ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS
C = Conforming
CA = Conditional
NC = Nonconforming
NA = Not Applicable

DECISION DATE: September 17, 2014

PROJECT ANALYST: Gene DePorter
INTERIM CHIEF: Martha J. Frisone

PROJECT I.D. NUMBER: Q-10299-14/Williamston Hospital Corporation, Inc. d/b/a Martin General Hospital / Develop a dedicated C-section operating room / Martin 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, ambulatory surgical operating rooms, or home health offices that may be approved.

NA

Martin General Hospital (MGH) is a 49-bed general acute care hospital located in Williamston in Martin County. It is the only hospital located in Martin County. The applicant, Williamston Hospital Corporation, proposes to develop a dedicated C-section operating room (OR) in the Labor and Delivery suite located on the second floor. C-sections are currently performed in one of the two existing shared ORs located on the ground floor of the hospital.

The applicant does not propose to add any new ORs, health service facility beds, medical equipment or new services for which there is a need determination in the 2014 State Medical Facilities Plan (2014 SMFP). On page 62, the 2014 SMFP states

"'Dedicated C-Section Operating Rooms' and associated cases are excluded from the calculation of need for additional 'operating rooms' by the standard methodology; therefore, hospitals proposing to add a new operating room for use as a 'Dedicated

C-Section Operating Room' shall apply for a certificate of need without regard to the need determinations in Chapter 6 of this Plan."

Furthermore, there are no policies in the 2014 SMFP that are applicable to this review. Therefore, this criterion is not applicable to this review.

(2) Repealed effective July 1, 1987.

(3) The applicant shall identify the population to be served by the proposed project, and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and, in particular, low income persons, racial and ethnic minorities, women, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.

C

The applicant proposes to develop one dedicated C-section OR in renovated space within the Labor and Delivery suite on the second floor. C-sections are currently performed in one of the two existing shared ORs located on the ground floor of the hospital.

Population to Be Served

In Section III, pages 37-39, the applicant provides the current and projected patient origin for obstetrical services provided at MGH, as shown in the following table.

Patient Origin for Obstetrical Services		
County	**Current**	**Projected**
Martin	71.4%	71.4%
Washington	14.6%	14.6%
Bertie	8.0%	8.0%
Onslow	1.0%	1.0%
Beaufort	1.0%	1.0%
All Others *	4.0%	4.0%
Total	100.0%	100.0%

* The percent for any one of these counties is less than 1%.

As shown in the table above, the applicant projects no change in its patient origin for obstetrical services. The applicant adequately identified the population to be served.

Need Analysis

In Section III, pages 28-29, the applicant states

"Currently, MGH does not have a dedicated C-section OR. MGH's Labor & Delivery unit is located on an upper floor and Surgical Services are located on the ground floor of the hospital. Therefore, when a C-section is needed, patients are transported from the labor and delivery room, down a public hallway to elevators. This travel time is unnecessary and inefficient and is not an ideal experience for laboring mothers.

More importantly, the lack of a dedicated C-section OR in the L&D Suite is a safety concern. MHG's two elevators are 42-years old and frequently experience unscheduled downtime. This has proven to be especially problematic for laboring mothers who require emergency C-sections. There have been at least three (3) incidents during the most recent nine months when both of MGH's elevators have been out-of-service and laboring mothers had to be escorted by hospital clinical staff down the stairs to the ground floor of the hospital. In addition to being sub-optimal from a patient perspective, the process of transporting laboring mothers down flights of stairs presents serious safety concerns.

By developing a dedicated C-section OR in the Labor & Delivery suite, the hospital can provide more effective and safer care for its patients … consistent with contemporary quality and safety standards. … The total capital cost of the proposed project is anticipated to be less than $250,000, and thus the proposal is a cost effective means to improving patient safety and quality of care at MGH."

The applicant adequately demonstrates the need to develop a dedicated C-section OR on the second floor in the Labor and Delivery suite for patient safety.

Projected Utilization

In Section III, pages 31-36, the applicant describes the assumptions and methodology used to project utilization of the proposed dedicated C-section OR.

On page 31, the applicant provides the number of births at MGH during the last three fiscal years, as illustrated in the following table.

Births at MGH			
	FY 2011	**FY 2012**	**FY 2013**
# of Vaginal Births	138	123	101
# of C-sections	53	59	65
# of Stillbirths	1	1	2
Total	192	183	168
C-sections as % of Total	27.6%	32.2%	38.7%

On page 31, the applicant states

> *"Martin County has experienced an increasing rate of out-migration for maternity services in recent years. This is largely due to some negative perceptions of MGH's older facility. Therefore, in addition to the improvements in quality and safety that will be garnered by the proposed project, development of a dedicated C-section OR will improve consumer perceptions in the local market, with the objective of reducing obstetrics out-migration in future years.*
>
> *Additionally, a laboring epidural program was recently implemented at MGH to improve the patient experience for laboring mothers. MGH's epidural program is expected to improve consumer perceptions in the local market and to reduce out-migration for maternity services.*
>
> *Finally, … MGH recently recruited a new OB/GYN physician to join the practice of Roanoke Women's Health Center, effective on August 1, 2014. … The addition of Dr. Harbin is expected to increase MGH's market presence in the local community and to increase OB/GYN utilization (including births) at the hospital."*

On page 32, the applicant states

> *"To project births for the proposed project, MGH anticipates FY 2014 births will remain consistent with FY 2013 utilization. MGH projects a modest increase in utilization during the initial three project years of 1%, 2% and 3% respectively based on 1) the development of a dedicated C-section OR, 2) addition of a new OB/GYN physician to the MGH Medical Staff and 3) recent development of the epidural program at MGH."*

On pages 32-35, the applicant provides the following information regarding C-sections.

- In FY 2013, approximately 39% of all births at MGH were by C-section.
- In 2012, the national C-section rate was 32.8% of all births.
- The rate of C-section deliveries *"has a direct correlation to the age of the mother. For example, nearly one half of all deliveries for mothers over age 40 are performed via C-section."*
- Martin County has a *"comparatively older female population compared to the state as a whole."* The median age for females statewide is 39.5. The median age for females in Martin County is 46.6.

On page 35, the applicant provides projected utilization during through the third operating year following project completion, as shown in the following table. On page 36, the applicant states that all C-sections will be performed in the dedicated C-section OR.

Births at MGH				
	FY 2014	FY 2015	FY 2016	FY 2017
# of Vaginal Births	101	104	106	109
# of C-sections	65	66	67	69
# of Stillbirths	2	0	0	0
Total	168	170	173	178
C-sections as % of Total	38.7%	38.7%	38.7%	38.7%

Projected utilization is based on reasonable and adequately supported assumptions.

Access

In Section III, page 30, the applicant provides the following comparison of the population of Martin County with the total population of North Carolina.

2008 – 2012	Martin County	North Carolina
Per capita income (in 2012 dollars)	$18,812	$25,285
Median household income	$35,585	$46,450
% of population living below the poverty level	24.9%	16.8%

Applicant's source: US Census Bureau

In Section VI, page 53, the applicant states the following:

- 100% of all obstetrical patients were female. Females make up 53.2% of the Martin County population.
- In FY 2013, 82.5% of all obstetrical patients were Medicaid, Self-pay, Indigent or Charity Care.
- More than 50% of all obstetrical patients were racial or ethnic minorities.
- Information about handicapped persons is not available.

In Section VI, page 63, the applicant projects that the payor mix for obstetrical services will not change as a result of this project.

The applicant adequately demonstrates 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 proposed obstetrical services.

Conclusion

In summary, the applicant adequately identifies the population to be served and adequately demonstrates the need the population to be served has for the proposed dedicated C-section

OR, including the extent to which medically underserved groups will have access to the proposed services. Therefore, the application is conforming to this criterion.

(3a) In the case of a reduction or elimination of a service, including the relocation of a facility or a service, the applicant shall demonstrate that the needs of the population presently served will be met adequately by the proposed relocation or by alternative arrangements, and the effect of the reduction, elimination or relocation of the service on the ability of low income persons, racial and ethnic minorities, women, handicapped persons, and other underserved groups and the elderly to obtain needed health care.

NA

(4) Where alternative methods of meeting the needs for the proposed project exist, the applicant shall demonstrate that the least costly or most effective alternative has been proposed.

C

In Section III.8, pages 40-42, the applicant discusses the following alternatives it considered prior to submitting this application.

Maintain Status Quo

On page 40, the applicant states that this option would not address concerns regarding the safety of mothers and infants. The Labor and Delivery suite is located on the second floor while the two existing shared ORs are located on the ground floor. Transporting the laboring mother-to-be "*is unnecessary, inefficient, poses a potential safety concern and is not an ideal experience."* Moreover, this alternative would not address the problem of both elevators being out-of-service at the same time which occurred three times during the last 9 months. Laboring mothers had to be escorted by hospital clinical staff down the stairs to the first floor.

Develop C-Section OR in New Construction

On pages 40-41, the applicant states

> *"Another alternative is to develop the proposed dedicated C-section OR via new construction. However, this is not the most cost effective alternative for the proposed project. New construction would include substantially higher capital costs compared to renovation of the existing space. Additionally, new construction is not necessary because sufficient space currently exists within the MGH's facility to develop the proposed C-section OR. Therefore, renovating existing facility space within the Labor and Delivery unit is a cost effective solution to enhance safety, quality and continuity of care for obstetrical services."*

Develop C-section OR in another location within MGH
On page 41, the applicant states

> *"Developing the proposed dedicated C-section OR in an area of the hospital other than the current Labor and Delivery suite would essentially be equivalent to the status quo. The addition of a dedicated C-section room in the Labor and Delivery suite will effectively co-locate all inpatient women's and children's services on the same floor, improving staff efficiency and providing patients a better, safer experience."*

Develop the Project as Proposed
On page 41, the applicant states

> *"By developing a dedicated C-section OR in the Labor and Delivery suite, the hospital can provide more effective and safer care for its patients and other obstetrical services consistent with contemporary quality and safety standards. The proposed project is a cost effective approach to improve local access to obstetrical services for residents of the area. Project capital costs are minimal, as MGH proposes to renovate existing department spaces and obtain reconditioned OR equipment."*

Furthermore, the application is conforming or conforming as conditioned to all other applicable statutory and regulatory review criteria. An application that cannot be approved cannot be an effective alternative.

The applicant adequately demonstrates that the proposal to develop a dedicated C-Section OR in existing space on the second floor is the least costly or most effective alternative to meet the need for improved patient safety. Consequently, the application is conforming to this criterion and approved subject to the following conditions:

1. **Williamston Hospital Corporation, Inc. d/b/a Martin General Hospital shall materially comply with all representations made in the certificate of need application.**

2. **Prior to issuance of the certificate of need, Williamston Hospital Corporation, Inc. d/b/a Martin General Hospital shall provide the Certificate of Need Section with a letter from a fiscally responsible officer of Community Health Systems, Inc. documenting that Community Health Systems, Inc. intends to fund the capital costs of this project.**

3. **Williamston Hospital Corporation, Inc. d/b/a Martin General Hospital 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. Martin General Hospital shall be licensed for no more than one dedicated C-Section and two shared operating rooms upon completion of this project.

5. Williamston Hospital Corporation, Inc. d/b/a Martin General Hospital 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.

CA

In Section VIII, page 73, the applicant projects that the total capital cost for this project will be $208,281, which includes $100,843 for renovations, $40,312 for fixed equipment, $20,000 for architect and engineering fees, $32,000 for administrative and legal fees, and $15,126 for contingencies. In Section VIII, page 74, and Exhibit 17, the applicant indicates that the capital cost will be funded with the accumulated reserves of Community Health Systems, Inc., the applicant's ultimate parent. In Section IX, the applicant states that there will be no start-up or initial operating expenses.

Exhibit 15 contains a letter dated June 11, 2014 signed by the hospital's Chief Financial Officer, which states

> *"As shown on our financial statements, Community Health Systems Inc. (CHS), has sufficient financial reserves to fund the modest financial project costs associated with the North Carolina certificate of need application to develop a dedicated C-section operating room at our Martin General Hospital facility in Martin County. The total capital cost of the project is estimated at less than $300,000. CHS will fund the proposed project through accumulated cash reserves. Upon approval of this project, the available funds will be used for the proposed project. As the Chief Financial Officer of Martin General Hospital, I am attesting to our organization's intent to commit all funds necessary for the development and operation of this CON project. Please contact me if you have any questions."*

Exhibit 16 contains a copy of the audited consolidated financial statements for Community Health Systems, Inc. for the last three calendar years. As of December 31, 2013,

Community Health System, Inc. had $373,403,000 in Cash and Cash Equivalents and $3,131,470,000 in Total Equity (Total Assets less Total Liabilities).

However, the applicant does not provide documentation from a fiscally responsible officer of Community Health Systems, Inc. to demonstrate that Community Health Systems, Inc. is willing to contribute the funds necessary for the capital needs of the project. Therefore, the application is conforming to this criterion subject to Condition #2 in Criterion (4).

In Form B behind Tab 13, the applicant projects operating expenses will exceed revenues for labor and delivery services during the first three operating years (OY) following completion of the proposed project, as shown in the following table.

Labor and Delivery Services	**OY 1 CY 2015**	**OY 2 CY 2016**	**OY 3 CY 2017**
Projected # of Discharges	170	173	178
Average Gross Revenue per Discharge	$17,674	$18,028	$18,388
Gross Patient Revenue	$2,998,978	$3,120,137	$3,278,015
Deductions from Gross Patient Revenue	$2,512,960	$2,614,484	$2,746,777
Total Revenue	$486,018	$505,653	$531,239
Total Expenses	$1,149,709	$1,172,409	$1,197,614
Net Income	($663,692)	($666,756)	($666,376)

However, in Form B behind Tab 13, the applicant projects revenues will exceed expenses for all services provided by the hospital during the first three operating years following completion of the proposed project, as shown in the following table.

All Hospital Services	**OY 1 CY 2015**	**OY 2 CY 2016**	**OY 3 CY 2017**
Gross Patient Revenue	$148,392,532	$151,360,383	$154,387,590
Deductions from Gross Patient Revenue	$119,967,204	$122,366,548	$124,813,879
Net Revenue	$28,425,328	$28,993,835	$29,573,712
Total Expenses	$26,766,042	$27,225,427	$27,692,861
Net Income	$1,842,617	$1,955,404	$2,071,587

The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs and charges. See Tab 13 for the assumptions regarding costs and charges. The discussion regarding projected utilization found in Criterion (3) is incorporated hereby as if set forth fully herein. The applicant adequately demonstrates that the immediate and long term financial feasibility of the proposal is based upon reasonable projections of costs and charges. Therefore, the application is conforming to this criterion subject to Condition #2 in Criterion (4).

(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

The applicant proposes to develop a dedicated C-section OR on the second floor of the hospital. C-sections are currently performed in one of the two shared ORs located on the ground floor of the hospital. MGH is the only hospital located in Martin County. In addition to serving residents of Martin County requiring obstetrical services, the hospital also serves residents of Bertie County (14.6% of all deliveries at MGH) and Washington County (8% of all deliveries at MGH). The hospitals in those counties do not provide obstetrical services. See Section III, page 42. Almost 40% of the deliveries at MGH are done by C-section. See Section III, page 31. The applicant adequately demonstrates that the proposed dedicated C-section OR is needed to ensure the safety of its patients. The discussion regarding need found in Criterion (3) is incorporated hereby as is set forth fully herein. Thus, the applicant adequately demonstrates that the proposal will not result in an 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.

C

In Section II.5, page 12, the applicant indicates that the scheduled hours of operation for the proposed C-section OR will be 7 am to 4 pm Monday through Friday. After hours staffing and weekend coverage will be provided by on-call staff.

The following table shows the current and projected staffing.

Current and Projected Staffing

Position	**CY 2014 # of FTE Positions**	**CY 2014 Salary Per FTE Position**	**CY 2016 # of FTE Positions**	**CY 2016 Salary Per FTE Position**
Nurse Manager	1.00	$78,356	1.00	$80,725
Registered Nurses	8.00	$55,212	8.00	$56,880
Surgical Technician	1.00	$32,108	1.00	$33,078
CRNA	0.20	$147,784	0.20	$151,520
Clerical / Scheduling	0.33	$21,112	0.33	$21,752
Total	**10.53**		**10.53**	

In Section VII, page 66, the applicant states *"MGH does not project to add staffing for this project."* On page 67, the applicant states that the current staffing is *"sufficient to also cover the proposed dedicated C-section OR."* On page 70, the applicant states that Melissa O'Neal, MD will continue to serve as the Chief of Obstetrics / Gynecology at MGH. The applicant adequately demonstrates the availability of resources, including a medical director, for 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, page 11, the applicant identifies the necessary ancillary and support services and states that all are currently available.

In Section V, page 46, the applicant states

> *"As a healthcare facility that has served Martin County residents for many decades, MGH has established relationships with other providers in the area. Specifically, MGH has existing transfer agreements with the following healthcare facilities:*
>
> - *Gambro Healthcare – Edenton*
> - *Gastroenterology East*
> - *Tar River LTC Group*
> - *University of North Carolina Hospitals*
> - *Vidant – Beaufort*
> - *Vidant – Outer Banks Hospital*
> - *Vidant Medical Center*
> - *Washington County Hospital*

Exhibit 17 contains 14 letters of support from physicians and the Martin-Tyrell and Washington District Health Department expressing support for the proposed project and/or an intent to refer patients to MGH. The applicant adequately demonstrates the availability of the necessary ancillary and support services and that the proposal will be coordinated with the existing health care system. Therefore, the application is conforming to this criterion.

(9) An applicant proposing to provide a substantial portion of the project's services to individuals not residing in the health service area in which the project is located, or in

adjacent health service areas, shall document the special needs and circumstances that warrant service to these individuals.

NA

(10) When applicable, the applicant shall show that the special needs of health maintenance organizations will be fulfilled by the project. Specifically, the applicant shall show that the project accommodates: (a) The needs of enrolled members and reasonably anticipated new members of the HMO for the health service to be provided by the organization; and (b)The availability of new health services from non-HMO providers or other HMOs in a reasonable and cost-effective manner which is consistent with the basic method of operation of the HMO. In assessing the availability of these health services from these providers, the applicant shall consider only whether the services from these providers: (i)would be available under a contract of at least 5 years duration; (ii) would be available and conveniently accessible through physicians and other health professionals associated with the HMO; (iii) would cost no more than if the services were provided by the HMO; and (iv) would be available in a manner which is administratively feasible to the HMO.

NA

(11) Repealed effective July 1, 1987.

(12) Applications involving construction shall demonstrate that the cost, design, and means of construction proposed represent the most reasonable alternative, and that the construction project will not unduly increase the costs of providing health services by the person proposing the construction project or the costs and charges to the public of providing health services by other persons, and that applicable energy saving features have been incorporated into the construction plans.

NA

(13) The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and of members of medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and handicapped persons, which have traditionally experienced difficulties in obtaining equal access to the proposed services, particularly those needs identified in the State Health Plan as deserving of priority. For the purpose of determining the extent to which the proposed service will be accessible, the applicant shall show:

(a) The extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved;

C

In Section VI, page 52, the applicant states

> *"MGH has historically provided care and services to medically underserved populations. As a certified provider under Title XVIII (Medicare), MGH provides its services to the elderly. Also, MGH provides services to low-income persons as a certified provider under Title XIX (Medicaid). And as described further in Section VI, MGH provides a community initiative to make its services more accessible to medically indigent residents of eastern North Carolina.*
>
> *Further, MGH does not discriminate based on race, ethnicity, creed, color, age, religion, national origin, gender, handicap, or ability to pay."*

In Section VI, page 62, the applicant provides the current payor mix for obstetrical services, as shown in the following table.

Payor Category	Cases As a Percent of Total Cases
Self-Pay/ Indigent	4.5%
Medicare/Medicare Managed Care	0.7%
Medicaid	78.0%
Commercial/ Managed Care	2.9%
Blue Cross/Blue Shield	13.2%
Other	0.7%
Total	100.0%

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

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

C

In Section VI, page 59, the applicant states; *"During the last five years, one civil rights claim was brought against the hospital, involving a single patient in 2010*

and 2011. A judicial determination was never made in the case and the parties reached a settlement in the matter." 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, page 63, the applicant provides the projected payor mix for obstetrical services, as shown in the following table.

Payor Category	Cases As a Percent of Total Cases
Self-Pay/ Indigent	4.5%
Medicare/Medicare Managed Care	0.7%
Medicaid	78.0%
Commercial/ Managed Care	2.9%
Blue Cross/Blue Shield	13.2%
Other	0.7%
Total	100.0%

The applicant assumes that the payor mix for obstetrical services will remain unchanged following completion of the project. The applicant demonstrates MGH will continue to provide adequate access to medically underserved populations. 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, page 58, the applicant states *"Most access to MGH is by physician referral."* Other means include referrals from county or district health departments and patients presenting at the emergency department. The applicant adequately demonstrates that it will offer a range of means by which patients will have access to obstetrical services. Therefore, the application is conforming to this criterion.

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

C

In Section V, page 45, the applicant states

> *"MGH is committed to accommodating the clinical needs of area professional training programs and will continue to provide access to programs requiring clinical training. MGH has existing affiliations agreements with several area health professional training programs, including:*
>
> - *Beaufort Community College*
> - *Bear Grass Charter School*
> - *DeVry University*
> - *Duke University*
> - *East Carolina University*
> - *Edgecombe Community College*
> - *Martin County Schools*
> - *Pitt Community College*
> - *Shenandoah University*
> - *Vidant Medical Center"*

Exhibit 10 contains a copy of the agreement with Beaufort Community College. The applicant adequately demonstrates that MGH will continue to accommodate the clinical needs of health professional training programs in the area. Therefore, the application is conforming to this criterion.

(15) Repealed effective July 1, 1987.
(16) Repealed effective July 1, 1987.
(17) Repealed effective July 1, 1987.
(18) Repealed effective July 1, 1987.

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

C

The applicant proposes to develop a dedicated C-section OR in the Labor and Delivery suite on the second floor of the hospital. C-sections are currently performed in one of the two shared ORs located on the ground floor of the hospital.

MGH is the only hospital located in Martin County. In addition to serving residents of Martin County requiring obstetrical services, the hospital also serves residents of Bertie County (14.6% of all deliveries at MGH) and Washington County (8% of all deliveries at MGH). The hospitals in those counties do not provide obstetrical services. See Section III, page 42. Almost 40% of the deliveries at MGH are done by C-section. See Section III, page 31.

In Section V, pages 49-50, the applicant discusses how any enhanced competition in the service area will promote the cost-effectiveness, quality and access to the proposed services. See also Sections II, III, V, VI and VII where the applicant discusses the impact of the project on cost-effectiveness, quality and access.

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

- The applicant adequately demonstrates that the proposed dedicated C-section OR is needed to ensure the safety of its patients and that it is a cost-effective alternative. The discussion regarding need found in Criterion (3) is incorporated hereby as if set forth fully herein.
- The applicant adequately demonstrates that MGH will continue to provide quality services.
- The applicant demonstrates that MGH 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

MGH is accredited by the Joint Commission on Accreditation of Health Care Organizations and certified for Medicare and Medicaid participation. According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, there is a alleged EMTALA violation that is pending CMS final review. No other incidents occurred at MGH 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

The application is conforming with all applicable Criteria and Standards for Surgical Services and Operating Rooms as promulgated in 10A NCAC 14C .2100. The specific criteria are discussed below.

.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 does not propose 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.

(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);

(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);

(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;

(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;

(5) a 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 proposed new operating rooms;

(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;

(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

(9) identification of providers of pre-operative services and procedures which will not be included in the facility's charge.

- NA - The applicant does not propose to increase the number of ORs in Martin County, to convert a specialty ambulatory surgical program to a multispecialty ambulatory surgical program or to add a specialty to a specialty ambulatory surgical program. Dedicated C-section ORs are not counted in the inventory of ORs in the SMFP.

(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 does not propose to relocate existing or approved ORs within Martin County.

(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 does not propose to establish a new single specialty separately licensed ambulatory surgical program pursuant to the demonstration project in the 2010 SMFP.

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** - On page 21, the applicant states that the dedicated C-section OR will be available for scheduled use at least five days per week and 52 weeks per year, and available at all times for emergency C-section cases.

(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: {[(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) plus (Number of facility's projected outpatient cases times 1.5 hours)] divided by 1872 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.

- NA - The applicant does not propose 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. The applicant proposes to develop a dedicated C-section OR.

(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: {[(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) plus (Number of projected outpatient cases for all the applicant's or related entities' facilities times 1.5 hours)] divided by 1872 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.

- **NA** - The applicant does not propose to increase the number of ORs (excluding dedicated C-section operating rooms) in Martin County. The applicant proposes to develop a dedicated C-section OR.

(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** - MGH is not currently licensed for a dedicated C-section OR.

(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.

- **NA** - The applicant proposes to develop its first dedicated C-section OR. No projections were required by this Rule.

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 does not propose 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 does not propose 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 VII, pages 65, 66 and 68, the applicant provides the number of current and proposed staff for each of the areas listed above.

(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** - In Section VII, page 71, the applicant identifies the number of physicians who currently utilize the facility and the number expected to utilize the facility.

(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** - MGH is a general acute care hospital and, as such, all physicians practicing at the facility are members of the hospital's Medical Staff. Exhibit 18 includes a letter signed by the Chief Executive Officer for the hospital which states that the physicians practicing at the hospital are in good standing.

(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 does not propose to develop a single specialty demonstration facility.

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 does not propose to establish a licensed ambulatory surgical facility that will be physically located in a physician's office, 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 does not propose to establish a licensed ambulatory surgery 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, page 26, the applicant states that the existing facility conforms to all requirements of federal, state and local bodies and will continue to do so.

(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 does not propose to establish a new 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 surgery program or propose to add a specialty to a specialty ambulatory surgical program that does not propose to add physical space to the existing ambulatory surgical facility.