

## ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: February 18, 2016

Findings Date: February 18, 2016

Project Analyst: Mike McKillip

Team Leader: Lisa Pittman

Project ID #: Q-11111-15

Facility: Carolina Breast Imaging Specialists

FID #: 150501

County: Pitt

Applicants: Carolina Breast Imaging, LLC

Project: Develop a new diagnostic center by upgrading an existing 2D mammography system to a 3D mammography system

### REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

G.S. 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

The applicant, Carolina Breast Imaging, LLC d/b/a Carolina Breast Imaging Specialists [CBIS] proposes to upgrade an existing 2D mammography system to a 3D mammography system and establish a new diagnostic center. CBIS is a freestanding outpatient imaging center located at 990 John Hopkins Drive in Greenville (Pitt County). The acquisition of the upgrade to the existing diagnostic equipment results in the development of a diagnostic center as that term is defined in G.S. 131E-176(7a). It is the development of a new diagnostic center that is subject to review.

The total cost or fair market value of the proposed 3D mammography equipment upgrade is \$100,196. However, when combined with the existing medical diagnostic equipment utilized by the facility which costs \$10,000 or more, the total capital cost exceeds \$500,000 and

therefore, pursuant to G.S. 131E-176(7a), acquisition of the proposed equipment upgrade results in the development of a diagnostic center, which requires a certificate of need. In Section XI.4, page 81, the applicant states that there will be no new construction or renovation of existing space at CBIS for the proposed project. The following table summarizes the capital cost of the existing diagnostic equipment and the proposed equipment, as described by the applicant on page 69 of the application.

<b>COST OF EXISTING EQUIPMENT</b>	<b>COST</b>
Existing Mammography, Ultrasound, Bone Densitometry*	\$488,571
<b>COST OF PROPOSED EQUIPMENT</b>	
3D Mammography Equipment Upgrade Purchase/Installation	\$100,196
<b>Total Projected Capital Costs</b>	<b>\$588,767</b>

\* CBIS already owns and operates this equipment (sunk cost). From page 69 of application.

There are no need determinations or policies in the 2015 State Medical Facilities Plan (SMFP) applicable to the acquisition of the type of equipment proposed in this application or to the establishment of a diagnostic center. Therefore, this criterion 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, CBIS, is a freestanding outpatient imaging center which is located at 990 John Hopkins Drive in Greenville, and currently offers mammography, breast ultrasound, bone densitometry, and breast biopsy services. In this application, CBIS proposes to purchase a 3D mammography upgrade for its existing 2D digital mammography machine, which will result in the development of a new diagnostic center as that term is defined in G.S. 131E-176(7a).

### Designation as a Diagnostic Center

In Section II.8, page 13, the applicant lists the costs of acquisition and installation of the existing diagnostic equipment at CBIS, which is summarized below:

<b>COST OF EXISTING CBIS DIAGNOSTIC EQUIPMENT</b>	<b>COST</b>
GE Senographe Essential Mammography System (2 units)	\$218,708
GE Stereotaxy (Biopsy) Device	\$25,000
Contrast Mammography upgrade	\$45,000
Contrast Injector	\$6,700
DEXA (Bone densitometry)	\$23,844
GE Logiq S8 Ultrasound	\$56,213
Tomosynthesis (3D mammography) adaptor	\$73,476
Taxes and Miscellaneous Expenses	\$39,590
<b>Total Cost of Existing Diagnostic Equipment</b>	<b>\$488,571</b>

Source: Section II.8, page 13, of the application.

The total project capital cost for the proposed 3D mammography equipment upgrade is \$100,196. The proposed new equipment plus the equipment currently in use at CBIS exceeds the \$500,000 threshold.

In Section II.1, page 9, the applicant describes the project as follows:

*“CBIS Greenville currently has 2 digital mammography units. 1 unit is already 3D capable. Since all mammograms at CBIS are performed with 3D technique, they all have to be done on this unit. The second unit is a standard 2D FFDM system capable of mammography, contrast enhanced mammography and stereotactic biopsy. The proposed project adds 3D capabilities to the already existing system.”*

### **Population to be Served**

The 2015 SMFP does not define a service area for diagnostic centers. However, 10A NCAC 14C .1802 does define the service area for diagnostic centers as *“the geographic area, as defined by the applicant, for which the proposed diagnostic center will provide services.”*

In Section III.5, page 39, the applicant projects the patient origin for mammography services at CBIS during the first two operating years following project completion, which is summarized in the table below:

**CBIS Mammography Services  
Projected Patient Origin (June 2016-May 2018)**

<b>County</b>	<b>Percent of Total Patients</b>
Pitt	68.60%
Beaufort	6.76%
Martin	2.86%
Lenoir	2.55%
Greene	1.97%
Wilson	2.17%
Edgecombe	1.21%
Craven	1.17%
Washington	0.69%
Wayne	1.00%
Chowan	0.52%
Nash	0.45%
Other	10.04%
<b>TOTAL</b>	<b>100.0%</b>

In Section III.5, page 39, the applicant states, “*This project assumes no change in patient origin as we are simply expanding an existing service.*” The applicant adequately identified the population proposed to be served.

**Analysis of Need**

In Section III.1(a) and (b) of the application, page 34, the applicant describes the factors which it states support the need for the proposed project as follows:

- 1) *Tomosynthesis has been proven to improve medical care by lowering false positive results and increasing cancer detection.*
- 2) *Based on the available literature and the CBIS experience, all patients [should] receive Tomosynthesis as their routine examination.*
- 3) *CBIS has shown exponential growth in patient volumes since opening in 2013. In order to continue to serve current and future patients an existing 2D system needs to be upgraded to 3D.*
- 4) *Since the upgrade will raise the total value of all diagnostic equipment to over \$500,000 a certificate of need must be obtained.”*

On page 43, the applicant states,

*“CBIS first opened on November 4, 2013. The only full FY prior to the year of application is FY 2014.”*

**Projected Utilization**

The applicant currently operates one 2D and one 3D mammography unit at CBIS, and proposes to operate two 3D mammography units at CBIS following completion of the project. In Section

IV.1, page 43, the applicant provides the historical and projected utilization for the existing and proposed mammography equipment at CBIS through the first three years of operation following completion of the project, which is summarized below.

Operating Year	# of Units*	Total Mammography Procedures	Procedures Per Unit	Annual Percent Increase
CY2014 Actual	2	3,089	1,545	---
CY2015 Annualized**	2	5,215	2,608	69%
CY2016 Projected	2	5,998	2,999	15%
CY2017 Project Year 1	2	6,897	3,449	15%
CY2018 Project Year 2	2	7,932	3,966	15%
CY2019 Project Year 3	2	9,122	4,561	15%

\*The applicant projects to operate one 2D and one 3D mammography unit until CY2016, and then two 3D mammography units from CY2017 onward.

\*\*On page 27, the applicant states projected CY2015 mammography procedures are based on three quarters of actual volumes and estimated volumes for the fourth quarter of 2015.

As shown in the above table, the applicant projects it will perform 6,897 mammography procedures on the two mammography units at CBIS proposed equipment in the first year of operation following completion of the project, and 9,122 mammography procedures in the third operating year. In Section IV.2, page 44, the applicant states the maximum annual capacity of the proposed 3D mammography equipment is 3,683 procedures. Therefore, the applicant projects the mammography equipment will operate at 124 percent of capacity in the third year of operation [ $4,561/3,683 = 1.24$ ].

The applicant describes the assumptions and methodology used to project utilization in Section IV.1(d), page 43, as follows:

*“These projections utilize an annual 15% growth rate, which is far less than the actual growth rate we have seen thus far. For example, the actual growth rate between FY 2014 and FY 2015 is 68% (3089 vs 5215).”*

In Section II.8, pages 25-26, the applicant states,

*“This project does not change the total number of mammography systems in the region. The unit to be upgraded is already in service. This upgrade will allow that unit to perform the state of the art 3D imaging exam which will increase the utilization of this existing system....”*

*The table in section (3e) [on page 25 of the application] shows actual and estimated mammography equipment utilization. 15% growth estimate was used as has been the convention throughout this application. This shows that we will need 3531 hours of mammography machine time by the end of the third year of the project. Based on the assumptions listed in NCAC 1803.b.3 each mammography system is capable of 1900 hours of use per year. Two systems would be 3800 hours. Based on our projections, our utilization of 3531 results in a projected utilization of 92.9%. Using 15% we expect*

*to cross the 80% utilization threshold at the end of year 2 of the project. In fact, we consider 15% growth to be extremely conservative given our historical growth rates during the development of our new practice and so will likely reach the 80% level much sooner than even Year 2. In addition, we have not factored in any population growth or aging of the population into the standard screening ages....*

*However, the population is aging in this region and is expected to increase from 11% of women over 65 to 13%. [See Exhibit 19: NC Population Statistics by County]. As our services are primarily geared to the older age groups, this will make the 15% organic growth assumptions even more likely to be realized during this project cycle.”*

In Section II.8, pages 27-28, the applicant states,

*“Throughout this application we have used 15% as our projected growth rate. This will achieve 80% utilization at the end of year 2 and 93% by the end of year 3. We believe those assumptions are extremely conservative based on the following:*

*Carolina Breast Imaging opened on 11/4/13 as a new practice with no active patient base. In our first full year of practice we performed 3089 imaging procedures. 2015 volume (actual through q3, estimated for Q4) is expected to be 5215. That represents a 68% growth rate between year 1 and 2....*

*We fully expect this trend to continue as we are seeing excellent return visit rates and many new patients who have heard about our practice through marketing and word of mouth. When comparing 2015 to 2014 we have seen a 68% increase in patient volume and that trend is continuing and even rising more rapidly than before. However, in the long run these growth rates are unlikely so we will use a more conservative growth estimate for the purposes of demonstrating our need.”*

As shown above, the applicant’s utilization projections are based on its historical experience providing mammography services and projected service area population growth for women age 65 and older. Exhibit 13 contains letters of support for the proposed project from physicians and other healthcare providers in the proposed service area. Projected utilization is based on reasonable and adequately supported assumptions. Therefore, the applicant adequately demonstrated the need to purchase a 3D mammography upgrade for its existing 2D digital mammography machine, and to establish a diagnostic center.

### **Access**

In Section VI.2, page 52, the applicant states CBIS will continue to provide services to all patients regardless of their ability to pay, racial/ethnic origin, age, gender, physical or mental conditions or other conditions that would classify them as underserved. In Section VI.15, page 60, the applicant projects that 30 percent of patients to be served will be Medicare or Medicaid recipients. The applicant adequately demonstrates the extent to which all residents of the area, including underserved groups, are likely to have access to the proposed services.

### **Conclusion**

In summary, the applicant adequately identified the population to be served by the proposed project, demonstrated the need the population has for the services proposed, and demonstrated the extent to which all residents of the area, including underserved groups, are likely to have access to the proposed services. Therefore, 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

- (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 III.3, page 35, the applicant describes the alternatives considered prior to submitting this application for the proposed project, which include:

- Maintain the Status Quo –The applicant states that maintaining the status quo is not an effective alternative because the existing mammography equipment cannot meet the current demand for services, resulting in occasional long wait times for patients.
- Offer Evening and Weekend Hours – The applicant states that expanding hours of operation has not worked well since patients prefer to come during regular business hours.
- Offer Only 2D Mammography to Some Patients– The applicant states that 3D mammography is the emerging standard of care for breast cancer screening services, so offering only 2D mammography to some patients is not an acceptable alternative.

After considering those alternatives, the applicant states the alternative represented in the application is the most effective alternative to meet the identified need.

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.

In summary, the applicant adequately demonstrates that the proposal is the least costly or most effective alternative to meet the identified need. Therefore, the application is conforming to this criterion and approved subject to the following conditions.

- 1. Carolina Breast Imaging, LLC shall materially comply with all representations made in the certificate of need application.**

2. **Carolina Breast Imaging, LLC shall not acquire, as part of this project, any equipment that is not included in the project’s proposed capital expenditures in Section VII of the application and that would otherwise require a certificate of need.**
  3. **Carolina Breast Imaging, LLC shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Certificate of Need Section 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

In Section VIII.1, page 70, the applicant states the total capital cost is projected to be as follows:

**CBIS Mammography Upgrade Project Capital Cost**

Equipment Cost	\$92,800
Miscellaneous Expenses	\$7,396
<b>TOTAL CAPITAL COST</b>	<b>\$100,196</b>

Source: Tables on page 70 of the application.

In Section IX.1, page 74, the applicant states there will be no start-up expenses and no initial operating expenses associated with the project.

**Availability of Funds**

In Section VIII.3, page 70, the applicant states that \$92,800 of the project capital costs will be funded by a conventional loan and \$7,396 will be funded by “operating revenue and/or reserves.” In Exhibit 15, the applicant provides a letter dated November 1, 2015, from the Chief Operating Officer of CBIS documenting its intention to fund the equipment purchase with a \$92,800 equipment loan from First Carolina Bank and the remaining capital costs with cash operating revenue or cash reserves. Exhibit 16 contains a copy of equipment loan terms for proposed upgrade between First Carolina Bank and CBIS. In the pro forma financial statements for CBIS (Form A), the applicant reports that it had \$70,688 in cash and cash equivalents as of September 30, 2015. The applicant adequately demonstrates that sufficient funds will be available for the capital needs of the project.

**Financial Feasibility**

In the pro forma financial statements for CBIS’s mammography services (Form C), the applicants project that revenues will exceed operating expenses in the third operating year of the project, as shown in the table below.



**CBIS Mammography Services**

	<b>CY2017</b>	<b>CY2018</b>	<b>CY2019</b>
Total Net Revenues	\$1,003,758	\$1,146,072	\$1,309,733
Total Operating Expenses	\$925,023	\$964,423	\$1,029,032
<b>Net Income (Loss)</b>	<b>\$78,734</b>	<b>\$181,649</b>	<b>\$280,701</b>

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

**Conclusion**

In summary, the applicant adequately demonstrates that sufficient funds will be available for the capital needs of the project. Furthermore, the applicant adequately demonstrates that the financial feasibility of the proposal is based upon reasonable projections of costs and charges. Therefore, 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

CBIS proposes to purchase a 3D mammography upgrade for its existing 2D digital mammography machine, which will result in the development of a new diagnostic center as that term is defined in G.S. 131E-176(7a).

The 2015 SMFP does not define a service area for diagnostic centers. However, 10A NCAC 14C .1802 does define the service area for diagnostic centers as *“the geographic area, as defined by the applicant, for which the proposed diagnostic center will provide services.”*

The patients to be served will be the same as the patients currently serviced in the existing location. No new services will be offered.

In Section III.6, page 39, the applicant states,

*“There are 6 providers accredited to perform mammography in our primary service area (Pitt County). Our Secondary area (Beaufort County) has 1 provider listed by MQSA [Mammography Quality Standards Act] (another has just opened). Another 21 MQSA certified mammography facilities are found in the region. There is no publically available information related to which facilities currently perform 3D mammography or their utilization rates.”*

The applicant states the existing 3D mammography equipment at CBIS has reached its capacity and projected utilization of 3D mammography services at CBIS is continued to grow. The applicant adequately demonstrated the need to upgrade the existing 2D mammography equipment to perform 3D mammography services. The discussion regarding analysis of need found in Criterion (3) is incorporated herein by reference. Therefore, the applicant adequately demonstrated that the proposal would not result in unnecessary duplication of existing or approved mammography services. Consequently, 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 VII.1, pages 62-63, the applicant states that they currently employ 8.5 full-time equivalents (FTE) to staff the diagnostic services at CBIS, and it projects to add 0.5 FTE radiologist and 0.5 FTE clerical position as a result of the proposed project. In Section VII.3, page 64, the applicant states that it does not anticipate any difficulty hiring and retaining staff. In Section VII.8, page 66, the applicant identifies Bruce Schroeder, M.D. as the Medical Director for CBIS. Exhibit 13 of the application contains copies of letters from other physicians expressing support for the proposed project. The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services. Therefore, 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 II.2, pages 9-10, the applicant describes the manner in which it will provide the necessary ancillary and support services. Exhibit 13 contains letters of support from physicians. The applicant adequately demonstrates that necessary ancillary and support services are available and that the proposed services will be coordinated with the existing healthcare system. Therefore, 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

- (10) When applicable, the applicant shall show that the special needs of health maintenance organizations will be fulfilled by the project. Specifically, the applicant shall show that the project accommodates: (a) The needs of enrolled members and reasonably anticipated new

members of the HMO for the health service to be provided by the organization; and (b) The availability of new health services from non-HMO providers or other HMOs in a reasonable and cost-effective manner which is consistent with the basic method of operation of the HMO. In assessing the availability of these health services from these providers, the applicant shall consider only whether the services from these providers:

- (i) would be available under a contract of at least 5 years duration;
- (ii) would be available and conveniently accessible through physicians and other health professionals associated with the HMO;
- (iii) would cost no more than if the services were provided by the HMO; and
- (iv) would be available in a manner which is administratively feasible to the HMO.

NA

- (11) 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

- (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 Division of Medical Assistance (DMA) maintains a website which offers information regarding the number of persons eligible for Medicaid assistance and estimates of the percentage of uninsured for each county in North Carolina. More current data, particularly with regard to the estimated uninsured percentages, was not available.

<b>County</b>	<b>Total # of Medicaid Eligibles as % of Total Population June 2010</b>	<b>Total # of Medicaid Eligibles Age 21 and older as % of Total Population June 2010</b>	<b>% Uninsured CY2008-2009 (Estimate by Cecil G. Sheps Center)</b>
Pitt	16%	6.7%	21.3%
Statewide	17%	6.7%	19.7%

The majority of Medicaid eligibles are children under the age of 21. This age group does not utilize the same health services at the same rate as older segments of the population, particularly the mammography services proposed in this application.

Moreover, the number of persons eligible for Medicaid assistance may be greater than the number of Medicaid eligibles who actually utilize health services. The DMA website includes information regarding dental services which illustrates this point. For dental services only, DMA provides a comparison of the number of persons eligible for dental services with the number actually receiving services. The statewide percentage of persons eligible to receive dental services who actually received dental services was 48.6% for those age 20 and younger and 31.6% for those age 21 and older. Similar information is not provided on the website for other types of services covered by Medicaid. However, it is reasonable to assume that the percentage of those actually receiving other types of health services covered by Medicaid is less than the percentage that is eligible for those services.

The Office of State Budget & Management (OSBM) maintains a website which provides historical and projected population data for each county in North Carolina. In addition, data is available by age, race or gender. However, a direct comparison to the applicants' current payer 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.

In Section VI.13, page 59, the applicant reports the following payer mix for CBIS's mammography services for CY2014:

<b>Payer Category</b>	<b>Mammography Services as Percent of Total</b>
Self Pay/Indigent/Charity	5%
Medicare/Medicare Managed Care	26%
Medicaid	4%
Commercial Insurance	62%
Other	2%
<b>Total</b>	<b>100.0%</b>

The applicant demonstrates that medically underserved populations currently have adequate access to the applicant's existing services and 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 VI.11, page 59, the applicant states, “*Although we have no obligation to do so, we provide care to any and all patients without regard to any of the above criteria [regarding access to care by medically underserved, minorities and handicapped persons].*” In Section VI.10, page 58, the applicant states that no civil rights access complaints have been filed against CBIS in last five years. 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 VI.15, page 60, the applicant projects the following payer mix for CBIS’s mammography services during the second operating year (CY2018):

<b>Payer Category</b>	<b>Mammography Services as Percent of Total</b>
Self Pay/Indigent/Charity	5%
Medicare/Medicare Managed Care	26%
Medicaid	4%
Commercial Insurance	62%
Other	2%
<b>Total</b>	<b>100.0%</b>

On page 60, the applicant states, “*We would not expect any change in payer mix related to this project which simply expands [sic] ability to serve more patients.*” The applicant demonstrated that the medically underserved population will have adequate access to the proposed services. Therefore, 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 VI.9, page 58, the applicant describes the range of means by which a person will have access to CBIS mammography services. The applicant adequately demonstrates that the facility will offer a range of means by which patients will have

access to the proposed services. Therefore, 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 V.1, page 47, the applicant states that already it has relationships with area health professional training programs, including Pitt County Community College. The information provided is reasonable and credible and supports a finding of conformity 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

CBIS proposes to purchase a 3D mammography upgrade for its existing 2D digital mammography machine, which will result in the development of a new diagnostic center as that term is defined in G.S. 131E-176(7a).

The 2015 SMFP does not define a service area for diagnostic centers. However, 10A NCAC 14C .1802 does define the service area for diagnostic centers as *“the geographic area, as defined by the applicant, for which the proposed diagnostic center will provide services.”*

The patients to be served will be the same as the patients currently serviced in the existing location. No new services will be offered.

In Section V.7, page 50, the applicant discusses how any enhanced competition will have a positive impact on the cost-effectiveness, quality and access to the proposed services. The applicant states,

*“Since the inception of CBIS in 2013, we have seen many benefits to the community related to competition. As the only medical practice in the region solely dedicated to breast imaging, CBIS has set the standard of care for all other practices. CBIS ordered the first 3D system in Greenville and also in Wilson. Almost immediately following our lead, other practices began to upgrade their equipment to the latest standards. Our*

*patients consistently rave about their experience at our office. This should force competing facilities to improve their services to compete. We are the only practice offering 3D mammography to all patients and not requiring patients to pay if their insurance does not cover the exam. We certainly hope other practices are forced to adopt similar patient-friendly policies. We have had many uninsured patients referred from several hours away to receive 3D mammography at our steeply discounted self-pay rates. There are other facilities closer to where they live, so we must assume that our price and/or quality make it worth the drive.”*

See also Sections II, III, V, VI and VII where the applicant discusses the impact of the project on cost-effectiveness, quality and access.

The information in the application is reasonable and adequately demonstrates that any enhanced competition in the service area includes a positive impact on the cost-effectiveness, quality and access to the proposed services. This determination is based on the information in the application and the following analysis:

- The applicant adequately demonstrates the need for the project and that it is a cost-effective alternative. The discussions regarding the analysis of need and alternatives found in Criteria (3) and (4), respectively, are incorporated herein by reference.
- The applicant adequately demonstrates it will provide quality services. The discussion regarding quality found in Criterion (20) is incorporated herein by reference.
- The applicant demonstrates that it will provide adequate access to medically underserved populations. The discussion regarding access found in Criterion (13) is incorporated herein by reference.

Therefore, 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 II.7, pages 11-12, the applicant describes the methods used by CBIS to insure and maintain quality care. In Section II.7(c), page 12, the applicant states that CBIS has not had its license revoked or had its Medicare or Medicaid provider agreements revoked. The information provided by the applicant is reasonable and supports the determination that the applicant 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 application is conforming to all applicable Criteria and Standards for Diagnostic Centers. The specific criteria are discussed below.

**SECTION .1800 CRITERIA AND STANDARDS FOR DIAGNOSTIC CENTERS**

**10A NCAC 14C .1803 INFORMATION REQUIRED OF APPLICANTS**

*(a) An applicant proposing to establish a new diagnostic center or to expand an existing diagnostic center shall use the Acute Care Facility/Medical Equipment application form.*

-C- The applicant used the correct application form.

*(b) An applicant shall also provide the following additional information:*

*(1) the number, type, cost, condition, useful life and depreciation schedule of all medical diagnostic equipment that either is proposed to be acquired or is currently owned or operated by the applicants, and will be part of the diagnostic center following completion of the project;*

-C- In Section II.8, page 15, the applicant identifies the existing medical diagnostic equipment at CBIS, the proposed medical diagnostic equipment to be located at the diagnostic center and the number, type, cost, condition, useful life, and depreciation schedule for each piece of equipment.

*(2) other than the equipment listed in Subparagraph (b) (1) of this Rule, a list of all equipment and related components which are necessary to perform the proposed procedures and services;*

-C- The applicant states there is no other equipment necessary to support the proposed project.

*(3) the maximum number of procedures that each piece of medical diagnostic equipment in the diagnostic center is capable of performing and the assumptions used to project capacity;*

-C- In Section II.8, pages 15-16, the applicant provides the assumptions it used to project capacity for the service component, and the projections, as shown below.



EQUIPMENT	WEEKS / YEAR	HOURS / WEEK	MACHINE DOWN TIME	PROCEDURES / HOUR	TOTAL PROCEDURE CAPACITY
Mammography	50	40	5%	1.94	3,683

(4) a list of all existing and approved health service facilities that operate or have been approved to operate medical diagnostic equipment and diagnostic suites by type and location in the proposed medical diagnostic equipment service area;

-C- In Section II.8, page 16-17, the applicant provides a listing of the existing and approved providers of the types of diagnostic equipment proposed for the facility that are located in the proposed service area, which is shown below:

Health Service Facility	Provider	Location	Type
Imaging Center	Eastern Radiologists Breast Imaging Center	201 W. Arlington Blvd Greenville NC 27834	Mammography
Imaging Center	Physicians East Diagnostic Center	1850 W. Arlington Blvd Greenville NC 27834	Mammography
Imaging Center	Eastern Radiologists	630 E. 11 <sup>th</sup> St Washington NC 27889	Mammography

Source: Application pages 16-17.

(5) the hours of operation of the proposed diagnostic center and each proposed diagnostic service;

-C- In Section II.8, page 17, the applicant states the diagnostic center is open from 8:00 AM to 5:00 PM, Monday-Friday.

(6) the patient origin by percentage by county of residence for each diagnostic service provided by the applicants in the 12 month period immediately preceding the submittal of the application;

-C- In Section II.8, page 18, the applicant provides the patient origin by percentage by county of residence for mammography services provided by CBIS for the preceding 12 months.

(7) the projected patient origin by percentage by county of residence for each service proposed, and all the assumptions and data supporting the methodology used for the projections;

-C- In Section II.8, page 19, the applicant provides projected patient origin by percentage by county of residence for the proposed service as well as the assumptions and data which support the methodology.

(8) drawings or schematics of the proposed diagnostic center that identifies a distinct, identifiable area for each of the proposed services; and

-C- In Exhibit 9, the applicant provides a line drawing of the diagnostic center that identifies a distinct, identifiable area for the mammography service.

*(9) a three year capital budget.*

-C- In Section II.8, page 20, the applicant provides a three year capital budget for CBIS.

*(c) An applicant proposing to establish a new mobile diagnostic program shall also provide the following information:*

*(1) the number, type and cost of all proposed mobile medical diagnostic equipment including the cost of the transporting equipment;*

*(2) other than the equipment listed in Subparagraph (b)(1) of this Rule, a list of all equipment and related components which are necessary to perform the proposed procedures and services;*

*(3) the number and type of all existing and approved mobile diagnostic equipment in the proposed mobile diagnostic center service area;*

*(4) the maximum number of procedures that each proposed piece of medical diagnostic equipment is capable of performing and the assumptions used to project capacity;*

*(5) the name, address and hours of service at each host facility that is proposed to be served by the mobile diagnostic program; and*

*(6) copies of letters of intent from, and proposed contracts with, all of the proposed host facilities of the mobile diagnostic program.*

-NA- The applicant does not propose to establish a mobile diagnostic program.

*(d) An applicant shall demonstrate that all equipment, supplies and pharmaceuticals proposed for the diagnostic center have been certified for clinical use by the U.S. Food and Drug Administration or will be operated or used under an institutional review board whose membership is consistent with U.S. Department of Health and Human Services' regulations.*

-C- In Section II.8, page 20, the applicant provides documentation that the equipment proposed for the diagnostic center has been certified for clinical use by the U.S. Food and Drug Administration.

*(e) An applicant proposing to establish a new diagnostic center or to expand an existing diagnostic center shall provide:*

*(1) the projected number of patients to be served, classified by diagnosis for each of the first twelve calendar quarters following completion of the project; and*

-C- In Section II.8, page 21, the applicant provides the projected number of patients to be served, classified by diagnosis (CPT code), for each of the first twelve calendar quarters following project completion.

*(2) the projected number of patients to be served by county of residence for each of the first twelve calendar quarters following completion of the project; and*

- C- In Section II.8, page 22, the applicant provides the projected number of patients to be served by county of residence for each of the first twelve calendar quarters following project completion, for the mammography equipment.
  - (3) *the projected number and type of diagnostic procedures proposed to be provided by CPT code or ICD-9-CM procedure code for each of the first twelve calendar quarters following completion of the project.*
- C- In Section II.8, page 23, the applicant provides the projected number and type of diagnostic procedures by procedure code to be provided for each of the first twelve calendar quarters following project completion.

### **10A NCAC 14C .1804 PERFORMANCE STANDARDS**

*An applicant proposing to establish a new diagnostic center or to expand an existing diagnostic center shall provide:*

- (1) *documentation that all existing health service facilities providing similar medical diagnostic equipment and services as proposed in the CON application in the defined diagnostic center service area were operating at 80% of the maximum number of procedures that the equipment is capable of performing for the twelve month period immediately preceding the submittal of the application;*
- C- In Section II.8, pages 16-17, the applicant identifies three existing health service facilities providing mammography services in the defined service area. However, on page 24, the applicant states there is no publicly available data which identifies the number of existing mammography machines located in health service facilities in CBIS's proposed service area or their utilization rates.
  - (2) *documentation that all existing and approved medical diagnostic equipment and services of the type proposed in this CON application are projected to be utilized at 80% of the maximum number of procedures that the equipment is capable of performing by the fourth quarter of the third year of operation following initiation of diagnostic services;*
- C- In Section II.8, page 25, the applicant projects that utilization for the proposed 3D mammography equipment will exceed 80 percent (92.9%) of the maximum number of procedures the proposed upgraded equipment is capable of performing by the third year of operation.
  - (3) *documentation that the applicants utilization projections are based on the experience of the provider and on epidemiological studies; and*
- C- In Section II.8, pages 25-26, the applicant states that all utilization projections are based on the applicant's experience providing mammography services at CBIS, and on the projected growth in the service area population of women age 65 and older.

(4) *all the assumptions and data supporting the methodologies used for the projections in this Rule.*

- C- In Section II.8, pages 25-29, the applicant provides the assumptions and data supporting the methodologies used to project utilization.

#### **10A NCAC 14C .1805 REQUIRED SUPPORT SERVICES**

*An applicant shall provide documentation showing the proximity of the proposed diagnostic center to the following services:*

(1) *emergency services;*

- C- In Section II.8, page 29, the applicant states that emergency services are available at Vidant Medical Center, which is approximately one mile from CBIS.

(2) *support services;*

- C- In Section II.8, page 30, the applicant states that support services, including scheduling, registration, billing, marketing, quality assurance and maintenance are currently provided at CBIS, and will continue to be provided upon implementation of the mammography equipment project.

(3) *ancillary services; and*

- C- In Section II.8, page 30, the applicant states that it is an existing outpatient imaging center which provides medical diagnostic services, and that the necessary ancillary services are currently in place at CBIS.

(4) *public transportation.*

- C- In Section II.8, page 30, the applicant states that patients have access to public transportation via the Greenville Area Transit (GREAT) bus route, the Pitt County Transit System, the Department of Social Services, and the Pitt County Council on Aging.

#### **10A NCAC 14C .1806 STAFFING AND STAFF TRAINING**

(a) *An applicant proposing to establish a new diagnostic center or to expand an existing diagnostic center shall identify the number of radiologists, radiation physicists, other physicians, laboratory staff, radiologic technologists and support staff that are projected to be involved in providing each of the proposed diagnostic services.*

- C- In Section II.8, page 31, and in Section VII.1, page 63, the applicant identifies the number of staff by type projected to provide the proposed services.

- (b) An applicant proposing to provide ionizing and nonionizing radiation procedures shall demonstrate that a physician, licensed to practice medicine in North Carolina shall be available to perform and supervise all radiation procedures and shall document the qualifications of this physician to perform radiation procedures.*
- C- In Section II.8, page 31, the applicant states that Dr. Schroeder is a board certified radiologist, licensed to practice medicine in North Carolina, who supervises all radiation producing equipment in the facility.
- (c) An applicant proposing to establish a new diagnostic center or to expand an existing diagnostic center shall document that a program of continuing education shall be available for technologists and medical staff.*
- C- In Section II.8, page 31, and Exhibit 25, the applicant provides documentation of its program of continuing education for technologists and medical staff.