

## ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

DECISION DATE: June 26, 2013

PROJECT ANALYST: Michael J. McKillip

ASSISTANT CHIEF: Martha J. Frisone

PROJECT I.D. NUMBER: R-10114-13 / The Outer Banks Hospital, Inc. / Develop one additional operating room / 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.

C

The applicant, The Outer Banks Hospital, Inc. [OBH] proposes to add one additional operating room by constructing a 5,156 square foot addition to its existing surgical department.

The 2013 State Medical Facilities Plan (SMFP) identifies a need determination for one additional operating room for Dare County. The applicant proposes to develop no more than one additional operating room. Thus, the application is conforming to the need determination in the 2013 SMFP.

Additionally, Policy GEN-3 of the 2012 SMFP is applicable to this review. Policy GEN-3: Basic Principles states:

*“A certificate of need applicant applying to develop or offer a new institutional health service for which there is a need determination in the North Carolina State Medical Facilities Plan shall demonstrate how the project will promote safety and quality in the delivery of health care services while promoting equitable access and maximizing healthcare value for resources expended. A certificate of need applicant shall document its plans for providing access to services for patients with limited*

*financial resources and demonstrate the availability of capacity to provide these services. A certificate of need applicant shall also document how its projected volumes incorporate these concepts in meeting the need identified in the State Medical Facilities Plan as well as addressing the needs of all residents in the proposed service area.”*

*Policy GEN-3* – In Section III.4, page 40, OBH describes how it believes the project conforms with Policy GEN-3. OBH describes how its proposal will promote safety and quality in Section II.8, pages 15-16, Exhibits D and E, and Section II.6, pages 13-14. The information provided by the applicant is reasonable, credible and supports the determination that the applicant’s proposal will promote safety and quality.

OBH describes how its proposal will promote equitable access in Section VI, pages 54-60. The information provided by the applicant is reasonable, credible and supports the determination that the applicant’s proposal will promote equitable access.

OBH describes how its proposal will maximize health care value for resources expended in Section II.6, pages 13-14, Section III.1, pages 33-38, Section IV, pages 45-46, Section X and the pro forma financial statements, pages 75-86. The information provided by the applicant is reasonable, credible and supports the determination that the applicant’s proposal will maximize health care value for resources expended.

OBH adequately demonstrates how its proposal will promote safety and quality, equitable access and maximize health care value for resources expended. Therefore, the application is consistent with Policy GEN-3.

Additionally, Policy GEN-4 of the 2012 SMFP is applicable to this review. Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities states:

*“Any person proposing a capital expenditure greater than \$2 million to develop, replace, renovate or add to a health service facility pursuant to G.S. 131E-178 shall include in its certificate of need application a written statement describing the project’s plan to assure improved energy efficiency and water conservation.*

*In approving a certificate of need proposing an expenditure greater than \$5 million to develop, replace, renovate or add to a health service facility pursuant to G.S. 131E-178, the Certificate of Need Section shall impose a condition requiring the applicant to develop and implement an Energy Efficiency and Sustainability Plan for the project that conforms to or exceeds energy efficiency and water conservation standards incorporated in the latest editions of the North Carolina State Building Codes. The plan must be consistent with the applicant’s representation in the written statement as described in paragraph one of Policy GEN-4.*

*Any person awarded a certificate of need for a project or an exemption from review pursuant to G.S. 131E-184 are required to submit a plan for energy efficiency and water conservation that conforms to the rules, codes and standards implemented by*

*the Construction Section of the Division of Health Service Regulation. The plan must be consistent with the applicant's representation in the written statement as described in paragraph one of Policy GEN-4. The plan shall not adversely affect patient or resident health, safety or infection control."*

In Section III.4, pages 40-41, the applicant states:

*"Vidant Health (VH), Chesapeake Hospital Authority (CHA), and The Outer Banks Hospital (OBH) are committed to constructing facilities that are energy efficient and promote water conservation. ... VH, CHA and OBH will conform to the energy efficiency and water conservation rules, codes and standards implemented by the Construction Section of the Division of Health Services Regulation and required by the North Carolina State Building Code. During the design of the this project, the Vidant Health Office of Facilities and Properties, in conjunction with the OBH Plant Operations Department, will work with the project Architects and Engineers to assure that the latest technologies for enhanced building energy and water conservation are evaluated for the project and incorporated into the facility where most appropriate."*

The applicant adequately demonstrates that it will assure improved energy efficiency and water conservation in the proposed addition of one operating room to the existing surgical department. Therefore, the application is consistent with Policy GEN-4.

In summary, the application is conforming to the need determination in the 2013 SMFP, and is consistent with Policy GEN-3 and Policy GEN-4. Therefore, the application is conforming to this criterion.

- (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, OBH, proposes to add one shared operating room to its existing surgical suite for a total of three shared operating rooms upon project completion. The applicant states that it will construct an addition to the existing surgical suite to accommodate the additional operating room and associated support functions. In Section II.1, page 11, the applicant describes the proposed project as follows:

*"To physically accommodate the additional operating room, OBH is proposing to add a new 5,165 square foot addition to the hospital. The addition will be physically connected to the existing hospital and adjacent to the existing surgical suite. The*

*new addition will be located in space between the existing hospital and the medical office building directly behind it. As a result of the project, OBH will only give up five parking spaces and will have to relocate a mobile trailer to a new location. The new addition will not only allow for an additional operating room, but will also allow for needed support space including equipment and supply storage, staff and surgeon lockers and lounge, offices, and public toilets for family members. ... OBH is also proposing to renovate 333 square feet of space in the existing surgical suite. Currently, there are three offices located in the pre/post operative area. These offices will be converted to allow for three additional pre/post operative areas to accommodate the additional operating room. The offices will be relocated to the new addition.”*

**Population to be Served**

In Section III.6, the applicant provides projected patient origin for OBH’s surgical services in the first two years of operation, as shown in the table below.

<b>County</b>	<b>Percent of Total</b>
Dare	79.3%
Currituck	9.1%
Hyde	2.2%
Other NC counties	2.9%
Out of State	6.5%
<b>TOTAL</b>	<b>100.0%</b>

On page 42 of the application, the applicant states, “OBH assumes future surgical patient origin will approximate current (FY12) actual patient origin.” The applicant adequately identified the population proposed to be served.

**Need for the Project**

In Section III.1(a) of the application, the applicant describes the factors supporting the need for the proposed project, including, the historical utilization and capacity of OBH’s existing operating rooms (pages 33-35), the projected growth in surgical service utilization at OBH (pages 35-37), the need to contain costs and operate efficiently (page 37), the need to accommodate additional surgeons and surgical specialties (page 37), and the need to improve patient and physician satisfaction (pages 37-38).

In Section IV.1, pages 45-47, the applicant provides tables showing the historical and projected utilization for OBH’s operating rooms through the first three years of operation (FY2016-FY2018) for the proposed project, which is summarized below:

**Outer Banks Hospital Operating Room Utilization**

<b>Fiscal Year</b>	<b>Operating Rooms**</b>	<b>Outpatient Surgical Cases</b>	<b>Inpatient Surgical Cases**</b>	<b>Total Surgical Cases</b>	<b>Percent Change</b>
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FY2011 Actual	2	1,478	296	1,774	---
FY2012 Actual	2	1,779	292	2,071	16.7%
FY2013 Projected*	2	1,713	336	2,049	-1.1%
FY2014 Projected	2	1,804	337	2,141	4.5%
FY2015 Projected	2	1,877	350	2,227	4.0%
FY2016 Project Year 1	3	1,942	362	2,304	3.5%
FY2017 Project Year 2	3	2,001	373	2,374	3.0%
FY2018 Project Year 3	3	2,051	383	2,434	2.5%

\*Applicant states FY2013 is projected based on five months of actual data annualized.

\*\*Excludes one dedicated C-Section surgical operating room and C-Section surgical cases.

As indicated in the above table, the applicant projects it will perform 383 inpatient surgical cases and 2,051 outpatient surgical cases in the three shared operating rooms at OBH in the third operating year of the proposed project (FY2018). Based on the utilization standards required in 10A NCAC 14C .2103(b)(1), the number of operating rooms required would be three  $[(2,051 \times 1.5 \text{ hours}) + (383 \times 3.0 \text{ hours}) = 4,225.5 \text{ hours}; 4,225.5 \text{ hours}/1,872 \text{ hours} = 2.26]$ .

In Section IV.2, page 46, the applicant describes the assumptions and methodology used to project the number of surgical cases to be provided at OBH during the first three years of operation as follows:

*“From FY08-13, OBH’s total OR volume growth averaged 8.6% per year. To be conservative, OBH does not believe this level of growth will continue. Much of the current growth is due to OBH being a relatively new hospital in a market that previously did not have a hospital in the county. OBH has been developing services and a medical staff over the last 10 years, generating significant year over year growth rates. However, since surgical volume at OBH is not heavily dependent on the tourist population like the ED and other outpatient services are, OBH believes the rate of growth will begin to significantly decline towards the county’s population growth rate of approximately 1% per year as the hospital completes and maintains its surgical recruitment and solidifies its complement of surgical services.”*

In Section III.1, pages 33-36, the applicant describes the historical and projected utilization of OBH’s operating rooms as follows:

*“Since its first full operating year in FY2003, OBH’s surgical volume has more than tripled from 610 surgeries in FY03 to an estimated annualized volume of 2,049 surgeries in FY13 (Figure III.1). In fact, from FY03-annualized FY13, volumes have increase on average 12.9% per year. Over this period, OBH has performed over 11,400 ambulatory surgical cases and over 3,300 inpatient surgical cases. In FY 2012 alone, 17 physicians performed almost 2,100 surgeries on patients. In order to accomplish this, OBH had to operate at 95% of its functional capacity in order meet the demand.*

*Operating close to full capacity of its existing two operating rooms is currently causing significant access issues at OBH. Without sufficient capacity, OBH cannot provide surgical services to all residents in its service area who need care. This ultimately*

*results in delayed care due to scheduling and block time constraints or forces patients to leave their community for care, with the next closest provider being an hour and 11 minutes drive time away. In fact, in FY11 (most recent data available at time of filing) 3 out of every 4 inpatient surgical patients left Dare County for care at another facility [See Table III.3 on page 35]. In total, 1 out of every 2 inpatient surgical patients leaves Dare County for a Virginia Hospital. With almost 15% of OBH's surgical patients being medically underserved (Medicare and Self Pay), the current capacity constraints are putting a greater unnecessary burden on this population, many of whom do not have the ability to travel to another facility for care. ... As the only provider of inpatient and outpatient surgery in Dare County, physicians and patients rely on OBH to possess the resources, technology, staff, and capacity needed to at least meet current demand for surgical services. OBH needs additional OR capacity to safely and effectively address demand already experienced by the facility.*

*With double digit annual percent increases in surgical volume since 2003 and with more recent 8.6% annual increases in surgical volumes over the last 5 years, OBH is reaching maximum capacity of its existing two operating rooms. Not only is the hospital experiencing difficulty in meeting current volume as stated above, the issues will amplify as the need for surgical services continues to increase. As Section IV of this application illustrates, OBH is conservatively projecting to experience average annual percent increases in surgical volume of 3.2% through FY18 (Figure III.4). At this rate of growth, OBH will have to operate at 113% capacity (Figure III.5) to meet the demand. Operating at this level is not achievable or obtainable without an additional operating room. OBH would be forced to scale back service lines, manage long wait lists, and/or divert patients to other facilities in order to meet the demand. None of these options are optimal for patient care and health status improvement.”*

The following table shows OBH's historical operating room utilization as reported in its *Hospital License Renewal Application* forms for 2009-2012.

**Outer Banks Hospital Operating Room Utilization**

<b>Fiscal Year</b>	<b>Operating Rooms*</b>	<b>Outpatient Surgical Cases</b>	<b>Inpatient Surgical Cases*</b>	<b>Total Surgical Cases</b>	<b>Percent Change</b>
2008	2	1,009	348	1,357	---
2009	2	917	243	1,160	-14.5%
2010	2	1,332	325	1,657	42.8%

2011	2	1,478	297	1,775	7.1%
2012	2	1,778	292	2,070	16.6%

Source: *Hospital License Renewal Application* forms for 2009-2013

\*Excludes one dedicated C-Section surgical operating room and C-Section surgical cases.

As indicated in the table above, the utilization of the applicant's operating rooms increased from 1,357 surgical cases in FY2008 to 2,070 surgical cases in FY2012, or by an average of approximately 11 percent per year over the four-year period. In this application, the applicant projects operating room utilization will increase from 2,071 surgical cases in FY2012 to 2,434 surgical cases in FY2018, or by less than three percent per year over the six-year period. Exhibit M of the application contains letters from physicians and surgeons expressing support for the proposed project. The projected utilization of the operating rooms at OBH is based on reasonable, credible and supported assumptions. OBH adequately demonstrates the need for one additional shared operating room.

### Access

The applicant projects 46.5% of its patients will be covered by Medicare (37.4%) and Medicaid (9.1%). The applicant demonstrates adequate access for medically underserved groups to the proposed services.

In summary, the applicant adequately identified the population to be served, adequately demonstrated the need the population projected to be served has for the proposed project, and demonstrated all residents of the service area, and, in particular, underserved groups, are likely to have access to the services proposed. 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.8, page 43, the applicant describes the alternatives considered, including maintaining the status quo and developing a freestanding ambulatory surgery center.

- The applicant states it rejected the status quo alternative due to the need to increase capacity to meet the current and projected need for surgical services, improve patient

and physician satisfaction, and contain costs while improving the efficiency of surgical services.

- The applicant considered the alternative of developing a freestanding ambulatory surgery center, but rejected it because of the higher operating costs due to the need to duplicate ancillary and support services.

The applicant adequately demonstrated that the proposal is its least costly or most effective alternative to meet the 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 its proposal is the least costly or most effective alternative to meet the need. Therefore, the application is conforming to this criterion and 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 develop no more than one additional operating room for a total of not more than three shared operating rooms and one dedicated C-Section operating room upon completion of the project.**
  - 3. 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.**
  - 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.1, the applicant projects its capital cost for the project to be \$4,246,095. In Section VIII.3, the applicant states the capital cost will be financed with accumulated reserves of OBH. In Section IX.1, the applicant projects no start-up or initial operating expenses. In Exhibit P of the application, the applicant provides a letter signed by both the President and Vice President of Business Operations for OBH, which states



*“I, Ronnie Sloan, President for The Outer Banks Hospital (OBH) and Todd Warlitner, Vice President of Business Operations for OBH, DO HEREBY CERTIFY that OBH will commit \$4,246,095 in accumulated reserves in order to acquire a new operating room, including all construction, renovation, and equipment needed. OBH’s accumulated reserves can support this project with no negative impact to the overall financial health of the hospital.”*

Exhibit Q of the application contains audited financial statements for OBH for the year ended September 30, 2012, which documents that OBH had \$5 million in cash and \$16.6 million in total current assets as of September 30, 2012. The applicant adequately demonstrated the availability of sufficient funds for the capital needs of the proposal.

In pro forma financial statements for OBH’s surgical services (Form C), the applicant projects revenues will exceed expenses in each of the first three operating years, as shown below:

**Outer Banks Hospital Surgical Services**

	<b>FY2016 Year 1</b>	<b>FY2017 Year 2</b>	<b>FY2018 Year 3</b>
Total Net Revenue	\$11,900,693	\$12,625,445	\$13,329,314
Total Expenses	\$9,298,623	\$9,685,896	\$10,065,958
Net Income (Loss)	\$2,602,070	\$2,939,549	\$3,263,356

Operating costs and revenues are based on reasonable assumptions including projected utilization. See the pro forma financial statements in the application for the assumptions. See Criterion (3) for discussion regarding utilization assumptions which is incorporated hereby as if set forth fully herein. The applicant adequately demonstrated that the financial feasibility of the proposal is based upon reasonable projections of operating costs and revenues, and the application is conforming with 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**

OBH proposes to add one shared operating room to its existing surgical suite for a total of three shared operating rooms upon project completion. There is currently one other provider of surgical services in the applicant’s proposed service area. RMS Surgery Center (RMS) is a multispecialty ambulatory surgery center located in Kitty Hawk in Dare County. RMS is listed as a “chronically underutilized” facility in the table of “Underutilized Facilities: Excluded from the Need Determinations” on page 85 of the 2013 State Medical Facilities Plan (SMFP). The 2013 SMFP defines chronically underutilized facilities as “licensed facilities operating at less than 40 percent utilization for the past two fiscal years, which have been licensed long enough to submit at least three License Renewal Applications to the Division of Health Service Regulation.” In FY2012, RMS reported performing 784 surgical cases in their two existing ambulatory surgery operating rooms, which is equivalent to an average utilization of 31 percent of capacity based on the utilization standards in the 2013

SMFP operating room need methodology [2 operating rooms X 1,872 hours = 3,744 total available surgical hours; 784 surgical cases X 1.5 hours/case = 1,176 hours of utilization; 1,176 hours of surgical utilization/3,744 available surgical hours = 0.31]. However, in addition to the 784 surgical cases performed during FY2012, 574 gastrointestinal endoscopy procedures and 283 pain management procedures were performed in the two operating rooms at RMS.

In Section III.9 (b), page 44, the applicant states

*“RMS currently has two operating rooms and is only operating at 27% capacity. In fact, the 2013 SMFP identified RMS as an underutilized facility. The ‘part-time’ nature of the facility using physicians that travel to the facility 1–2 days per week from other areas of the State is not sufficient to meet the demand. This is evident by OBH operating its two operating rooms at 95% capacity. The RMS model is not conducive to meeting the daily surgical needs of Dare County residents. Therefore, the additional operating is best located at an over utilized facility that can provide both inpatient and ambulatory surgery care on a 24/7 basis.”*

In Section IV.1, pages 45-47, the applicant provides tables showing the historical and projected utilization for OBH’s operating rooms through the first three years of operation (FY2016-FY2018) for the proposed project, which is summarized below:

**Outer Banks Hospital Operating Room Utilization**

<b>Fiscal Year</b>	<b>Operating Rooms**</b>	<b>Outpatient Surgical Cases</b>	<b>Inpatient Surgical Cases**</b>	<b>Total Surgical Cases</b>	<b>Percent of Capacity</b>
FY2011 Actual	2	1,478	296	1,774	82.9%
FY2012 Actual	2	1,779	292	2,071	94.7%
FY2013 Projected*	2	1,713	336	2,049	95.6%
FY2014 Projected	2	1,804	337	2,141	99.3%
FY2015 Projected	2	1,877	350	2,227	103.2%
FY2016 Project Year 1	3	1,942	362	2,304	71.2%
FY2017 Project Year 2	3	2,001	373	2,374	73.4%
FY2018 Project Year 3	3	2,051	383	2,434	75.2%

\*Applicant states FY2013 is projected based on five months of actual data annualized.

\*\*Excludes one dedicated C-Section surgical operating room and C-Section surgical cases.

As shown above, in FY2105, OBH projects the two operating rooms will operate at 103.2% of capacity  $(((1,877 \times 1.5) + (350 \times 3.0)) / (2 \times 1,872)) = 1.032$ . OBH adequately demonstrated the need to develop one additional shared operating room, given that the two existing shared operating rooms would no longer be able to accommodate the hospital’s projected surgical case volumes. Consequently, the applicant adequately demonstrates the proposed project would not result in the unnecessary duplication of existing or approved health service capabilities or facilities in the applicant’s service area. Therefore, the application is conforming with 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 61-62, the applicant provides the current and proposed staffing for OBH's surgical services, as shown in the table below.

<b>OBH Surgical Services Staffing</b>	<b>Current FTEs</b>	<b>Proposed FTEs</b>
Administrator	1.0	1.0
Registered Nurse	10.3	12.3
Surgical Technicians	4.0	6.0
Non-Health Technical Personnel	3.1	4.1
<b>Total</b>	<b>18.4</b>	<b>23.4</b>

The applicant states the proposed project will result in the addition of two registered nurses two surgical technicians, and one clerical support position. In Section VII.3, page 63, the applicant states that it does not anticipate any difficulties identifying, hiring, and retaining qualified staff for the proposed project. In Section VII.8, page 66, the applicant identifies Gary Hunter, D.O. as the Surgery Department Chair for OBH. Exhibit M of the application contains copies of letters from physician and surgeons 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, page 12, the applicant states that all of the necessary ancillary and support services for the proposed services are currently provided at OBH. Section V.2, page 48, contains a list of facilities with which OBH has transfer agreements, and Exhibit L of the application contains a copy of a sample transfer agreement. Exhibit M contains copies of letters from physician and surgeons expressing support for the proposed project. The applicant adequately demonstrates that necessary ancillary and support services will be available and that the proposed project will be coordinated with the existing health care system. Therefore, the application is conforming with 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.

C

In Section XI.53, the applicant states the proposed addition will be 5,156 square feet, and the project includes 333 square feet of renovations. Exhibit R contains a letter from the Chief Facilities Officer for Vidant Health, who is a registered architect, which certifies that the total construction and equipment costs are estimated to be \$4,246,095, which is consistent with the costs reported by the applicant in Section VIII.1, page 69. In Section X.8, pages 90-92, the applicant states that applicable energy savings features will be incorporated into the plans. The applicant adequately demonstrates that the cost, design and means of construction represent the most reasonable alternative for the project it proposes, and that the construction costs will not unduly increase costs and charges for health services. See Criterion (5) for discussion of costs and charges, which is incorporated hereby as if set forth fully herein. Therefore, the application is conforming to this criterion.

- (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.13, page 59, the applicant provides the payer mix during FY2012 for the surgical services at OBH, as shown in the table below.

<b>OBH Surgical Services Payer Category</b>	<b>Procedures as % of Total</b>
Medicare	37.4%
Medicaid	9.1%
Commercial	44.8%
Self Pay	5.6%
Other	3.1%
<b>Total</b>	<b>100.0%</b>

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 CY 2008-2009 (Estimate by Cecil G. Sheps Center)</b>
Dare	11%	4.0%	20.8%
Currituck	11%	4.6%	20.2%
Hyde	20%	10.3%	26.8%
<b>Statewide</b>	<b>17%</b>	<b>6.7%</b>	<b>19.7%</b>

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 surgical 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 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 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;

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 58, the applicant states:

*“OBH has no federal, state or local obligations to provide uncompensated care for medically underserved, minorities, or handicapped persons. However, as described in the response to Question VI.2, OBH provides care for any person, regardless of their ability to pay, social status, race, sex, or physical abilities. During the past year, OBH has provided over \$12 million in uncompensated care. OBH expects to continue its open access of care following the implementation of the proposed project.”*

In Section VI.10 (a), page 58, the applicant states that no Office of Civil Rights complaints have been filed against OBH in last five years. 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, page 59, the applicant provides the projected payer mix for the second full fiscal year following completion of the proposed project (FY2017) for the surgical services at OBH, as shown in the table below.

<b>OBH Surgical Services Payer Category</b>	<b>Procedures as % of Total</b>
Medicare	37.4%
Medicaid	9.1%
Commercial	44.8%
Self Pay	5.6%
Other	3.1%
<b>Total</b>	<b>100.0%</b>

On page 59, the applicant states, *“OBH assumes the projected payer mix will approximate the historical payer mix.”* The applicant demonstrates that medically underserved populations 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(a), page 57, the applicant describes the range of means by which a person will have access to its services. The information provided is reasonable and credible and supports a finding of conformity 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 OBH has established relationships with area health professional training programs, including the East Carolina Schools of Medicine, Nursing, Allied Health Sciences, and Social Work, Medical College of Virginia, Pitt Edgecombe Community College, and Pitt Community College. Exhibit K contains a sample copy of OBH's training program affiliation agreement. The information provided in Section V.1 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

OBH proposes to add one shared operating room to its existing surgical suite for a total of three shared operating rooms upon project completion. There is currently one other provider of surgical services in the applicant's proposed service area. RMS Surgery Center (RMS) is a multispecialty ambulatory surgery center located in Kitty Hawk in Dare County. RMS is listed as a "*chronically underutilized*" facility in the table of "*Underutilized Facilities: Excluded from the Need Determinations*" on page 85 of the 2013 State Medical Facilities Plan (SMFP). In FY2012, RMS reported performing 784 surgical cases in their two existing ambulatory surgery operating rooms, which is equivalent to an average utilization of 31 percent of capacity based on the utilization standards in the 2013 SMFP operating room need methodology [2 operating rooms X 1,872 hours = 3,744 total available surgical hours; 784 surgical cases X 1.5 hours/case = 1,176 hours of utilization; 1,176 hours of surgical utilization/3,744 available surgical hours = 0.31]. However, in addition to the 784 surgical cases performed during FY2012, 574 gastrointestinal endoscopy procedures and 283 pain management procedures were performed in the two operating rooms at RMS.



In Section V.7, pages 52-53, 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. The applicant states

*“The proposed project will foster competition by promoting high quality, delivering cost effective services, and providing enhanced access to inpatient and outpatient surgical services. Some examples of how OBH will accomplish this through the proposed project are described below:*

- *OBH will use long-standing experience it has in providing community level surgical services to provide the highest quality services to its patients.*
- *OBH is uniquely positioned to support the efficient integration of local community health care services, while maintaining the highest standards of patient care. OBH will use this unique position to promote, integrate, and deliver high quality surgical services to the residents of Dare County and beyond.*
- *OBH’s comprehensive quality assurance program ensures continuation of a high standard of care for all people in the service area. The proposed additional operating room will be seamlessly integrated into OBH’s overall surgical capacity and assure patients receive the highest level of service the hospital can offer.*
- *OBH will use the proposed additional operating room to enhance the operational efficiency of surgical services and to increase patient access. These efforts will contain costs and improve access to surgical services.*
- *As the only acute care hospital in Dare County, OBH offers additional support and ancillary services on-site and provides care to both inpatients and outpatients. OBH uses these services to assure patients have timely, complete, comprehensive, and quality healthcare.*
- *OBH’s mission is to ‘enhance quality of life for the residents and visitors of Dare County and the surrounding region by promoting wellness and providing the highest quality healthcare services.’ OBH is dedicated to offering needed healthcare services to anyone in the community, especially the medically underserved populations. OBH will use the proposed additional operating room capacity to assure surgical services are available to all members of the community – particularly the medically underserved.*
- *The proposed project will also allow OBH to offer more education and research opportunities due to the larger patient base that can obtain care there.*

*The proposed project will improve quality, reduce patient costs and increase patient access to the latest advancements in medicine. All of the above examples will promote cost effectiveness, quality and access to services and ultimately foster competition in eastern NC.”*

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 develop one additional operating room and that it is a cost-effective alternative;
- ◆ The applicant adequately demonstrates that it will continue to provide quality services; and
- ◆ The applicant demonstrates that it 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 certified by CMS for Medicare and Medicaid participation, and licensed by the NC Department of Health and Human Services. According to files in the Acute and Home Care Licensure and Certification Section in the Division of Health Service Regulation, no incidents have occurred at OBH within the eighteen months immediately preceding the date of the decision for which any sanctions or penalties related to quality of care were imposed by the State. 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.

C

OBH proposes to add one shared operating room to its existing surgical suite for a total of three shared operating rooms upon project completion. Therefore, the Criteria and Standards for Surgical Services and Operating Rooms, promulgated in 10A NCAC 14C .2100 are applicable to this review. The application is conforming to all applicable Criteria and Standards for Surgical Services and Operating Rooms. The specific criteria are discussed below.

**SECTION .2100 – CRITERIA AND STANDARDS FOR SURGICAL SERVICES AND OPERATING ROOMS**

**10A NCAC 14C .2102 INFORMATION REQUIRED OF APPLICANT**

*(a) An applicant proposing to establish a new ambulatory surgical facility, to establish a new campus of an existing facility, to establish a new hospital, to convert a specialty ambulatory surgical program to a multispecialty ambulatory surgical program or to add a specialty to a specialty ambulatory surgical program shall identify each of the following specialty areas that will be provided in the facility:*

- (1) gynecology;*
- (2) otolaryngology;*
- (3) plastic surgery;*
- (4) general surgery;*
- (5) ophthalmology;*
- (6) orthopedic;*
- (7) oral surgery; and*
- (8) other specialty area identified by the applicant.*

-NA- The applicant proposes to add one operating room to its existing surgical department in the hospital. The applicant is not proposing to establish a new ambulatory surgical facility, or establish a new campus of an existing facility, or establish a new hospital, or convert a specialty ambulatory surgical program to a multispecialty ambulatory surgical program, or to add a specialty to a specialty ambulatory surgical program.

*(b) An applicant proposing to increase the number of operating rooms in a service area, to convert a specialty ambulatory surgical program to a multispecialty ambulatory surgical program or to add a specialty to a specialty ambulatory surgical program shall provide the following information:*

- (1) the number and type of operating rooms in each facility which the applicant or a related entity owns a controlling interest in and is located in the service area, (separately identifying the number of dedicated open heart and dedicated C-Section rooms);*

-C- In Section II.10, page 19, the applicant states OBH has two shared operating rooms and one dedicated C-Section operating room.

- (2) *the number and type of operating rooms to be located in each facility which the applicant or a related entity owns a controlling interest in and is located in the service area after completion of the proposed project and all previously approved projects related to these facilities (separately identifying the number of dedicated open heart and dedicated C-Section rooms);*
- C- In Section II.10, page 19, the applicant states OBH will have three shared operating rooms and one dedicated C-Section operating room after completion of the proposed project.
- (3) *the number of inpatient surgical cases, excluding trauma cases reported by Level I, II, or III trauma centers, cases reported by designated burn intensive care units, and cases performed in dedicated open heart and dedicated C-section rooms, and the number of outpatient surgical cases performed in the most recent 12 month period for which data is available, in the operating rooms in each facility listed in response to Subparagraphs (b)(1) and (b)(2) of this Rule;*
- C- In Section II.10, page 19, the applicant states OBH performed 292 inpatient surgical procedures and 1,779 outpatient surgical procedures in FY2012.
- (4) *the number of inpatient surgical cases, excluding trauma cases reported by level I, II, or III trauma centers, cases reported by designated burn intensive care units and cases performed in dedicated open heart and dedicated C-section rooms, and the number of outpatient surgical cases projected to be performed in each of the first three operating years of the proposed project, in each facility listed in response to Subparagraphs (b)(1) and (b)(2) of this Rule;*
- C- In Section II.10, page 20, the applicant provides the projected operating room utilization at OBH, which is summarized below:

**Outer Banks Hospital Projected Operating Room Utilization**

<b>Fiscal Year</b>	<b>Operating Rooms</b>	<b>Outpatient Surgical Cases</b>	<b>Inpatient Surgical Cases</b>	<b>Total Surgical Cases</b>
FY2016 Project Year 1	3	1,942	362	2,304
FY2017 Project Year 2	3	2,001	373	2,374
FY2018 Project Year 3	3	2,051	383	2,434

- (5) *a description of and documentation to support the assumptions and methodology used in the development of the projections required by this Rule;*
- C- In Section III.1, pages 33-38, and Section IV.1, pages 45-46, the applicant provides a detailed description of and documentation to support the assumptions and methodology used in the development of the projections. An analysis of the assumptions, methodology, and utilization projections was conducted in Criterion (3), which is incorporated hereby as if set forth fully herein.

- (6) *the hours of operation of the proposed new operating rooms;*
- C- In Section II.10, page 20, the applicant states the hours of operation of the OBH surgical service is 7:00 AM to 3:30 PM, Monday through Friday, with 24/7 coverage provided through an on-call system.
- (7) *if the applicant is an existing facility, the average reimbursement received per procedure for the 20 surgical procedures most commonly performed in the facility during the preceding 12 months and a list of all services and items included in the reimbursement;*
- C- In Exhibit F of the application, the applicant provides the current average reimbursement received per procedure for the 20 surgical procedures most commonly performed in OBH's operating rooms. In Section II.10, page 20, the applicant states, "*The reimbursement amount includes all services from the hospital. The reimbursement does not include individual physician bills.*"
- (8) *the projected average reimbursement to be received per procedure for the 20 surgical procedures which the applicant projects will be performed most often in the facility and a list of all services and items included in the reimbursement; and*
- C- In Exhibit F of the application, the applicant provides the projected average reimbursement to be received per procedure for the 20 surgical procedures that will most commonly be performed in OBH's operating rooms. In Section II.10, page 20, the applicant states, "*The reimbursement amount includes all services from the hospital. The reimbursement does not include individual physician bills.*"
- (9) *identification of providers of pre-operative services and procedures which will not be included in the facility's charge.*
- C- In Section II.10, page 21, the applicant states all pre-operative services and procedures will be provided by OBH except for physician services.
- (c) *An applicant proposing to relocate existing or approved operating rooms within the same service area shall provide the following information:*
- (1) *the number and type of existing and approved operating rooms in each facility in which the number of operating rooms will increase or decrease (separately identifying the number of dedicated open heart and dedicated C-Section rooms);*
- (2) *the number and type of operating rooms to be located in each affected facility after completion of the proposed project and all previously approved projects related to these facilities (separately identifying the number of dedicated open heart and dedicated C-Section rooms);*
- (3) *the number of inpatient surgical cases, excluding trauma cases reported by Level I, II, or III trauma centers, cases reported by designated burn intensive care units, and cases performed in dedicated open heart and dedicated C-section rooms, and the number of outpatient surgical cases performed in the most recent 12 month period for*

*which data is available, in the operating rooms in each facility listed in response to Subparagraphs (c)(1) and (c)(2) of this Rule;*

- (4) the number of inpatient surgical cases, excluding trauma cases reported by level I, II, or III trauma centers, cases reported by designated burn intensive care units and cases performed in dedicated open heart and dedicated C-section rooms, and the number of outpatient surgical cases projected to be performed in each of the first three operating years of the proposed project, in each facility listed in response to Subparagraphs (c)(1) and (c)(2) of this Rule;*
- (5) a detailed description of and documentation to support the assumptions and methodology used in the development of the projections required by this Rule;*
- (6) the hours of operation of the facility to be expanded;*
- (7) the average reimbursement received per procedure for the 20 surgical procedures most commonly performed in each affected facility during the preceding 12 months and a list of all services and items included in the reimbursement;*
- (8) the projected average reimbursement to be received per procedure for the 20 surgical procedures which the applicant projects will be performed most often in the facility to be expanded and a list of all services and items included in the reimbursement; and*
- (9) identification of providers of pre-operative services and procedures which will not be included in the facility's charge.*

**-NA-** The applicant is not proposing to relocate existing or approved operating rooms within the same service area.

*(d) An applicant proposing to establish a new single specialty separately licensed ambulatory surgical facility pursuant to the demonstration project in the 2010 State Medical Facilities Plan shall provide:*

- (1) the single surgical specialty area in which procedures will be performed in the proposed ambulatory surgical facility;*
- (2) a description of the ownership interests of physicians in the proposed ambulatory surgical facility;*
- (3) a commitment that the Medicare allowable amount for self-pay and Medicaid surgical cases minus all revenue collected from self-pay and Medicaid surgical cases shall be at least seven percent of the total revenue collected for all surgical cases performed in the proposed facility;*
- (4) for each of the first three full fiscal years of operation, the projected number of self-pay surgical cases;*
- (5) for each of the first three full fiscal years of operation, the projected number of Medicaid surgical cases;*
- (6) for each of the first three full fiscal years of operation, the total projected Medicare allowable amount for the self-pay surgical cases to be served in the proposed facility, i.e. provide the projected Medicare allowable amount per self-pay surgical case and multiply that amount by the projected number of self-pay surgical cases;*
- (7) for each of the first three full fiscal years of operation, the total projected Medicare allowable amount for the Medicaid surgical cases to be served in the facility, i.e. provide the projected Medicare allowable amount per Medicaid surgical case and multiply that amount by the projected number of Medicaid surgical cases;*

- (8) *for each of the first three full fiscal years of operation, the projected revenue to be collected from the projected number of self-pay surgical cases;*
- (9) *for each of the first three full fiscal years of operation, the projected revenue to be collected from the projected number of Medicaid surgical cases;*
- (10) *for each of the first three full fiscal years of operation, the projected total revenue to be collected for all surgical cases performed in the proposed facility;*
- (11) *a commitment to report utilization and payment data for services provided in the proposed ambulatory surgical facility to the statewide data processor, as required by G.S. 131E-214.2;*
- (12) *a description of the system the proposed ambulatory surgical facility will use to measure and report patient outcomes for the purpose of monitoring the quality of care provided in the facility;*
- (13) *descriptions of currently available patient outcome measures for the surgical specialty to be provided in the proposed facility, if any exist;*
- (14) *if patient outcome measures are not currently available for the surgical specialty area, the applicant shall develop its own patient outcome measures to be used for monitoring and reporting the quality of care provided in the proposed facility, and shall provide in its application a description of the measures it developed;*
- (15) *a description of the system the proposed ambulatory surgical facility will use to enhance communication and ease data collection, e.g. electronic medical records;*
- (16) *a description of the proposed ambulatory surgical facility's open access policy for physicians, if one is proposed;*
- (17) *a commitment to provide to the Agency annual reports at the end of each of the first five full years of operation regarding:*
  - (A) *patient payment data submitted to the statewide data processor as required by G.S. 131E-214.2;*
  - (B) *patient outcome results for each of the applicant's patient outcome measures;*
  - (C) *the extent to which the physicians owning the proposed facility maintained their hospital staff privileges and provided Emergency Department coverage, e.g. number of nights each physician is on call at a hospital; and*
  - (D) *the extent to which the facility is operating in compliance with the representations the applicant made in its application relative to the single specialty ambulatory surgical facility demonstration project in the 2010 State Medical Facilities Plan.*

-NA- The applicant is not proposing to establish a new single specialty separately licensed ambulatory surgical facility pursuant to the demonstration project in the 2010 State Medical Facilities Plan.

**10A NCAC 14C .2103                      PERFORMANCE STANDARDS**

(a) *In projecting utilization, the operating rooms shall be considered to be available for use five days per week and 52 weeks a year.*

-C- In Section II.10, page 24 of the application, the applicant states the program is considered to be available for use five days per week and 52 weeks per year.

*(b) A proposal to establish a new ambulatory surgical facility, to establish a new campus of an existing facility, to establish a new hospital, to increase the number of operating rooms in an existing facility (excluding dedicated C-section operating rooms), to convert a specialty ambulatory surgical program to a multispecialty ambulatory surgical program or to add a specialty to a specialty ambulatory surgical program shall:*

- (1) demonstrate the need for the number of proposed operating rooms in the facility which is proposed to be developed or expanded in the third operating year of the project based on the following formula:  $\{[(\text{Number of facility's projected inpatient cases, excluding trauma cases reported by Level I or II trauma centers, cases reported by designated burn intensive care units and cases performed in dedicated open heart and C-section rooms, times 3.0 hours}) \text{ plus } (\text{Number of facility's projected outpatient cases times 1.5 hours})] \text{ divided by } 1872 \text{ hours}\}$  minus the facility's total number of existing and approved operating rooms and operating rooms proposed in another pending application, excluding one operating room for Level I or II trauma centers, one operating room for facilities with designated burn intensive care units, and all dedicated open heart and C-section operating rooms or demonstrate conformance of the proposed project to Policy AC-3 in the State Medical Facilities Plan titled "Exemption From Plan Provisions for Certain Academic Medical Center Teaching Hospital Projects;" and*
- (2) The number of rooms needed is determined as follows:*
  - (A) in a service area which has more than 10 operating rooms, if the difference is a positive number greater than or equal to 0.5, then the need is the next highest whole number for fractions of 0.5 or greater and the next lowest whole number for fractions less than 0.5; and if the difference is a negative number or a positive number less than 0.5, then the need is zero;*
  - (B) in a service area which has 6 to 10 operating rooms, if the difference is a positive number greater than or equal to 0.3, then the need is the next highest whole number for fractions of 0.3 or greater and the next lowest whole number for fractions less than 0.3, and if the difference is a negative number or a positive number less than 0.3, then the need is zero; and*
  - (C) in a service area which has five or fewer operating rooms, if the difference is a positive number greater than or equal to 0.2, then the need is the next highest whole number for fractions of 0.2 or greater and the next lowest whole number for fractions less than 0.2; and if the difference is a negative number or a positive number less than 0.2, then the need is zero.*

-C- OBH is located in the Dare County Service Area, which has five or fewer operating rooms. The applicant proposes to operate three shared operating rooms at OBH, excluding one dedicated C-section operating room. In Section IV.1, page 45, the applicant projects it will perform 383 inpatient surgical cases and 2,051 outpatient surgical cases at OBH in the third operating year of the proposed project (FY2018). Based on the utilization standards required in this rule, the number of operating rooms required would be three  $[(2,051 \times 1.5 \text{ hours}) + (383 \times 3.0 \text{ hours}) = 4,225.5 \text{ hours}; 4,225.5 \text{ hours}/1,872 \text{ hours} = 2.26]$ . Therefore, the application is conforming with this rule.



*(c) A proposal to increase the number of operating rooms (excluding dedicated C-section operating rooms) in a service area shall:*

- (1) demonstrate the need for the number of proposed operating rooms in addition to the rooms in all of the licensed facilities identified in response to 10A NCAC 14C .2102(b)(2) in the third operating year of the proposed project based on the following formula:  $\{[(\text{Number of projected inpatient cases for all the applicant's or related entities' facilities, excluding trauma cases reported by Level I or II trauma centers, cases reported by designated burn intensive care units and cases performed in dedicated open heart and C-section rooms, times 3.0 hours}) \text{ plus } (\text{Number of projected outpatient cases for all the applicant's or related entities' facilities times 1.5 hours})] \text{ divided by } 1872 \text{ hours}\}$  minus the total number of existing and approved operating rooms and operating rooms proposed in another pending application, excluding one operating room for Level I or II trauma centers, one operating room for facilities with designated burn intensive care units, and all dedicated open heart and C-Section operating rooms in all of the applicant's or related entities' licensed facilities in the service area; and*
- (2) The number of rooms needed is determined as follows:*
  - (A) in a service area which has more than 10 operating rooms, if the difference is a positive number greater than or equal to 0.5, then the need is the next highest whole number for fractions of 0.5 or greater and the next lowest whole number for fractions less than 0.5; and if the difference is a negative number or a positive number less than 0.5, then the need is zero;*
  - (B) in a service area which has 6 to 10 operating rooms, if the difference is a positive number greater than or equal to 0.3, then the need is the next highest whole number for fractions of 0.3 or greater and the next lowest whole number for fractions less than 0.3, and if the difference is a negative number or a positive number less than 0.3, then the need is zero; and*
  - (C) in a service area which has five or fewer operating rooms, if the difference is a positive number greater than or equal to 0.2, then the need is the next highest whole number for fractions of 0.2 or greater and the next lowest whole number for fractions less than 0.2; and if the difference is a negative number or a positive number less than 0.2, then the need is zero.*

*-C- OBH is located in the Dare County Service Area, which has five or fewer operating rooms. In Section II.10, page 19, the applicant states neither OBH nor a related entity owns a controlling interest in any other facility in Dare County. The applicant proposes to operate three shared operating rooms at OBH, excluding one dedicated C-section operating room. In Section IV.1, page 45, the applicant projects it will perform 383 inpatient surgical cases and 2,051 outpatient surgical cases at OBH in the third operating year of the proposed project (FY2018). Based on the utilization standards required in this rule, the number of operating rooms required would be three  $[(2,051 \times 1.5 \text{ hours}) + (383 \times 3.0 \text{ hours}) = 4,225.5 \text{ hours}; 4,225.5 \text{ hours}/1,872 \text{ hours} = 2.26]$ . Therefore, the application is conforming with this rule.*

*(d) An applicant that has one or more existing or approved dedicated C-section operating rooms and is proposing to develop an additional dedicated C-section operating room in the same facility shall demonstrate that an average of at least 365 C-sections per room were performed in the*

*facility's existing dedicated C-section operating rooms in the previous 12 months and are projected to be performed in the facility's existing, approved and proposed dedicated C-section rooms during the third year of operation following completion of the project.*

-NA- The applicant does propose to develop an additional C-section operating room.

*(e) An applicant proposing to convert a specialty ambulatory surgical program to a multispecialty ambulatory surgical program or to add a specialty to a specialty ambulatory surgical program shall:*

- (1) provide documentation to show that each existing ambulatory surgery program in the service area that performs ambulatory surgery in the same specialty area as proposed in the application is currently utilized an average of at least 1,872 hours per operating room per year, excluding dedicated open heart and C-Section operating rooms. The hours utilized per operating room shall be calculated as follows: [(Number of projected inpatient cases, excluding open heart and C-sections performed in dedicated rooms, times 3.0 hours) plus (Number of projected outpatient cases times 1.5 hours)] divided by the number of operating rooms, excluding dedicated open heart and C-Section operating rooms; and*
- (2) demonstrate the need in the third operating year of the project based on the following formula: [(Total number of projected outpatient cases for all ambulatory surgery programs in the service area times 1.5 hours) divided by 1872 hours] minus the total number of existing, approved and proposed outpatient or ambulatory surgical operating rooms and shared operating rooms in the service area. The need is demonstrated if the difference is a positive number greater than or equal to one, after the number is rounded to the next highest number for fractions of 0.50 or greater.*

-NA- The applicant does not propose to convert a specialty ambulatory surgical program to a multispecialty ambulatory surgical program or to add a specialty to a specialty ambulatory surgical program.

*(f) The applicant shall document the assumptions and provide data supporting the methodology used for each projection in this Rule.*

-C- In Section III.1, pages 33-38, and Section IV.1, pages 45-46, the applicant provides documentation to support the assumptions and methodology used in the development of the projections. An analysis of the assumptions, methodology, and utilization projections was conducted in Criterion (3), which is incorporated hereby as if set forth fully herein.

#### **10A NCAC 14C .2104            SUPPORT SERVICES**

*(a) An applicant proposing to establish a new ambulatory surgical facility, a new campus of an existing facility, or a new hospital shall provide copies of the written policies and procedures that will be used by the proposed facility for patient referral, transfer, and follow-up.*

-NA- The applicant is not proposing to establish a new ambulatory surgical facility, a new campus of an existing facility, or a new hospital.

*(b) An applicant proposing to establish a new ambulatory surgical facility, a new campus of an existing facility, or a new hospital shall provide documentation showing the proximity of the proposed facility to the following services:*

- (1) emergency services;*
- (2) support services;*
- (3) ancillary services; and*
- (4) public transportation.*

-NA- The applicant is not proposing to establish a new ambulatory surgical facility, a new campus of an existing facility, or a new hospital.

**10A NCAC 14C .2105 STAFFING AND STAFF TRAINING**

*(a) An applicant proposing to establish a new ambulatory surgical facility, to establish a new campus of an existing facility, to establish a new hospital, to increase the number of operating rooms in a facility, to convert a specialty ambulatory surgical program to a multispecialty ambulatory surgical program or to add a specialty to a specialty ambulatory surgical program shall identify, justify and document the availability of the number of current and proposed staff to be utilized in the following areas in the facility to be developed or expanded:*

- (1) administration;*
- (2) pre-operative;*
- (3) post-operative;*
- (4) operating room; and*
- (5) other.*

-C- In Section II.10, page 29, and Sections VII.1, VII.2, and VII.6 of the application, the applicant identifies and documents the availability of the number of proposed staff to be utilized in the areas listed in this rule.

*(b) The applicant shall identify the number of physicians who currently utilize the facility and estimate the number of physicians expected to utilize the facility and the criteria to be used by the facility in extending surgical and anesthesia privileges to medical personnel.*

-C- Exhibit G contains a listing of providers who are currently privileged to provide surgical and anesthesia services at OBH. The applicant states, “OBH expects these providers plus others as more surgeons are recruited to utilize the facility in the future.” Exhibit H contains the criteria used by the facility in extending surgical and anesthesia privileges to medical personnel.

*(c) The applicant shall provide documentation that physicians with privileges to practice in the facility will be active members in good standing at a general acute care hospital within the service area in which the facility is, or will be, located or documentation of contacts the applicant made with hospitals in the service area in an effort to establish staff privileges.*

-C- In Section II.10, page 30, and Exhibit I of the application, the applicant provides documentation that physicians with privileges to practice in the facility will be active members in good standing at OBH, which is the only general acute care hospital in Dare County.

*(d) The applicant shall provide documentation that physicians owning the proposed single specialty demonstration facility will meet Emergency Department coverage responsibilities in at least one hospital within the service area, or documentation of contacts the applicant made with hospitals in the service area in an effort to commit its physicians to assume Emergency Department coverage responsibilities.*

-NA- The applicant is not proposing to establish a new single specialty separately licensed ambulatory surgical facility pursuant to the demonstration project in the 2010 State Medical Facilities Plan.

**10A NCAC 14C .2106 FACILITY**

*(a) An applicant proposing to establish a licensed ambulatory surgical facility that will be physically located in a physician's or dentist's office or within a general acute care hospital shall demonstrate that reporting and accounting mechanisms exist and can be used to confirm that the licensed ambulatory surgery facility is a separately identifiable entity physically and administratively, and is financially independent and distinct from other operations of the facility in which it is located.*

-NA- The applicant is not proposing to establish a licensed ambulatory surgical facility that will be physically located in a physician's or dentist's office or within a general acute care hospital.

*(b) An applicant proposing to establish a licensed ambulatory surgical facility or a new hospital shall receive accreditation from the Joint Commission for the Accreditation of Healthcare Organizations, the Accreditation Association for Ambulatory Health Care or a comparable accreditation authority within two years of completion of the facility.*

-NA- The applicant is not proposing to establish a licensed ambulatory surgical facility or a new hospital.

*(c) All applicants shall document that the physical environment of the facility to be developed or expanded conforms to the requirements of federal, state, and local regulatory bodies.*

-C- In Section II.10, page 31 of the application, the applicant provides documentation that the physical environment of the facility conforms to the requirements of federal, state, and local regulatory bodies.

*(d) An applicant proposing to establish a new ambulatory surgical facility, a new campus of an existing facility or a new hospital shall provide a floor plan of the proposed facility identifying the following areas:*

- (1) receiving/registering area;*
- (2) waiting area;*
- (3) pre-operative area;*
- (4) operating room by type;*
- (5) recovery area; and*
- (6) observation area.*

-NA- The applicant is not proposing to establish a licensed ambulatory surgical facility, a new campus of an existing facility, or a new hospital.

*(e) An applicant proposing to expand by converting a specialty ambulatory surgical program to a multispecialty ambulatory surgical program or by adding a specialty to a specialty ambulatory surgical program that does not propose to add physical space to the existing ambulatory surgical facility shall demonstrate the capability of the existing ambulatory surgical program to provide the following for each additional specialty area:*

- (1) physicians;*
- (2) ancillary services;*
- (3) support services;*
- (4) medical equipment;*
- (5) surgical equipment;*
- (6) receiving/registering area;*
- (7) clinical support areas;*
- (8) medical records;*
- (9) waiting area;*
- (10) pre-operative area;*
- (11) operating rooms by type;*
- (12) recovery area; and*
- (13) observation area.*

-NA- The applicant does not propose to expand by converting a specialty ambulatory surgical program to a multispecialty ambulatory surgical program or by adding a specialty to a specialty ambulatory surgical program.