

REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: July 26, 2024

Findings Date: July 26, 2024

Project Analyst: Crystal Kearney

Co-Signer: Mike McKillip

Project ID #: E-12511-24

Facility: Graystone Eye Surgery Center

FID #: 923248

County: Catawba

Applicants: Graystone Eye Surgery Center, LLC

Graystone Enterprises, LLC

Project: Develop no more than one additional operating room pursuant to the 2024 SMFP need determination for total of no more than four operating rooms upon project completion

REVIEW CRITERIA

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

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

C

Graystone Eye Surgery Center, LLC (GESOC) and Graystone Enterprises, LLC (hereinafter referred to as “the applicant” or “GESOC”), proposes to develop one additional operating room (OR) at an existing licensed ambulatory surgical facility (ASF) in Hickory, for a total of four operating rooms serving ophthalmology patients, pursuant to the 2024 State Medical Facilities Plan (SMFP) need determination for one additional OR in Catawba County.

Need Determination

In the 2024 SMFP, Table 6C: Operating Room Need Determination shows a need determination for one OR in Catawba County operating room (OR) service area. The applicant

is proposing to develop one OR. The application is consistent with the need determination in the 2024 SMFP.

Policies

There is one policy in the 2024 SMFP which is applicable to this review: *Policy GEN-3: Basic Principles*.

Policy GEN-3: Basic Principles, on page 30 of the 2024 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.”

In Section B, pages 26-27, the applicant explains why they believe the application is conforming to Policy GEN-3.

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 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 for the following reasons:
 - The applicant adequately documents how the project will promote safety and quality, and equitable access in the delivery of care,
 - The applicant states that it will maximize healthcare value for resources expended in the delivery of service
 - The applicant states that it will incorporate the concepts of safety and quality and maximum value for resources expended in meeting the need identified in the 2024 SMFP.

- (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, ... persons [with disabilities], the elderly, and other underserved groups are likely to have access to the services proposed.

C

The applicant proposes to develop no more than one additional operating room pursuant to the 2024 SMFP need determination for total of no more than four operating rooms upon project completion.

In Section C, pages 28-29, the applicant states that,

“The applicant will develop the additional operating room by converting a procedure room within the existing GESC ASF located at 2424 Century Place SE in Catawba County. The Hickory facility is located in a healthcare focused office park off of Tate Boulevard, less than two miles from Catawba Valley Medical Center, and proximate to Interstate 40 and U.S. Highways 70 and 321, which makes GESC accessible to residents from throughout Catawba County and to residents of other counties. GESC will continue to be committed to offering superior service, including prompt appointments, exceptional patient care, efficient and customized communication, and on-going patient education.”

Patient Origin

On page 47, the 2024 SMFP defines the service area for OR as “single or multicounty grouping shown in Figure 6.1.” Figure 6.1, on page 53, shows Catawba County is a single county operating room service area. Thus, the service area for this facility consists of Catawba County. Facilities may also serve residents of counties not included in their service area.

In Section C, page 29, the applicant provides the following table showing historical patient origin for the existing ORs at GESC.

Graystone Eye Surgery Center Operating Rooms	Historical Patient Origin 10/01/2022 to 09/30/2023	
	# of Patients	% of Total
Catawba	2,773	35.86%
Caldwell	1,181	15.27%
Burke	655	8.47%
Lincoln	504	6.52%
Watauga	497	6.43%
Alexander	448	5.79%
Wilkes	399	5.16%
Avery	261	3.38%
Iredell	232	3.00%
Ashe	191	2.47%
Cleveland	149	1.93%
Gaston	121	1.56%
Other NC Counties	267	3.45%
Other States	53	0.69%
Total	7,732	100.00%

Source: Section C, page 29

In Section C, page 32, the applicant provides projected patient origin for the ORs at GESG for the first three project years (PY), CYs 2025-2027, as shown in the following table:

GRAYSTONE EYE SURGERY CENTER PROJECTED PATIENT ORIGIN - ORs						
COUNTY	1 ST FULL FY CY 2025		2 ND FULL FY CY 2026		3 RD FULL FY CY2027	
	# OF PATIENTS	% OF TOTAL	# OF PATIENTS	% OF TOTAL	# OF PATIENTS	% OF TOTAL
Catawba	3,458	35.86%	3,527	35.86%	3,596	35.86%
Caldwell	1,473	15.27%	1,502	15.27%	1,532	15.27%
Burke	817	8.47%	833	8.47%	849	8.47%
Lincoln	629	6.52%	641	6.52%	654	6.52%
Watauga	620	6.43%	632	6.43%	645	6.43%
Alexander	559	5.79%	570	5.79%	581	5.79%
Wilkes	498	5.16%	507	5.16%	517	5.16%
Avery	325	3.38%	332	3.38%	338	3.38%
Iredell	289	3.00%	295	3.00%	301	3.00%
Ashe	238	2.47%	243	2.47%	248	2.47%
Cleveland	186	1.93%	189	1.93%	193	1.93%
Gaston	151	1.56%	154	1.56%	157	1.56%
Other NC Counties	334	3.46%	340	3.46%	347	3.46%
Other States	67	0.69%	68	0.69%	69	0.69%
Total	9,642	100.00%	9,833	100.00%	10,028	100.00%

Source: Section C, page 32

In Section Q, the applicant provides the assumptions and methodology used to project its patient origin. The applicant's assumptions are reasonable and adequately supported because they are based on the historical patient origin of outpatient surgical cases performed at the facility.

Analysis of Need

In Section C, pages 34-35, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services, as summarized below:

- The applicant states that the six-year compound average growth rate of outpatient surgical cases at GESC is 5.93%. The applicant states that the three existing GESC's operating rooms are well utilized.
- The Catawba County population has been steadily increasing and aging and is projected to continue to grow during the next four years. The projected elderly population growth is greater than the overall projected population growth for Catawba County. These characteristics will contribute to the continuing need for adequate access to outpatient surgery, and in particular, ophthalmic surgical services.
- The applicant states that the Catawba County is the medical hub for the western Piedmont region and exhibits a high percentage of ambulatory surgery in-migration. The applicant serves patients from a broad geographic catchment area, with 64% of patients originating from outside Catawba County.
- The applicant states that the additional OR capacity at the ASF will help Catawba County to improve its health ranking, by benefiting Catawba County residents with enhanced local access to value-based outpatient surgical services.
- The applicant states patients prefer the simplified admissions process and discharge procedures, the onsite parking, and the less institutional atmosphere of an ASF.
- The applicant states that with a medical staff of 15 physicians, the facility has continued to grow in the number of cases performed each year, and that the busy schedule has resulted in delays for scheduling new patient appointments.

The information is reasonable and adequately supported based on the following:

- The applicant provides historical utilization data at GESC to support its assertions regarding growth.
- The applicant relies on population growth and age data for the service area from the North Carolina Office of State Budget and Management (NCOSBM).
- The applicant provides utilization data for the proposed services from the National Health Statistics Report from the Centers for Disease Control (CDC).

Projected Utilization

In Section Q, page 115, the applicant provides projected utilization, as illustrated in the following table:

GRAYSTONE EYE SURGERY CENTER			
Projected Utilization			
	1ST Full FY CY 2025	2ND Full FY CY 2026	3RD Full FY CY 2027
Operating Rooms			
Total # ORs	4	4	4
Outpatient Surgical Cases	9,642	9,833	10,028
Outpatient Surgical Case Time	35.0	35.0	35.0
Total Outpatient Surgical Hours	5,625	5,736	5,849
Group Assignment	5	5	5
Standard Hours per OR per Year	1,312	1,312	1,312
Total Surgical Hours/Standard Hours per OR per Year	4.29	4.37	4.46

Source: Section Q, page 115

In Section Q, pages 116-117, the applicant provides the assumptions and methodology used to project utilization, summarized as follows:

The applicant states that GESG currently operates three operating rooms under the ASF license. The table below summarizes the most recent historical utilization of the facility.

**Graystone Eye Surgery Center
 Historical Outpatient Surgery Utilization, CY2017- CY2023**

	CY 2017	CY 2018	CY 2019	CY 2020	CY 2021	CY 2022	CY 2023	6-Yr CAGR
Outpatient Surgical Cases	6,561	7,298	7,583	7,092	8,794	8,894	9,272	5.93%

The applicant states that the six-year compound average growth rate of outpatient surgical cases at GESG is 5.93%.

The applicant states that to project future utilization, GESG conservatively projected increasing utilization CY 2024 through CY 2027 based on 33% of the historical (CY2017-CY2023) compound annual growth rate (CAGR) of 5.93%, or 1.98% (5.93/3).

**Graystone Eye Surgery Center
 Projected Outpatient Surgery Utilization, CY2024-CY2027**

	CY2024	CY2025	CY2026	CY2027	3-Yr CAGR
Outpatient Surgical Cases	9,445	9,642	9,833	10,028	1.98%

The applicant states that the following table projects OR need at GESG through 2027 using the projected OR cases and applying the 2024 SMFP OR need methodology, using the historical GESG average outpatient surgery case time of 35.0 minutes (or 0.5833 hours), and the stipulated standard hours per operating room per year of 1,312.

Projected GESC Operating Room Need

Year	CY2025	CY2026	CY2027
Total OP Surgery Cases	9,642	9,833	10,028
Average Case Time (Hours)	0.583	0.583	0.583
Total Surgical Hours	5,625	5,736	5,849
Group 5 Facility Standard Hours/OR	1,312	1,312	1,312
ORs Needed	4.29	4.37	4.46
ORs Needed (Rounded)	5.0	5.0	5.0

Projected utilization is reasonable and adequately supported based on the following:

- The utilization projection methodology is based on in the applicant’s experience providing outpatient surgical services and supported by the historical utilization of GESC.
- The applicant provides letters of support from surgeons and physicians in Exhibit I.2.

Access to Medically Underserved Groups

In Section C, page 58, the applicant states:

“All Catawba County residents (plus residents of other North Carolina counties), including low-income persons, racial and ethnic minorities, women, persons with disabilities, the elderly, Medicare and Medicaid beneficiaries, and any other underserved group, will continue to have access to GESC, as clinically appropriate.”

In Section C, page 58, the applicant provides the estimated percentage for each medically underserved group, as shown in the following table:

Medically Underserved Groups	Percentage of Total Patients
Low-income persons	12.3%
Racial and ethnic minorities	3.9%
Women	57.8%
Persons with Disabilities	10.0%
Persons 65 and older	73.8%
Medicare beneficiaries	68.6%
Medicaid recipients	1.9%

*On page 58, the applicant states GESC considers the estimated percentage of low-income persons and persons with disabilities will approximate the respective Catawba County population cohort percentages.

In Section C, page 57-58, the applicant adequately describes the extent to which all residents of the service area, including underserved groups, are likely to have access to 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 all the reasons described above.

- (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, ... persons [with disabilities], and other underserved groups and the elderly to obtain needed health care.

NA

The applicant does not propose reducing or eliminating any service, nor does it propose relocation of 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

The applicant proposes to develop no more than one additional operating room pursuant to the 2024 SMFP need determination for total of no more than four operating rooms upon project completion.

In Section E, pages 67-68, 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 Status Quo - The applicant states GESC could choose not to pursue development of an additional operating room. However, the applicant states that a decision to maintain the status quo unnecessarily limits needed operating room capacity. The applicant states that maintaining the status quo means the existing ORs continue to operate above the SMFP-defined capacity, and does not allow for capacity for additional surgeons, nor does it provide for long-term scalable solutions to meet expected demand, and will result in overworked staff, increased wait times for scheduling surgery, and potentially risk impacting quality of care. For these reasons, maintaining the status quo is not the most effective alternative.

Increase Hours of Operation - The applicant states that due to the continued growth in ophthalmic surgical cases, OR time is limited at GESC. The capacity constraints are problematic from an operational and patient access perspective. This is not an effective long-term solution, and thus, increasing hours of operation at GESC is not the most effective alternative.

Develop the Operating Room in Another Location – The applicant states that the proposed OR addition project is in response to growing demands in the local area for ophthalmic surgery. The applicant states that GESC provides ambulatory surgical services at its existing ASF in Hickory, which is located in the same building as the GOA physician clinic. An additional OR is needed at the existing GESC facility. The facility is located in close proximity to the physician clinics and to the county’s hospitals, so patients and physicians have convenient access to the facility’s services. The applicant states developing an entirely new, single -OR ASF is an expensive and comparatively inefficient solution. It would not be cost effective to develop a surgical operating room in another area of Catawba County. The applicant states that a major benefit of this proposal is leveraging the economies of scale from expanding an existing ASF, which already has existing administrative and support staff and spaces. The applicant states for these reasons, developing the proposed additional OR in another location is neither the least costly nor the most effective alternative.

Proposed Project - The applicant states that expanding OR capacity at GESC will enhance access to high quality, cost effective and accessible ambulatory surgical services for residents of Catawba County and surrounding communities. The applicant states that the existing ASF already has a procedure room designed to the specifications of an operating room, and thus the project capital cost is minimal. The applicant states that the expansion of OR capacity at GESC leverages the pre-existing support spaces, plus facility ancillary and support staff, for greater economies of scale. The applicant states that GESC ASF is adjacent to one of the Graystone physician clinics, which is convenient for both patients and surgeons. The applicant states that the addition of one OR at GESC would reduce the likelihood of patient travel outside the county to obtain outpatient surgery. The applicant states that the most effective alternative is to develop an additional OR at GESC, to better meet the on-going and growing need for value-based surgical services in Catawba County.

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

- The applicant provides reasonable information to explain why it believes the proposed project is the most effective alternative.
- The application is conforming to all other statutory and regulatory review criteria. Therefore, the application can be approved.

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 all the reasons described above. Therefore, the application is approved subject to the following conditions:

1. **Graystone Eye Surgery Center, LLC and Graystone Enterprises, LLC (hereinafter certificate holder) shall materially comply with all representations made in the certificate of need application.**
 2. **The certificate holder shall develop no more than one additional operating room at the existing ambulatory surgical facility, Graystone Eye Surgery Center.**
 3. **Upon completion of the project, Graystone Eye Surgery Center shall be licensed for a total of no more than four operating rooms.**
 4. **Progress Reports:**
 - a. **Pursuant to G.S. 131E-189(a), the certificate holder shall submit periodic reports on the progress being made to develop the project consistent with the timetable and representations made in the application on the Progress Report form provided by the Healthcare Planning and Certificate of Need Section. The form is available online at: <https://info.ncdhhs.gov/dhsr/coneed/progressreport.html>.**
 - b. **The certificate holder shall complete all sections of the Progress Report form.**
 - c. **The certificate holder shall describe in detail all steps taken to develop the project since the last progress report and should include documentation to substantiate each step taken as available.**
 - d. **The first progress report shall be due on January 1, 2025.**
 5. **The certificate holder shall not acquire as part of this project any equipment that is not included in the project's proposed capital expenditures in Section Q of the application and that would otherwise require a certificate of need.**
 6. **The certificate holder 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 following licensure of the facility.**
 7. **For the first three years of operation following completion of the project, the certificate holder shall not increase charges more than 5% of the charges projected in Section Q 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.**
 8. **The certificate holder 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

The applicant proposes to develop no more than one additional operating room pursuant to the 2024 SMFP need determination for total of no more than four operating rooms upon project completion.

Capital and Working Capital Costs

In Section Q, page 118, the applicant projects the total capital cost of the project, as shown in the table below.

GRAYSTONE EYE SURGERY CENTER, LLC PROJECTED CAPITAL COSTS	
Medical Equipment	\$17,441
Non-Medical Equipment	\$31,619
Consultant Fees	\$63,050
Other (project contingency)	\$22,422
Total Capital Cost	\$134,531

In Section F, page 71, the applicant states there will be no start-up costs or initial operating expenses because GESC is an existing and operational ambulatory surgical facility.

On page 69, F.2, the applicant provides the assumptions used to project the capital cost. The applicant adequately demonstrates that the projected capital cost is based on reasonable and adequately supported assumptions based on the following:

- The applicant states that the projected capital cost includes acquisition of minor equipment and instrumentation to equip the additional OR, plus consultant and project contingency.
- The applicant states that the addition of a fourth operating room at GESC does not require any facility expansion or uplift costs because GESC will convert its existing procedure room to an OR.
- The applicant states that they originally designed the procedure room to the specifications of an OR; the room has the same size and specifications as the three existing ORs.

Availability of Funds

In Section F, page 69, the applicant states that the capital cost will be funded as shown in the table below.

Sources of Capital Cost Financing

Type	GESC, LLC	Total
Loans	\$	\$
Accumulated reserves or OE *	\$ 134,531	\$134,531
Bonds	\$	\$
Other (Specify)	\$	\$
Total Financing	\$134,531	\$134,531

* OE = Owner's Equity

Exhibit F.2 includes documentation from GESC's Chief Financial Officer confirming the availability of funds for the project. Exhibit F.2 includes a copy of the CY2023 GESC financial statement, which confirms the availability of funds in the checking account. The applicant adequately demonstrates the availability of sufficient funds for the capital needs of the project.

Financial Feasibility

The applicant provided pro forma financial statements for the first three full fiscal years of operation following completion of the project. In Form 2 and F.3, the applicant projects that revenues will exceed operating expenses in the first three full fiscal years following completion of the project, as shown in the table below.

Graystone Eye Surgery Center Operating Rooms	1 st Full Fiscal Year CY2025	2 nd Full Fiscal Year CY2026	3 rd Full Fiscal Year CY2027
Total Cases	9,642	9,833	10,028
Total Gross Revenues (Charges)	\$47,249,260	\$49,147,432	\$51,121,862
Total Net Revenue	\$14,744,975	\$15,337,308	\$15,953,436
Average Net Revenue per Case	\$1,529	\$1,560	\$1,591
Total Operating Expenses (Costs)	\$11,817,521	\$12,476,054	\$13,208,059
Average Operating Expense per Case	\$1,226	\$1,269	\$1,317
Net Income	\$2,927,454	\$2,861,254	\$2,745,377

The assumptions used by the applicant in preparation of the pro forma financial statements are provided in Section Q. The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs and charges. See the discussion regarding projected utilization in Criterion (3) which is incorporated herein by reference.

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 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 revenues and operating expenses.
- (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 no more than one additional operating room pursuant to the 2024 SMFP need determination for total of no more than four operating rooms upon project completion.

On page 47, the 2024 SMFP defines the service area for OR as “single or multicounty grouping shown in Figure 6.1.” Figure 6.1, on page 53, shows Catawba County is a single county operating room service area. Thus, the service area for this facility consists of Catawba County. Facilities may also serve residents of counties not included in their service area.

The following table summarizes the existing operating rooms in Catawba County from Table 6A, page 55, of the 2024 SMFP.

Operating Room Inventory – Catawba County

Facility	OR Planning Inventory
Graystone Eye Surgery Center	3
Viewmont Surgery Center	3
Frye Regional Medical Center	21
Catawba Valley Medical Center	12

Source: Table 6A, 2024 SMFP

In Section G, pages 79-80, the applicant states the proposed project will not result in unnecessary duplication. The applicant states:

“Graystone Eye Surgery Center’s three existing operating rooms operated at 137 percent (9,272 cases x 35/60 minutes = 5,409 surgical hours/3 rooms (5,409/1,312) during CY2023, and the ASF currently demonstrates a need for 4.12 operating rooms (5,409/1,312). Demand for ophthalmic ambulatory surgical services is increasing among local, aging population cohort... If the OR capacity constraint at GESG is not relieved, Catawba County residents will increasingly be forced to either wait for extended periods of time to schedule their surgery at GESG or have to travel to another county for outpatient surgical care.”

The applicant adequately demonstrates that the proposal would not result in an unnecessary duplication of existing or approved OR services in the service area based on the following:

- There is a need determination for one OR in Catawba County in the 2024 SMFP and the applicant proposes to develop one OR.
- The applicant adequately demonstrates the proposed OR is needed in addition to the existing ORs in Catawba County.

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 all the reasons described above.

- (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

The applicant proposes to develop no more than one additional operating room pursuant to the 2024 SMFP need determination for total of no more than four operating rooms upon project completion.

In Section Q, page 124, the applicant provides full-time equivalent (FTE) staffing for the proposed services for each of the first three full years of operation, CYs 2025-2027, as illustrated in the following table:

POSITION	GRAYSTONE EYE SURGICAL CENTER PROJECTED FTE STAFF			
	CURRENT STAFF	1 ST FULL FY CY 2025	2 ND FULL FY CY 2026	3 RD FULL FY CY 2027
Registered Nurses (RNs)	22	26	27	28
Licensed Practical Nurses	1	1.5	1.5	2
Director of Nursing	1	1	1	1
Assistant Director of Nursing	1	1	1	1
Surgical Technicians	8	10	11	12
Materials Management	1	1	1	1
Information Technology	0.5	0.5	0.5	0.5
Administrator/CEO	0.1	0.1	0.1	0.1
Chief Financial Officer	0.3	0.3	0.3	0.3
Business Office	7	8	8	8
Clerical	2.5	3	3	3
Other (Medical Director)	1	1	1	1
Other (Patient Care Tech)	2	2.5	2.5	2.5
Total	47.4	55.9	57.9	60.4

The assumptions and methodology used to project staffing are provided in Section H. In Section H, pages 81-82, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs.

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services based on the following:

- The applicant states it uses variety of methods to recruit staff, including staff transfer opportunities from Graystone clinic locations, advertising in online employment sites and newspapers, digital recruiting services, open houses and community college job fairs, and staff recruitment/referral bonuses.
- The applicant states that GESG offers comprehensive training and continuing education for its staff members.
- The applicant states that all employees are required to attend new employee orientation at the beginning of their employment and continue to participate in annual safety and care environment training.

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 all the reasons described 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

The applicant proposes to develop no more than one additional operating room pursuant to the 2024 SMFP need determination for total of no more than four operating rooms upon project completion.

Ancillary and Support Services

In Section I, page 85, the applicant identifies the necessary ancillary and support services for the proposed services. On pages 85-86, the applicant explains how each ancillary and support service is or will be made available and provides supporting documentation in Exhibit I.1.3. The applicant adequately demonstrates that the necessary ancillary and support services will be made available.

Coordination

In Section I, page 86, the applicant describes its existing and proposed relationships with other local health care and social service providers and provides supporting documentation in Exhibit I.2. The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system based on the following:

- The applicant provides letters of support from area providers stating their support for the project and their interest in utilizing the proposed facility.
- The applicant states that the physicians of Graystone Ophthalmology Associates own GESC and are longstanding existing healthcare providers in the western piedmont of North Carolina. These physicians have long-standing, established relationships with local healthcare providers and work closely with other local health care and social service providers to promote wellness and access to care within the local community.

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 all the reasons described above.

- (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

- (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

The applicant proposes to develop no more than one additional operating room pursuant to the 2024 SMFP need determination for total of no more than four operating rooms upon project completion.

In Section K, page 95, the applicant states the proposed project does not require any construction or renovation. Therefore, Criterion (12) is not applicable to this review.

- (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 ... persons [with disabilities], 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

The applicant proposes to develop no more than one additional operating room pursuant to the 2024 SMFP need determination for total of no more than four operating rooms upon project completion.

In Section L, page 93, the applicant provides a table showing the historical (CY2023) payor mix for GESC, as summarized below:

Graystone Eye Surgery Center	
Payor Source	Percentage of Total Patients Served
Self-Pay	8.9%
Charity Care	0.9%
Medicare*	68.6%
Medicaid*	1.9%
Insurance*	16.1%
Other (VA)	3.6%
Total	100.0%

*Including any managed care

In Section L, page 94, the Applicant provides the following comparison:

GRAYSTONE EYE SURGERY CENTER	PERCENTAGE OF TOTAL PATIENTS SERVED BY THE FACILITY OR CAMPUS DURING THE LAST FULL FY	PERCENTAGE OF THE POPULATION OF THE SERVICE AREA
Female	57.8%	50.7%
Male	42.2%	49.3%
Unknown	--	--
64 and Younger	26.2%	81.0%
65 and Older	73.8%	19.0%
American Indian	Not available	0.6%
Asian	0.6%	4.9%
Black or African American	3.2%	9.0%
Native Hawaiian or Pacific Islander	0.1%	0.2%
White or Caucasian	77.6%	73.7%
Other Race**	Not available	11.6%
Declined / Unavailable	18.6%	0.0%

*The percentages can be found online using the United States Census Bureau's QuickFacts, available at: <https://www.census.gov/quickfacts/fact/table/US/PST045218>

On page 96, the applicant states it does not collect patient data related to race/ethnicity.

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the applicant adequately documents 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. 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 persons with disabilities to programs receiving federal assistance, including the existence of any civil rights access complaints against the applicant;

C

The applicant proposes to develop no more than one additional operating room pursuant to the 2024 SMFP need determination for total of no more than four operating rooms upon project completion.

In Section L, page 95, the applicant states that the facility has no obligation under federal regulations to provide uncompensated care or community service, or access by minorities and persons with disabilities. In Section L, page 95, the applicant states:

“For information purposes, GESC met or exceeded all medically underserved requirements in Table 6E of the SMFP, as is demonstrated in annual report on file with NC DHSR Healthcare Planning Section.”

In Section L, page 96, the applicant states that GESC has not had any patient civil rights equal access complaints during the 18 months immediately preceding submission of this application.

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, page 96, the applicant projects the following payor mix for the proposed services during the third full fiscal year of operation following project completion, as shown in the following table:

**Graystone Eye Surgery Center Projected Payor Mix
Third Full FY (CY2027)**

Payor Source	Percentage of Total
Self-Pay	8.9%
Charity Care *	0.9%
Medicare *	68.6%
Medicaid *	1.9%
Insurance	16.1%
Other (VA)	3.6%
Total	100.0%

*Including any managed care plans

As shown in the table above, during the third full fiscal year of operation, the applicant projects that 8.9% of total services will be provided to self-pay patients, 0.9% to charity care patients, 68.6% to Medicare patients, and 1.9% to Medicaid patients.

On pages 97-98, the applicant provides the assumptions and methodology used to project GESC payor mix during the third full fiscal year of operation following completion of the project. The project payor mix is reasonable and adequately supported based on the historical payor mix at GESC for operating room services.

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (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, page 97, the applicant adequately describes the range of means which patients will have access to the proposed services.

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

The applicant proposes to develop no more than one additional operating room pursuant to the 2024 SMFP need determination for total of no more than four operating rooms upon project completion.

In Section M, page 99, 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 M.1. The applicant adequately demonstrates that health professional

training programs in the area have access to the facility for training purposes based on the following:

- The applicant states that GESC currently provides opportunities for training area clinical health services students.
- The applicant states that GESC has an existing relationship with a health professional training program, Catawba Valley Community College.
- The applicant states that Graystone physicians provides educational opportunities to local referring clinicians.
- The applicant provides documentation of GESC existing clinical training affiliation agreement with Catawba Valley Community College.

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 all the reasons described above.

- (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 no more than one additional operating room pursuant to the 2024 SMFP need determination for total of no more than four operating rooms upon project completion.

On page 47, the 2024 SMFP defines the service area for OR as “*single or multicounty grouping shown in Figure 6.1.*” Figure 6.1, on page 53, shows Catawba County is a single county operating room service area. Thus, the service area for this facility consists of Catawba County. Facilities may also serve residents of counties not included in their service area.

The following table summarizes the existing operating rooms in Catawba County from Table 6A, page 55, of the 2024 SMFP.

Operating Room Inventory – Catawba County

Facility	OR Planning Inventory
Graystone Eye Surgery Center	3
Viewmont Surgery Center	3
Frye Regional Medical Center	21
Catawba Valley Medical Center	12

Source: Table 6A, 2024 SMFP

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 100, the applicant states:

“Addition of one operating room at GESOC will enhance competition in the service area because the project will enhance local surgeons to better meet the needs of the existing patient population, and to ensure timely provision of and convenient access to high quality, cost effective, outpatient surgical services for residents of Catawba County and surrounding communities.”

Regarding the impact of the proposal on cost effectiveness, in Section N, page 101, the applicant states:

“The proposed project for one additional OR at GESOC will enhance value. As previously discussed, costs and charges are lower in freestanding, non-hospital based ASF settings than a hospital outpatient department. Freestanding surgical centers are most cost-effective for insurance companies and for the patients because they do not have the higher overhead costs of hospitals.”

See also Sections C, F, and Q of the application and any exhibits.

Regarding the impact of the proposal on quality, in Section N, page 103, the applicant states:

“GESOC will continue to be dedicated to ensuring quality care and patient safety through compliance with all applicable licensure and certification standards established for ambulatory surgical facilities.”

See also Sections C and O of the application and any exhibits.

Regarding the impact of the proposal on access by medically underserved groups, in Section N, pages 104-105, the applicant states:

“Additional OR capacity is needed at GESOC to provide sufficient access to surgical services for Graystone’s patients, and to meet the projected growth in the county population previously described ...Surgical procedures will be more readily accessible, including for the medically underserved.”

See also Section L and C of the application and any exhibits.

The applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates the proposal would have a positive impact on cost-effectiveness, quality, and access because the applicant adequately demonstrates that:

- 1) The proposal is cost effective because the applicant adequately demonstrated: a) the need the population to be served has for the proposal; b) that the proposal would not result in an unnecessary duplication of existing and approved health services; and c) that projected revenues and operating costs are reasonable.
- 2) Quality care would be provided based on the applicant's representations about how it will ensure the quality of the proposed services and the applicant's record of providing quality care in the past.
- 3) Medically underserved groups will have access to the proposed services based on the applicant's representations about access by medically underserved groups and the projected payor mix.

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 based on all the reasons described 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 Q, page 126, the applicant states GESC is the only facility owned and operated by the applicant. GESC, and the physician owners of Graystone, do not own, manage or operate any other licensed healthcare facility located in North Carolina

In Section O, page 109, the applicant states that, during the 18 months immediately preceding the submittal of the application, the Division of Health Service Regulation has not identified any situation resulting in a finding of immediate jeopardy. According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, during the 18 months immediately preceding submission of the application through the date of this decision, no incidents related to quality of care had occurred in this facility. After reviewing and considering information provided by the applicant and by the Acute and Home Care Licensure and Certification Section and considering the quality of care provided at the facility, 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.

G.S. 131E-183 (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 applicant proposes to develop no more than one additional operating room pursuant to the 2024 SMFP need determination for total of no more than four operating rooms upon project completion.

The applications are conforming with all applicable Criteria and Standards for Surgical Services and Operating Rooms. The specific criteria are discussed below.

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

10A NCAC 14C .2103 PERFORMANCE STANDARDS

(a) *An applicant proposing 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 applicant's third full fiscal year following completion of the proposed project based on the Operating Room Need Methodology set forth in the annual State Medical Facilities Plan. The applicant is not required to use the population growth factor.*

-C- The applicant proposes to develop no more than one additional operating room pursuant to the 2024 SMFP need determination for total of no more than four operating rooms upon project completion. The service area is Catawba County single county operating room service area. In Section Q, the applicant projects sufficient surgical cases and hours to demonstrate the need for one additional OR in the third full fiscal year following completion of the proposed project based on the Operating Room Need Methodology in the 2024 SMFP. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

(b) *The applicant shall provide the assumptions and methodology used for the projected utilization required by this Rule.*

-C- In Section Q, Form C *Utilization Projection Methodology and Assumptions*, Form C.3b, pages 115-117, the applicant provides the assumptions and methodology used in the development of

the projections required by this Rule. The discussion regarding analysis of need, including projected utilization, found in Criterion (3) is incorporated herein by reference.