

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: September 28, 2018

Findings Date: October 5, 2018

Project Analyst: Ena Lightbourne

Team Leader: Lisa Pittman

Project ID #: E-11531-18

Facility: Graystone Eye Surgery Center, LLC

FID #: 923248

County: Catawba

Applicant: Graystone Eye Surgery Center, LLC
Graystone Enterprises, LLC

Project: Develop one procedure room and one additional operating room (OR) at its existing facility (for a total of one procedure room and three ORs) pursuant to an adjusted need determination in the 2018 SMFP

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

G.S. 131E-183(a) The Agency shall review all applications utilizing the criteria outlined in this subsection and shall determine that an application is either consistent with or not in conflict with these criteria before a certificate of need for the proposed project shall be issued.

- (1) The proposed project shall be consistent with applicable policies and need determinations in the State Medical Facilities Plan, the need determination of which constitutes a determinative limitation on the provision of any health service, health service facility, health service facility beds, dialysis stations, operating rooms, or home health offices that may be approved.

C

Graystone Eye Surgery Center, LLC (GESC) and Graystone Enterprises, LLC, located in Hickory, propose to develop one procedure room and one additional operating room (OR) at its an existing ambulatory surgical facility, GESC (for a total of three ORs one procedure room) pursuant to an adjusted need determination in the 2018 SMFP. The applicants may be referred to collectively as the applicant or individually by name.

In July 2017, Graystone petitioned the State Health Coordinating Council (SHCC) for an adjusted need determination for one additional OR for Catawba County. The petition was approved by the SHCC and the adjusted need determination was included in the 2018 SMFP as signed by the Governor. In response, the applicant proposes to develop one procedure room and one additional OR by renovating adjacent administrative space.

Need Determination

The 2018 State Medical Facilities Plan (2018 SMFP) includes an adjusted need determination for one additional OR in the Catawba County operating room service area. The applicant, proposes to develop one procedure room and one additional OR in existing space in GESG. Following the addition of the proposed OR, the hospital will have a total of 3 ORs and one procedure room.

Policies

Policy GEN-3: Basic Principles in the 2018 SMFP is applicable to this review.
Policy GEN-3, on page 33 of the 2018 SMFP, 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.”

The applicant addresses Policy GEN-3 as follows:

Promote Safety and Quality – The applicant describes how it believes the proposed project will promote safety and quality in Section N.2, pages 92-93 and Exhibit 8, which include GESG’s quality-related policies and procedures. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal will promote safety and quality.

Promote Equitable Access – in Section N.2, page 94, the applicant describes how it believes the proposed project will promote equitable access. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal will promote equitable access.

Maximize Healthcare Value – The applicant describes how it believes the proposed project will maximize healthcare value in Section N.2, page 91. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal will maximize healthcare value.

Policy GEN-4: Basic Principles in the 2018 SMFP is applicable to this review.

Policy GEN-4, on page 33 of the 2018 SMFP, 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, Certificate of Need 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 is 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.”

The applicant addresses Policy GEN-4 as follows:

In Section B.4, page 13, the applicant explains why it believes its application is conforming to Policy GEN-4. On page 13 the applicant states:

“The expansion project will be designed to be energy efficient and to conserve water, and will specifically conform to the 2012 North Carolina Energy Conservation Code. The applicant states Graystone will continue to implement an Energy Efficiency and Sustainability Plan that conforms to or exceeds energy efficiency and water conservation standards incorporated in the latest North Carolina State Building code.”

Conclusion

The agency reviewed the:

- Application
- Exhibits to the application
- Information publicly available during the review and used by the Agency.

Based on the review, the Agency concludes that the application is conforming to this criterion for the following reasons:

- The applicant does not propose to develop more ORs than are determined to be needed in the service area.
- The applicant adequately demonstrates that the proposal is consistent with Policy GEN 3 and GEN 4 for the following reasons:
 - The applicant demonstrates how the project will promote safety and quality, equitable access, and maximize healthcare value.
 - The applicant demonstrates how the project plan will assure improved Energy Efficiency.

(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

Graystone Eye Surgery Center, LLC (GESG) and Graystone Enterprises, LLC, located in Hickory, propose to develop one procedure room and one additional operating room (OR) at its an existing ambulatory surgical facility, GESG (for a total of three ORs one procedure room) pursuant to an adjusted need determination in the 2018 SMFP.

Patient Origin

On page 57, the 2018 SMFP states, “*An operating room’s service area is the operating room planning area in which the operation room is located. The operating room planning areas are the single and multicounty groupings shown in Figure 6.1.*” Figure 6.1 on page 62 of the 2018 SMFP shows Catawba County as a single-county OR service area. Thus, the service area for the facility consists of Catawba County. Facilities may also serve residents not included in their service area.

The following table illustrates current patient origin for surgical cases at GESG, based on dated provided in the 2018 License Renewal Application:

Ambulatory Surgery Patient Origin FY 2017		
County	Patients	% of Patients
Catawba	1,799	28.25%
Caldwell	827	12.98%
Lincoln	456	7.16%
Wilkes	424	6.66%
Alexander	323	5.07%
Burke	261	4.10%
Watauga	221	3.47%
Iredell	217	3.41%
Ashe	111	1.74%
Avery	91	1.43%
Other	1,639	25.73%
Total	6,369	100.00%

*Other identified on p.18 and in the 2018 LRA

In Section C.3, page 20, the applicant provides the projected patient origin for surgical services for the first two years of operation following completion of the project as follows:

Counties	2020		2021	
	Patients	% of Patients	Patients	% of Patients
Catawba	2,125	28.25%	2,210	28.25%
Caldwell	977	12.98%	1,016	12.98%
Lincoln	539	7.16%	560	7.16%
Wilkes	501	6.66%	521	6.66%
Alexander	381	5.07%	397	5.07%
Burke	308	4.10%	321	4.10%
Watauga	261	3.47%	271	3.47%
Iredell	256	3.41%	267	3.41%
Ashe	131	1.74%	136	1.74%
Avery	107	1.43%	112	1.43%
*Other	1,936	25.73%	2,013	25.7%
Total	7,522	100.00%	7,824	100.00%

*includes remaining counties

In Section C, page 20, the applicant states that projected patient origin is based on its 2017 ambulatory surgery patient origin. The applicant's assumptions are reasonable and adequately supported.

Analysis of Need

In Section Q.1, page 102, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. On page 102, the applicant states:

“Despite the capacity constraints of only two ORs, Graystone has managed to steadily increase its surgical volume in recent years. Graystone has facilitated this growth by starting surgical cases earlier in the morning and remaining open later in the evening. Graystone has also grown its medical staff to include three new surgeons within the past two years. These aspects along with the aging demographics in the local serving area, have directly contributed to the growth in surgical volume at Graystone. Based on to-date FY2018 data (Oct-May), Graystone’s surgical case volume is projected to increase an additional 9.7%.”

The information is reasonable and adequately supported for the following reasons:

- In Section C.4, pages 23-24, the applicant demonstrates the need for the OR based on the increase in surgical volume and its need to make adjustments to accommodate the need. These adjustments include:
 - Starting surgical cases early in the morning and remaining open later in the evening.
 - Adding three new surgeons with the past two years.
- In Section Q.1, page 102, the applicant provides a table reflecting a 4.8% increase for surgical cases between for FY2015-FY2018. The applicant states that based on annualized FY2018 data (Oct-May), GESC’s surgical case volume is projected to increase an additional 9.7%.

Projected Utilization

In Section Q.2, the applicant provides historical and projected surgical utilization as illustrated in the following table(s).

**Graystone Eye Surgery Center (GESC)
Historical Ambulatory Surgical Cases, FY2014-FY2018**

Year	Cases	Growth
FY2014	5,924	
FY2015	6,069	2.4%
FY2016	6,208	2.3%

FY2017	6,369	2.6%
FY2018*	6,989	9.7%

*Annualized based on 8 months data (Oct-May)

Graystone Eye Surgery Center	Last full FY (2019)	1st Full FY (2020)	2ND Full FY (2021)	3rd Full FY (2022)
Number of ORs (1)	2	3	3	3
Standard Hours per OR per year (2)	1312.5	1312.5	1312.5	1312.5
Ambulatory Surgical Cases*	6,989	7,164	7,522	7,823
Final Ambulatory Case Time in Minutes (3)	30	30	30	30
Ambulatory Surgical Hours (4)	3494.5	3582.0	3761.0	3911.5
Total Surgical Hours (5)	3494.5	3582.0	3761.0	3911.5
# of ORs Needed (6)	2.7	2.7	2.9	3.0

- (1) Last Full FY is from Table 6A in the 2018 SMFP. The first three full FYs includes the OR proposed in this application
- (2) From Table 6A in the 2018 SMFP
- (3) From Table 6B in the 2018 SMFP
- (4) Surgical Hours equals Surgical Cases multiplied by the Final Case Time.
- (5) Total Surgical Hours equals inpatient Surgical Hours plus Ambulatory Surgical Hours.

Summary	Graystone Eye Surgery Center
Number of Existing ORs	2
# of ORs Needed by FY2022	3
Difference	1

In Section Q, the applicant provides the assumptions and methodology used to project utilization, which is summarized below.

The applicant states the need for the OR is based the following:

- CAGR for Graystone surgical cases is 2.4% from FY2014 - FY2015 (page 34)
- CAGR for Graystone surgical cases is 4.8% from FY2015 - FY2018 (annualized). (page 35)
- The 4-year population growth rate for all ages is projected to increase at a CAGR of 0.3% through 2012. (page 38)
- The 4-year population growth rate for age 65+ is projected to increase at a CAGR of 2.5% through 2022.
- 75.7% of GESC’s surgical cases are paid for by Medicare. (page 37)
- In Section Q.2 pages 103-104, the applicant uses the projected population growth rate for Catawba County residents age 65 and older of 2.5% to grow utilization for the interim year FY2019.
- GESC projects 5% growth in cases in PY1 based on pent-up demand.

- Growth in cases is slightly lower in PY2 and PY3 at 4% and 3% respectively.

Projected utilization is reasonable and adequately supported for the following reasons:

- GESCC's historic and current utilization shows applicant applied conservative CAGR growth rates in its projections.
- Methodology and assumptions are adequately supported.
- There is an adjusted need determination in the 2018 SMFP for one OR in Catawba County.

Access

In Section C.8, pages 43-44, the applicant states all area residents, including low income persons, racial and ethnic minorities, women, handicapped persons, elderly and other underserved groups, will continue to have access to the proposed expanded Ambulatory Service Center (ASC) as clinically appropriate. Exhibit 10 contains copies of policies and procedures on financial hardship/charity care to indigent and Medicaid patients. In Section L, page 87, the applicant projects the following payor mix during the second full fiscal year of operation following completion of the project, as illustrated in the following table:

**Projected Payor Mix
Year 2 FY2021**

Payor Source	Operating Rooms	Procedure Rooms as Percent of total
Self-Pay	0.68%	1.14%
Medicare*	75.71%	76.10%
Medicaid*	1.88%	1.14%
Insurance*	19.52%	20.03%
Other (VA, Tricare & other government	2.21%	1.59%
Total	100.0%	100.0%

The projected payor mix is based on the historical mix of surgical and non-surgical cases and reasonable and adequately supported.

Conclusion

The agency reviewed the:

- Application
- Exhibits to the application
- Information publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the application is conforming to this criterion for the following reason:

- The applicant adequately identifies the population to be served
- The applicant adequately explains why the population to be served needs the services proposed on the application
- Projected utilization is reasonable and adequately supported
- The applicant projects the extent to which all residents, including underserved groups, will have access to the proposed services (payor mix) and adequately supports its assumptions.

- (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

The applicant does not propose to reduce, eliminate or relocate a facility or service; therefore, Criterion (3a) is not applicable to this review.

- (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

Graystone Eye Surgery Center, LLC (GESC) and Graystone Enterprises, LLC, located in Hickory, propose to develop one procedure room and one additional operating room (OR) at its an existing ambulatory surgical facility, GESC (for a total of three ORs one procedure room) pursuant to an adjusted need determination in the 2018 SMFP.

In Section E.2, pages 55-56, the applicant describes the alternatives it considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

- Maintain the Status Quo – The applicant states that this was not an effective alternative because it unnecessarily eliminates needed local access to cost-effective outpatient surgery services. Due to the continued growth of ophthalmic surgical cases, OR time is limited at Graystone (GESC). The capacity constraints are problematic from an operational and patient access perspective.
- Develop the OR in Another Geographical Location – The applicant states that the proposed project is in response to the growing demands in the local area for ophthalmic surgery. The facility is located in close proximity to area hospitals and

physician offices, thus patients and physicians have convenient access to the facility's services.

- Develop a Multi-Specialty ASC with Procedure Rooms – The applicant states that there is insufficient surgical capacity to accommodate surgical cases from different surgical specialties. The applicant demonstrates in Section Q, the need for three ORs based on projected ophthalmic surgical utilization.

The applicant adequately demonstrates that the alternative proposed in this application is the most effective alternative to meet the need for the following reasons:

Developing an additional surgical operation room at its existing facility will address the increase in utilization as well as the projected utilization growth of 9.7% in FY 2018 as demonstrated by the applicant in Section Q, pages 101-106.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above. Therefore, the application is approved subject to the following conditions:

- 1. Graystone Eye Surgery Center, LLC and Graystone Enterprises, LLC shall materially comply with all representations made in the certificate of need application.**
- 2. Graystone Eye Surgery Center, LLC and Graystone Enterprises, LLC shall develop one additional operating room for a total of no more than 3 surgical operating rooms.**
- 3. Graystone Eye Surgery Center, LLC and Graystone Enterprises, LLC shall developed no more than 1 procedure room.**
- 4. Graystone Eye Surgery Center, LLC and Graystone Enterprises, LLC shall not acquire as part of this project any equipment that is not included in the project's proposed capital expenditures in Sections F and Q of the application and that would otherwise require a certificate of need.**
- 5. For the first three years of operation following completion of the project, Graystone Eye Surgery Center, LLC and Graystone Enterprises, LLC shall not increase charges more than 5% of the charges projected in Section F of the application without first obtaining a determination from the Healthcare Planning**

and Certificate of Need Section that the proposed increase is in material compliance with the representations in the certificate of need application.

- 6. The procedure room shall not be used for procedures that should be performed only in an operating room based on current standard of practice.**
 - 7. Procedures performed in the procedure room shall not be reported for billing purposes as having been performed in an operation room and shall not be reported on the facility's license renewal application as procedures performed in an operation room.**
 - 8. No later than three months after the last day of each of the first three full years of operation following initiation of the services authorized by this certificate of need, Graystone Eye Surgery Center, LLC and Graystone Enterprises, LLC shall submit, on the form provided by the Healthcare Planning and Certificate of Need Section, an annual report containing the:**
 - a. Payor mix for the services authorized in this certificate of need.**
 - b. Utilization of the services authorized in this certificate of need.**
 - c. Revenues and operating costs for the services authorized in this certificate of need.**
 - d. Average gross revenue per unit of service.**
 - e. Average net revenue per unit of service.**
 - f. Average operating cost per unit of service.**
 - 9. Graystone Eye Surgery Center, LLC and Graystone Enterprises, LLC shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency 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 Q, Form F.1a, the applicant projects the total capital cost as follows:

DESCRIPTION	COST
Equipment /Furniture Costs	\$ 666,594
Site Costs	N/A
Construction/Renovation Costs	\$1,800,000
Professional Fees	\$ 140,000
Miscellaneous Costs	\$ 181,820

TOTAL	\$2,788,414
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In Section F.3, page 60, the applicant states there are no start-up expenses or initial operating expenses associated with the project, since it involves developing an OR in existing OR space and the facility is currently operational.

Availability of Funds

In Section F.2, page 58, the applicant states that the capital cost will be funded as shown in the table below.

Source of Capital Funding

Type	Graystone Enterprise, LLC	Graystone Eye Surgery Center, LLC	Total
Loans	\$2,055,150	\$678,264	\$ 2,733,414
Accumulated reserves or OE *	\$0	\$ 55,000	\$ 55,000
Bonds	\$0	\$0	\$0
Other (Specify)	\$0	\$0	\$0
Total Financing **	\$2,055,150	\$ 733,264	\$2,788,414

*OE = Owner's equity

In Section F.2, page 58, the applicant states that the applicants will fund most of the proposed project using commercial bank loans. Exhibit 14 contains a letter from First Citizens Bank confirming the availability of commercial loans for the proposed project.

In Section F.2, page 59, the applicant states that Graystone will fund a portion of the project via accumulated reserve. Exhibit 14 contains a letter dated June 7, 2018 from the Chief Executive Officer for Graystone Eye Surgery Center, LLC, authorizing and committing cash reserves of \$55,000 for costs associated with CON consultant and CON application fees. Exhibit 14 also contains a balance sheet for Graystone Eye Surgery Center, LLC, for the year ending in December 31, 2017. For Year ending December 31, 2017, Graystone Eye Surgery Center, LLC, had \$2,948,601 in total assets and \$431,253 in net assets (total assets less total liabilities).

Financial Feasibility

The applicant provides pro forma financial statements for the first three full fiscal years of operation following completion of the project. In the pro forma financial statement (Form F.3) for surgical services, the applicant projects that revenues will exceed operating expenses in the first three operating years of the project, as shown in the table below.

	1st Full Fiscal Year 2020	2nd Full Fiscal Year 2021	3rd Full Fiscal Year 2022
Total Cases and Procedures	9767	10,180	10,533
Total Gross Revenues (Charges)	\$31,436,121	\$32,707,707	\$33,718,635
Net Patient Revenue	\$11,386,791	\$11,847,418	\$12,213,665
Total Operating Expenses (Costs)	\$8,588,852	\$9,240,356	\$9,550,298
Net Income	\$2,799,581	\$2,608,736	\$2,665,075

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

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for the following reasons:

- The applicant adequately demonstrates that the capital costs are based on reasonable and adequately supported assumptions.
- The applicant adequately demonstrates availability of sufficient funds for the capital needs of the proposal.
- The applicant adequately demonstrates sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.

- (6) The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

Graystone Eye Surgery Center, LLC (GESc) and Graystone Enterprises, LLC, located in Hickory, propose to develop one procedure room and one additional operating room (OR) at its an existing ambulatory surgical facility, GESc (for a total of three ORs one procedure room) pursuant to an adjusted need determination in the 2018 SMFP.

On page 57, the 2018 SMFP defines the service area for operating rooms as

“An operating room’s service area is the operating room planning area in which the operating room is located.”

Thus, the service area for the facility consists of Catawba County. Facilities may also serve residents not included in their service area.

The following table identifies all existing and approved operating rooms located in Catawba County, as shown in Table 6A, page 64, of the 2018 SMFP.

FACILITY	INPATIENT ORS	AMBULATORY ORS	SHARED ORS	EXCLUDED C-SECTION ORS	TOTAL
Graystone Eye Surgery Center	0	2	0	0	2
Viewmont Surgery Center	0	3	0	0	3
Frye Regional Medical Center	2	4	15	0	21
Catawba Valley Medical Center	1	0	12	-1	12
Total	3	9	27	-1	38

In Section G, page 66, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved surgical services in Catawba County. The applicant states:

“Graystone demonstrates the need the population has for the proposed additional OR based on demographic data specific to the OR service area, historical Graystone surgical utilization, and qualitative benefits.”

The applicant adequately demonstrates that the proposal would not result in an unnecessary duplication of existing or approved ORs in the service area for the following reasons:

- There is an adjusted need determination in the 2018 SMFP for the proposed OR.
- The applicant adequately demonstrates that the proposed OR is needed in addition to the existing or approved ORs.

(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 Q, Form H, the applicant provides current and projected staffing for the proposed services as illustrated in the following table:

Position	Current	Projected		
	As of 6/30/18	1 st Full Fiscal Year	2 nd Full Fiscal Year	3 rd Full Fiscal Year
RNs	15.0	21.0	24.0	24.0
LPNs	1.0	1.0	1.0	1.0
Technicians	10.0	13.0	15.0	15.0
Administrator	1.0	1.0	1.0	1.0
Asst. Administrator	1.0	1.0	1.0	1.0
Clerical/Registration	3.0	3.0	3.0	3.0
Medical Director	1.0	1.0	1.0	1.0
Chief Financial Officer	0.33	0.33	0.33	0.33
Business Office Manager	0.33	0.33	0.33	0.33
Clerical/Registration	4.0	4.0	4.0	4.0
Manager (CEO)	0.2	0.2	0.2	0.2
Accounting	1.0	1.0	1.0	1.0
IT	0.5	0.5	0.5	0.5
TOTAL	38.36	47.36	52.36	52.36

The assumptions and methodology used to project staffing are provided in Section H. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form F.3, which is found in Section Q. In Section H, pages 68-69, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs. In Section H, page 70, the applicant identifies the current medical director, James Harris, Jr, MD. In Exhibit 4, the applicant provides a letter from Dr. Harris indicating an interest in continuing to serve as medical director for the proposed services. In Section H, page 69, the applicant describes its physician recruitment plans.

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

- (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 I.1, page 72, the applicant states that the following ancillary and support services are necessary for the proposed services, and explains how each will be made available:

- Administration provided by GESC, via an employed ASC Administrator
- Surgical services are provided by surgeons with privileges at GESC.
- Reception, medical records and associated office requirements provided by a GESC receptionist and business office personnel.
- Medical supplies are ordered from vendors by surgery staff.
- Dietary/light nourishment/snacks are provided post-operatively as needed, by nursing staff
- Laundry, maintenance, housekeeping, and pharmacy are supported through second-party contracts.
- Anesthesiology and Pathology are provided via an arrangement with the clinical contractors (Carolina Anesthesia Associates and Piedmont Pathology respectively) that bill patients directly for those professional services.

On page 72, the applicant adequately explains how each ancillary and support service is or will be made available and provides supporting documentation in Exhibit 16.

In Section I.1, page 73, the applicant describes its existing and proposed relationships with other local health care and social service providers and provides supporting documentation in Exhibit 16. The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that 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

The applicant does not project to provide the proposed services to a substantial number of persons residing in Health Service Areas (HSAs) that are not adjacent to the HSA in which the services will be offered. Furthermore, the applicant does not project to provide the proposed services to a substantial number of persons residing in other states that are not adjacent to the North Carolina County in which the services will be offered.

- (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

The applicant is not an HMO. Therefore, this Criterion is not applicable to this review.

- (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 K.2, page 77, the applicant states that the project involves expanding the ASC by converting adjacent administrative spaces into an additional operating room, procedure room, and the necessary surgical support spaces. Line drawings are provided in Exhibit 12.

On page 78, the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal and provides supporting documentation in Exhibit 12.

On page 78, the applicant adequately explains why the proposal will not unduly increase the costs to the applicant of providing the proposed services or the costs and charges to the public for the proposed services. The applicant states that GESC is not affiliated with any Hospital Outpatient Department (HOPD), does not have hospital payor contracts and its reimbursement eligibility is below HOPDs, enabling GESC to provide services for less than the HOPDs.

On pages 78-79, the applicant identifies any applicable energy saving features that will be incorporated into the construction plans. The applicant states the existing GESC facility was constructed in 2008 and uses modern energy conservation practices and methods, featuring energy efficiency and water conservation. GESC's design for the expanded ASC will ensure continued compliance with all applicable federal, state, and local building codes, and requirements for energy efficiency and consumption, including Policy Gen-4. The existing facility was designed to be energy efficient and to conserve water, with water fixtures such as, toilet and faucets designed as low flow to conserve water.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that 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;

In Section L.1, page 85, the applicant provides the historical payor mix during FY 2017 for the proposed services as shown in the table below.

**Greystone Eye Surgery Center (GESC)
 Payor Mix, FY2017**

Payor Category	Operating rooms as Percent of total	Procedure rooms as Percent of total
Self-Pay	0.68%	1.14%
Medicare*	75.71%	76.10%
Medicaid*	1.88%	1.14%
Insurance	19.52%	20.03%
Other (VA, Tricare & other government)	2.21%	1.59%
Total	100.0%	100.0%

*including any managed care plans

In Section L, page 84, the applicant provides the following comparison:

	Percentage of Total Patients Served by Graystone, CY2017	Percentage of the Population of Catawba County
Female	58.5%	51.0%
Male	41.4%	49.0%
Unknown	0.1%	0.0%
64 and Younger	24.2%	83.0%
65 and Older	75.8%	17.0%
American Indian	0.0%	0.06%
Asian	1.0%	4.2%
Black or African-American	4.0%	8.9%
Native Hawaiian or Pacific Islander	0.0%	0.1%
White or Caucasian	94.0%	84.4%
Other Race	1.0%	1.8%
Declined / Unavailable	0.0%	0.0%

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

C

Regarding any obligation to provide uncompensated care, community services or access by minorities and persons with disabilities, in Section L.2, page 85, the applicant states the following:

“Graystone has no obligation under applicable Federal regulations to provide uncompensated care, community service, or access by minorities and handicapped persons. However, continuing its current business practice, Graystone does not discriminate based on race, color, religion, national origin, age, disability, gender, or ability to pay.”

On page 87, the applicant describes how it provides charity or reduced cost care.

In Section L.2, page 86, the applicant states that during the last five years no patient civil rights access complaints have been filed against the facility or any similar facilities owned by the applicant or a related entity and located in North Carolina.

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that 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 L.3, page 87, the applicant projects the following payor mix for the proposed services during the second full fiscal year of operation following completion of the project, as shown in the table below.

**Greystone Eye Surgery Center (GESC)
Projected Payor Mix, FY2021**

Payor Category	Operating rooms as Percent of total	Procedure rooms as Percent of total
Self-Pay	0.68%	1.14%
Medicare *	75.71%	76.10%
Medicaid*	1.88%	1.14%
Insurance	19.52%	20.03%
Other (VA, Tricare & other government)	2.21%	1.59%
Total	100.0%	100.0%

*including any managed care plans

As shown in the table above, during the second full fiscal year of operation, the applicant projects that approximately 1% of services will be provided to self-pay patients, 76% to Medicare patients and 2% to Medicaid patients.

In Section L.3, page 87, the applicant states that the projected GESC payor mix is based on the historical payor mix of surgical cases and non-surgical procedures performed by GESC surgeons. GESC does not anticipate any significant change in payor mix for surgical services during the initial three project years.

The Projected payor mix is reasonable and adequately supported because it is based on the historical payor mix.

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that 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 L.5, page 88, the applicant describes the range of means by which a person will have access to its surgical services. The applicant adequately demonstrates that the facility will offer a range of means by which patients will have access to surgical services. Therefore, the application is conforming to this criterion.

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that 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 M.1, page 89, the applicant describes the extent to which health professional training programs in the area have access to the facility for training purposes and provides supporting documentation in Exhibit 15.

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the applicant adequately demonstrates that the proposed services will accommodate the clinical needs of area health professional training programs, and 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

Graystone Eye Surgery Center, LLC (GES) and Graystone Enterprises, LLC, located in Hickory, propose to develop one procedure room and one additional operating room (OR) at its an existing ambulatory surgical facility, GES (for a total of three ORs one procedure room) pursuant to an adjusted need determination in the 2018 SMFP.

On page 57, the 2018 SMFP defines the service area for operating rooms as:

“An operating room’s service area is the operating room planning area in which the operating room is located.”

Figure 6A on page 64 of the 2018 SMFP shows Catawba County as a single-county operating room service area. Thus, the service area is Catawba County. Providers may serve residents of counties not included in their service area.

In Section, G.2, page 66, the applicant identifies the existing and approved services in the service area as demonstrated in the table below.

FACILITY	INPATIENT ORS	AMBULATORY ORS	SHARED ORS	EXCLUDED C-SECTION ORS	TOTAL
Graystone Eye Surgery Center	0	2	0	0	2
Viewmont Surgery Center	0	3	0	0	3
Frye Regional Medical Center	2	4	15	0	21
Catawba Valley Medical Center	1	0	12	-1	12
Total	3	9	27	-1	38

In Section N, pages 91-94, the applicant describes the expected effects of the proposed services on competition in the service area and discusses how any enhanced competition in the service area will promote the cost-effectiveness, quality and access to the proposed services. On page 91, the applicant states:

“The Graystone OR expansion project will promote cost-effectiveness, quality and access to services via an ASC with increased capacity to better serve the residents, and therefore will enhance competition in the proposed service area because it will enable Graystone to better meet the needs of Graystone’s existing patient population, and to ensure more timely provision of and convenient access to outpatient surgical services for all area residents.”

The applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates:

- The cost-effectiveness of the proposal (see Sections F and Q of the application and any exhibits)
- Quality services will be provided (see Sections N and O of the application and any exhibits)
- Access will be provided to underserved groups (see Sections L and N of the application and any exhibits)

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

- (19) Repealed effective July 1, 1987.
- (20) An applicant already involved in the provision of health services shall provide evidence that quality care has been provided in the past.

C

In Section O.3, page 98, the applicant states that GESC and the physical owners of GESC, do not own, manage, or operate another licensed healthcare facility.

In Section O, page 97, the applicant states that, during the 18 months immediately preceding the submittal of the application that no incidents related to the quality of care occurred. According to files in the Acute and Home Care Licensure and certification Section, during the 18 months immediately preceding submission of the application through the date of this decision, no incidents related to quality of care occurred.

The applicant provided sufficient evidence that quality care has been provided in the past. 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 Criteria and Standards for Surgical Services and Operating Rooms, promulgated in 10A NCAC 14C.2100, are applicable to this review. The specific criteria are discussed below.

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

.2103 PERFORMANCE STANDARDS

- .2103 (a) *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 demonstrate the need for the number of proposed operating rooms in the facility that is proposed to be developed or expanded in the third operating year of the project based on the Operating Room Need Methodology set forth in the 2018 State Medical Facilities Plan. The applicant is not required to use the population growth factor.*
- C- The proposal would increase the number of ORs at GESC. The applicant projects sufficient surgical cases and hours to demonstrate the need for one additional OR at GESC in the third operating year of the project based on the Operating Room Need Methodology in the 2018 SMFP. The discussion regarding the projected utilization found in Criterion (3) is incorporated herein by reference.
- .2103 (b) *A proposal to increase the number of operating rooms (excluding dedicated C-section operating rooms) in a service area shall demonstrate the need for the number of proposed operating rooms in addition to the existing and approved operating rooms in the applicant's health system in the third operating year of the proposed project based on the Operating Room Need Methodology set forth in the 2018 State Medical Facilities Plan. The applicant is not required to use the population growth factor.*
- NA- Existing operating rooms are not in a health system. GESC is a single facility.
- .2103 (c) *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 not proposed to develop an additional dedicated C-section operating room as part of this proposal.

.2103 (d) An applicant proposing to convert a specialty ambulatory surgical program to a multispecialty ambulatory surgical program or to add a specialty area 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 1,312.5 hours per operating room per year; and*
- (2) demonstrate the need in the third operating year of the project based on the Operating Room Need Methodology set forth in the 2018 State Medical Facilities Plan. The applicant is not required to use the population growth factor.*

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

.2103(e) The applicant shall document the assumptions and provide data supporting the methodology used for each projection in this Rule.

-C- The applicant provides assumptions and data supporting the methodology used for the OR projections in Section C, pages 34, 40-41 and Section Q, Form C.