

## ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: March 10, 2017

Findings Date: March 10, 2017

Project Analyst: Jane Rhoe-Jones

Team Leader: Fatimah Wilson

Project ID #: R-11274-16

Facility: Chesapeake Regional Healthcare Mobile Mammography and Health Screenings Unit

FID #: 160558

Counties: Camden, Currituck, Dare, Pasquotank and Perquimans

Applicant: Chesapeake Regional Medical Center

Project: Bring existing mobile mammography van into northeastern North Carolina to provide services which results in the development of a mobile diagnostic program

### REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

N.C. Gen. Stat. §131E-183(a) The Department 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

Chesapeake Regional Medical Center (CRMC) (“the applicant”) proposes to bring an existing mobile mammography van into primarily five counties in northeastern North Carolina (Camden, Currituck, Dare, Pasquotank and Perquimans) to provide 3D mammography services which results in the development of a mobile diagnostic program. A mobile diagnostic program is a diagnostic center as defined by N.C. Gen. Stat. §131E -176(7a). The CRMC mobile mammography van is docked/recharged at Chesapeake Regional Medical Center, 736 Battlefield Boulevard North in Chesapeake, Virginia. The value of the existing 3D mammography unit that was purchased in February 2016 (\$760,000), already being utilized by CRMC, exceeds the statutory threshold promulgated in N.C. Gen. Stat. §131E -176(7a) of \$500,000 for a diagnostic center; therefore, bringing the existing equipment from Virginia into North Carolina requires a certificate of need.

### **Need Determination**

There are no need determinations in the 2016 State Medical Facilities Plan (SMFP) which are applicable to the acquisition of the type of equipment proposed in this application or to the establishment of a diagnostic center.

### **Policies**

There are no policies in the 2016 SMFP which are applicable to this review.

### **Conclusion**

In summary, the applicant does not propose to develop any beds, operating rooms, or other services or acquire equipment for which there is a need determination in the 2016 SMFP. There are no policies in the 2016 SMFP that are applicable to this review. 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

Chesapeake Regional Medical Center proposes to bring an existing mobile mammography van into primarily five counties in northeastern North Carolina (Camden, Currituck, Dare, Pasquotank and Perquimans) to provide 3D mammography services which results in the development of a mobile diagnostic program. A mobile diagnostic program is a diagnostic center as defined by N.C. Gen. Stat. §131E -176(7a). The CRMC mobile mammography van is docked/recharged at Chesapeake Regional Medical Center, 736 Battlefield Boulevard North in Chesapeake, Virginia. The value of the existing 3D mammography unit that was purchased in February 2016 (\$760,000), exceeds the statutory threshold promulgated in N.C. Gen. Stat. §131E -176(7a) of \$500,000 for a diagnostic center; therefore, bringing the existing equipment from Virginia into North Carolina requires a certificate of need.

### **Patient Origin**

The 2016 SMFP does not provide a need methodology for the establishment of diagnostic centers in North Carolina; nor does the SMFP specify a service area relative to diagnostic centers. The Criteria and Standards for Diagnostic Centers promulgated in 10A NCAC 14C .1802(3) 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 15, CRMC states that the geographic service area for its mobile mammography services will primarily be Camden, Currituck, Dare, Pasquotank and Perquimans counties; though if requested and

feasible – it may travel into Gates or other nearby counties. The applicant may also serve residents of counties not included in the service area.

The applicant does not currently offer mobile mammography services in the state of North Carolina and therefore has no existing patient origin to report. In Section III.5(c), page 16, the applicant does provide CRMC’s FY2015 and FY2016 mammography patient origin which includes its North Carolina patients. In FY2015 and FY2016, the applicant served over 1,000 patients who traveled from North Carolina to Virginia for mammography services.

In clarifying information received from the applicant on February 28, 2017, the applicant provides updated projected patient origin for the mobile mammography unit as shown in the following table:

<b>CRMC MOBILE MAMMOGRAPHY PROJECTED PATIENT ORIGIN</b>				
<b>NC County</b>	<b>OY1 FY2018</b>		<b>OY2 FY2019</b>	
	<b>#</b>	<b>%</b>	<b>#</b>	<b>%</b>
Camden	253	12.6%	311	12.6%
Currituck	1,202	60.0%	1,482	60.0%
Dare	112	5.6%	138	5.6%
Pasquotank	255	12.7%	314	12.7%
Perquimans	54	2.7%	67	2.7%
Other	128	6.0%	158	6.0%
<b>Total NC</b>	<b>2,004</b>	<b>100.0%</b>	<b>2,470</b>	<b>100.0%</b>
<b>Patients/Day</b>	<b>20</b>		<b>25</b>	

The applicant uses the word “procedures” in some parts of the application and “patients” in other parts of the application without distinguishing whether the number of procedures differs from the number of patients. In clarifying information submitted by the applicant on February 27, 2017, the applicant states that it is using patients, cases and procedures interchangeably. The applicant states,

*“Yes, we assumed 1 patient day = 1 mammogram ... .”*

In clarifying information received from the applicant on March 8, 2017, the applicant states the following in justifying the projected volume for its patient origin,

*“The proforma volume was built after several conversations with physicians and practice managers in the NE NC region about our program and their level of interest in being one of our mobile mammography locations. Chesapeake Regional currently owns two very busy practices in the region: Currituck Internal Medicine in Moyock and Carolina Surgical Care in Elizabeth City. Both of these locations have requested that we plan to bring the unit to their site one day each week as soon as possible. They are confident they can fill the schedule ‘at least’ 1 day/week. Additional interest and demand for our services has been expressed by Dr. Paul Moncla of Northeastern OB/GYN. We are planning to begin providing services at his location 1 day a month and ramping up from there depending on demand.”*

*Recognizing the need for conservatism and a ramp up of volumes in all of these locations, we have planned for 2004 screening mammograms in the first year of operations. This is an average daily volume of 20 patients, assuming we are in North Carolina approximately 100 days in the first 12 months. The unit's capacity in a typical 8 hour day is 30 patients.*

*Growth is anticipated in subsequent years (2470 in Year 2, 2600 in Year 3) as we plan to market our services to both patients, employers, and referring physicians for new volume while capturing "repeat" patients from Year 1 coming in for their annual mammogram. One of our most successful efforts to increase screening rates with the mobile program in Chesapeake has been to partner with local business, municipalities, churches and community groups to bring our services to the patients – providing a great service to the women associated with these organizations and creating a relationship for continued collaboration in the future."*

The applicant adequately identifies the North Carolina population to be served.

### **Analysis of Need**

In Section III, pages 12-23, and referenced exhibits, the applicant states that the following factors support the need to bring existing mobile mammography services from CRMC into northeastern North Carolina:

- The mobile van will increase geographic accessibility to mammography for North Carolina residents.
  - Currently, patients from Camden, Currituck and other parts of northeastern North Carolina may receive mammography services at Sentara Albemarle Medical Center (Pasquotank County), Sentara Kitty Hawk (Dare County), the Outer Banks Hospital (Dare County), CRMC Carolina Surgical Care (Pasquotank County), or travel into Virginia for mammography services.
  - In FY2015 and FY2016, more than 1,100 patients from North Carolina traveled to CRMC for their mammograms. It is unknown how many additional North Carolina residents traveled to Chesapeake, Norfolk, Portsmouth, Suffolk, or Virginia Beach, or postponed their annual breast screenings due to limited access in their own communities.
  - Rather than having to travel to the aforementioned sites, the mobile diagnostic mammography unit will travel to the communities in which the northeastern North Carolina patients live.
  - Although there are mammography facilities in Dare and Pasquotank counties, the geographic area is vast. The land area in Dare County is 383 square miles. A significant number of these square miles – where a notable percentage of the population resides are contained in a long, narrow north to south configuration with limited access to the mainland (due to the Atlantic Ocean and sounds). The

driving distance from one end of Dare County to Kitty Hawk is 82 miles on a two-lane highway. To reach the Outer Banks Hospital from Hatteras takes an hour and 20 minutes. For residents of Ocracoke Island, there is also a 60-minute ferry ride (See maps on pages 17 and 19).

- Presently, there is only one facility offering 3D mammography capability within the 1,360 square miles that make up the five counties of northeastern North Carolina.
- The proposed project will remove some of the other challenges that many northeastern North Carolina underserved patients traveling into Virginia for breast images face such as tolls, child care expenses, taking periods of time from work, limited access to and/or affordable transportation.
- Each year thousands of lives are saved by one diagnostic test – the mammogram. The mammogram is the only medical diagnostic tool proven to decrease breast cancer mortality. The most effective means to detect early-stage breast cancer is screening. When breast cancer is treated in its earliest stage, a patient’s five-year survival rate is nearly 100 percent. The applicant states that according to the American College of Radiology, since 1990, annual mammograms have contributed to the reduction in breast cancer deaths by one-third.
- CRMCs mobile mammography unit will increase the likelihood of early detection and treatment thus reducing mortality and the cost of care for later stage breast cancers.
- Breast Cancer Incident Rates – the North Carolina incidence rate is higher than the U.S. incidence rate. Camden and Dare counties have higher incidence rates than the state and the nation; 8.9% and 6.9% higher, respectively.

<b>NC County</b>	<b>Age Adjusted Incidence Rate/100,000</b>
Camden	134.3
Currituck	108.8
Dare	131.8
Pasquotank	122.7
Perquimans	106.0
<b>NC Statewide</b>	<b>128.4</b>
<b>United States</b>	<b>123.3</b>

The applicant adequately demonstrates the need to bring an existing 3D mammography mobile unit from the CRMC in Chesapeake, Virginia and to develop a new mobile diagnostic program to serve northeastern North Carolina patients from Camden, Currituck, Dare, Pasquotank and Perquimans counties.

*Projected Utilization*

In clarifying information received on February 28, 2017, the applicant provides projected utilization for CRMC mobile mammography services in northeastern North Carolina through

the first three years of operation following completion of the project, as shown in the following table.

CRMC PROJECTED MOBILE MAMMOGRAPHY PROCEDURES NORTHEASTERN NORTH CAROLINA OYs 1-3			
	OY 1 FY2017-2018	OY 2 FY2018-2019	OY 3 FY2019-2020
Mammography Procedures*	2,004	2,470	2,600

In additional clarifying information about projected utilization received from the applicant on March 7, 2017, the applicant states,

- *“The unit of service is defined as a screening mammogram*
- *The unit is projected to be located at two of our owned physician practice offices each week – Currituck Internal Medicine in Moyock, NC and Carolina Surgical Care in Elizabeth City*
- *Based on current patient volumes at the practice and the demand for additional services in both counties, we have projected approximately 20 patients per day in year 1*
- *2004 units of service in year 1 is based on 20 patients/day, 2 days/week and service 50 out of 52 weeks of the year (to account for holidays)*
- *The increase in volume in subsequent years is in anticipation of seeing more patients per day and being in more community locations each month”*

Projected utilization is based on reasonable and adequately supported assumptions regarding continued growth.

**Access**

In Section VI.2, page 33, the applicant states that it provides access without regard to income, race, ethnicity, gender, age, disability, payor or ability to pay.

In Sections VI.12 and VI.13, page 37, the applicant provides the historical payor mix for mammography services at CRMC for CY2016, as shown in the following table.

CRMC – MAMMOGRAPHY SERVICES HISTORICAL PAYOR MIX AS % OF TOTAL UTILIZATION (FY2016)	
Self-Pay/Indigent/Charity	5%
Medicare/Medicare Managed Care	30%
Medicaid	2%
Commercial Insurance	55%
Managed Care	0%
Other	8%
<b>Total</b>	<b>100%</b>

In Section VI.14-15, page 38, the applicant provides the projected payor mix for mammography services at CRMC (during the second full fiscal year of operation/FY 2018-2019), as shown in the following table:

<b>CRMC – MAMMOGRAPHY SERVICES PROJECTED PAYOR MIX AS % OF TOTAL UTILIZATION (OY2/FY2018-2019)</b>	
Self-Pay/Indigent/Charity	5%
Medicare/Medicare Managed Care	30%
Medicaid	2%
Commercial Insurance	55%
Managed Care	0%
Other	8%
<b>Total</b>	<b>100%</b>

As shown in the above referenced table, 42.0 percent of the facility's patients are projected to have some or all of their services paid for by Medicare and/or Medicaid; while 32.0 percent is true for the mammography service component. The applicant states that projected payor mixes are expected to be similar to current payor mixes for the facility and for the mammography service component.

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 identifies the population to be served, adequately demonstrates the need that population has for the proposed project, and adequately demonstrates the extent to which all North Carolina residents, 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 14, and in clarifying information received on January 30, 2017, the applicant describes the alternatives considered 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 applicant historically has served North Carolina patients and keeping the mobile mammography service in Virginia would not meet the need that has been identified in northeastern North Carolina.
- Purchase of a fixed 3D Mammography unit to be placed in one of its existing practices in northeastern North Carolina. – The applicant states this alternative was rejected because it was not determined to be the most effective option as it would not improve access to meet need. Thus, it would not be the best use of capital funds.

After considering those alternatives, the applicant states the alternative represented in the application to bring mobile mammography into northeastern North Carolina is the most effective alternative to meet the identified need.

Furthermore, the application is conforming to all other applicable statutory and regulatory review criteria, and thus, is approvable. An application 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 to meet the identified need. Therefore, the application is conforming to this criterion and approved subject to the following conditions.

- 1. Chesapeake Regional Medical Center shall materially comply with all representations made in the certificate of need application and in supplemental information received March 7, 2017, March 3, 2017, February 28, 2017, February 27, 2017 and January 30, 2017. In those instances where representations conflict, Chesapeake Regional Medical Center shall materially comply with the last made representation.**
  - 2. Chesapeake Regional Medical Center shall not acquire, as part of this project, any equipment that is not included in the project's proposed capital expenditure in Section VIII of the application or that would otherwise require a certificate of need.**
  - 3. Chesapeake Regional Medical Center shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Healthcare Planning and 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

The applicant proposes to bring an existing mobile mammography van into primarily five counties in northeastern North Carolina (Camden, Currituck, Dare, Pasquotank and Perquimans) to provide 3D mammography services which results in the development of a



mobile diagnostic program. The CRMC mobile mammography van will be docked/recharged at Chesapeake Regional Medical Center, 736 Battlefield Boulevard North in Chesapeake, Virginia. The value of the existing 3D mammography unit that was purchased in February 2016 (\$760,000), combined with the existing medical diagnostic equipment already being utilized by CRMC, exceeds the statutory threshold promulgated in N.C. Gen. Stat. §131E - 176(7a) of \$500,000 for a diagnostic center; therefore, bringing the existing equipment from Virginia into North Carolina requires a certificate of need.

**Capital and Working Capital Costs**

In Section VIII.2, page 47, the applicant projects no capital cost for the project, as the mobile mammography unit is an existing service in Virginia. In Section IX, page 51, the applicant states no working capital (start-up and initial operating expenses) is required for the proposed project because no new service is being proposed and the service is already staffed and operational.

**Financial Feasibility**

In Form D of the pro formas, the applicant provides its projected average charge per treatment for each payment source, as illustrated below in the table:

<b>CRMC AVERAGE CHARGES</b>	
<b>Payor</b>	<b>Per Mammogram</b>
Self-Pay/Indigent/ Charity	\$416.00
Medicare/Medicare Managed Care	\$567.89
Medicaid	\$488.95
Commercial Insurance	\$519.28
TriCare	\$500.90

In Form D, the applicant states projected number of patients to calculate its revenues for the first, second and third years of the project. The applicant uses 2,005 patients in operating year one, and 2,470 patients in operating year two, and 2,600 patients in operating year three.

In clarifying information received from the applicant on February 28, 2017, the applicant provides the following information for the estimated North Carolina procedures for its proposed CRMC mobile mammography program for two of its three initial operating years, as follows:

<b>CRMC PROJECTED # PROCEDURES</b>	
<b>Year</b>	<b>Number of Procedures</b>
FY2017-2018	2,004
FY2018-2019	2,470
FY2019-2020	2,600

In Form C, the applicant projects operating expenses and revenues, respectively, summarized as follows:

<b>CRMC</b>		
<b>PROJECTED EXPENSES AND REVENUES</b>		
	<b>OY1 (FY2018)</b>	<b>OY2 (FY2019)</b>
Total Mammograms/Patients	* 2,004	2,470
Total Gross Revenues (Charges)	\$1,055,919	\$1,300,756
Deductions from Gross Revenues	(\$540,711)	(\$665,842)
Total Net Revenue	\$515,208	\$634,914
Total Operating Expenses (Costs)	\$109,985	\$110,777
<b>Net Income</b>	<b>\$405,223</b>	<b>\$524,137</b>

\*Per clarifying information received on February 28, 2017.

In clarifying information received February 28, 2017, the applicant provides the assumptions it used in preparation of the pro forma financial statements. The assumptions provided by the applicant on February 28, 2017 are reasonable, including projected utilization, costs and charges. See the financial section of the application for the projections used regarding costs and charges. On the first page of the pro forma the applicant states 2,004 as the projected number of North Carolina patients in OY1 of the proposed project. In the other sections of the pro forma, the applicant states 2,005 as the projected number of procedures for North Carolina patients in OY1 of the proposed project. The applicant states in clarifying information on March 8, 2017 that 2,004 is the number of North Carolina procedures upon which its financial projections are based. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference. The applicant adequately demonstrates that the financial feasibility of the proposal is based upon reasonable and adequately supported assumptions regarding projected utilization, revenues (charges) and operating costs.

**Conclusion**

In summary, the applicant states that no funds are be required for capital needs for the project to bring the mobile mammography unit to North Carolina because the unit is already operational in Virginia. 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

Chesapeake Regional Medical Center proposes to bring an existing mobile mammography van into primarily five counties in northeastern North Carolina (Camden, Currituck, Dare, Pasquotank and Perquimans) to provide 3D mammography services which results in the development of a mobile diagnostic program. A mobile diagnostic program is a diagnostic center as defined by N.C. Gen. Stat. §131E -176(7a). The CRMC mobile mammography van is docked/recharged at Chesapeake Regional Medical Center in Chesapeake, Virginia. The

value of the existing 3D mammography unit that was purchased in February 2016 (\$760,000), already being utilized by CRMC, exceeds the statutory threshold promulgated in N.C. Gen. Stat. §131E -176(7a) of \$500,000 for a diagnostic center; therefore, bringing the existing equipment from Virginia into North Carolina requires a certificate of need.

The 2016 SMFP does not provide a need methodology for the establishment of diagnostic centers in North Carolina; nor does the SMFP specify a service area relative to diagnostic centers. The Criteria and Standards for Diagnostic Centers promulgated in 10A NCAC 14C .1802(3) 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 15, CRMC states that the geographic service area for its mobile mammography services will primarily be Camden, Currituck, Dare, Pasquotank and Perquimans counties; though if requested and feasible – it may travel into Gates or other nearby counties. The applicant may also serve residents of counties not included in the service area.

In Section III.6, page 18, the applicant provides a list by name and location of all existing facilities that operate mammography services in northeastern North Carolina, as illustrated below in the table:

<b>EXISTING MAMMOGRAPHY PROVIDERS NORTHEASTERN NORTH CAROLINA</b>		
<b>Facility</b>	<b>Mammography Service</b>	<b>County</b>
Outer Banks Hospital	Digital	Dare
Sentara Kitty Hawk	Digital	Dare
Chesapeake Regional Medical Group Surgical Care	Digital	Pasquotank
Sentara Albemarle Medical Center	Digital and 3D	Pasquotank

In Section III.6(a), page 19, the applicant states that although there are mammography facilities in Dare and Pasquotank counties, the geographic area is vast as summarized in these findings, Criterion (3), Analysis of Need. On page 20, the applicant states that there is a wide disparity by city, county and region in the number of mammography providers per 1,000 females, age 40 and above and per 100 miles. The applicant also states on page 20 that the data does not show how many mammography units operate at each provider location because the data is unavailable ([www.accessdata.fda.gov](http://www.accessdata.fda.gov)). Further, the applicant states that there are no mammography sites in three of the five counties in the proposed northeastern North Carolina service area - Camden, Currituck or Perquimans counties.

The discussions regarding analysis of need, alternatives, and competition found in Criteria (3), (4), and (18a), respectively, are incorporated herein by reference.

The applicant adequately demonstrates that the proposed project would not result in the unnecessary duplication of existing or approved mammography services in the proposed service area. 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

CRMC's mobile mammography services for northeastern North Carolina are proposed for 10 days per month, 12 months per year. Staff for the mobile van are already employed at CRMC's Breast Imaging Center. Staff are not permanently assigned to the mobile van and the mobile mammography service component does not require any additional FTEs. In Section VII, pages 39-41, the applicant states that CRMC's mobile mammography services staff 3.0 Full Time Equivalents (FTE): 1.0 (FTE) mammography technologist, 1.0 FTE registrar and 1.0 FTE driver. In Section VII.8, page 44, the applicant identifies Michael Petruschak, MD and Natalie Simmons, MD, as the Medical Directors for this program. In Section VII.7, page 44, the applicant states that nine of its eleven board certified radiologists are licensed in North Carolina, with at least six radiologists that will read all mammograms. Adequate costs for the health manpower positions proposed by the applicant are budgeted in the pro forma financial statements. 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 7-8, the applicant describes the ancillary and support services that will be provided by the facility. Exhibits C and D contain copies of the plan of care for the mammography service component and a sample hospital transfer agreement, respectively. Exhibit H contains copies of letters from physicians and Exhibit I has letters from other health care providers expressing support for the proposed project.

The applicant adequately demonstrates that the necessary ancillary and support services will be available and that the proposed services will be coordinated with the existing health care 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

In Section VI.12 and VI.13, pages 37, the applicant provides the historical payor mix for the mammography services component for FY2016, as shown in the following table.

<b>CRMC – MAMMOGRAPHY SERVICE COMPONENT HISTORICAL PAYOR MIX AS % OF TOTAL UTILIZATION (FY2016)</b>	
Self-Pay/Indigent/Charity	5%
Medicare/Medicare Managed Care	30%
Medicaid	2%
Commercial Insurance	55%
Managed Care	0%
Other	8%
<b>Total</b>	<b>100%</b>

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

<b>PERCENT OF POPULATION</b>						
<b>County</b>	<b>% 65+</b>	<b>% Female</b>	<b>% Racial &amp; Ethnic Minority *</b>	<b>% Persons in Poverty**</b>	<b>% &lt; Age 65 with a Disability</b>	<b>% &lt; Age 65 without Health Insurance**</b>
Camden	15%	50%	20%	10%	10%	16%
Currituck	15%	50%	13%	11%	8%	18%
Dare	19%	51%	12%	11%	10%	20%
Pasquotank	16%	51%	45%	19%	11%	17%
Perquimans	24%	52%	29%	17%	14%	17%
Statewide	15%	51%	36%	17%	10%	15%

Source: <http://www.census.gov/quickfacts/table>, 2014 Estimate as of December 22, 2015. \*Excludes “White alone” who are “not Hispanic or Latino” \*\*This geographic level of poverty and health estimates are not comparable to other geographic levels of these estimates. Some estimates presented here come from sample data, and thus have sampling errors that may render some apparent differences between geographies statistically indistinguishable. The vintage year (e.g., V2015) refers to the final year of the series (2010 thru 2015). Different vintage years of estimates are not comparable.”

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

The applicant demonstrates that it currently provides adequate access to medically underserved populations. Therefore, the application is conforming to this criterion.

- (b) Its past performance in meeting its obligation, if any, under any applicable regulations requiring provision of uncompensated care, community service, or access by minorities and handicapped persons to programs receiving federal assistance, including the existence of any civil rights access complaints against the applicant;

C

In Section VI.11, page 36, the applicant states that it has no obligation to provide uncompensated care or community service under federal regulations. However, for

CRMC Certificates of Public Need in Virginia, most of its projects have charity care conditions ranging from one to four percent of gross revenue derived from the specified approved service, regardless of patient origin.

The applicant states,

*“These charity care conditions require that CRMC must provide the COPN-approved services to all persons in need of the services, regardless of their ability to pay for them, and must provide as charity care to indigent patients free services or rate reductions for the services.”*

In Section VI.10, page 36, the applicant states that there have been no civil rights access complaints filed within the last five years against CRMC. Therefore, 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.14-15, page 38, the applicant provides the projected payor mix for the mammography services at CRMC (during the second full fiscal year of operation/FY 2018-2019), as shown in the following table:

<b>CRMC – MAMMOGRAPHY SERVICES PROJECTED PAYOR MIX AS % OF TOTAL UTILIZATION (OY2/FY2018-2019)</b>	
Self-Pay/Indigent/Charity	5%
Medicare/Medicare Managed Care	30%
Medicaid	2%
Commercial Insurance	55%
Managed Care	0%
Other	8%
<b>Total</b>	<b>100%</b>

As shown in the above referenced table, 42.0 percent of the facility's patients are projected to have some or all of their services paid for by Medicare and/or Medicaid; while 32.0 percent is true for the mammography service component. The applicant states that projected payor mixes are expected to be similar to current payor mixes for the facility and the mammography service component.

The applicant demonstrates that medically underserved populations would 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 V.4(c), page 31, and Section VI.5, page 34, the applicant describes the range of means by which a person will have access to CRMC's services. The applicant adequately demonstrates that they will provide a range of means by which a person can access the diagnostic imaging 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 clarifying information received on January 30 for Section V.1, page 27, the applicant states the following about how the mobile diagnostic program will accommodate the clinical needs of area health professional training programs:

*“There are no radiology technician programs in the proposed service area. There are, however, nursing and other health professional programs at Elizabeth City State University and the College of Albemarle. The mobile mammography unit, when in the State of North Carolina, can offer shadowing/observation opportunities as well as training for anyone in the process of receiving their radiologic technician certification.*

*Due to Chesapeake Regional Medical Center's long-standing interest in Northeastern North Carolina, we have established relationships with decision makers at both Elizabeth City State University and the College of Albemarle. We have shared the plans we have for this program with board members for each school and have made them aware of the educational opportunities and contact information for scheduling our unit.  
...*

The clarifying information received on January 30 includes correspondence from the chairman of the board of trustees of Elizabeth City State University. The information provided is reasonable and adequately supports a determination that the application is conforming to this criterion.

- (15) Repealed effective July 1, 1987.  
(16) Repealed effective July 1, 1987.  
(17) Repealed effective July 1, 1987.  
(18) Repealed effective July 1, 1987.
- (18a) The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact upon the cost effectiveness, quality, and access to the services proposed; and in the case



of applications for services where competition between providers will not have a favorable impact on cost-effectiveness, quality, and access to the services proposed, the applicant shall demonstrate that its application is for a service on which competition will not have a favorable impact.

C

Chesapeake Regional Medical Center proposes to bring an existing mobile mammography van into primarily five counties in northeastern North Carolina (Camden, Currituck, Dare, Pasquotank and Perquimans) to provide 3D mammography services which results in the development of a mobile diagnostic program. A mobile diagnostic program is a diagnostic center as defined by N.C. Gen. Stat. §131E -176(7a). The CRMC mobile mammography van is docked/recharged at Chesapeake Regional Medical Center in Chesapeake, Virginia. The value of the existing 3D mammography unit that was purchased in February 2016 (\$760,000), already being utilized by CRMC, exceeds the statutory threshold promulgated in N.C. Gen. Stat. §131E -176(7a) of \$500,000 for a diagnostic center; therefore, bringing the existing equipment from Virginia into North Carolina requires a certificate of need.

The 2016 SMFP does not provide a need methodology for the establishment of diagnostic centers in North Carolina; nor does the SMFP specify a service area relative to diagnostic centers. The Criteria and Standards for Diagnostic Centers promulgated in 10A NCAC 14C .1802(3) 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 15, CRMC states that the geographic service area for its mobile mammography services will primarily be Camden, Currituck, Dare, Pasquotank and Perquimans counties; though if requested and feasible – it may travel into Gates or other nearby counties. The applicant may also serve residents of counties not included in the service area.

The total number of mammography systems in the service area defined by the applicant will not increase as a result of this proposal.

In Section III.6, page 18, the applicant provides a list by name and location of all existing facilities that operate mammography services in northeastern North Carolina, as illustrated below in the table:

<b>EXISTING MAMMOGRAPHY PROVIDERS NORTHEASTERN NORTH CAROLINA</b>		
<b>Facility</b>	<b>Mammography Service</b>	<b>County</b>
Outer Banks Hospital	Digital	Dare
Sentara Kitty Hawk	Digital	Dare
Chesapeake Regional Medical Group Surgical Care	Digital	Pasquotank
Sentara Albemarle Medical Center	Digital and 3D	Pasquotank

In Section III.6(a), page 19, the applicant states that although there are mammography facilities in Dare and Pasquotank counties, the geographic area is vast as summarized in these findings, Criterion (3), Analysis of Need. On page 20, the applicant states that there is a wide disparity by city, county and region in the number of mammography providers per 1,000 females, age

40 and above and per 100 miles. The applicant also states on page 20 that the data does not show how many mammography units operate at each provider location because the data is unavailable ([www.accessdata.fda.gov](http://www.accessdata.fda.gov)). Further, the applicant states that there are no mammography sites in three of the five counties in the proposed northeastern North Carolina service area - Camden, Currituck or Perquimans counties.

In Section V.7, page 31, the applicant discusses how any enhanced competition in the service area will promote the cost-effectiveness, quality, and access to the proposed services. The applicant states,

*“The mobile mammography unit will foster healthy competition, as it will provide high quality services to underserved communities, at charges that are comparable to those offered by fixed-site mammography facilities.”*

The information in the application is reasonable and adequately demonstrates that any enhanced competition in the service area includes a positive impact on 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 to bring the existing mobile equipment into North Carolina and become a diagnostic center and that it is a cost-effective alternative. The discussions regarding analysis of need and alternatives found in Criteria (3) and (4), respectively, are incorporated herein by reference.
- The applicant adequately demonstrates that CRMC will continue to provide quality services. The discussion regarding quality found in Criterion (20) is incorporated herein by reference.
- The applicant adequately demonstrates that CRMC will continue to provide adequate access to medically underserved populations. The discussions regarding access found in Criteria (3) and (13) are 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.6-7, pages 9-10, the applicant describes efforts to ensure and maintain quality care and in Attachments C, E and F, the applicant provides documentation of CRMC's quality measures, including statements that no licenses or Medicare or Medicaid provider agreements associated with any of CRMC's facilities have ever been revoked. On page 9, the applicant states:

*“The mobile mammography unit is accredited by the American College of Radiology and meets all FDA and Mammography Quality and Safety Assurance (‘MQSA’) standards. ...*

*The mobile mammography unit adheres to the same quality assurance processes and standards as CRMC’s Breast Imaging Center. Staff competencies and licenses are tracked, daily quality tests are completed and logged, and data is reported to the MQSA database.”*

The information provided by the applicant is reasonable and supports the determination that 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 application is conforming to all applicable Criteria and Standards for Diagnostic Centers promulgated by 10A NCAC 14C Section .1800. See discussion below.

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

**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- The applicant proposes to bring an existing mobile mammography van into primarily five counties in northeastern North Carolina (Camden, Currituck, Dare, Pasquotank and Perquimans) to provide 3D mammography services which results in the development of a mobile diagnostic program. In Section III, pages 12 and 18, the applicant identifies other health service facilities that operate or have been approved to operate similar medical diagnostic equipment. However, the applicant correctly notes

in Sections II.8, page 11, III.5(c), page 16 and III.6(e) page 22, that comparable data about mammography utilization is unavailable. Therefore, one can reasonably conclude that there is insufficient publicly available data to determine if the similar medical diagnostic equipment was operating at 80 percent 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.

(2) *documentation that all existing and approved medical diagnostic equipment and services of the type proposed in the 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- The applicant states in Sections II.8, page 11, III.5(c), page 16 and III.6(e) page 22, that comparable data about mammography utilization is unavailable. Therefore, it can be reasonably concluded that the applicant cannot determine if the existing and approved medical diagnostic equipment and services of the type proposed in this CON application are projected to be utilized at 80 percent of the maximum number of procedures that the equipment is capable of performing at any time for other providers.

Furthermore, the applicant does not currently have existing or approved medical diagnostic equipment and services of the type proposed in the CON application operating in North Carolina, therefore, the applicant cannot project utilization 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 in North Carolina.

(3) *documentation that the applicant's utilization projections are based on the experience of the provider and on epidemiological studies; and*

-C- In Section II.5, pages 8-9, Section III, pages 12-23, and Section IV, page 24, the applicant documents that its utilization projections are based on its experience providing mammography services at CRMC and on epidemiological studies.

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

-C- In Sections II, III, IV, the pro formas, and in clarifying information received on February 28, 2017, the applicant provides the assumptions and data supporting the methodologies used to project utilization.