

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: October 23, 2019

Findings Date: October 23, 2019

Project Analyst: Tanya M. Saporito

Team Leader: Gloria C. Hale

Project ID #: O-11720-19

Facility: Wilmington Eye Surgery Center

FID #: 190277

County: New Hanover

Applicants: Wilmington Eye Surgery Center, LLC
WESCP, LLC

Project: Develop a freestanding ASF with 2 ORs and 4 procedure rooms pursuant to the 2019 SMFP need determination

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

Wilmington Eye Surgery Center, LLC (Wilmington Eye) and WESCP, LLC (the applicants) propose to develop a freestanding ambulatory surgical facility (ASF) with two ORs dedicated to ophthalmic surgical procedures and plastic surgery. The applicants also propose to develop four procedure rooms.

Need Determination

Chapter 6 of the 2019 State Medical Facilities Plan (SMFP) identifies a need for six additional operating rooms (ORs) in the New Hanover County OR service area. The applicants propose

to develop two ORs in New Hanover County. Therefore, the application is consistent with the need determination in the 2019 SMFP.

Policies

There are two policies in the 2019 SMFP that are applicable to this review: *Policy GEN-3: Basic Principles* and *Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities*.

Policy GEN-3: Basic Principles, on page 31 of the 2019 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.”

Promote Safety and Quality - The applicants describe how they believe the proposed project would promote safety and quality in Section B, pages 10 - 11; Section N, pages 76 - 77; Section O, page 79 and referenced exhibits. The information provided by the applicants is reasonable and adequately supports the determination that the applicants’ proposal would promote safety and quality.

Promote Equitable Access - The applicants describe how they believe the proposed project would promote equitable access in Section B, pages 12 - 14; Section C, pages 41 - 42; Section L, pages 72 - 73; Section N, pages 77 - 78 and referenced exhibits. The information provided by the applicants is reasonable and adequately supports the determination that the applicants’ proposal would promote equitable access.

Maximize Healthcare Value - The applicants describe how they believe the proposed project would maximize health care value in Section B, pages 14 - 15, Section C, pages 34 - 36; Section K, page 67, Section N, pages 75 - 76; the applicants’ pro forma financial statements in Section Q and referenced exhibits. The information provided by the applicants is reasonable and adequately supports the determination that the applicants’ proposal would maximize healthcare value.

In Section B.3, pages 11 - 15 and referenced exhibits, the applicants adequately explain why they believe the application is consistent with Policy GEN-3. The applicants state that the project will enhance patient safety, quality and access by providing access to quality specialized ophthalmic surgical procedures in a facility uniquely dedicated to the provision of

those services. This will maximize value to patients by ensuring patients are provided these surgical services in a lower-cost outpatient setting.

Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities, on page 31 of the 2019 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 are required to submit a plan of 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 proposed expenditure for this project is greater than \$5 million. In Section B, pages 15 - 16, the applicants explain why they believe the application is conforming to Policy GEN-4. The applicants state the ASF will be designed to earn EnergyStar certification, and that the facility will meet or exceed the North Carolina State Building Codes for energy efficiency and water conservation standards. The applicants adequately demonstrate that the application includes a written statement describing the project’s plan to assure improved energy efficiency and water conservation. Therefore, the application is consistent with Policy GEN-4.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Remarks made at the public hearing
- 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 more ORs than are determined to be needed in the service area.
 - The applicants adequately demonstrate that the proposal is consistent with Policy GEN-4.
 - The applicants adequately demonstrate that the proposal is consistent with Policy GEN-3.
- (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 develop a freestanding ASF with two ORs dedicated to ophthalmic surgical procedures and plastic surgery pursuant to the need determination in the 2019 SMFP. The applicants also propose to develop four procedure rooms, which are not regulated by Certificate of Need law.

WESCP, LLC was granted an exemption from CON law on June 20, 2019 to develop a medical office building (MOB) in Wilmington. As part of this proposal, WESCP, LLC will lease a portion of that space to Wilmington Eye within which to operate the ASF. According to the applicants on page 18, one of the four procedure rooms will be equipped with femtosecond laser technology, which will allow the surgeons to perform cataract surgery and astigmatism correction with a laser beam rather than a blade. Wilmington Eye will be the only licensed freestanding ASF in New Hanover County to provide ophthalmic surgery with this type of technology.

Patient Origin

On page 55, the 2019 SMFP defines the service area for operating rooms 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 60 of the 2019 SMFP, New Hanover County is shown as a single-county OR service area. Thus, the service area for this review consists of New Hanover County. Facilities may also serve residents of counties not included in the service area.

The following table illustrates projected patient origin, from application page 25:

COUNTY	THIRD FULL FY OF OPERATION FOLLOWING PROJECT COMPLETION (CY 2024)	
	# OF PATIENTS	% OF TOTAL
New Hanover	1,437	40.0%
Brunswick	1,011	28.2%
Onslow	355	9.9%
Pender	340	9.5%
Columbus	100	2.8%
Craven	85	2.4%
Other*	263	7.3%
Total	3,590	100.0%

*On page 25, the applicants state “other” includes Beaufort, Bladen, Carteret, Cumberland, Durham, Duplin, Forsyth, Greene, Hoke, Iredell, Johnston, Jones, Lenoir, Nash, Pamlico, Pitt, Robeson, Sampson, Wake, and Wayne counties, as well as other states.

Numbers may not sum due to rounding.

In Section C, page 25, the applicants provide the assumptions and methodology used to project patient origin. The applicants’ assumptions are reasonable and adequately supported.

Analysis of Need

In Section C, pages 25 - 38, the applicants explain why they believe the population projected to utilize the proposed surgical services needs the proposed services. The applicants summarize the need for the ASF with two ORs as summarized below:

- The 2019 SMFP need determination – the applicants acknowledge the 2019 SMFP need determination for six ORs in New Hanover County, and state there is a specific need for additional non-hospital based outpatient ORs, to provide lower cost options to patients. The applicants state ophthalmic surgery is highly specialized, and the current ORs in the county are not the best suited to these types of surgical procedures for a variety of reasons, including but not limited to the need for specialized equipment and the use of the existing ORs for various types of surgeries. The applicants propose specialized equipment and ORs dedicated to performing ophthalmic surgical procedures in a lower-cost outpatient setting that is dedicated to these procedures (pages 25 – 27).
- The need for specialized eye surgery centers – the applicants state that currently, there are eight ASFs in North Carolina that specialize in ophthalmic surgery, all of which are west of New Hanover County, either in central or western North Carolina. The applicants state the closest of these facilities is in Moore County, approximately 150 miles west of New Hanover County. Additionally, the applicants state that New Hanover County ranks second in the top ten counties in the state with the highest volume of ophthalmic surgery cases, as shown in the following table from page 29:

**FY 2017 North Carolina
Ophthalmology Cases by County**

RANK	COUNTY	# OPHTHALMOLOGY SURGERY CASES
1	Mecklenburg	17,157
2	New Hanover	10,117
3	Guilford	9,868
4	Durham	8,936
5	Forsyth	8,912
6	Wake	7,262
7	Catawba	6,787
8	Moore	6,147
9	Buncombe	5,207
10	Cabarrus	5,032

On page 29, the applicants state “... *the clear geographic absence of the type of ASF proposed in this application, relative to a comparison of the number of ophthalmology cases performed in counties across North Carolina, makes New Hanover County a compelling location for the next facility of this type in the state.*” (pages 27 – 29).

- Benefits of a specialized ASF – the applicants state there are economic benefits to an ASF specializing in ophthalmic surgeries. In general, the applicants state that 68% of the existing ORs in New Hanover County are hospital-based, and thus billed at high hospital rates. The remaining ORs are, or will be, in ASFs, but none of those ORs or ASFs specialize in ophthalmic surgical procedures, even though New Hanover County is second in the state in volume of these types of surgeries. Additionally, surgeons associated with this project, who currently seek OR scheduling in the county experience consistent scheduling issues, which negatively impacts them and their patients (pages 29 – 30).
- Lack of necessary equipment in existing ORs in the county – the applicants state that obtaining access to appropriate and up-to-date equipment at existing facilities is an issue impacting the ophthalmic surgeons. According to the applicants, in 2018, New Hanover Regional Medical Center (NHRMC) requested information to update ophthalmic equipment at Atlantic SurgiCenter; however, that equipment has not been ordered. Even if NHRMC were to obtain the equipment, the issues with multiple types of surgical procedures being performed in the ORs and the issues with scheduling would remain (page 31).
- Lack of appropriate staffing at the existing facilities – the applicants state that, even if the surgeons are able to obtain some block time for performing ophthalmic surgeries at existing facilities, they must bring their own staff with them to supplement patient care (page 31).
- Ophthalmic surgery is driving the need for ORs in the county – the applicants state that the need for ORs in New Hanover County is driven by the increasing volume of

ophthalmic surgeries, which increased at a compound annual growth rate (CAGR) of 3.6% in the county from 2016 to 2018 (pages 32 – 34).

- Cost savings to the patients and payors – the applicants state that the cost of surgical procedures performed in an ASF rather than a hospital outpatient department (HOPD) is significantly lower. On page 35, the applicants provide a table to illustrate the cost comparison between ophthalmic procedures performed in a hospital outpatient department and an ASF, as shown below:

SURGERY	ASF AVG. TOTAL COST	HOPD AVG. TOTAL COST	DIFFERENCE
Cataract	\$977	\$1,917	\$940
Glaucoma	\$190	\$496	\$306
Strabismus	\$805	\$1,812	\$1,007
Corneal Transplant	\$1,771	\$3,640	\$1,869
Oculoplastic	\$2,176	\$4,424	\$2,248
Average			\$1,274

The applicants also state that it is important to equip the ORs in the proposed ASF with the necessary equipment to perform the specialized ophthalmic surgical procedures for optimal patient satisfaction and surgeon efficiency. That equipment is currently available only at NHRMC Atlantic SurgiCenter, which is hospital-based (pages 35 – 36).

- Advantages of a new provider in the area with experience in the market – the applicants state the structure of the proposed ASF would be unique in that it would be wholly owned by local physicians, each of whom specializes in ophthalmic procedures. Given the large volume of ophthalmic procedures in the county, combined with the need in the 2019 SMFP for additional ORs, the proposed ASF would benefit existing and future patients (pages 36 – 37).
- Population growth in the county – the applicants state the population of New Hanover County is projected to grow by a CAGR of 1.7% from 2019 to 2024. Additionally, the population of persons age 65 and over is projected to grow by a CAGR of 3.2% during that same time. Citing information from The Johns Hopkins Medicine Wilmer Eye Institute, the applicants state most cataract surgeries are performed in persons age 65 and over (pages 37 – 38).

Projected Utilization

In Section Q, Form C, the applicants provide projected utilization for the ASF, as illustrated in the following table:

	INTERIM YEAR (7/1/21 – 12/31/21)*	PROJECT YEAR 1 (CY 2022)	PROJECT YEAR 2 (CY 2023)	PROJECT YEAR 3 (CY 2024)
ORs	2	2	2	2
Outpatient Cases	596	2,508	3,996	4,202
Case Times	0.68	0.68	0.68	0.68
Total Surgical Hours	406	1,706	2,717	2,857
Procedure Rooms	4	4	4	4
# Procedures	510	2,143	3,414	3,590
Total Facility Procedures	1,106	4,651	7,410	7,792

*The applicants project to begin providing services on July 1, 2021; therefore, the first interim year is a partial year (see application Section P).

In Section Q, the applicants provide the assumptions and methodology used to project utilization, which are summarized below:

- The applicants project completion of the ASF by July 1, 2021 and determine that the project years will be calendar years. The first full project year will thus be calendar year 2022, and the interim year will be what is left of calendar year 2021.
- Currently, eight surgeons, identified in a table in Section Q, associated with this project are also associated with Wilmington Eye, PA and perform surgeries in multiple facilities in the region. The applicants state other surgeons will likely seek privileges at Wilmington Eye once it becomes operational; however, to remain conservative, the applicants based projections on the historical utilization of those eight surgeons identified in Section Q. The applicants provide 17 letters of support from area surgeons who indicate support for the project and an intent to seek privileges once the facility is operational. The following table illustrates the number of cases performed by surgeons associated with Wilmington Eye increased by a compound annual growth rate (CAGR) of 10.3% from CY 2016 – CY 2018:

**Number of Cases Performed by Wilmington Eye Surgeons
 CY 2016 – CY 2018**

	CY 2016	CY 2017	CY 2018	CAGR
Number of Cases	5,370	5,958	6,534	10.3%

Source: Section Q, page 2 of applicants' assumptions

- The applicants examined historical utilization for those eight surgeons by facility in the region to determine which cases would likely shift to the proposed ASF. The following table, from Section Q page 2, illustrates the cases by facility based on CY 2018:

FACILITY	CY 2018 # OF CASES
Dosher Memorial Hospital	456
Pender Memorial Hospital	40
NHRMC Atlantic Surgicenter*	3,064
NHRMC Main Campus	247
Wilmington SurgCare	2,728
Total	6,534

*This is as ASF that is licensed as part of NHRMC

The applicants do not project that any of the cases historically performed at Dosher Memorial Hospital or Pender Memorial Hospital will shift, as these hospitals are smaller community hospitals. The applicants state they will continue to perform surgeries for the patients in those communities in those facilities. The applicants project that all of the remaining cases currently performed in OP ORs are *appropriate* to shift to the ASF; however, to remain conservative, the applicants project only one-half of the CY 2018 cases to shift. It is worth noting that NHRMC submitted a letter of support for this project, as one of the facilities in which the surgeons currently perform surgeries. On page 3 in Section Q, the applicants illustrate the cases that they consider are appropriate to shift to the ASF, as shown in the following table:

FACILITY	# CASES CY 2018	% APPROPRIATE TO SHIFT	# APPROPRIATE TO SHIFT
Dosher Memorial Hospital	456	0%	0
Pender Memorial Hospital	40	0%	0
NHRMC Atlantic Surgicenter	3,064	100%	3,064
NHRMC Main Campus	247	50%	123
Wilmington SurgCare	2,728	94%*	2,577
Total	6,534	--	5,764

*The applicants state one of the eight surgeons will continue to perform at least 30% of her cases at Wilmington SurgCare. The applicants assume that approximately 60% of her cases will shift to Wilmington Eye, which results in a 94% shift in the aggregate.

- The applicants thus assume 5,764 cases will be a “baseline” to begin future utilization projections. Referring to the population growth analysis in Section C, page 37, the applicants project growth of that baseline number of cases by 5.2%, which represents one-half of the CAGR calculated from CY 2016 to CY 2018. On page 3 of the assumptions in Section Q, the applicants provide a table to illustrate their projections of total numbers of cases to be performed in the ASF:

	CY 2019	CY 2020	CY 2021	CY 2022	CY 2023	CY 2024	CAGR
# OF CASES	6,061	6,374	6,702	7,047	7,411	7,792	5.2%

- Next, the applicants analyzed the types of cases historically performed in the facilities from which cases are projected to shift. Of the 5,764 cases from CY 2018, the applicants determined the following percentages according to types, as illustrated in the following table, from page 4 of the applicants' assumptions in Section Q:

Distribution of Wilmington Eye Surgery Cases by Type

TYPE OF CASE	2018 CASES	PERCENT OF TOTAL
Cornea	490	8.5%
Glaucoma	617	10.7%
Cataracts and Refractive	3,510	60.9%
Oculoplastics	899	15.6%
Strabismus	248	4.3%
Total	5,764	100.0%

The applicants state the numbers of cases include pediatric surgery volumes as well, spread among the specialties. The applicants grew the totals each year by 5.2%

- On page 4 of the applicants' assumptions in Section Q, the applicants state: *“In order to project the number of cases appropriate to shift to WESC by subspecialty, the CY 2018 adjusted distribution is applied to the total number of projected cases for CY 2019 through the third full fiscal year of the project, CY 2024.”* The applicants calculated, year by year, the percentages of cases according to type, consistent with the percentages of cases by type calculated from CY 2018, to project cases appropriate to shift. See the following table, from page 4 of the assumptions in Section Q:

Projected Number of Cases Appropriate to Shift to Wilmington Eye

TYPE OF CASE	CY 2019	CY 2020	CY 2021	CY 2022	CY 2023	CY 2024
Cornea	480	505	571	600	631	664
Glaucoma	601	632	715	751	790	831
Cataracts and Refractive	3,689	3,879	4,080	4,290	4,511	4,744
Oculoplastics	1,048	1,102	1,048	1,102	1,159	1,219
Strabismus	243	255	289	304	319	336
Total	6,061	6,374	6,702	7,047	7,411	7,792

The numbers of cases as shown in the table above in CYs 2019 and 2020 are not consistent with the percentages the applicants calculated on page 4 of its assumptions in Section Q. For example, 480 is actually 7.9% of 6,061; 601 is 9.9% of 6,061 and 1,048 is 17.3% of 6,061. The same is true for the numbers in CY 2020. However, the numbers for each type of case in the three project years (CY 2022, CY 2023 and CY 2024) accurately reflect the percentages of the totals calculated by the applicants on page 4 of the assumptions in Section Q. Therefore, the Project Analyst concludes the first two years are most likely rounding differences and thus present no material issues that would adversely affect the reasonableness of the applicants' assumptions and projections.

- The applicants next examined the numbers and types of cases considered appropriate to shift to Wilmington Eye, and further separated the types of cases into those appropriate for ORs and those appropriate for procedure rooms, because the proposal includes development of four procedure rooms. See the following table, from page 5 of the assumptions in Section Q:

Numbers of Cases Projected to Shift by Subspecialty and Room

	CY 2019	CY 2020	CY 2021	CY 2022	CY 2023	CY 2024
Cornea	480	505	571	600	631	664
Glaucoma	601	632	715	751	790	831
Cataracts/Refractive	1,845	1,940	2,040	2,145	2,256	2,372
Strabismus	243	255	289	304	319	336
OR Subtotal	3,169	3,332	3,615	3,800	3,996	4,203
Cataracts/Refractive	1,845	1,940	2,040	2,145	2,256	2,372
Oculoplastics	1,048	1,102	1,048	1,102	1,159	1,219
Proc. Rm. Subtotal	2,893	3,042	3,088	3,247	3,415	3,591
Grand total	6,062	6,374	6,703	7,047	7,411	7,794

Since the ASF is projected to become operational as of July 1, 2021, the applicants project six months worth of volume for CY 2021. Additionally, the applicants project that utilization would be 33% of total capacity in the partial CY 2021, ramping up to 100% of capacity by the third operating year, CY 2024. See the following table, from page 5, representing the cases projected for the ORs at Wilmington Eye:

Projected Number of OR Cases

	CY 2021*	CY 2022	CY 2023	CY 2024	% OF TOTAL CASES
Cornea	285	600	631	664	100.0%
Glaucoma	357	751	790	831	100.0%
Cataracts/Refractive	1,020	2,145	2,256	2,372	50.0%
Strabismus	144	304	319	336	100.0%
Total	1,087	3,800	3,996	4,202	
Ramp up	33.0%	66.0%	100.0%	100.0%	
Total Cases	596	2,508	3,996	4,202	

*CY 2021 is a partial year, from 7/1/2021 – 12/31/2021.

Thus, the applicants account for the partial year in CY 2021 in their projections. The applicants' proposed ASF will be a Category 5 per the 2019 SMFP, since it projects that at least 50% of the OR cases will be ophthalmology cases.

- According to the OR need methodology in the 2019 SMFP, the applicants applied an average case time of 0.68 hours per case, and 1,312 standard hours per operating year to the projections of cases in the ORs in each of the three project years (PY). See the following table, from page 6 of the assumptions in Section Q:

	PY 1 (CY 2022)	PY 2 (CY 2023)	PY 3 (CY 2024)
Total Cases	2,508	3,996	4,202
Case Time (Group 5)	0.68	0.68	0.68
Total Hours	1,706	2,717	2,857
Standard Hours per OR per Year	1,312	1,312	1,312
ORs Needed	1.3	2.1	2.2

The projections show a need for 2 ORs. The applicants are applying for two ORs in the proposed ASF.

- Procedure Rooms – the applicants project the remainder of the cases to be performed in the four proposed procedure rooms. The applicants state one of the procedure rooms will be dedicated to procedures involving femtosecond laser equipment, where laser incisions will be performed prior to a patient proceeding to an OR for surgery. The projected number of cases that are not projected to be performed in ORs will therefore be spread among the three remaining procedure rooms, as illustrated in the following table from page 6 of the assumptions in Section Q:

	CY 2021*	PY 1 (CY 2022)	PY 2 (CY 2023)	PY 3 (CY 2024)
Procedures	1,544	3,247	3,414	3,590
Ramp Up	33%	66%	100%	100%
Total Procedures	510	2,143	3,414	3,590
Number of Procedure Rooms	3	3	3	3
Procedures per Room	170	714	1,138	1,197

*CY 2021 is a partial CY, from 7/1/2021 to 12/31/2021.

There are no performance standards for procedure rooms; however, the applicants demonstrate that the proposed procedure rooms will be well utilized at the proposed ASF.

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

- Currently, 68% of the ORs located in New Hanover County are hospital-based.
- Patients and third-party payors pay less for the same procedure performed at an ASF than one done on an outpatient basis in a hospital-based OR.
- There are only eight ASFs in North Carolina that specialize in ophthalmic surgical procedures, and the closest of these is 150 miles west of New Hanover County.
- Projected surgical case growth is supported by projected population growth and historical ophthalmic surgeries performed in the county.
- The methodology and assumptions with regard to utilization of the ORs and the procedure rooms are reasonable and adequately supported.
- WESC will be a new freestanding ASF dedicated to ophthalmic surgeries in New Hanover County.
- New Hanover Regional Medical Center has submitted a letter of support for the proposed project.

Access

In Section C.8, pages 41 - 42, the applicants state the development of the proposed ASF “will increase access to timely, clinically appropriate, and high quality surgical services in New Hanover County as well as enhance geographic access to lower cost ophthalmic and plastic surgery services in a freestanding ASF.”

In Section L.3, page 72, the applicants project the following payor mix during the third full fiscal year (CY 2024) of operation following completion of the project, as illustrated in the following table:

	ORs	PROCEDURE ROOMS	ENTIRE FACILITY
Self-Pay	1.5%	1.5%	1.5%
Charity Care ¹	0	0	0
Medicare*	71.3%	71.3%	71.3%
Medicaid*	3.2%	3.2%	3.2%
Insurance*	20.1%	20.1%	20.1%
Other (specify)**	4.0%	4.0%	4.0%
Total	100.0%	100.0%	100.0%

(1) the applicants state their internal data does not include *Charity Care* as a payor source; however, the applicants state “Patients in any payor category can and do receive charity care.”

*This includes any managed care plans.

**Other includes TRICARE and worker’s comp.

Totals may not sum due to rounding.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Remarks made at the public hearing

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 based on reasonable and adequately supported assumptions.
- The applicants project the extent to which all residents, including underserved groups, will have access to the proposed services (payor mix) and adequately supports the assumptions.

(3a) In the case of a reduction or elimination of a service, including the relocation of a facility or a service, the applicant shall demonstrate that the needs of the population presently served will

be met adequately by the proposed relocation or by alternative arrangements, and the effect of the reduction, elimination or relocation of the service on the ability of low income persons, racial and ethnic minorities, women, handicapped persons, and other underserved groups and the elderly to obtain needed health care.

NA

The applicants do not propose to:

- Reduce a service
- Eliminate a service
- Relocate a facility or service

Therefore, Criterion (3a) is not applicable to this review.

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

CA

The applicants propose to develop a freestanding ASF with 2 ORs dedicated to ophthalmic surgical procedures and plastic surgery and 4 procedure rooms.

In Section E, pages 49 - 51, the applicants describe the alternatives they considered and explain 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 this alternative would ignore the need in New Hanover County for an ASF dedicated to ophthalmology, plastic surgery and similar cases. Currently, these procedures are being performed in a hospital, which is a significantly higher cost to the patient. Additionally, ophthalmic surgeons associated with this project face multiple barriers with existing resources to providing quality eye surgery for their patients.
- Develop the project with a different number of ORs – the applicants determined that this option would not be the most effective method to meet the needs of people in New Hanover County who need ophthalmic surgery. The applicants state that an ASF with fewer than two ORs is generally not financially feasible, and because of the low case times and high volume, quick OR turnover is a unique aspect of ASFs. The applicants also stated that the 2019 SMFP need determination was for six ORs in New Hanover County. Since the applicants applied for two, that leaves four ORs for other applicants to apply for.
- Offer a different complement of surgical procedures at the proposed ASF – the applicants considered offering other types of surgical specialties at the proposed ASF, in addition to the ophthalmology and ophthalmic plastic surgery. However, the staffing

inefficiencies and difficulty of moving surgical equipment in and out of the ORs for different types of procedures, particularly considering the historical and projected volume of ophthalmology procedures indicate that offering additional surgical specialties is not an effective alternative for surgeons or patients.

- Use the Wilmington ASF – the applicants considered utilizing the ORs at the Wilmington ASF, which is approved but not yet developed. However, the applicants state that ASF was approved to develop one OR with multiple surgical specialties, and thus is not an effective alternative for the ophthalmic surgeons proposing this project.

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 meets the need for additional ORs identified in the 2019 SMFP in New Hanover County.
- The application proposes a solution to OR capacity constraints at New Hanover Regional Medical Center.
- The application proposes to meet the increasing demand for ophthalmic surgical procedures in a low-cost outpatient setting in the county.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Remarks made at the public hearing

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. Wilmington Eye Surgery Center, LLC and WESCP, LLC shall materially comply with all representations made in the certificate of need application.**
- 2. Wilmington Eye Surgery Center, LLC and WESCP, LLC shall develop one ambulatory surgical facility with no more than two operating rooms and no more than four procedure rooms.**
- 3. Wilmington Eye Surgery Center, LLC and WESCP, 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.**

- 4. For the first three years of operation following completion of the project, Wilmington Eye 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.**
 - 5. The procedure rooms shall not be used for procedures that should be performed only in operating rooms based on current standards of practice.**
 - 6. Procedures performed in procedure rooms shall not be reported for billing purposes as having been performed in operating rooms and shall not be reported on the facility's license renewal application as procedures performed in operating rooms.**
 - 7. Wilmington Eye Surgery Center, LLC and WESCP, LLC 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.**
 - 8. No later than three months after the last day of each of the first three full years of operation following initiation of the services authorized by this certificate of need, Wilmington Eye Surgery Center, LLC and WESCP, LLC shall submit, on the form provided by the Healthcare Planning and Certificate of Need Section, an annual report containing the:**
 - a. Payor mix for the services authorized in this certificate of need.**
 - b. Utilization of the services authorized in this certificate of need.**
 - c. Revenues and operating costs for the services authorized in this certificate of need.**
 - d. Average gross revenue per unit of service.**
 - e. Average net revenue per unit of service.**
 - f. Average operating cost per unit of service.**
 - 9. Wilmington Eye Surgery Center, LLC and WESCP, 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 develop a freestanding ASF with 2 ORs dedicated to ophthalmic surgical procedures and plastic surgery. The applicants also propose to develop 4 procedure rooms, which are not regulated by Certificate of Need law.

Capital and Working Capital Costs

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

Site Costs	\$1,191,926
Construction Costs	\$5,670,458
Miscellaneous Costs	\$3,003,457
Total	\$9,865,840

In Section Q, the applicant provides the assumptions used to project the capital cost.

In Section F, page 54, the applicants project that start-up costs will be \$396,973 and initial operating expenses will be \$402,620 for a total working capital of \$799,593. On page 54, the applicants provide the assumptions and methodology used to project the working capital needs of the project.

Availability of Funds

In Section F, page 52, the applicants state that the capital cost will be funded as shown in the table below:

Sources of Capital Cost Financing

TYPE	WILMINGTON EYE SURGERY CENTER, LLC	WESCP, LLC	TOTAL
Loans	\$1,660,049	\$8,205,791	\$9,865,840
Accumulated Reserved or OE*	\$0	\$0	\$0
Bonds	\$0	\$0	\$0
Other	\$0	\$0	\$0
Total	\$1,660,049	\$8,205,791	\$9,865,840

*OE = owner's equity

In Section F, page 55, the applicants state that the working capital needs of the project will be funded as shown in the table below:

Sources of Working Capital Financing

TYPE	WESCP, LLC
Loans	\$799,593
Cash or Cash Equivalents, Accumulated Reserves or OE	\$0
Lines of Credit	\$0
Bonds	\$0
Total	\$799,593

In Exhibit F.1 the applicants provide a certified construction cost estimate that confirms the proposed construction costs for the project. In Exhibit F.2-1, the applicants provide a June 17, 2019 letter from First National Bank documenting its willingness to enter into a loan agreement with WESCP, LLC for its portion of the capital cost of the project. In Exhibit F.2-2, the applicants provide a June 17, 2019 letter from First National Bank documenting its willingness to enter into a loan agreement with WESCP for its portion of the capital cost and the working capital costs of the project. Those same exhibits also contain copies of letters from each applicant indicating that the loan proceeds will be utilized to develop the project.

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.2, the applicants project that revenues will exceed operating expenses in the first three operating years of the project, as shown in the table below:

	1 ST FULL FISCAL YEAR (CY 2022)	2 ND FULL FISCAL YEAR (CY 2023)	3 RD FULL FISCAL YEAR (CY 2024)
Total Surgical Cases*	4,651	7,410	7,792
Total Gross Revenue (charges)	\$13,521,351	\$21,542,670	\$22,652,854
Total Net Revenue	\$7,019,332	\$11,183,436	\$11,759,765
Average Net Revenue per Case*	\$1,509.21	\$1,509.24	\$1,509.21
Total Operating Expenses (costs)	\$5,066,987	\$6,139,606	\$6,509,104
Average Operating Expense per Case*	\$1,089.44	\$828.56	\$835.36
Net Income	\$1,952,345	\$5,043,830	\$5,250,661

*Total cases includes those performed in the procedure rooms and ORs; the applicants did not separate the cases according to where they were performed.

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
- Remarks made at the public hearing

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 costs are based on reasonable and adequately supported assumptions.
 - The applicants adequately demonstrate the 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 develop a freestanding ASF with two ORs dedicated to ophthalmic surgical procedures and plastic surgery. The applicants also propose to develop four procedure rooms, which are not regulated by Certificate of Need law.

On page 55, the 2019 SMFP states, “An operating room’s service area is 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 60 of the 2019 SMFP, New Hanover County is shown as a single-county OR service area. Thus, the service area for this review consists of New Hanover County. Facilities may also serve residents of counties not included in the service area.

The following table identifies the existing and approved inpatient (IP), outpatient (OP), and shared operating rooms located in New Hanover County, and the inpatient and outpatient case volumes for each provider, from Tables 6A and 6B, pages 68 and 80 respectively, of the 2019 SMFP:

FACILITY	IP ORS	OP ORS	SHARED ORS	EXCLUDED C-SECTION/TRAUMA /BURN ORS	CON ADJUSTMENT	IP SURGERY CASES	OP SURGERY CASES	GROUP
Wilmington ASC	0	0	0	0	1	0	0	-
Wilmington SurgCare	0	7	0	0	3	0	8,531	5
New Hanover Regional Medical Center	5	4	29	-3	0	11,924	25,301	2
Total New Hanover County ORs	5	11	29	-3	4			

As the table above indicates, there is one hospital and two existing or approved ambulatory surgical facilities (ASF) in New Hanover County with a total of five inpatient, 11 ambulatory and 29 shared operating rooms, including one C-Section OR.

In Section G, pages 58 - 59, the applicants explain why they believe the proposal would not result in the unnecessary duplication of existing or approved surgical services in New Hanover County. The applicants state:

“...as a proposal to develop the only ASF in New Hanover County focusing on ophthalmology and plastic surgery cases, the proposed project will provide a unique setting for care that does not currently exist in the service area.

In addition, ... there are no ASFs focused on ophthalmology in the eastern region of North Carolina; thus, there will be no duplication in the counties adjacent to the service area. ... the existing licensed surgical settings in New Hanover County are not suitable for constant high volumes of ophthalmic surgery. ... the majority of ophthalmic surgery cases are currently performed in the county are done in the more expensive hospital-based setting at NHRMC Atlantic Sugicenter, which charges patients and payors at hospital rates, when these same procedures can be safely performed in an ASF that operates with a lower billing structure. Also, the only other existing ASF in the county, Wilmington SurgCare, either does not allow all of the cases currently performed by the surgeons associated with WESC or lacks the equipment necessary to perform certain ophthalmic surgical procedures commonly performed by Wilmington Eye surgeons on an outpatient basis.”

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:

- There is a need determination in the 2019 SMFP for six ORs and the applicants propose two ORs.
- The applicants propose to develop an ASF that will specialize in ophthalmic surgical procedures in a county that currently does not have an ASF that offers this specialty.
- The applicants adequately demonstrate that the proposed ORs are needed in addition to the existing or approved ORs in New Hanover County.

The Agency reviewed the:

- Application,
- Exhibits to the application,
- Remarks made at the public hearing,
- 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.

- (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 applicants propose to develop a freestanding ASF with two ORs dedicated to ophthalmic surgical procedures and four procedure rooms.

In Section Q, Form H, the applicants provide projected full-time equivalent (FTE) staffing for the proposed services, as illustrated in the following table:

POSITION	PROJECTED FTE POSITIONS			
	INTERIM CY 2021	PY1 CY 2022	PY2 CY 2023	PY 3 CY 2024
CRNAs	7.0	7.0	7.0	7.0
Registered Nurses	11.0	11.0	13.0	14.0
Surgical Technicians	7.0	7.0	8.0	8.0
Clerical Staff	2.0	2.0	2.5	3.0
Central Sterile Supply	1.0	1.0	1.0	1.0
Administrator	1.0	1.0	1.0	1.0
Director of Nursing	1.0	1.0	1.0	1.0
Business Office	1.0	1.0	1.0	1.0
TOTAL	31.0	31.0	34.5	36.0

The assumptions and methodology used to project staffing are provided in Section Q following Form H. Adequate costs for the health manpower and management positions proposed by the applicants are budgeted in Form F.3, which is found in Section Q. In Section H, pages 60 - 61, the applicants describe the methods to be used to recruit or fill new positions and its proposed training and continuing education programs. In Section I.3(b), page 64, the applicants identify the proposed Medical Director as Samantha Watson, MD. In Exhibit I.3-2, the applicants provide a letter from Dr. Watson indicating a willingness to serve as medical director for the proposed ASF. In Section H.2, pages 60 - 61, the applicants describe their physician recruitment plans.

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,
- Remarks made at the public hearing, and

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

The applicants propose to develop a freestanding ASF with two ORs dedicated to ophthalmic surgical procedures and plastic surgery. The applicant also proposes to develop 4 procedure rooms, which are not regulated by certificate of need law.

In Section I, page 62, the applicants state that ancillary and support services that are necessary for the provision of the proposed services will be available, including:

- Diagnostic imaging
- Laboratory tests
- Pathology
- Anesthesia
- Sterile Processing
- Patient Reception
- Medical Records
- Billing and Insurance
- Housekeeping
- Maintenance

On page 62, the applicants adequately explain how the ancillary and support services will be made available and provide supporting documentation in Exhibit I.1.

In Section I, page 63, the applicants describe their efforts to develop relationships with other local health care and social service providers and provide supporting documentation in Exhibits C.4-2.

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,
- Remarks made at the public hearing

Based on that review, the Agency concludes that the application is conforming to this criterion.

- (9) An applicant proposing to provide a substantial portion of the project's services to individuals not residing in the health service area in which the project is located, or in adjacent health service areas, shall document the special needs and circumstances that warrant service to these individuals.

NA

The 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.

- (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

Neither of the applicants is 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

The applicants propose to develop a freestanding ASF with two ORs dedicated to ophthalmic surgical procedures and plastic surgery. The applicant also proposes to develop 4 procedure rooms, which are not regulated by Certificate of Need law.

In Section K, page 66, the applicants state that the ASF will be developed in a medical office building (MOB) for which WESCP, LLC was granted an exemption from CON law in June 2019. WESCP, LLC will incur the cost for construction of the shell and core of the building and will lease 15,500 square feet of space within the MOB to Wilmington Eye to operate the proposed ASF. Line drawings are provided in Exhibit C.1-1.

On pages 66 - 67, the applicants adequately explain how the cost, design and means of construction represent the most reasonable alternative for the proposal and provide supporting documentation in Exhibit F.1. In addition, on page 67 the applicants adequately explain why the proposal will not unduly increase the costs to the applicants of providing the proposed services or the costs and charges to the public for the proposed services.

On page 67, the applicants identify applicable energy saving features that will be incorporated into the construction plans.

Conclusion

The Agency reviewed the:

- Application,
- Exhibits to the application, and
- Remarks made at the public hearing

Based on that review, the Agency concludes that the application is conforming to this criterion.

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

NA

Neither the applicants nor any related entities own, operate or manage an existing health service facility located in the service area. Therefore, Criterion (13a) is not applicable to this review.

- (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;

NA

Neither the applicants nor any related entities own, operate or manage an existing health service facility located in the service area. Therefore, Criterion (13b) is not applicable to this review.

- (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 72, the applicants project the payor mix for the proposed services during the third full fiscal year of operation following completion of the project, as shown in the table below:

	ORs	PROCEDURE ROOMS	ENTIRE FACILITY
Self-Pay	1.5%	1.5%	1.5%
Charity Care ¹	0	0	0
Medicare*	71.3%	71.3%	71.3%
Medicaid*	3.2%	3.2%	3.2%
Insurance*	20.1%	20.1%	20.1%
Other (specify)**	4.0%	4.0%	4.0%
Total	100.0%	100.0%	100.0%

(1) the applicants state their internal data does not include *Charity Care* as a payor source; however, the applicants state "*Patients in any payor category can and do receive charity care.*"

*This includes any managed care plans.

**Other includes TRICARE and worker's comp.

Totals may not sum due to rounding.

As shown in the table above, during the third full fiscal year of operation, the applicants project 1.5% of total surgical services will be provided to self-pay patients, 71.3% to Medicare patients and 3.2% to Medicaid patients.

On pages 72 and 73, the applicants provide the assumptions and methodology used to project payor mix during the third full fiscal year of operation following completion of the project. The projected payor mix is reasonable and adequately supported for the following reasons:

- The applicants base the projected payor mix on the surgeons' experience in providing similar services in the service area.
- The applicants state that WESC will be positioned to provide surgical services to underserved patients and charity care patients because the surgeons will own the facility.

The Agency reviewed the:

- Application,
- Exhibits to the application,
- Remarks made at the public hearing, and
- 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 73, the applicants adequately describe the range of means by which patients will have access to the proposed services.

The Agency reviewed the:

- Application, and
- Exhibits to the application.

Based on that review, the Agency concludes that the application is conforming to this criterion.

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

C

In Section M, page 74, the applicants describe the extent to which health professional training programs in the area will have access to the proposed ASF for training purposes. The applicants state the surgeons currently have relationships with training programs at NHRMC in affiliation

with UNC Chapel Hill School of Medicine, and that training opportunities will continue to be made available as needed.

The Agency reviewed the:

- Application, and
- Exhibits to the application.

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 develop a freestanding ASF with two ORs dedicated to ophthalmic surgical procedures and plastic surgery. The applicant also proposes to develop 4 procedure rooms, which are not regulated by Certificate of Need law.

On page 55, the 2019 SMFP states, “*An operating room’s service area is 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 60 of the 2019 SMFP, New Hanover County is shown as a single-county OR service area. Thus, the service area for this review consists of New Hanover County. Facilities may also serve residents of counties not included in the service area.

The following table identifies the existing and approved inpatient (IP), outpatient (OP), and shared operating rooms located in New Hanover County, and the inpatient and outpatient case volumes for each provider, from Tables 6A and 6B, pages 68 and 80 respectively, of the 2019 SMFP:

FACILITY	IP ORs	OP ORs	SHARED ORs	EXCLUDED C-SECTION/TRAUMA /BURN ORs	CON ADJUSTMENT	IP SURGERY CASES	OP SURGERY CASES	GROUP
Wilmington ASC	0	0	0	0	1	0	0	-
Wilmington SurgCare	0	7	0	0	3	0	8,531	5
New Hanover Regional Medical Center	5	4	29	-3	0	11,924	25,301	2
Total New Hanover County ORs	5	11	29	-3	4			

As the table above indicates, there is one hospital and two existing or approved ambulatory surgical facilities (ASF) in New Hanover County with a total of five inpatient, 11 ambulatory and 29 shared operating rooms, including one C-Section OR.

In Section N, pages 75 - 78, 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. Beginning on page 75, the applicants state:

“WESC believes the proposed project will foster competition in the proposed service area, particularly as the project proposed is to develop the only freestanding ASF in New Hanover County mainly focused on ophthalmology and plastic surgery. ... the proposed project [sic] will provide a freestanding surgery option for one of the fastest growing surgical specialties in New Hanover County.... The proposed project will enhance competition in the service area as WESC proposes to provide the only freestanding ASF in New Hanover County to offer laser-assisted refractive and cataract surgery, which will greatly reduce the cost of this service for patients.

...

Given the unique characteristics of the eye and the fact that intra-ocular infections are exceptionally devastating, exposing the eye to pathogens from other surgeries poses a unique risk, which can be mitigated in a facility focused on ophthalmic and similar cases, like WESC proposes.

...

...WESC will utilize policies related to access which ensure that the facility will provide services to all persons in need of medical care, regardless of race, color, religion, disability or source of payment.”

The applicants adequately describe the expected effects of the proposed services on competition in the service area and adequately demonstrate:

- 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,
- Remarks made at the public hearing, and
- 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.

- (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.

NA

Neither of the applicants nor any related entities own, operate or manage an existing health service facility located in North Carolina. Therefore, Criterion (20) is not applicable to this review.

- (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. The specific criteria are discussed below.

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

The following definitions apply to all rules in this Section:

- (1) *"Approved operating rooms" means those operating rooms that were approved for a certificate of need by the Healthcare Planning and Certificate of Need Section (Agency) prior to the date on which the applicant's proposed project was submitted to the Agency, but that have not been licensed.*
- (2) *"Dedicated C-section operating room" means an operating room as defined in Chapter 6 in the 2018 State Medical Facilities Plan. For purposes of this Section, Chapter 6 in the 2018 State Medical Facilities Plan is hereby incorporated by reference including subsequent amendments and editions. This document is available at no cost at <https://www.ncdhhs.gov/dhsr/ncsmfp/index.html>.*
- (3) *"Existing operating rooms" means those operating rooms in ambulatory surgical facilities and hospitals that were reported in the Ambulatory Surgical Facility License Renewal Application Form or in the Hospital License Renewal Application Form submitted to the Acute and Home Care Licensure and Certification Section of the Division of Health Service Regulation, and that were licensed prior to the beginning of the review period.*
- (4) *"Health System" shall have the same meaning as defined in Chapter 6 in the 2018 State Medical Facilities Plan.*
- (5) *"Operating room" means a room as defined in G.S. 131E-176(18c).*
- (6) *"Operating Room Need Methodology" means the Methodology for Projecting Operating Room Need in Chapter 6 in the 2018 State Medical Facilities Plan.*
- (7) *"Service area" means the Operating Room Service Area as defined in Chapter 6 in the 2018 State Medical Facilities Plan.*

.2103 PERFORMANCE STANDARDS

.2103(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 2019 State Medical Facilities Plan. The applicant is not required to use the population growth factor.

- C-** The applicants project sufficient surgical cases and hours to demonstrate the need for two ORs in a freestanding ASF in the third operating year of the project based on the Operating Room Need Methodology in the 2019 SMFP, as shown in Section C, Form C and the assumptions to Form C. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

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

-C- In Section Q, immediately following Form C, the applicants provide 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.