

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

DECISION DATE: November 29, 2012

FINDINGS DATE: December 6, 2012

PROJECT ANALYST: F. Gene DePorter

ASSISTANT CHIEF: Martha J. Frisone

PROJECT I.D. NUMBER: R-10023-12/ The Outer Banks Hospital, Inc. / Acquire the assets of Outer Banks Cancer Center in Nags Head, including one linear accelerator, CT simulator and related assets. /Dare County

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

G.S. 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

The Outer Banks Hospital, Inc. (OBH) proposes to acquire the assets of Outer Banks Cancer Center in Nags Head, including a linear accelerator (2009 Siemens OncoRay), CT simulator (GE Lightspeed) and related assets. The building is currently owned by Oncology Associates of NC, PLLC. OBH will continue operating the linear accelerator and CT simulator equipment in its current location and will lease the space which it is not acquiring. The applicant does not propose to acquire any medical equipment or develop any health service facility beds or services for which there is a need determination in the 2012 State Medical Facilities Plan (SMFP). Therefore, there are no need determinations that are applicable to this proposal. Furthermore there are no policies in the 2012 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- (2) Repealed effective July 1, 1987.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.

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The Outer Banks Hospital, Inc. (OBH) proposes to acquire the assets of the Outer Banks Cancer Center (OBCC). Outer Banks Cancer Center is currently owned and operated by Alliance Oncology of NC, PLLC (Alliance Oncology). The asset purchase includes the existing 3 year old linear accelerator and CT simulator. Alliance Oncology of North Carolina, an affiliate of Oncology Associates of Virginia, owns the building which houses the equipment. Upon acquiring the assets of OBCC, the facility will be renamed The Outer Banks Hospital Cancer Center (OBHCC). OBH proposes to lease the existing building located at 4125 Croatan Highway in Nags Head.

Population to be Served

The following table illustrates historical patient origin for the services provided at Outer Banks Hospital as reported by the applicant in Section III.4 (a), page 46.

COUNTY	% OF TOTAL PATIENTS
Dare	67.0%
Currituck	8.0%
Hyde	1.0%
Pasquotank	1.0%
Tyrrell	1.0%
Other counties *	22.0%
Total	100.0%

The other counties, which represent less than 1% each, are identified in a footnote note on page 46.

The following table illustrates projected patient origin for the radiation therapy services to be provided at OBHCC as reported by the applicant in Section III.5(c), page 47.

COUNTY	% OF TOTAL PATIENTS
Dare	85.7%
Other counties *	14.3%
Total	100.0%

*The other counties are identified in a footnote on page 47.

In Section III.1, page 39, the applicant provides the historical patient origin for Outer Banks Cancer Center, which the applicant obtained from the facility's 2012 Registration and Inventory which was submitted to the Division of Health Service Regulation. The facility reported that 72 of the 84 patients served were residents of Dare County, which is 85.7% [72 / 84 = 0.857]. The facility reported that 12 of the 84 patients were residents of

other counties, which is 14.3% [12 / 84 = 0.143]. In Section III.5 (d), page 47, the applicant states that projected patient origin at OBHCC is based on the historical patient origin at Outer Banks Cancer Center.

The applicant adequately identified the population to be served.

Analysis of Need to Acquire the Existing Linear Accelerator and CT Simulator

The applicant describes the “*unmet need that necessitated the inclusion of each of the proposed project components*” in Section III.1 (a), pages 26-34. On pages 26-28, the applicant states

“Since 2005, the Outer Banks Cancer Center has been in operation in Dare County providing radiation therapy treatment services to residents of the area. In 2009, Alliance Oncology acquired the Cancer Center from its previous owner and since that time has continued to provide radiation oncology services to residents of Dare County from the Nags Head facility. Recently, Alliance Oncology made the decision to divest itself of the Outer Banks Cancer Center and OBH made the decision to acquire the equipment and assets of the facility and to operate the service as a department of the hospital. Local access for residents of Dare County is critical because of the remoteness and configuration of this Outer Banks county [sic]. ... [T]here are only two roads connecting Dare County with the mainland ... 1) north of Kitty Hawk where US 158 crosses the Currituck Sound into Currituck County toward Elizabeth City and 2) south of Nags Head where US 64 crosses Roanoke Sound to Roanoke Island and Manteo, then across the Croatan Sound to the mainland and points west. Without the availability of the radiation therapy service in Nags Head, patients needing daily radiation therapy treatments would have to drive to Elizabeth City, the closest radiation therapy service, which is 58 miles away and approximately one hour driving time from Nags Head. For residents living farther south or farther north of Nags Head on the barrier island portion of Dare County, the drive would be even longer because there are no access roads to the mainland other than the two mentioned above. In addition to the radiation therapy service in Elizabeth City, there are two other options for Dare County residents; the Marion L. Shepard Cancer Center in Washington (two hours and 107 miles from Nags Head) and the Leo W. Jenkins Cancer Center in Greenville (two and a half hours and 129 miles from Nags Head). Clearly the best option for radiation therapy services for residents of Dare County is for the existing Cancer Center in Nags Head to remain part of the healthcare services available in the county.”

In Section III.1, page 32, the applicant states

“approximately 60 percent of all cancer patients will receive radiation therapy at some point during their treatment. Based on projections included in Section III.1.(b), nearly 100 patients in Year 1 would have to travel a minimum of two hours per day (round trip from Nags Head), five times a week to receive radiation therapy

treatments if no such service existing [sic] in Dare County. Certainly, that is not the best option for cancer patients in Dare County.”

Projected Utilization

The applicant describes the assumptions and methodology used to project utilization of the linear accelerator in Section III.1 (b), pages 34-42. The applicant projects that the linear accelerator will perform 2,500 equivalent simple treatment visits (ESTVs) in Project Year Three (10/1/15 to 9/30/16).

According to Table 9G in the 2012 SMFP, page 141, Dare County is Linear Accelerator Service Area 27, which includes Pasquotank, Camden, Chowan, Currituck, Dare, Gates, Perquimans and Tyrrell counties. According to Table 9E, page 139, there are two existing and no approved linear accelerators in Service Area 27: the one in Dare County and one in Pasquotank County. During Federal Fiscal Year 2010, the Pasquotank linear accelerator performed 5,426 ESTVs and the Dare County linear accelerator performed 3,370 ESTVs. Thus, the applicant projects that the linear accelerator will perform fewer procedures than it currently performs.

According to the 2012 SMFP there is a surplus of 0.7 linear accelerators in Service Area 27. However, the applicant does not propose to increase the number of linear accelerators in Service Area 27. The applicant proposes to acquire the existing Dare County linear accelerator so that radiation therapy services can continue to be provided in Dare County rather than forcing residents of Dare County to travel to other counties. If the existing Dare County linear accelerator did not exist and the ESTVs performed on the Dare County linear accelerator were performed on the Pasquotank linear accelerator instead (they would have to have been performed somewhere), based on the need methodology described on pages 134-135 of the 2012 SMFP, there would be a need for a second linear accelerator in Service Area 27 because the total number of ESTVs performed during FFY 2010 divided by 6,750 ESTVs per linear accelerator minus the number of linear accelerators (1) would be 0.3 [$8,796 / 6,750 = 1.3$; $1.3 - 1 = 0.3$].

Therefore, the Outer Banks Hospital [OBH], Inc, proposes to acquire the assets of The Outer Banks Cancer Center in Nags Head, including a linear accelerator (2009 Siemens Oncor) and CT simulator (GE Lightspeed). OBH will lease the Outer Banks Cancer Center building from the current owner (Oncology Associates of NC, PLLC).

If this service is not maintained in Nags Head current and future patients would have a 1 hour drive to Elizabeth City for radiation therapy and a 58 mile return trip. Residents living on the barrier island portion of Dare County would have a longer drive to the Marion L. Shepard Cancer Center in Washington [2 hours and 107 miles from Nags Head] and the Leo W. Jenkins Cancer Center in Greenville [a 2 ½ hour and 129 miles from Nags Head]. The best alternative is for the Outer Banks Cancer Center in Nags Head to remain a functioning part of the healthcare services in the county while operating as a department of the hospital. According to Table 9E, page 139, Chapter 9-Linear Accelerators, Outer

Banks Cancer Center (Dare County) and Albemarle Hospital (Pasquotank County) are in Service Area 27.

The applicant adequately demonstrates the need to acquire the existing assets of Alliance Oncology so that radiation therapy services can continue to be available to residents of Dare County.

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 45, the applicant discusses the following alternatives that were considered.

- 1) Maintain the status quo – The applicant states this alternative is *“not a viable alternative if Dare County residents are to be assured of local access to radiation therapy services in the future. Because Alliance Oncology has chosen to divest itself of the Outer Banks Cancer Center ..., another entity must assume ownership to keep the service active lest the Cancer Center be forced to close. The logical purchaser is the hospital as it is already the primary healthcare provider in the county and has strong ties with two major cancer programs at Vidant Health and Chesapeake Regional Medical Center.”*
- 2) Replace the Cancer Center in a new location – The applicant states this is not a cost-effective alternative compared to keeping the existing linear accelerator and CT simulator in the current location.

Furthermore, the application is conforming to all other applicable statutory review criteria, and is, therefore, approvable. An application that cannot be approved cannot be an effective alternative.

The applicant adequately demonstrates that the proposal to acquire the assets of the existing Outer Banks Cancer Center and to keep the equipment in the same location is the least costly or most effective alternative to meet the need to ensure continuing local access to radiation

therapy services for residents of Dare County. Therefore, the application is conforming to this criterion and is approved subject to the following conditions.

1. **The Outer Banks Hospital, Inc. shall materially comply with all representations made in the certificate of need application.**
 2. **The Outer Banks Hospital, Inc. 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 and that would otherwise require a certificate of need.**
 3. **The Outer Banks Hospital, Inc. shall acquire and operate no more than one linear accelerator and no more than one CT simulator.**
 4. **The Outer Banks Hospital, Inc. 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, page 80, the applicant projects the total capital cost for the proposed project will be \$1,132,000, as shown in the table below.

Description	Capital Cost
Asset Purchase	\$423,180
Fixed Equipment Purchase	\$597,000
Moveable Equipment Purchase	\$79,820
Consulting Fees	\$32,000
Total	\$1,132,000

In Section IX.1 (a), page 85 the applicant states there will be no start-up costs or initial operating expenses.

In Section VIII.8, Page 82, the applicant states that the capital cost will be funded with its reserves. Exhibit 20 contains a letter from the Vice-President, Business Operations OBH, and dated August 15, 2012, which states:

“OBH will fund the capital costs of the project, estimated to be \$1,132,000, with hospital reserves. As shown on page eight of the FY 2011 audited financials, included with the application, OBH has sufficient cash and Assets Limited as to Use in reserves for the capital costs of the proposed project.”

Exhibit 21 contains audited financial statements for OBH which show that, as of September 30, 2011, OBH had \$4,565,000 in cash and \$54,585,000 in net assets (total assets less total liabilities). The applicant adequately demonstrates the availability of sufficient funds for the capital needs of the proposed project.

The following table illustrates projected treatments, average charge, gross revenue, net revenue, expenses and net income for OBHCC through the third full fiscal year of operation, as reported by the applicant in Form C.

Year	# of Treatments	Average Charge	Gross Revenue	Net Revenue	Expenses	Net Income
4/1/13-9/30/13	1,201	\$1,908	\$2,291,613	\$958,785	\$967,342	(\$8,557)
10/1/13-9/30/14	2,434	\$2,004	\$4,878,268	\$1,996,314	\$1,994,453	\$1,860
10/1/14-9/30/15	2,478	\$2,104	\$5,215,073	\$2,103,434	\$2,052,827	\$50,607
10/1/15-9/30/16	2,500	\$2,209	\$5,523,826	\$2,200,484	\$2,112,069	\$88,415

As shown in the table above, the applicant projects that revenues will exceed expenses in each of the first three full fiscal years of operation.

The assumptions used by the applicant in preparation of the pro formas are reasonable. See the Financials Section for the pro formas and the applicant's assumptions. The applicant adequately demonstrated that the financial feasibility of the proposal is based upon reasonable projections of costs and revenues, and 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.

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The applicant proposes to acquire the assets of Outer Bank Cancer Center, including a 3 year old linear accelerator and CT Simulator. The applicant proposes to continue to operate the equipment at the current location. Dare County is part of Service Area 27, which also includes, Pasquotank, Camden, Chowan, Currituck, Gates, Perquimans, and Tyrell counties. The following table illustrates the existing and approved linear accelerators in Service Area 27.

Service Area 27 Linear Accelerators

Site	County	Number of Linear Accelerators	# of ESTVs FFY 2010
Albemarle Hospital	Pasquotank	1	5,426
Outer Banks Cancer Center	Dare	1	3,370

Source: 2012 SMFP, page 139.

The applicant does not propose to add an additional linear accelerator to the service area.

The applicant adequately demonstrated the need to acquire the existing linear accelerator and CT Simulator so that residents of Dare County would continue to have access to radiation therapy services. See Criterion (3) for discussion regarding the need to acquire the existing equipment which is incorporated hereby as if set forth fully herein. Therefore, the applicant adequately demonstrated that the proposal would not result in the unnecessary duplication of existing or approved health service capabilities or facilities. 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.

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In Section VII.1 (a), page 67, the applicant provides current and projected staffing, as illustrated in the table below.

Position	Alliance Full Time Equivalent Positions	Current Average Annual Salary	OBHCC Full Time Equivalent Positions	2015 Average Annual Salary
Radiation Therapist	1.75	\$72,245	1.75	\$79,405
Medical Physicist	0.5	\$170,775	0.5	\$187,700
Dosimetrist	0.5	\$95,013	0.5	\$104,430
Receptionist/Scheduler	1.0	\$27,040	1.00	\$29,720
Total	3.75	-	3.75	-

In Section VII.3, page 72, the applicant states that no new staff will be required.

In Section VII.8, page 75, the applicant identifies the Medical Director for OBHCC. See Exhibit 15 for letters from the two physicians who have expressed an interest in serving as Medical Director.

The applicant adequately demonstrates the availability of resources, including health manpower and management personnel, for the provision of the services proposed. 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.

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In Section II.2, page 20, the applicant states:

“As an existing radiation oncology service, all ancillary and support services are in place. The project does not propose to add any services or equipment; therefore, all

required support services for the radiation oncology service are currently available and will not change with the proposed project.”

The applicant also states on page 21:

“The ancillary and support services will be provided by staff already in place supporting the existing radiation oncology services. As an acute care provider OBH also has a full complement of ancillary and support service infrastructure in place.”

Exhibit 2 includes a letter signed by the President of OBH which states that all support services will be available.

Exhibit 14 contains letters from physicians and Vidant Health which document that the proposed services will be coordinated with the existing health care system.

The applicant adequately demonstrates that the necessary ancillary and support services would be available and that the proposed services would 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

NA

- (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, page 67, the applicant provides the FY 2011 payor mix for OBH, which is illustrated in the following table.

Payor Category	% of Total Patients / Cases / Procedures
Self Pay / Indigent / Charity	6.9%
Medicare / Medicare Managed Care	48.0%
Medicaid	17.5%
Managed Care	27.6%
Total	100.0%

In Section VI.13, page 68, the applicant provides the FY 2011 payor mix for Outer Banks Cancer Center, which is illustrated in the following table.

Payor Category	% of Total Patients / Procedures
Self Pay / Indigent / Charity	4.0%
Medicare / Medicare Managed Care	55.0%
Medicaid	5.0%
Managed Care	36.0%
Total	100.0%

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. The following table illustrates those percentages for Dare county and statewide.

	2010 Total # of Medicaid Eligibles as % of Total Population *	2010 Total # of Medicaid Eligibles Age 21 and older as % of Total Population *	2008-2009 % Uninsured (Estimate by Cecil G. Sheps Center) *
Dare County	11.0%	4.0%	20.8%
Statewide	17.0%	6.7%	19.7%

*More current data, particularly with regard to the estimated uninsured percentages was not available.

The majority of Medicaid eligibles are children under the age of 21. This age group would not typically utilize the health services proposed in this application.

Moreover, the number of persons eligible for Medicaid assistance may be greater than the number of Medicaid eligible's 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 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 or women utilizing health services. Furthermore, OSBM's website does not include information on the number of handicapped persons.

The applicant demonstrates that medically underserved populations have adequate access to the services provided by the hospital as well as the existing cancer center. 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;

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Recipients of Hill-Burton funds were required to provide uncompensated care, community service and access by minorities and handicapped persons. In Section VI.11, page 67, the applicant states “*OBH has no federal, state or local obligations to provide uncompensated care, community service or access to care for the medically underserved. However ... OBH provides care for any persons, regardless of their ability to pay, social status, race, sex, or physical abilities.*” In Section VI.10, pages 66-67, the applicant states that it is not aware of any documented civil rights equal access complaints or violations filed against OBH in the 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 69, the applicant provides the projected payor mix for the second project year, as illustrated in the table below.

FY 2015 Cancer Center Payor Mix

Cancer Center 10/1/2014 to 09/30/2015 Projected Patient Days/Procedures As A Percent of Total Utilization	
Self Pay Indigent/Charity	4.0%
Medicare/Medicare Managed Care	55.0%
Medicaid	5.0%
Commercial Insurance	NA
Managed Care	36.0%
Other	NA
TOTAL	100.0%

On page 69, the applicant states the projected payor mix is based on the historical payor mix. The applicant demonstrated that medically underserved populations will

have adequate access to the proposed radiation therapy 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.

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In Section VI.5, page 63, the applicant states that access will primarily be through physician referral.

The information provided is reasonable and credible and supports a finding of conformity with 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.

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In Section V.1, pages 53-54, the applicant identifies the eleven professional training programs for which the hospital currently serves as a clinical training site. The applicant states that OBHCC will also serve as a clinical training site. Exhibit 12 includes a sample agreement. The information provided by the applicant is reasonable, credible and supported. The application is conforming to this criterion.

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

C

The applicant proposes to acquire the assets of Outer Banks Cancer Center, including the existing linear accelerator and CT simulator. The equipment will continue to be operated in its current location by the hospital as a hospital department. The name of the facility will be changed to Outer Banks Hospital Cancer Center.

According to Table 9G in the 2012 SMFP, page 141, Dare County is Linear Accelerator Service Area 27, which includes Pasquotank, Camden, Chowan, Currituck, Dare, Gates, Perquimans and Tyrrell counties. According to Table 9E, page 139, there are two existing and no approved linear accelerators in Service Area 27: the one in Dare County and one in Pasquotank County. According to the 2012 SMFP there is a surplus of 0.7 linear accelerators in Service Area 27. However, the applicant does not propose to increase the number of linear accelerators in Service Area 27. The applicant proposes to acquire the existing Dare County linear accelerator so that radiation therapy services can continue to be provided in Dare County rather than forcing residents of Dare County to travel to other counties. If the existing Dare County linear accelerator did not exist and the ESTVs performed on the Dare County linear accelerator were performed on the Pasquotank linear accelerator instead (they would have to have been performed somewhere), based on the need methodology described on pages 134-135 of the 2012 SMFP, there would be a need for a second linear accelerator in Service Area 27 because the total number of ESTVs performed during FFY 2010 divided by 6,750 ESTVs per linear accelerator minus the number of linear accelerators (1) would be 0.3 [$8,796 / 6,750 = 1.3$; $1.3 - 1 = 0.3$].

In Section V.7, pages 59-60, the applicant discusses the impact of the proposed project on competition in the service area as it relates to promoting cost-effectiveness, quality and access. 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 provided by the applicant in those sections is reasonable and credible and adequately demonstrates that the expected effects of the proposal on competition in the service area include 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 acquire the assets of Outer Banks Cancer Center so that the residents of Dare County will continue to have access to radiation therapy services and that it is a cost-effective alternative;
- The applicant has and will continue to provide quality services; and
- The applicant has and will continue to provide adequate access to medically underserved populations.

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

OBH is accredited by the Joint Commission and certified for Medicare and Medicaid participation. According to the files in the Department of Health and Human Services, Centers for Medicare & Medicaid Services, no incidents occurred, within the eighteen months immediately preceding the date of this decision, for which any sanctions or

penalties related to quality of care were imposed by the State on the hospital. Therefore, the application is conforming to this criterion.

- (21) Repealed effective July 1, 1987.
- (b) The Department is authorized to adopt rules for the review of particular types of applications that will be used in addition to those criteria outlined in subsection (a) of this section and may vary according to the purpose for which a particular review is being conducted or the type of health service reviewed. No such rule adopted by the Department shall require an academic medical center teaching hospital, as defined by the State Medical Facilities Plan, to demonstrate that any facility or service at another hospital is being appropriately utilized in order for that academic medical center teaching hospital to be approved for the issuance of a certificate of need to develop any similar facility or service.

NA