to be acquired exceeds \$500,000 which requires diagnostic center status.

Projected Utilization

In Section Q, the applicant provides projected utilization as illustrated in the following table(s).

CT Scanner

	OY1 (CY2019)	OY2 (CY2020)	OY3 (CY2021)
# of Units	1	1	1
# of Scans	3,286	3,378	3,512
# of HECT Units	4,902	5,039	5,239

Source: Form D, Section Q, page 131.

Fixed X-Ray

	OY1 (CY2019)	OY2 (CY2020)	OY3 (CY2021)
# of Units	1	1	1
# of Procedures	1,692	1,765	1,872

Source: Form D, Section Q, page 132

Mammography

	OY1 (CY2019)	OY2 (CY2020)	OY3 (CY2021)
# of Units	1	1	1
# of Procedures	937	956	987

Source: Form D, Section Q, page 132

Ultrasound

	OY1 (CY2019)	OY2 (CY2020)	OY3 (CY2021)
# of Units	1	1	1
# of Procedures	726	746	776

Source: Form D, Section Q, page 132

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

- 1st: The applicant identified the population to be served by the CT scanner, ultrasound and x-ray.

	2018	2019	2020	2021
Service Area Population	20,338	20,400	20,463	20,526
Tourist Population*	2,769	2,775	2,780	2,783
Total	23,107	23,175	23,243	23,309

Note: The proposed service area contains no freestanding diagnostic imaging centers or hospitals in the proposed service area.

*Tourists are added in as resident equivalent using the formula: $(0.25 + 0.25 * 0.25) \times$ Graham population. Tourist estimates from Graham County Tourism Office 2016

Source: Table in Section Q on page 135 of the application.

2nd: *Projected CT Scanner Utilization by:*

- *Identifying the 2016 CT scanner use rate for the region:* (See page 135 of the application.)

*17.73 scans per 100 population. (See page 135 of the application.)

- *Projected the CT scanner need for the population to be served.* (See page 135 of the application.)

2019: $23,175/100 = 231.75 \times 17.73 = 4,108$

2020: $23,243/100 = 232.43 \times 17.73 = 4,120$

2021: $23,309/100 = 233.09 \times 17.73 = 4,132$

- *Projected GCUCFM Market Share of the CT scanner need.* (See page 135 of the application.)

The applicant projects market share of

2019: 80.0%

2020: 82.0%

2021: 85.0%

- *Project GCUCFM CT Scanner utilization.* (See page 135 of the application.)

2019: $4,108 \times .80 = 3,286$

2020: $4,120 \times .82 = 3,378$

2021: $4,132 \times .85 = 3,512$

- *Identify the CT scans by HECT for OY1 to OY3.*

2019: HECTS- 4,902

2020: HECTS- 5,040

2021: HECTS- 5,239

Assumptions and methodology are set forth on page 135 of the application.

3rd: *Projected X-Ray utilization by:*

- *Identifying the 2016 X-ray use rate for the region:* 14.61 scans per 100 population.

- *Projected the X-ray need for the population to be served.* (See page 136 of the application.)

2019: $23,175/100 = 231.75 \times 14.61 = 3,385$

2020: $23,243/100 = 232.43 \times 14.61 = 3,395$

2021: $23,309/100 = 233.09 \times 14.61 = 3,405$

- *Projected GCUCFM Market Share of the X-ray need.* (See page 136 of the application.)

2019: 50.0%

2020: 52.0%

2021: 55.0%

- *Project GCUCFM X-ray utilization.* (See page 136 of the application.)

2019: 3,385 x .50 = 1,692
 2020: 3,395 x .52 = 1,765
 2021: 3,405 x .55 = 1,872

4th: *Projected Ultrasound Utilization*

- *Identifying the 2016 ultrasound use rate for the region:* 3.91 ultrasounds per 100 population. (See page 136 of the application.)
- *Projected the ultrasound need for the population to be served.* (See page 136 of the application.)

2019: 23,175/100= 231.75 x 3.91 = 906
 2020: 23,243/100= 232.43 x 3.91 = 909
 2021: 23,309/100= 233.09 x 3.91 = 911

- *Projected GCUCFM Market Share of the ultrasound need.* (See page 136 of the application.)

2019: 80.0%
 2020: 82.0%
 2021: 85.0%

- *Project GCUCFM ultrasound utilization.* (See page 136 of the application.)

2019: 906 x .80 = 725
 2020: 909 x .82 = 745
 2021: 911 x .85 = 774

5th: *Projected Mammogram Utilization*

- *Identify the population to be served by mammogram.* (See page 137 of the application.)

Graham County: Projected Number of Females over age 45

County	2018	2019	2020	2021
Graham	2,351	2,343	2,331	2,322

Note: Out of the projected service area only Graham County is used. Population data from NC OSBM as of 3/28/18.

Source: Table in Section Q on page 137 of the application.

- *Identify the percent of woman [sic] who received mammogram.* (See page 137 of the application.)

50% of the total female population over age 45.

- *Projected 3D mammogram need in the population to be served.* (See page 137 of the application.)

2019: $2,343 \times .50 = 1,172$
 2020: $2,331 \times .50 = 1,166$
 2021: $2,322 \times .50 = 1,161$

- *Projected GCUCFM Market Share of Mammogram need.* (See page 137 of the application.)

2019: 80.0%
 2020: 82.0%
 2021: 85.0%

- *Project GCUCFM mammogram utilization.* (See page 137 of the application.)

2019: $1,172 \times .80 = 937$
 2020: $1,166 \times .82 = 956$
 2021: $1,161 \times .85 = 987$

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

- The Criteria and Standards for Diagnostic Centers were repealed. Therefore, there are no performance standards applicable and required for review of the x-ray, ultrasound and mammography equipment. Projected utilization for the proposed x-ray, ultrasound and mammography equipment are based on reasonable and adequately supported assumptions regarding projected utilization.
- The projected utilization of the CT scanner in OY3 (CY2021) is 5,239 HECT units which exceeds the minimum of 5,100 HECT units annually in the third year of operations as required by 10A NCAC 14C .2303

Access

In Section C, page 61, the applicant states “*Low income persons, racial and ethnic minorities, women, handicapped persons, elderly, and other underserved groups, will have access to the proposed services. GCUCFM will not deny medical care to any person on the basis of race, creed, religion, handicap, economic status, gender, age, or social status. Ability to pay will not be a limiting factor for persons with a true emergency.*” In supplemental information, the applicant projects the following payor mix during the second full fiscal year of operation following completion of the project, as illustrated in the following table.

Diagnostic Center, CY2020

Payor Category	Services as Percent of Total
Medicaid*	25.5%
Medicare*	35.7%
Charity Care	9.1%
Self-Pay	10.2%
Insurance*	17.6%
Other (Worker’s Comp; VA; Champus)	1.9%
Total	100.0%

*Including any managed care plans.

The projected payor mix is reasonable and adequately supported.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Supplemental information requested by the Agency
- 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, eliminate or relocate a facility or a 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

Graham County Government proposes to develop a new diagnostic center in Graham County at an existing urgent care center at 21 South Main Street in Robbinsville.

In Section E, pages 75-79, 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 Status Quo* – After hours calls to EMS and EMS having to transport patients out-of-county result in no EMS staff present in the County. Many of the out-of-county trips were for non-life threatening calls. Further, the county has no CT scanners or mammography equipment. Therefore, the applicant determined that maintaining the status quo was the less effective alternative.
- *Develop the Project in a Different Location than Robbinsville*- Alternative locations were considered, however, Graham County is a rural county and Robbinsville is the center of the county, is located at the crossroads of two major highways and is the location of dispatching center for EMS, the government center and the only location with a nursing home, post office, pharmacy and grocery store. The location also has existing water, sewer, parking and broadband. Therefore, the applicant determined that developing the project in a different location would be more costly and a less effective alternative.
- *Limit Equipment Purchases under \$500,000 to avoid designation as a diagnostic center*- The applicant, in an effort to reduce out of county transports and increase county resident access to mammography service, sought to add a CT scanner and a 3D mammography unit to its initial plans to develop an urgent care center which would include x-ray, ultrasound and lab services. The applicant considered purchasing refurbished equipment to reduce costs however the project is being funded by the Golden Leaf Foundation which requires that any grant-funded equipment be purchased new as new equipment lasts longer/has better warranties. Therefore, the applicant determined that limiting equipment purchases overall to under \$500,000 to avoid designation as a diagnostic center was not the least costly or most effective alternative.
- *Joint Venture*- The applicant contacted various existing neighboring hospitals however, for various reasons, no partnerships worked out. Therefore, the applicant determined that a joint venture was not the most effective alternative.

On page 80, the applicant states that its proposal is the most effective alternative because

“The proposed purchase costs are reasonable and the individual items are required to support urgent care and/or to support preventive care in Graham County. ... With the CT scanner and mammography unit located in practice that will bill as a physician office, patients will enjoy the benefit of a lower charge structure... CMS reimbursement will also require that the CT scanner and staff performance on it be accredited... This will assure that competency is maintained. Together, these elements represent a solution that is the least costly and most effective of the options considered.”

The applicant adequately demonstrates that the alternative proposed in this application is the most effective alternative to meet the need because the proposed project provides greater access to the propose services and is the most cost-efficient option.

Conclusion

The Agency reviewed the:

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

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

- (1) Graham County Government, shall materially comply with all representations made in the certificate of need application and any supplemental responses. In the event that representations conflict, Graham County Government shall materially comply with the last made representation.**
 - (2) Graham County Government shall develop a new diagnostic center.**
 - (3) Graham County Government shall not acquire as part of this project any equipment that is not included in the project's proposed capital expenditures in Section Q, Form F.1a of the application and that would otherwise require a certificate of need.**
 - (4) No later than three months after the last day of each of the first three full years of operation following initiation of the services authorized by this certificate of need, Graham County Government, 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) Graham County Government shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.**
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of

the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

Graham County Government proposes to develop a new diagnostic center in Graham County at an existing urgent care center at 21 South Main Street in Robbinsville.

Capital and Working Capital Costs

In supplemental information, the applicant projects the total capital cost of the project as shown in the table below.

Site Costs	\$0.00
Construction Costs	\$170,106
Medical Equipment	\$754,050
Consultant Fees	\$50,000
Total	\$974,156

In Section Q and in supplemental information, the applicant provides the assumptions used to project the capital cost.

In Section F, pages 85-86, the applicant projects that the proposed project requires no working capital.

Availability of Funds

In supplemental information, the applicant states that the capital cost will be funded as shown in the table below.

Sources of Capital Cost Financing

Type	Graham County	Total
Loans	\$	\$
Accumulated reserves or OE *	\$	\$
Bonds	\$	\$
Other (Golden Leaf Foundation)	\$974,156	\$ 974,156
Total Financing **	\$974,156	\$974,156

* OE = Owner's Equity

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.3, the applicant projects that revenues will exceed operating expenses in the first three operating years of the project, as shown in the table below.

	1st Full Fiscal Year	2nd Full Fiscal Year	3rd Full Fiscal Year
Total Gross Revenues (Charges)	\$2,705,398	\$2,831,925	\$2,993,468
Total Net Revenue	\$1,304,139	\$1,338,431	\$1,371,639
Total Operating Expenses (Costs)	\$1,096,982	\$1,271,206	\$1,298,323
Net Income	\$207,156	\$67,225	\$73,316

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 and supplemental information 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
- Supplemental information requested by the Agency
- 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 demonstrates that the capital costs are 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

Graham County Government proposes to develop a new diagnostic center in Graham County at an existing urgent care center at 21 South Main Street in Robbinsville.

On page 421 of the 2018 SMFP the North Carolina Certificate of Need Statute §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 2018 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. Facilities may also serve residents of counties not included in their service area.

The proposed service area is depicted in Figure C.4 on page 44 of the application and further defined in Table C.9 on page 45. In Section C, pages 43-44, the applicant defines its service area as a “30-mile drive distance from the proposed diagnostic center address”. The proposed service area consists of all of Graham County even though parts of Graham County are outside the 30-mile drive parameters because much of that portion of the county is owned by the federal government and is not available for residential or commercial development. In addition, portions of Cherokee, Clay, Macon and Swain Counties, defined by some or all of certain census tracts, are also part of the proposed service area.

In Section G, page 93, the applicant states that there is no accredited CT, mammography or ultrasound equipment in the proposed service area. On page 92, the applicant states that “Based upon Graham County’s own knowledge and research, no other diagnostic centers are located in the proposed service area.”

In Section G, page 93, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved CT, mammography, ultrasound or x-ray services in the proposed service area. The applicant states:

“There are no CT or 3D mammography units in the service area. ... Ultrasound and x-ray are often available in physician offices and used on the same day as a necessary adjunct to office visits. This project will not unnecessarily duplicate those services. In fact, Graham County Health Department has no x-ray or ultrasound. Its patients will benefit from the existing diagnostic capabilities.”

The applicant adequately demonstrates that the proposal would not result in an unnecessary duplication of existing or approved services in the service area for the following reasons:

- The proposal would not result in an increase in diagnostic centers, CT scanners or 3D mammography units in the proposed service area.
- The applicant adequately demonstrates that the proposed x-ray, CT, mammography, and ultrasound equipment is needed.

Conclusion

The Agency reviewed the:

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

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

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

C

In Section Q, Form H., pages 158-166, the applicant provides current and projected staffing for the proposed services as illustrated in the following table.

Position	Current	Projected		
	4/1/2018	1 st Full Fiscal Year	2 nd Full Fiscal Year	3 rd Full Fiscal Year
Physicians	0.75	1.00	1.00	1.00
Physicians Assistants	0.50	1.00	1.00	1.00
Aides/Orderlies	1.20	1.60	1.60	1.60
Technologists	0.20	2.00	2.00	2.00
Clerical	1.20	1.60	1.60	1.60
Other (IT)	0.38	0.50	0.50	0.50
TOTAL	4.23	7.70	7.70	7.70

Source: Form H in Section Q of the application.

The assumptions and methodology used to project staffing are provided in Section Q. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form F.3, which is found in Section Q. In Section H, pages 96-97, the applicant describes the methods to be used to recruit or fill new positions and its proposed training and continuing education programs. In Section H, page 97, the applicant identifies the proposed medical director. In Exhibit H.4, the applicant provides a letter from the proposed medical director indicating an interest in serving as medical director for the proposed services. In Section H, page 98, the applicant describes its physician recruitment plans.

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
- Supplemental information requested by the Agency
- Information which was publicly available during the review and used by the Agency.

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

- (8) The applicant shall demonstrate that the provider of the proposed services will make available, or otherwise make arrangements for, the provision of the necessary ancillary and support

services. The applicant shall also demonstrate that the proposed service will be coordinated with the existing health care system.

C

In Section I, page 100, the applicant states that the following ancillary and support services are necessary for the proposed services:

- Radiology
- Laboratory
- Materials Management
- Administration
- Finance and Billing
- Medical Records
- Physics
- Housekeeping
- Pharmacy
- EMS

On pages 101-102, the applicant adequately explains how each ancillary and support service is or will be made available and provides supporting documentation in Exhibits A.9 and I.1.

In Section I, page 103, the applicant describes its efforts to develop 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
- Supplemental information requested by the Agency
- Information which was publicly available during the review and used by the Agency.

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

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

NA

The applicant does not project to provide the proposed services to a substantial number of persons residing in Health Service Areas (HSAs) that are not adjacent to 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 a 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 does not propose to make more than minor renovations to 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;

NA

Neither the applicant nor any related entities owns, operates or manages an existing facility located in the service area. 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;

NA

Neither the applicant nor any related entities owns, operates or manages an existing facility located in the service area. Therefore, Criterion (13b) is not applicable to this review.

- (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 supplemental information, the applicant projects the following payor mix for the proposed services during the second full fiscal year of operation following completion of the project, as shown in the table below.

Diagnostic Center, CY2020

Payor Category	Services as Percent of Total
Medicaid*	25.5%
Medicare*	35.7%
Charity Care	9.1%
Self-Pay	10.2%
Insurance*	17.6%
Other (Worker's Comp; VA; Champus)	1.9%
Total	100.0%

*Including any managed care plans.

As shown in the table above, during the second full fiscal year of operation, the applicant projects that 10.2% of total services will be provided to self-pay patients, 9.1% to charity care patients, 61.2% to Medicare and Medicaid patients.

On page 114, the applicant provides the assumptions and methodology used to project payor mix during the second full fiscal year of operation following completion of the project. The projected payor mix is reasonable and adequately supported for the following reasons:

- The projected payor sources are based on Medicaid eligibility in the county, SMUC experience in nearby practices, and the payor profile at Murphy Medical Center.
- The projected payor mix for mammography accounted for the fact that the patient base would be primarily females over the age of 45 and the fact that Medicaid eligible individuals over the age of 65 would have Medicare as the primary payor.

The Agency reviewed the:

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

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

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

C

In Section L.5, page 115, the applicant adequately describes the range of means by which patients will have access to the proposed services.

The Agency reviewed the:

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

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

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

C

In Section M, page 116, the applicant describes the extent to which health professional training programs in the area will have access to the facility for training purposes and provides supporting documentation in Exhibit M-2.

The Agency reviewed the:

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

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

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

C

Graham County Government proposes to develop a new diagnostic center in Graham County at an existing urgent care center at 21 South Main Street in Robbinsville.

On page 421 of the 2018 SMFP the North Carolina Certificate of Need Statute §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 2018 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. Facilities may also serve residents of counties not included in their service area.

The proposed service area is depicted in Figure C.4 on page 44 of the application and further defined in Table C.9 on page 45. In Section C, pages 43-44, the applicant defines its service area as a “30-mile drive distance from the proposed diagnostic center address”. The proposed service area consists of all of Graham County even though parts of Graham County are outside the 30-mile drive parameters because much of that portion of the county is owned by the federal government and is not available for residential or commercial development. In addition, portions of Cherokee, Clay, Macon and Swain Counties, defined by some or all of certain census tracts, are also part of the proposed service area.

In Section G, page 93, the applicant states that there is no accredited CT, mammography or ultrasound equipment in the proposed service area. On page 92, the applicant states that “Based upon Graham County’s own knowledge and research, no other diagnostic centers are located in the proposed service area.”

In Section N, pages 117-119, the applicant describes the expected effects of the proposed services on competition in the service area and discusses how any enhanced competition in the service area will promote the cost-effectiveness, quality and access to the proposed services. On pages 117-118, the applicant states:

“No other facility in the county or service area offers the same level of diagnostic imaging services and the closest facility to Robbinsville is at least a 40-minute drive in good weather. The location of the proposed facility creates ideal access for all residents and tourists in Graham County and to others who reside or tour just outside the county line. ...

The pricing, hours of operation, CMS certification for Medicare and Medicaid and the accreditation of CT and mammography will set quality and access standards of competition in the service area. ...

The proposed facility will increase the cost effectiveness of the diagnostic imaging services to be offered because the facility will have affordable rates and will be a non-hospital-based facility. Most of the CT scanners and mammography equipment in this region of the state are in a hospital-based facility. Hospital rates are historically more costly to access.”

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

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

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Supplemental information requested by the Agency
- Information publicly available during the review and used by the Agency.

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

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

C

In Section O, pages 120-121, the applicant states that Graham County does not own, operate or manage any diagnostic centers in North Carolina. SMUC, the proposed management entity of the proposed diagnostic center, operates three other diagnostic centers in North Carolina. Diagnostic centers are not licensed facilities, therefore there are no Division of Health Service Regulation requirements regarding diagnostic centers. On page 121, the applicant states that over the last eighteen months none of the three diagnostic centers currently operated by SMUC were out of compliance with CMS conditions of participation and that all three are in good standing with the North Carolina Medical Board. Therefore, the applicant provided sufficient evidence that quality care has been provided in the past. 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.

C

The Criteria and Standards for Diagnostic Centers were repealed. Therefore, there are no performance standards required for Diagnostic Centers.

The Criteria and Standards for Computed Tomography Equipment promulgated in 10A NCAC 14C .2300 are applicable to this review. The application is conforming to all applicable criteria. The specific criteria are discussed below.

**SECTION .2300 – CRITERIA AND STANDARDS FOR COMPUTED TOMOGRAPHY
EQUIPMENT**

10A NCAC 14C .2303 PERFORMANCE STANDARDS

An applicant proposing to acquire a CT scanner shall demonstrate each of the following:

- (1) each fixed or mobile CT scanner to be acquired shall be projected to perform 5,100 HECT units annually in the third year of operation of the proposed equipment;
- C- In Exhibit C-4 and in Section Q, Form D, page 131, the applicant projects the proposed CT scanner to perform 5,239 HECT units annually in the third year of operation (CY2021). This exceeds the minimum of 5,100 HECT units annually in the third year of operations as required by 10A NCAC 14C .2303. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.
- (2) each existing fixed or mobile CT scanner which the applicant or a related entity owns a controlling interest in and is located in the applicant's CT service area shall have performed at least 5,100 HECT units in the 12 month period prior to submittal of the application; and
- NA- Neither the applicant, nor any related entities, own a controlling interest in an existing CT scanner located within the applicant's proposed CT service area.
- (3) each existing and approved fixed or mobile CT scanner which the applicant or a related entity owns a controlling interest in and is located in the applicant's CT service area shall be projected to perform 5,100 HECT units annually in the third year of operation of the proposed equipment.
- NA- Neither the applicant, nor any related entities, own a controlling interest in an existing CT scanner located within the applicant's proposed CT service area.