

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: November 29, 2018

Findings Date: November 29, 2018

Project Analyst: Bernetta Thorne-Williams

Team Leader: Gloria Hale

Project ID #: O-11559-18

Facility: Iron Gate Surgery Center

FID #: 180213

County: New Hanover

Applicants: Iron Gate Surgery Center, LLC

OWP4, LLC

Project: Relocate three surgical operating rooms from New Hanover Regional Medical Center - Orthopedic Hospital to develop a new ambulatory surgical center

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

N.C. Gen. Stat. §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

The applicants, Iron Gate Surgery Center, LLC (Iron Gate) and OWP4, LLC, (OWP4) propose to relocate three surgical operating rooms (ORs) from New Hanover Regional Medical Center - Orthopedic Hospital to develop a new ambulatory surgical center (ASC) in New Hanover County to be known as Iron Gate Surgery Center (Iron Gate). The new facility will also have one procedure room.

Need Determination

The proposed project does not involve the addition of any new health service facility beds, services or equipment for which there is a need determination in the 2018 State Medical Facilities Plan (SMFP). Therefore, there are no need determinations applicable to this review.

Policies

There is one policy in the 2018 SMFP applicable to this review. **Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities** 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 capital expenditure for the proposed project is greater than \$5 million. In Section B.4, page 25, the applicants state, “Iron Gate has designed the project to be in compliance with all applicable federal, state, and local building codes, and requirements for energy efficiency and consumption.” In Section K.4(a), page 94 and Exhibit C.1, the applicants provide additional information about their plans for energy efficiency and water conservation. The applicants adequately demonstrate that the application includes a written statement to assure improved energy efficiency and water conservation for the proposed facility. On pages 25-26, the applicants state their energy efficiency and water conservation plan.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- Responses to comments
- 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 reasons:

- The applicants do not propose to develop any new health service facility beds, services, or equipment for which there is a need determination in the 2018 SMFP.
 - The applicants adequately demonstrate that the proposal is consistent with Policy GEN-4 because the applicants propose 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.
- (2) Repealed effective July 1, 1987.
- (3) The applicant shall identify the population to be served by the proposed project, and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and, in particular, low income persons, racial and ethnic minorities, women, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.

C

The applicants propose to relocate three surgical operating rooms from New Hanover Regional Medical Center - Orthopedic Hospital to develop a new ambulatory surgical center in New Hanover County. The proposed new ASC will be located on Iron Gate Drive in Wilmington. OWP4 will own the building and is a wholly-owned, limited liability company of New Hanover Regional Medical Center (NHRMC). NHRMC is a 50 percent owner of Iron Gate Surgery Center.

In Section C.1, page 27, the applicants state the proposed ASC will be constructed in a freestanding facility. The proposed ASC will consist of 27,648 square feet of space on property adjacent to the EmergeOrtho medical practice on Ashton Drive. OWP4 will acquire the property, all medical and non-medical equipment necessary for the operation of Iron Gate Surgery Center. Iron Gate Surgery Center will lease the property from OWP4. On page 30, the applicants state that Iron Gate ASC will consist of the following:

- three ORs
- one procedure room
- twelve pre-operative/recovery cubicles
- two pre-operative/recovery rooms

- four post-anesthesia care unit cubicles
- OR and pre-operative/recovery support
- sterile supply
- waiting area
- reception and business area
- staff dressing and break area
- mechanical and center support space

Patient Origin

On page 57, the 2018 SMFP defines the service area for ORs as, “... *the operating room planning area in which the operating room is located. The operating room planning areas are the single and multicounty groupings shown in Figure 6.1.*” In Figure 6.1, page 62 of the 2018 SMFP, New Hanover County is shown as a single-county operating room service area. Thus, the service area for this facility consists of New Hanover County. Facilities may also serve residents of counties not included in their service area.

In Section C.2, page 35, the applicants state that Iron Gate Surgery Center is not an existing facility and therefore has no historical patient origin data to report. In Section C.2, page 26, the applicants provide the projected patient origin for the first three operating years (OY), FY2021 through FY2023, for the proposed ASC, as shown in the table below.

Iron Gate ASC - Surgical Cases Projected Patient Origin FY2021-FY2023						
	FY2021 OY1		FY2022 OY2		FY2023 OY3	
County	# of Patients	% of Patients	# of Patients	% of Patients	# of Patients	% of Patients
New Hanover	1,320	49.40%	1,444	49.40%	1,471	49.40%
Onslow	369	13.80%	403	13.80%	411	13.80%
Pender	329	12.30%	360	12.30%	366	12.30%
Other	243	9.10%	266	9.10%	271	9.10%
Brunswick	200	7.50%	219	7.50%	223	7.50%
Duplin	107	4.00%	117	4.00%	119	4.00%
Columbus	104	3.90%	114	3.90%	116	3.90%
Total	2,672	100.00%	2,923	100.00%	2,978	100.00%

On page 36, the applicants state that projected patient origin for the proposed ASC is based on historical ambulatory surgery patient origin for surgeons who will provide services at Iron Gate. The applicant notes on page 36, that Brunswick and Columbus counties have lower projected surgical cases due to the opening of Brunswick Surgery Center, LLC. In Section C.7, pages 52-55 and Exhibit C.7, the applicants provide their assumptions and methodology used to project patient origin. The applicants’ assumptions are reasonable and adequately supported.

Analysis of Need

In Section C, pages 37-45, the applicants explain why they believe the population projected to utilize the proposed services needs the proposed services. The applicants provide a list of the reasons they believe supports the need for the proposed project, as summarized below:

- *NHRMC-Orthopedic Hospital*
- *Physician Requirement and Support*
- *Projected Population Growth within the Service Area*
- *Ambulatory Surgical Facility Industry Growth*

NHRMC-Orthopedic Hospital - In Section C.4, pages 38-39, the applicants states that NHRMC- Orthopedic Hospital is a collection of individual buildings spanning 70 years which are in need of “*considerable renovations or complete demolition and reconstruction to be viable facilities for the level of quality healthcare delivery expected from NHRMC in the future.*” Through the approval of Project I.D. # O-11189-16, all orthopedic services, including acute care bed and inpatient operating rooms, will be relocated to NHRMC’s 17th street campus. Therefore, the applicants state that due to design and organizational issues, they are proposing to relocate the three remaining outpatient ORs.

Physician Requirement and Support - In Section C.4, pages 40-41, the applicants states that the proposed ASC will allow local physicians from nine medical practices to perform surgical cases in a cost-effective ASC, improve throughput, and allow for future expansion.

The applicants provide the following tables, which identify the medical practices, their specialty and the projected number of cases to be performed at the proposed ASC in operating year (OY) one, as shown below.

Projected Orthopedic OR Cases and Procedure Room Cases

Physician	Specialty	Projected OR Cases	Percent of Cases	Projected Procedure Room Cases	Percent of Cases
Bowling Orthopedic	Orthopedics	84	4.0%	21	4.0%
Cape Fear Sports Medicine	Orthopedics	146	6.9%	37	7.0%
Carolina Sports Medicine	Orthopedics	370	17.5%	93	17.6%
EmergeOrtho	Orthopedics Spine	1,332	63.0%	333	63.0%
Moore Orthopaedics	Orthopedics	49	2.3%	12	2.3%
Port City Orthopaedics	Orthopedics	77	3.6%	19	3.6%
Other Orthopedic Surgeons	Orthopedics	55	2.6%	14	2.3%
Total Projected OR Cases		2,113	100.0%	528	100.0%

The applicants project to perform 2,113 orthopedic OR cases and not 2,642 cases, as reported on page 41 of the application. In addition, the applicants project to perform 558 spine neurosurgery OR cases at the proposed ASC in OY1, as shown below.

Spine Neurosurgery Projected Cases

Physician	Specialty	Projected Number of Cases	Percent of Cases
Atlantic Neurosurgical & Spine	Spine Neurosurgery	137	24.6%
EmergeOrtho	Orthopedics Spine	260	46.6%
Port City Neurosurgery & Spine	Spine Neurosurgery	131	23.5%
Other Neurosurgery Surgeons	Spine Neurosurgery	30	5.4%
Total Projected OR Cases		558	100.0%

Projected Population Growth within the Service Area - In Section C.4, pages 42-43, the applicants state the overall population of New Hanover County grew by 8.1 percent from 2013 to 2018 and is projected to grow an additional 7.9 percent from 2018 to 2023. In addition the 65+ age population is projected to increase an additional 17.7 percent from 2018 to 2023.

Ambulatory Surgical Facility Industry Growth - In Section C.4, pages 44-45, the applicants state the need for ASC facilities is based on projected increases in outpatient surgical volumes at lower cost than inpatient surgeries.

The applicants demonstrate the need for a freestanding ASC in New Hanover County based on the number of outpatient procedures at NHRMC Orthopedic Hospital, physicians support, growth and aging in the service area, and an increase in the number of procedures Medicare care will reimburse for and overall projected cost-effectiveness of having certain procedures performed in an ASC instead of in a hospital.

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

- The applicants use publicly available data to document the projected increase in population in its service area.
- The applicants demonstrate the need for increased ASC access in New Hanover County.
- The applicants use the methodology in the 2018 SMFP combined with their own historical data to project future utilization of their ORs.

Projected Utilization

In Section Q, page the applicants provide projected utilization for the proposed ORs and procedure room at Iron Gate ASC, as illustrated in the following table.

Iron Gate ASC Projected OR Cases

	FY2020	FY2021	FY2022
Projected Number of Outpatient Surgical Cases*	2,672	2,923	2,978
Outpatient Case Times	68.6	68.6	68.6
Total Surgical Hours	3,055	3,342	3,405
Standard Hours per OR per Year	1,312.5	1,312.5	1,312.5
Surgical/Standard Hours per OR	2.3	2.5	2.6
Number of ORs	3	3	3
Number of Procedure Rooms	1	1	1
Total Number of Procedures	528	587	597

*Excludes C-Sections

In Section C, page 49 and Exhibit C.7, the applicants state that Iron Gate falls into operating room assignment group six as a free standing ASC, operating 7 hours per day, and 250 days per year with standard operating hours of 1,312.5.

In Section C, pages 52-55, the applicants provide the assumptions and methodology used to project utilization, which is summarized below.

Step 1:

The applicants identify the two facilities in New Hanover County that performed outpatient (OP) surgical cases from 2013-2017, as illustrated below.

**New Hanover County
 Licensed Facilities with Surgical Operating Rooms**

Facility	2013	2014	2015	2016	2017
Wilmington SurgCare	8,378	7,935	8,463	8,584	8,531
NHRMC	20,761	21,666	21,944	23,421	25,301
Total OP Surgical Cases	29,139	29,601	30,407	32,005	33,832

Step 2:

The applicants calculate the five year CAGR for the surgical cases performed in New Hanover County from 2013-2017, as illustrated below.

**New Hanover County
 2013-2017 Compound Annual Growth Rate**

	2013	2014	2015	2016	2017	5 Year CAGR
Total OP Surgical Cases	29,139	29,601	30,407	32,005	33,832	3.03%

As illustrated above, total outpatient surgical cases in New Hanover County increased by a CAGR of 3.03% during the same timeframe.

Step 3:

The applicants state the projected annual growth of outpatient surgical cases for 2017 were multiplied by the CAGR. The projected annual growth was then added to the previous year's outpatient surgical cases to project future surgical cases, as illustrated below.

**New Hanover County
 Projected Annual Growth and Total Projected Surgical Cases**

	2017	2018	2019	2020	2021	2022	2023
Total OP Surgical Cases	33,832						
5-year CAGR		3.03%	3.03%	3.03%	3.03%	3.03%	3.03%
Projected Annual Growth		1,026	1,057	1,089	1,122	1,156	1,191
Total Projected Surgical Cases		34,858	35,914	37,003	38,125	39,281	40,472

Step 4:

The applicants use the surgical cases performed by physicians who utilized NHRMC-Orthopedic Hospital, and who will perform surgical cases at Iron Gate ASC, to project the number of surgical procedures to be performed at the new ASC. The applicants assume a three month ramp-up period, as illustrated in the table below.

**Projected OR Cases by Specialty
 for the First Three Fiscal Years**

Specialty	FY2020	FY2021	FY2023
Spine Neurosurgery	558	573	589
Orthopedics	2,114	2,350	2,389
Total OR Cases	2,672	2,923	2,978
Projected OR cases per OR per day	3.6	3.9	4.0

On page 55, the applicants also project the number of surgical cases, by specialty, to be performed in the one procedure room, as shown below.

Projected Procedure Room Cases for the First Three Fiscal Years

Specialty	FY2020	FY2021	FY2023
Orthopedics	528	587	597
Total Procedure Room Cases	528	587	597
Projected Procedure Room cases per Procedure Room per day	2.1	2.4	2.4

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

- The applicants use historical data to project future OR utilization.
- The applicants use a reasonable CAGR to project future OR utilization.

Access

In Section C.8, page 56, the applicants state that Iron Gate will provide services to all residents regardless of age, sex, religion, race, handicap, ethnicity or ability to pay. In Section L.3, page 104, the applicants project the following payor mix during the second full fiscal year of operation following completion of the project, as illustrated in the following table.

Iron Gate ASC Entire Facility	
Payor Source	Percent of Total Patients
Self Pay	4.2%
Medicare*	17.9%
Medicaid*	6.9%
Insurance*	55.2%
TRICARE	10.5%
Worker's Compensation	5.4%
Total	100.0%

*Includes managed care plans.

The projected payor mix is reasonable and adequately supported.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- Responses to comments
- 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 reasons:

- The applicants adequately identify the population to be served.
- The applicants adequately explain why the population to be served needs the services proposed in this application.
- Projected utilization is reasonable and adequately supported.
- The applicants project the extent to which all residents, including underserved groups, will have access to the proposed services (payor mix) and adequately support their 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.

The applicants propose to relocate three surgical operating rooms from New Hanover Regional Medical Center - Orthopedic Hospital to develop a new ASC in New Hanover County to be known as Iron Gate Surgery Center. The new facility will also have one procedure room and will be located on Iron Gate Drive, in Wilmington. New Hanover Regional Medical Center - Orthopedic Hospital is a separate campus from the main hospital, New Hanover Regional Medical Center, and upon completion of the proposed project, no operating rooms will remain on the New Hanover Regional Medical Center - Orthopedic Hospital campus.

In Section D, page 65, the applicants explain why they believe the needs of the population presently utilizing the services to be reduced, eliminated or relocated will be adequately met following completion of the project. On page 65, the applicants state:

“Upon completion of the project, the patients treated at NHRMC Orthopedic Hospital will be treated at Iron Gate. Iron Gate is located 3.9 miles or 8 minutes from the NHRMC Orthopedic Hospital site.”

In Section D.4, page 68, the applicants state that upon completion of the proposed project, no ORs or GI endoscopy rooms will be in use at NHRMC Orthopedic Hospital. Additionally, the applicants state on page 68, that the relocation of the three ORs will not affect access of low income persons, racial and ethnic minorities, women, handicapped persons, the elderly and other underserved groups from obtaining other services provided at NHRMC Orthopedic Hospital.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- Responses to comments
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the applicants adequately demonstrate that:

- The needs of the population currently using the services to be reduced, eliminated or relocated will be adequately met following project completion.
- The project will not adversely impact the ability of underserved groups to access these services following project completion.

- (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.

The applicants propose to relocate three surgical operating rooms from New Hanover Regional Medical Center - Orthopedic Hospital to develop a new ASC in New Hanover County to be known as Iron Gate Surgery Center. The new facility will also have one procedure room.

In Section E.2(b), pages 70-73, the applicants describe the alternatives they 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 applicants state that NHRMC is approved to relocate five orthopedic ORs and all acute beds located at NHRMC Orthopedic Hospital to the NHRMC 17th street campus. This would leave outpatient orthopedic surgical and emergency services at NHRMC Orthopedic Hospital. This leaves limited health services in a facility that there are no plans to renovate. The applicants concluded that this is not a cost effective alternative. Therefore, this alternative was rejected.
- Develop a Freestanding ASC Not Adjacent to NHRMC - The applicants state this would not assure physician coverage, ease of travel between all local physician practices and the ASC, and ease of transfer to NHRMC in the event of an emergency. Therefore, this alternative was rejected.
- Relocate a different number of ORs - The applicants state the size of the proposed ASC was considered, whether to relocate one, two or three operating rooms. The applicants state that based on the volume of cases currently performed at NHRMC Orthopedic Hospital, the applicants concluded that relocating less than three ORs would not be the best alternative. Therefore, this alternative was rejected.
- Joint Venture - The applicants conclude that the best alternative is the joint venture between NHRMC and local physicians, as proposed in this application, to develop Iron Gate ASC. The applicants state NHRMC is the primary tertiary referral facility in south eastern North Carolina and they have partnered with local physicians who are primarily patient focused. This venture will meet the needs of patients and their surgeons.

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

- The application is conforming to all statutory and regulatory criteria.
- The applicants provide credible information to explain why they believe the proposed in the most effective alternative.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments

- Remarks made at the public hearing
- Responses to comments
- 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 reasons stated above. Therefore, the application is approved subject to the following conditions:

- 1. Iron Gate Surgery Center, LLC and OWP4, LLC shall materially comply with all representations made in the certificate of need application.**
- 2. Iron Gate Surgery Center, LLC and OWP4, LLC shall develop a new ambulatory surgical facility in New Hanover County by relocating three existing operating rooms from New Hanover Regional Medical Center - Orthopedic Hospital.**
- 3. Upon completion of this project, Iron Gate Surgery Center shall be licensed for no more than three operating rooms and one procedure room.**
- 4. Upon completion of this project, New Hanover Regional Medical Center shall take the necessary steps to delicense three operating rooms at New Hanover Regional Medical Center - Orthopedic Hospital. Upon project completion, New Hanover Regional Medical Center - Orthopedic Hospital will have no licensed operating rooms.**
- 5. Iron Gate Surgery Center, LLC and OWP4, LLC as part of this project, shall not acquire any equipment that is not included in the project's proposed capital expenditures in Section F and Exhibit F.1 of the application or that would otherwise require a certificate of need.**
- 6. Iron Gate Surgery Center, LLC and OWP4, LLC 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, Iron Gate Surgery Center 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 procedure room shall not be used for procedures that should be performed only in an operating room based on current standards of practice.**
- 9. Procedures performed in the procedure room shall not be reported for billing purposes as having been performed in an operating room and shall not be reported**

on the facility's license renewal application as procedures performed in an operating room.

10. Iron Gate Surgery Center, LLC and OWP4, LLC shall 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.

11. 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, Iron Gate Surgery Center, LLC and OWP4, 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.**

12. Iron Gate Surgery Center, LLC and OWP4, 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

The applicants propose to relocate three surgical operating rooms from New Hanover Regional Medical Center - Orthopedic Hospital to develop a new ASC in New Hanover County to be known as Iron Gate Surgery Center. The new facility will also have one procedure room.

Capital and Working Capital Costs

In Section Q, Form F.1(a), the applicants project the total capital cost of the project as shown in the table below.

Building/Land Costs	\$1,497,080
Site Costs	\$1,175,776
Construction Costs	\$14,947,021
Miscellaneous Costs	\$4,513,867
Total	\$22,133,744

In Section Q, the applicants provide the assumptions used to project the capital cost.

In Section F, page 77, the applicants project that start-up costs will be \$205,603 and initial operating expenses will be \$894,397 for a total working capital of \$1,100,000. In Section Q, the applicants provide the assumptions and methodology used to project the working capital needs of the project.

Availability of Funds

In Section F, page 75, the applicants state that the capital cost will be funded as shown in the table below.

Sources of Capital Cost Financing			
Type	OWP4, LLC	Iron Gate Surgery Center, LLC	Total
Loans	\$0	\$0	\$0
Accumulated reserves or OE *	\$22,133,744	\$0	\$22,133,744
Bonds	\$0	\$0	\$0
Other (Specify)	\$0	\$0	\$0
Total Financing **	\$22,133,744	\$0	\$22,133,744

* OE = Owner’s Equity

OWP4 is a wholly-owned, limited liability company of New Hanover Regional Medical Center.

In Section F, page 78, the applicants state that the working capital needs of the project will be funded by OWP4 owner’s equity, as shown in the table below.

Sources of Financing for Working Capital		Amount
(a)	Loans	\$0
(b)	Cash or Cash Equivalents, Accumulated Reserves or Owner’s Equity	\$1,100,000
(c)	Lines of credit	\$0
(d)	Bonds	\$0
(e)	Total	\$1,100,000

See Exhibit F.2 for projected funding letters and NHRMC’s audited financial statements.

Financial Feasibility

The applicants provided pro forma financial statements for the first three full fiscal years of operation following completion of the project. In Form F.4, the applicants project that revenues will exceed operating expenses in the first three operating years of the project, as shown in the table below.

**Iron Gate Surgery Center
Projected Revenue**

	1st Full Fiscal Year	2nd Full Fiscal Year	3rd Full Fiscal Year
Total Number of Cases	2,672	2,923	2,978
Total Gross Revenues (Charges)	\$30,076,395	\$32,691,605	\$33,338,183
Total Net Revenue	\$12,946,048	\$14,083,295	\$14,360,227
Average Net Revenue per Case	\$4,845.08	\$4,818.10	\$4,822.12
Total Operating Expenses (Costs)	\$10,522,028	\$11,361,919	\$11,297,331
Average Operating Expense per Case	\$3,937.88	\$3,887.07	\$3,793.60
Net Income	\$2,424,020	\$2,721,376	\$3,062,895

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

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- Responses to comments

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

- The applicants adequately demonstrate that the capital and working capital costs are based on reasonable and adequately supported assumptions.
 - The applicants adequately demonstrate availability of sufficient funds for the capital and working capital needs of the proposal.
 - The applicants adequately demonstrate 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.

C

The applicants propose to relocate three surgical operating rooms from New Hanover Medical Center - Orthopedic Hospital to develop a new ASC in New Hanover County to be known as Iron Gate Surgery Center. The new facility will also have one procedure room.

On page 57, the 2018 SMFP defines the service area for ORs as, "... the operating room planning area in which the operating room is located. The operating room planning areas are the single and multicounty groupings shown in Figure 6.1." In Figure 6.1, page 62 of the 2018 SMFP, New Hanover County is shown as a single-county operating room service area. Thus, the service area for this facility consists of New Hanover County. Facilities may also serve residents of counties not included in their service area.

According to Table 6A, on page 68 of the 2018 SMFP, there are 45 ORs in New Hanover County, as illustrated below.

Facility	# of Inpatient ORs	# of Ambulatory ORs	# of Shared ORs	Total
Wilmington SurgCare	0	7	0	7
New Hanover Regional Medical Center	5	4	29	38
Total*	5	11	29	45

*Includes C-Section and Trauma/Burn ORs

Source: 2018 SMFP and 2018 License Renewal Applications

In Section G.3, page 84, the applicants explain why they believe their proposal would not result in the unnecessary duplication of existing or approved OR services in New Hanover County. The applicants state:

"NHRMC and local physicians only propose to relocate existing ORs in New Hanover County. The project will not result in any increase in the service area's OR inventory. Projected OR surgical cases will follow the three ORs from NHRMC Orthopedic Hospital to Iron Gate."

The applicants adequately demonstrate that the proposal would not result in an unnecessary duplication of existing or approved services in the service area for the following reasons:

- The proposal would not result in an increase of ORs in New Hanover County.
- The applicants adequately demonstrate that the proposed relocation of three ORs is needed to provide accessible and cost effective ambulatory surgical services to New Hanover County and surrounding counties.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- Responses to comments

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

Iron Gate Surgery Center is a proposed new facility and therefore does not have existing staff. In Section Q, Form H, the applicants provide projected staffing for the proposed ASC services, as illustrated in the following table.

Position	Projected		
	1 st Full Fiscal Year	2 nd Full Fiscal Year	3 rd Full Fiscal Year
Registered Nurse	13.0	14.0	14.0
Patient Navigator	1.0	1.0	1.0
Nurse Aide	2.0	2.0	2.0
Surgical Technician	8.0	9.0	9.0
Radiological Technologists	2.0	2.0	2.0
ASC Administrator	1.0	1.0	1.0
Biomed	1.0	1.0	1.0
Clinical Director	1.0	1.0	1.0
Environmental Services Tech	1.0	1.0	1.0
IT Administrator	1.0	1.0	1.0
Materials Management Tech	1.0	1.0	1.0
Medicals Records Administrator	1.0	1.0	1.0
Nurse Educator/Infection Control/OSHA	1.0	1.0	1.0
OR Coordinator	1.0	1.0	1.0
Sterile Supply Technicians	2.5	2.5	2.5
Other	7.0	7.0	7.0
TOTAL	44.5	46.5	46.5

Source: Form H in Section Q of the application

The assumptions and methodology used to project staffing are provided in Section Q. Adequate costs for the health manpower and management positions proposed by the applicants are budgeted in Form F.2, which is found in Section Q. In Section H, pages 86-87, the applicants describe the methods to be used to recruit new positions and their proposed training and continuing education programs. In Section H, page 87, the applicants identify Dr. Daniel Todd Rose as the proposed medical director. In Exhibit H.4, the applicants provide a letter from the proposed medical director indicating an interest in serving as medical director for the proposed services. In Section H, page 87, the applicants describes their physician recruitment plans. In Exhibit H.4, the applicants provide supporting documentation.

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

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- Responses to comments

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, page 89, the applicants state that the following ancillary and support services are necessary for the proposed services:

- Billing, accounts payable, and general accounting;
- Business office/admitting;
- Facility management;
- Human resources/wages and benefits;
- Information management;
- Legal services;
- Materials management;
- Medical record services;
- Planning and marketing;
- Precertification and insurance;
- Purchasing;
- Quality management and infection control;
- Risk management and utilization review;
- Scheduling; and
- Staff education.

In Section I, page 90, the applicants describe their efforts to develop relationships with other local health care and social service providers and provides supporting documentation in Exhibit I.2.

The applicants adequately demonstrate that the proposed services will be coordinated with the existing health care system.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- Responses to comments

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated 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 applicants do 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 applicants do 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. Therefore, Criterion (9) is not applicable to this review.

- (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 applicants are not an HMO. Therefore, Criterion (10) 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, page 93, the applicants state that the project involves 27,648 square feet of new construction to develop a freestanding ASC. Line drawings are provided in Exhibit K.1.

On page 94, the applicants adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal.

On page 95, the applicants adequately explain 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.

On page 96, the applicants identify any applicable energy saving features that will be incorporated into the construction plans.

On pages 98-99, the applicants identify the proposed site and provides information about the current owner, zoning and special use permits for the site, and the availability of water, sewer and waste disposal and power at the site.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- Responses to comments

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

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

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

C

In Section L, page 103, the applicants state that Iron Gate does not currently provide healthcare services in the proposed service area. The applicants propose to relocate three existing ORs from New Hanover Regional Medical Center - Orthopedic Hospital. New Hanover Regional Medical Center - Orthopedic Hospital is on the license of New Hanover Regional Medical Center. The co-applicant, OWP4, LLC, is a limited liability company wholly owned by NHRMC. Additionally, NHRMC is 50 percent owner of Iron Gate Surgical Center. As such, the extent to which medically underserved populations currently use the applicant's existing services ORs is applicable to this review. The 2018 license renewal application (LRA) for NHRMC provides a table on page 10, which lists the payor category for all services provided at all the sites listed on the license. The payor category for ambulatory surgical cases for all sites, including NHRMC - Orthopedic Hospital, NHRMC main campus, and NHRMC Atlantic Surgicenter, is illustrated below.

**New Hanover Regional Medical Center
Ambulatory Surgical Cases
All Sites
10/1/2016 - 9/30/2017**

Payor Source	Number of Cases	Percent of Total Patients
Self Pay/Indigent/Charity	1,016	4.0%
Medicare & Medicare Managed Care	11,283	44.6%
Medicaid	2,064	8.2%
Commercial Insurance	7,867	30.1%
Managed Care	1,399	5.5%
Other	1,672	6.6%
Total	25,301	100.0%

Source: New Hanover Regional Medical Center 2018 LRA

As shown in the table above, during the last full fiscal year of operation, NHRMC facilities provided 4.0% of total ambulatory surgical services to self-pay/indigent/charity patients, 44.6% to Medicare/Medicare managed care patients and 8.2% to Medicaid patients.

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- Responses to comments
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the applicants adequately document the extent to which medically underserved populations served by a related entity, currently uses the applicants' services.

- (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 service or access by minorities and persons with disabilities, in Section L, page 103, the applicants state Iron Gate is not an existing facility and therefore has not obligation under any federal regulations to provide uncompensated care.

In Section L, page 103, the applicants state that during the last five years no patient civil rights access complaints have been filed against the facility, NHRMC or any similar facilities owned by the applicants or a related entity and located in North Carolina.

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- Responses to comments

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 104, the applicants project 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.

Iron Gate ASC Entire Facility 10/1/2021-9/30/2022	
Payor Source	Percent of Total Patients
Self Pay	4.2%
Medicare*	17.9%
Medicaid*	6.9%
Insurance*	55.2%
TRICARE	10.5%
Worker's Compensation	5.4%
Total	100.0%

*Includes managed care plans.

As shown in the table above, during the second full fiscal year of operation, the applicants project that 4.2% of total ASC services will be provided to self-pay patients, 17.9% to Medicare patients and 6.9% to Medicaid patients.

On page 104, the applicants provide the assumptions and methodology used to project payor mix during the second full fiscal year of operation following completion of the project. The projected payor mix is reasonable and adequately supported because it is based on the historical payor mixes as reported by NHRMC for the physicians expected to perform ambulatory surgical cases at Iron Gate.

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- Responses to comments

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, page 106, the applicants adequately describe the range of mean by which patients will have access to the proposed services.

The Agency reviewed the:

- Application
- Exhibits to the application

- Written comments
- Remarks made at the public hearing
- Responses to comments

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, page 108, the applicants describe the extent to which health professional training programs in the area will have access to the facility for training purposes and provides supporting documentation in Exhibit M.1.

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- Responses to comments

Based on that review, the Agency concludes that the applicants adequately demonstrate 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

The applicants propose to relocate three surgical operating rooms from New Hanover Medical Center - Orthopedic Hospital to develop a new ASC in New Hanover County to be known as Iron Gate Surgery Center. The new facility will also have one procedure room.

On page 57, the 2018 SMFP defines the service area for ORs as, “... *the operating room planning area in which the operating room is located. The operating room planning areas are the single and multicounty groupings shown in Figure 6.1.*” In Figure 6.1, page 62 of the 2018 SMFP, New Hanover County is shown as a single-county operating room service area. Thus, the service area for this facility consists of New Hanover County. Facilities may also serve residents of counties not included in their service area.

According to Table 6A, on page 68 of the 2018 SMFP, there are 45 ORs in New Hanover County, as illustrated below.

Facility	# of Inpatient ORs	# of Ambulatory ORs	# of Shared ORs	Total
Wilmington SurgCare	0	7	0	7
New Hanover Regional Medical Center	5	4	29	38
Total*	5	11	29	45

*Includes C-Section and Trauma/Burn ORs

Source: 2018 SMFP and 2018 License Renewal Applications

In Section N, pages 110 and 116, the applicants describe the expected effects of the proposed services on competition in the service area and discuss how any enhanced competition in the service area will promote the cost-effectiveness, quality and access to the proposed services. On page 110, the applicant states,

“Iron Gate proposes to operate a cost-effective alternative to performing ambulatory surgery procedures at the local hospital. With the rising demand for both inpatient and outpatient surgical services that is driven by a growing community, an aging population and expanding physician base, Iron Gate expects that completion with existing providers will be robust. This project will not hinder any existing provider’s ability to compete; rather, it will offer patients a convenient and cost-effective option for outpatient surgery.”

The applicants adequately describe 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 Section O of the application and any exhibits)
- Access will be provided to underserved groups (see Section L of the application and any exhibits)

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments

- Remarks made at the public hearing
- Responses to comments

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, page 124, the applicants states Iron Gate does not own, operate or manage any similar health service facilities in North Carolina. However, New Hanover Regional Medical Center is a related entity that operates 45 operating rooms, including three dedicated C-Section operating rooms and one trauma/burn OR.

In Section O, page 124 and Exhibit O.3, the applicants state that, during the 18 months immediately preceding the submittal of the application, there were no incidents related to quality of care at any facility in North Carolina owned, operated or managed by the applicants or a related entity. 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, there were no incidents related to quality of care in any of NHRMC facilities. After reviewing and considering information provided by the applicants and by the Acute and Home Care Licensure and Certification Section and considering the quality of care provided at all the facilities owned, operated or managed by the applicants or a related entity, the applicants 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 application is conforming with all applicable Criteria and Standards for Surgical Services and Operating Rooms promulgated in 10A NCAC 14C .2100. The specific criteria are discussed below.

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

10A NCAC 14C .2103 PERFORMANCE STANDARDS

- (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- In Section C, page 61, Section Q, Form C, page 130, and Exhibit C.7, the applicants provide a table which illustrates the need for the three relocated operating rooms in the third year of the proposed project based on the Operating Room Need Methodology set forth in the 2018 State Medical Facilities Plan. The applicants project that Iron Gate ASC, in OR group 6 would have an average final ambulatory case time of 68.6. The discussion regarding analysis of need, including projected utilization, found in Criterion (3) is incorporated herein by reference. Therefore, the application is conforming with this rule.
- (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- The applicants do not propose to increase the number of existing ORs in New Hanover County, rather they propose the relocation of three existing ORs.
- (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 proposed project does not involve dedicated C-section ORs.
- (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 applicants do not propose to convert a specialty ambulatory surgical program into a multispecialty ambulatory surgical program or to add a specialty area to a specialty ambulatory surgical program.
- (e) *The applicant shall document the assumptions and provide data supporting the methodology used for each projection in this Rule.*
- C- In Section C.7, pages 52-55 and Section Q, page 137, the applicants provide the assumptions methodology used to project utilization. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference. Therefore, the application is conforming with this rule.