

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: May 15, 2020

Findings Date: May 15, 2020

Project Analyst: Celia C. Inman

Assistant Chief: Lisa Pittman

Project ID #: G-11855-20

Facility: Piedmont Surgical Center

FID #: 944499

County: Guilford

Applicant: The Foot Surgery Center of NC, LLC

Project: Convert specialty ambulatory surgical program to a multispecialty ambulatory surgical program

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.

NA

The Foot Surgery Center of NC, LLC, (FSCNC), the applicant, proposes to convert Piedmont Surgical Center (PSC), a specialty ambulatory surgical program, to a multispecialty ambulatory surgical program. PSC currently provides podiatry surgical services in two licensed operating rooms in Guilford County. In Section C.1, page 20, the applicant states that it proposes to add ophthalmology, orthopedics and plastic surgery at PSC. This meets the requirements in Gen. Stat. 131E-176(15a) for a multispecialty ambulatory surgical program: *“A formal program for providing on a same-day basis surgical procedures for at least three of the following specialty areas: gynecology, otolaryngology, plastic surgery, general surgery, ophthalmology, orthopedic, or oral surgery.”*

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 2020 State Medical Facilities Plan (SMFP). Therefore, there are no need determinations applicable to this review.

Policies

There are no policies in the 2020 SMFP which are applicable to this review.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that this criterion is not applicable to this review.

- (2) Repealed effective July 1, 1987.
- (3) The applicant shall identify the population to be served by the proposed project, and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and, in particular, low income persons, racial and ethnic minorities, women, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.

C

The applicant proposes to convert PSC, a specialty ambulatory surgical program, to a multispecialty ambulatory surgical program. Surgical specialties to be offered at the existing ambulatory surgical facility (ASF) include podiatry, ophthalmology, orthopedics, and plastic surgery. This meets the requirements in Gen. Stat. 131E-176(15a) for a multispecialty ambulatory surgical program.

Patient Origin

On page 51, the 2020 SMFP states, “An operating room’s “service area” is the service area in which the operating room is located. The operating room service areas are the single or multicounty groupings shown in Figure 6.1.” In Figure 6.1, page 57 of the 2020 SMFP, Guilford and Caswell counties are shown as a multicounty operating room (OR) service area. Thus, the service area for this application is Guilford and Caswell Counties. Facilities may also serve residents of counties not included in the service area.

In Section C.2, page 21, the applicant provides the historical patient origin data for PSC’s two operating rooms for the last full fiscal year (FY), as summarized in the table below.

**PSC Historical Patient Origin
 FY2019
 10/1/2018-9/30/2019**

County	Patients	% of Total
Forsyth	224	34.8%
Guilford	213	33.1%
Davie	39	6.1%
Davidson	23	3.6%
Rockingham	19	3.0%
Yadkin	19	3.0%
Stokes	18	2.8%
Chatham	14	2.2%
Alamance	11	1.7%
Randolph	11	1.7%
Wilkes	8	1.2%
Surry	7	1.1%
Ashe	6	0.9%
Caswell	6	0.9%
Iredell	6	0.9%
Buncombe	4	0.6%
Brunswick	2	0.3%
Rowan	2	0.3%
Alleghany	1	0.2%
Catawba	1	0.2%
Cleveland	1	0.2%
Halifax	1	0.2%
Hoke	1	0.2%
Mecklenburg	1	0.2%
Montgomery	1	0.2%
State of Virginia	4	0.6%
Total	643	100.0%

Source: Application, page 21, sorted from larger to smaller number of North Carolina patients and out of state
 Percentages and totals may not calculate/sum due to rounding

The applicant provides the projected patient origin for the PSC operating rooms on page 23, as summarized below.

PSC Projected Patient Origin

County	FY2021		FY2022		FY2023	
	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total
Guilford	325	33.0%	444	32.2%	619	32.0%
Forsyth	301	30.5%	399	28.9%	529	27.4%
Davie	60	6.1%	86	6.2%	126	6.5%
Davidson	47	4.8%	70	5.1%	98	5.1%
Rockingham	29	2.9%	42	3.0%	61	3.2%
Yadkin	29	2.9%	44	3.2%	65	3.4%
Stokes	28	2.8%	42	3.0%	61	3.2%
Alamance	27	2.7%	40	2.9%	58	3.0%
Randolph	26	2.6%	38	2.8%	56	2.9%
Chatham	20	2.0%	31	2.2%	47	2.4%
Surry	19	1.9%	33	2.4%	53	2.7%
Caswell	15	1.5%	26	1.9%	40	2.1%
Wilkes	12	1.2%	17	1.2%	24	1.2%
Ashe	9	0.9%	13	0.9%	18	0.9%
Iredell	9	0.9%	13	0.9%	18	0.9%
Buncombe	6	0.6%	8	0.6%	12	0.6%
Montgomery	4	0.4%	6	0.4%	8	0.4%
Brunswick	3	0.3%	4	0.3%	6	0.3%
Rowan	3	0.3%	4	0.3%	6	0.3%
Alleghany	2	0.2%	3	0.2%	4	0.2%
Catawba	2	0.2%	3	0.2%	4	0.2%
Cleveland	2	0.2%	3	0.2%	4	0.2%
Halifax	2	0.2%	3	0.2%	4	0.2%
Hoke	2	0.2%	3	0.2%	4	0.2%
Mecklenburg	2	0.2%	3	0.2%	4	0.2%
Virginia	2	0.2%	4	0.3%	6	0.3%
Total	986	100.0%	1,380	100.0%	1,933	100.0%

Source: Application, page 23, sorted from larger to smaller number of North Carolina patients and out of state

Percentages and totals may not calculate/sum due to rounding

In Section C, pages 24-25, the applicant provides the assumptions and methodology used to project operating room patient origin, stating that historical data was used as the basis for the projection. The applicant states that it expects a higher percentage of patients to come from rural counties and other higher poverty areas, with the assumption that PSC's number of surgeries will increase by 40% per year in the 2nd and 3rd years with higher and higher percentages coming from poorer rural counties and low-income areas because of PSC's Formal Charity, Poverty and Rural Increased Access Program (Exhibit C.3.b). In Section L, page 60, the applicant states that the targeted outreach area includes the 12 counties of Stokes, Rockingham, Caswell, Alamance, Randolph, Davidson, Chatham, Davie, Surry, Yadkin, Guilford and Forsyth.

The applicant's assumptions are reasonable and adequately supported

Analysis of Need

In Section B.1, pages 14-18, the applicant discusses why it submitted this application. On page 14, the applicant states:

“We submit this application to address equitable access to the medically underserved and the barriers to access per SMFP wording that this is a foundational principle for the SMFP.

We propose that conversion from single to multispecialty (per § Chapter 131E-176(16)(r) enables this ASC to serve significantly more medically underserved patients.”

On page 15, the applicant states that large numbers of patients decline needed surgery due to inability to afford co-pay and other costs. The applicant further states that these patients are more likely to be served at PSC because of its charity and lower cost access policies and documents this statement with physician support letters in Exhibit C.7.e; and with PSC's Charity Care and Financial Assistance Policy; Billing and Collecting Policy; Charity Policy, Reduced Charges & Write-Offs; and Medicare Co-Pay Write Off Policy in Exhibit B.3.a.2. On pages 15-16, the applicant further states:

“We propose that our outreach policies uniquely enable us to expand access in the service area. This entire application is not about addressing OR facility need but rather supporting key state objectives with an existing, proven, approved facility regarding access to low income persons (limited financial resources), racial and ethnic minorities, women, handicapped persons, the elderly and other underserved groups.

...

As a single specialty ASC we have been aggressive in our charity, free service, discounted service, in outreach. As a multispecialty center we will be able to expand the number of medically underserved patients, elderly, medical indigent, low income, Medicaid and Medicare recipients, racial minority, ethnic minorities, women and handicapped person.

...

We have been and will be aggressive in serving the underserved in Guilford and Forsyth counties and the 10 surrounding counties.”

In support of PSC's ability to serve the underserved, the applicant states on pages 16-17, that PSC:

- has much lower overall charges than other ASFs in the area,
- has generous and progressive policies for charity and low income and high deductible care, i.e. PSC only bills a Medicare patient two times and then assumes paying the bill would be hardship on that patient,
- has an aggressive outreach program in its 12-county outreach area for patients in need of low or no cost surgery (Exhibit C.8), and
- is developing a grant program to attract charitable donations from large and small donors to allow PSC to provide more service to more charity outreach patients (Exhibit B.3.b).

In Section C.4, pages 24-26, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services, summarized as follows:

- Lack of access to surgery for economic reasons (pages 24-26);
- Poverty rates in all 12 of PSC's target counties, as listed in Section L, page 60 (page 25);
- Transportation difficulties and distance from medical resources (page 25); and
- High deductibles in the market place (page 25).

The applicant states that the multispecialty center will be able to expand the number of medically underserved patients served with the added specialties. The information is reasonable and adequately supported for the following reasons:

- The applicant provides information and data from reputable sources to support population, poverty rates, and income levels in the service area.
- The applicant uses clearly cited and reasonable historical and demographic data to make the assumptions with regard to identifying the population to be served, their health and financial status, and the need for the proposed services.
- The applicant reasonably demonstrates service area patients' lack of access to surgery by reports from its staff surgeons and other surgeons (physician support letters in Exhibit C).
- The applicant reasonably demonstrates that a minimal investment to convert from a specialty to a multispecialty ASF will benefit patients, physicians and the ASF, improving physician and facility efficiency, improving access to reasonably low-cost surgery, and providing stability that will ultimately sustain customer friendly pricing. Exhibit E.2.b. contains a charge comparison with area ASFs.

Projected Utilization

In Section Q Form C, the applicant provides historical and projected utilization, as summarized in the following table.

**Historical and Projected Operating Room Utilization
 Form C Utilization As Provided by Applicant**

Operating Rooms	Prior Full FY2019	Interim FY2020	1 st Full FY FY2021	2 nd Full FY FY2022	3 rd Full FY FY2023
Dedicated Ambulatory ORs	2	2	2	2	2
Outpatient Surgical Cases [^]	643	322	986	1,380	1,933
Outpatient Surgical Case Time*	90	90	85	81	77
Outpatient Surgical Hours	965	483	1,397	1,864	2,480
Group Assignment	6	6	6	6	6
Standard Hours per OR per Year**	1,950	1,950	1,950	1,950	1,950
Total Surgical Hours/Standard Hours Per OR per Year	0.25	0.12	0.36	0.48	0.64

*Applicant uses the times as reported in the 2020 SMFP Table 6B, page 74, for FY2019 and FY2020, reduced to 85, 81, and 77 in the first three full operation years following completion of the project.

**Applicant uses 1,950 standard hours per OY per year, the correct number of hours for Groups 1 and 2, but not Group 6 (1,312)

[^]In Supplemental Information requested by the Agency, the applicant provides the supporting documentation which explains the number of outpatient surgical cases, as included in the table above.

The following table prepared by the Agency uses the applicant’s two ORs, the applicant’s total number of cases, the outpatient surgical case time from Table 6B in the 2020 SMFP (as required in Form C instructions), and the correct standard hours per OR per year for Group 6.

**Historical and Projected Operating Room Utilization
 As Calculated by the Agency**

Operating Rooms	Prior Full FY2019	Interim FY2020	1 st Full FY FY2021	2 nd Full FY FY2022	3 rd Full FY FY2023
Dedicated Ambulatory ORs	2	2	2	2	2
Outpatient Surgical Cases	643	322	986	1,380	1,933
Outpatient Surgical Case Time*	90	90	90	90	90
Outpatient Surgical Hours	965	483	1,479	2,070	2,900
Group Assignment**	6	6	6	6	6
Standard Hours per OR per Year***	1,312	1,312	1,312	1,312	1,312
Total Surgical Hours/Standard Hours Per OR per Year	0.37	0.18	0.56	0.79	1.10

*From Section C, Question 6(c), “as reported in Table 6B in the SMFP in effect at the time the review begins and use those times to project estimated surgical hours in Form C”

**From Section C, Question 6(a)

*** From Section C, Question 6(b)

In Section Q Exhibit Form C.1 Utilization and Projections, the applicant provides the assumptions and methodology used to project PSC operating room utilization, as summarized below:

- Assume the recovery to the numbers of surgeries performed “until within the last year or so pressures from large organizations forced physicians in their associations to stop doing surgery outside their systems despite the fact that it is more expensive for most of their patients.” In Section C.7, page 31, the applicant states: “Goliaths have interfered to drop our utilization. In the past we had approximately 75% utilization. With large health systems buying up practices and discouraging their surgeons from

going out of their system, our utilization has dropped to 25%. Going to multispecialty will benefit patients to lower cost & a more efficient venue such as ours.”

- Assume that *“with persistent effort in our Charity, Poverty and Rural Increased Access Program and in recruiting more surgeons to become medical staff members, the number of surgeries will increase progressively over 3 years.”* In Section C.3(b), page 24, the applicant states that it expects to recruit more surgeons to become medical staff members, thereby increasing the number of surgeries at the center, as more surgeons *“become aware of the lower pricing, high quality of care, efficiency and convenience we offer”* In Section L, page 55, the applicant states an expectation of 36 surgeons on the Medical Staff by the third year of operation.
- Assume *“our number of surgeries will increase by 40% per year in the 2nd and 3rd years with higher and higher percentages coming from poorer rural counties [sic] low income areas because of our comprehensive approach through [sic] Charity, Poverty and Rural Increased Access Program.”*
- Assume the *“synergy”* between insured patients and charity outreach will provide PSC more ability to afford to provide free and discounted care.

In clarifying supplemental information requested by the Agency, the applicant provides support for the utilization projections, expectations on the size of the future medical staff, and for its charity program.

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

- The applicant states that it is common for patients to decline or delay surgery because it is not affordable. (page 31 of application and Exhibit C.7e.)
- Population projections and demographics reasonably support the projections.
- The applicant’s expectations to increase the number of surgeons on its medical staff, thereby increasing the number of surgeries performed at PSC.
- Physician support letters in Exhibit C.7.e. and explanation in the supplemental information requested by the Agency:
 - Expectation for existing PSC surgeons to increase surgical cases, returning to historical case level with current surgeons
 - Referral of 240 orthopedic cases per year
 - Referral of 660 ophthalmological cases per year
 - Referral of 100 plastic surgery cases per year

Access

In Section C, pages 31-33, the applicant addresses how it will provide access to its services, stating: *“Our history of providing charity service is generous and our longstanding actions are backed up by our policies.”* See Exhibit B.3.a.2 for pertinent policies.

On pages 32-33, the applicant states that PSC:

- has a history of providing generous charity service backed up by policies (Exhibit B.3.a.2.).

- serves a greater number of women and racial and ethnic minorities than the population demographics in the area,
- provides free transport and special services to any patient to ensure access to services,
- will help the elderly directly and indirectly through its Formal Charity, Poverty and Rural Increased Access Program (See Exhibit C.3.b.),
- expects its Medicare and Medicaid recipients will increase in response to its Formal Charity, Poverty and Rural Increased Access Program, and
- will seek out Medicaid recipients and arrange access to surgeons who participate in PSC’s Charity, Poverty and Rural Increased Access Program.

In Section L, pages 60-63, the applicant discusses PSC’s Formal Charity, Poverty and Rural Increased Access Program (See Exhibit C.3.b.) and PSC’s 12-county outreach area, stating:

- PSC has initiated outreach to 38 free and income-based clinics, 20 county health department locations, more than 100 medical clinics, nurses, nurse practitioners, physician assistants and physicians mostly in high poverty areas (Exhibit L.0.2).
- The purpose of the free and low-income policies is to further extend our medical services to the underserved, elderly, minority, women, handicapped and medically indigent and low-income patients.
- PSC has offered assistance to the DHHS Office of Rural Healthcare.
- PSC will start a rural and poverty charity to raise money through grants and contributions specifically for addressing rural healthcare problems. A list of Foundations and Companies PSC plans to solicit is provided in Exhibit B.3.b.
- Poverty rates in all 12 target counties are higher than the US average (Exhibit L.0.4).
- PSC has never discriminated because of a patient’s ability to pay and does not refer any patients to collections.

In Section L.3, page 66, the applicant projects the payor mix during the third full fiscal year of operation following completion of the project, as summarized in the following table.

Payor Source	Entire Facility
Self-Pay	5%
Charity Care	19%
Medicare*	33%
Medicaid*	19%
Insurance*	33%
Other (Workers compensation, TRICARE)	2%
Total	100% [111%]

*Including any managed care plans.

In clarifying supplemental information requested by the Agency, the applicant confirms errors in transcribing figures into the table provided on page 66 and summarized above; and provides the corrected numbers and percentages, as shown below.

Payor Source	Entire Facility
Self-Pay	5%
Charity Care	20%
Medicare*	29%
Medicaid*	15%
Insurance*	29%
Other (Workers compensation, TRICARE)	2%
Total	100%

*Including any managed care plans.

The projected payor mix is reasonable and adequately supported based on the following:

- The applicant states that it bases the projection on historical payor sources.
- The applicant states that it projects increased self-pay, charity care, Medicare and Medicaid based on the estimated numbers of underserved and impoverished patients and the potential effect of PSC's Formal Charity, Poverty and Rural Increased Access Program.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Information publicly available during the review and used by the Agency
- Supplemental information requested by the Agency

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

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

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

NA

The applicant proposes to convert PSC, a specialty ambulatory surgical program, to a multispecialty ambulatory surgical program. The proposal does not result in the reduction, relocation, or elimination of a service. Therefore, Criterion (3a) is not application 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 applicant proposes to convert PSC, a specialty ambulatory surgical program, to a multispecialty ambulatory surgical program.

In Section E, pages 42-43, the applicant states that the status quo is the only alternative, further stating:

“All alternatives to ours, per our information and belief, result in high costs to patients and decreased access compared to our proposal. We have this from innumerable sources and especially patients, surgeons & our own direct fact finding. We are committed to expand access and lower costs to all patients whether underserved or not.”

On page 43, the applicant states that its proposed alternative is the most effective alternative, stating:

“Status quo IS THE ALTERNATIVE [emphasis in original]. But the status quo is inferior for access and it does not increase access for the underserved. The alternative to our proposal leaves the current higher priced limited access subject to the concentration of power and in the hands of giant organizations. It is not in our control to influence other large ASC operators to join us in outreach that addresses better access to the underserved and lower costs to those that cannot afford the typical costs of many if not most ASC procedures.”

The applicant provides supporting documentation in Exhibit E.2.b., which illustrates the survey results comparing pricing at local ASFs compared to PSC. In Section E.3, page 43, the applicant states:

“The results of this survey are completely consistent with what I have been told emphatically by over 25 surgeons in this area. Clearly the higher cost at other ASC [sic] compared to ours especially for self-pay and private insurance can be dramatic. With high deductibles the financial damage to patients can be stunning and would certainly be a tremendous barrier to access for many or most of the population.”

The applicant adequately demonstrates 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 review criteria.
- The applicant provides credible information to explain why it believes the proposed project is the most effective alternative.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Supplemental information requested 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. The Foot Surgery Center of NC, LLC shall materially comply with all representations made in the certificate of need application and any supplemental responses. In the event that representations conflict, The Foot Surgery Center of NC, LLC shall materially comply with the last made representation.**
- 2. The Foot Surgery Center of NC, LLC shall convert a specialty ambulatory surgical program to a multispecialty ambulatory surgical facility by adding ophthalmology, orthopedic and plastic surgery surgical services.**
- 3. Upon project completion, Piedmont Surgical Center shall be licensed for no more than two operating rooms.**
- 4. The Foot Surgery Center of NC, 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.**
- 5. For the first three years of operation following completion of the project, The Foot Surgery Center of NC, LLC 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.**
- 6. No later than three months after the last day of each of the first three full fiscal years of operation following initiation of the services authorized by this certificate of need, The Foot Surgery Center of NC, 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.**

7. **The Foot Surgery Center of NC, 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 applicant proposes to convert PSC, a specialty ambulatory surgical program, to a multispecialty ambulatory surgical program.

Capital and Working Capital Costs

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

Medical Equipment	\$135,000
Total*	\$135,000

*the applicant's Form F.1a Capital Cost total includes \$60,000 in working capital costs for a total of \$195,000.

In Section Q Form F-1a Capital Cost Assumptions, the applicant provides the assumptions used to project the capital cost.

In Section F, pages 45-46, the applicant projects there will be \$25,000 start-up costs and \$35,000 initial operating expenses for total working capital needs of \$60,000.

Availability of Funds

In Section F, page 44, the applicant states that the capital cost will be funded as summarized in the table below.

Sources of Capital Cost Financing

Type	The Foot Surgery Center of NC, LLC (Applicant 1)	Total
Loans	\$0	\$0
Accumulated Reserves or OE*	\$0	\$0
Bonds	\$0	\$0
Other***	\$135,000	\$135,000
Total Financing **	\$135,000	\$135,000

* OE = Owner’s Equity

**Total financing should equal the total capital cost reported on Form F.1a Capital Cost.

*** Dr. Cosgrove will donate money for capital equipment to fulfill CON and licensing requirements in the interest of our future patients

In Section F, page 46, the applicant states that the working capital cost will be funded as summarized in the table below.

Sources of Working Capital Financing

Type	The Foot Surgery Center of NC, LLC (Applicant 1)	Total
Loans	\$0	\$0
Accumulated Reserves or OE	\$60,000	\$60,000
Lines of credit	\$0	\$0
Bonds	\$0	\$0
Total* From Robert J. Cosgrove, M.D.	\$60,000	\$60,000

*Total sources of financing for working capital should equal the amount listed in Question F.3(c).

In supplemental information requested by the Agency, the applicant provides documentation of Dr. Cosgrove’s intent to provide \$195,000 capital and working capital to convert PSC to a multispecialty ASF. The applicant also submitted an account statement confirming Dr. Cosgrove’s access to adequate cash and cash equivalents to develop the proposed project. Exhibit F.3 contains the PSC Profit and Loss Statements for January through August 2019, CY2018, and CY2017.

Financial Feasibility

The applicant provides pro forma financial statements for the first three full fiscal years of operation following completion of the project. In Form F.2 Revenues and Net Income, the

applicant projects that revenues will exceed operating expenses in the first three full fiscal years following completion of the project, as shown in the table below.

	FY2021*	FY2022	FY2023
Operating Room Cases (Form C)	986	1,380	1,933
Total Gross Revenues (Charges)	\$709,368	\$1,020,426	\$1,428,596
Other Revenues	\$5,000	\$20,000	\$30,000
Total Net Revenue	\$500,058	\$728,298	\$1,021,017
Average Net Revenue per Case	\$507	\$528	\$528
Total Operating Expenses (Costs)	\$477,667	\$685,426	\$914,365
Average Operating Expense per Case	\$484	\$497	\$473
Net Income	\$22,391	\$42,872	\$106,652

* As corrected in clarifying supplemental information requested by the Agency, in which the applicant confirms errors in transcribing figures into the table in the application and provides the correct figures for FY2021. The corrected information for FY2021 has no effect on FY2022 or FY2023.

The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs and charges. See Section Q Form F.2 Assumptions & Methodology 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
- Supplemental information requested by the Agency

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

- The applicant adequately demonstrates that the capital costs and working capital costs are based on reasonable and adequately supported assumptions.
 - The applicant adequately demonstrates availability of sufficient funds for the capital and working capital needs of the proposal.
 - The applicant adequately demonstrates sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.
- (6) The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

C

The applicant proposes to convert PSC, a specialty ambulatory surgical program, to a multispecialty ambulatory surgical program.

On page 51, the 2020 SMFP states, “An operating room’s “service area” is the service area in which the operating room is located. The operating room service areas are the single or multicounty groupings shown in Figure 6.1.” In Figure 6.1, page 57 of the 2020 SMFP, Guilford and Caswell counties are shown as a multicounty operating room service area. Thus, the service area for this application is Guilford and Caswell counties. 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 Guilford County, and the inpatient and outpatient case volumes for each provider, from pages 62 and 74 of the 2020 SMFP. Caswell County has no ORs.

	IP ORs	OP ORs	Shared ORs	Excluded C-Sec, Trauma, Burn	CON Adjustments	IP Surgery Cases	OP Surgery Cases	Group
Greensboro Specialty Surgical Center	0	3	0	0	0	0	1,304	6
Surgical Center of Greensboro	0	13	0	0	0	0	13,806	6
High Point Surgery Center	0	6	0	0	0	0	4,424	6
Premier Surgery Center	0	2	0	0	0	0	9	6
High Point Regional Health	3	0	8	-1	0	3,064	2,602	4
Valleygate Dental Surgery Ctr of the Triad	0	2	0				57	6
Surgical Eye Center	0	4	0				2,892	5
Piedmont Surgical Center	0	2	0				652	6
Kindred Hospital-Greensboro	0	0	1			261	16	4
Cone Health	4	13	33	-1	-4	13,289	15,957	2
Total Guilford County ORs	7	45	42	-2	-4			

Source: 2020SMFP, page 62 and 74

In Section G, page 51, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved ambulatory surgical services in the Guilford County operating room service area. The applicant states:

“There will not be unnecessary duplication. There is no new facility or ORs, just better utilization of existing. There is greater access to needy people by approval of my multispecialty programs. There is more help at lower costs than alternative ASCs resulting in needy patients finding ways to receive lower costs and more affordable costs for needed surgery. Instead of competition, we can look forward to many fewer patients declining needed surgery for the reason of not being able to afford it. Our focus is on underserved through the various mechanisms so that many in need of medical help will not get neglected.”

The applicant further states that PSC's volume of projected surgery is trivial when compared to the volume of surgery at ambulatory surgical facilities in Guilford County and the applicant's outreach area. The applicant provides documentation in Exhibit G.2.c.

The applicant states that based on the numbers of surgeries published in the 2020 SMFP, PSC's 652 surgeries compose only 1.6% of the total 41,719 surgeries in Guilford County. The applicant further states:

“Even if we triple that volume in 3 years as projected, which we expect will consist of largely otherwise unserved patients, we have a very small share of outpatient surgeries. We will not be a competitive detriment to other ASCs in the county.”

The applicant adequately demonstrates 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 in ORs in the Guilford County operating room service area.
- The applicant adequately demonstrates that the proposed conversion to multispecialty is needed in addition to the existing or approved ASF's in Guilford County.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Information which was 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

In Section Q Form H Staffing, the applicant provides projected full-time equivalent (FTE) positions for the proposed services, as summarized in the following table.

Projected FTE Positions

Position	FY2021*	FY2022	FY2023
Registered Nurses	0.125	0.750	1.000
Surgical Technicians	2.250	4.000	5.000
Director of Nursing	0.125	0.250	0.250
Administrator	0.500	0.500	0.500
Business Office	0.250	0.500	0.500
Medical Records	0.250	0.375	0.500
TOTAL	4 [3.500]	6 [6.375]	8 [7.750]

* As corrected in clarifying supplemental information requested by the Agency, in which the applicant confirms errors in FY2021 FTE positions as stated in the application and provides the correct FTE positions for FY2021. The applicant rounds the total FTE positions to the nearest whole number. The Agency reflects the actual FTE total positions in brackets.

The assumptions and methodology used to project staffing are provided in Sections H and Q and in the supplemental information requested by the Agency. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form F.3, which is found in Section Q. In Section H.2 and H.3, page 53, the applicant describes the methods used to be used to recruit or fill new positions and its proposed training and continuing education programs. In supplemental information requested by the Agency, the applicant identifies the medical director as Robert J. Cosgrove, PhD, MD and provides documentation indicating his intent to continue to serve as medical director for the proposed services.

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

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Supplemental information requested by the Agency

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 54, the applicant discusses the necessary ancillary and support services and how they will be provided, including postoperative home healthcare.

On page 54, the applicant describes its outreach program with all free and income-based clinics and county health departments in the 12-county outreach area and provides supporting documentation in Exhibits L.02 and C.3.b.

On page 55, the applicant states that it projects 36 surgeons on the PSC medical staff by FY2023. The applicant provides physician support letters in Exhibit C.7.e and provides clarifying support information in the supplemental information requested by the Agency.

The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Supplemental information requested by the Agency

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

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

NA

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

NA

The applicant proposes to convert PSC, a specialty ambulatory surgical program, to a multispecialty ambulatory surgical program. The applicant does not propose any additional construction or renovation. Thus, Criterion (12) is not applicable to this review.

- (13) The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and of members of medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and 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 66, the applicant provides the historical payor mix during the last full calendar year (CY2019) for the operating rooms at PSC, as summarized in the table below.

Payor Source	Operating Rooms	Procedure Rooms**
Self-Pay	2.3%	0%
Charity Care	3.4%	0%
Medicare*	25.7%	0%
Medicaid*	13.1%	0%
Insurance*	55.4%	0%
Other (Workers Compensation, TRICARE)	0.7%	0%
Total	100.0%	0.0%

Totals may not sum due to rounding

*Including any managed care plans.

**No cases were performed in the procedure room in CY2019

In Section L, page 65, the applicant provides the comparison of the population of PSC's service area and PSC's patients, as summarized below.

	Percentage of the Population of PSC Patients	Percentage of the Population in the Service Area*
Female	62.0%	52.1%
Male	38.0%	47.9%
Unknown	0.0%	0.0%
64 and Younger	54.0%	84.7%
65 and Older	46.0%	15.3%
American Indian	1.3%	0.5%
Asian	2.3%	5.1%
Black or African-American	44.8%	33.5%
Native Hawaiian or Pacific Islander	0.8%	0.1%
White or Caucasian	40.2%	49.7%
Other Race	9.2%	0.5%
Declined/Unavailable	1.3%	2.6%

*The percentages can be found online using the United States Census Bureau's QuickFacts which is at: <https://www.census.gov/quickfacts/fact/table/US/PST045218> . Just enter in the name of the county.

The Agency reviewed the:

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

Based on that review, the Agency concludes that the applicant adequately documents the extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved. Therefore, the application is conforming to this criterion.

- (b) Its past performance in meeting its obligation, if any, under any applicable regulations requiring provision of uncompensated care, community service, or access by minorities and 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 supplemental information requested by the Agency, the applicant states:

“Yes. I have in the past and will in the future provide uncompensated care, community service and access by minorities and handicapped person, because it is morally the right thing to do, regardless of whether there are Federal Regulations or Requirements in the State Medical Facility Plan or not. I am aware of the requirements of both the State and Federal Regulations.”

In supplemental information requested by the Agency, the applicant states that there has never been a patient civil rights access complaint filed against PSC, which is the only similar facility owned by the applicant or a related entity and located in North Carolina.

The Agency reviewed the:

- Application
- Exhibits to the application
- Supplemental information requested by the Agency

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 66, the applicant projects the following payor mix for the proposed services during FY2023, the third full fiscal year of operation following completion of the project, as summarized in the table below.

Payor Source	Entire Facility
Self-Pay	5%
Charity Care	19%
Medicare*	33%
Medicaid*	19%
Insurance*	33%
Other (Workers Compensation, TRICARE)	2%
Total	100% [111%]

*Including any managed care plans.

In supplemental information requested by the Agency, the applicant confirmed errors in the percentages listed and revised the payor source percentages, as summarized below.

Payor Source	Entire Facility
Self-Pay	5%
Charity Care	20%
Medicare*	29%
Medicaid*	15%
Insurance*	29%
Other (Workers compensation, TRICARE)	2%
Total	100%

As shown in the table above, during the third full fiscal year of operation, the applicant projects 5% of total services will be provided to self-pay patients, 20% to charity care patients, 29% to Medicare patients and 15% to Medicaid patients.

In Section L, page 67, the applicant provides the assumptions and methodology used to project payor mix during the first three full fiscal years of operation following completion of the project, stating that it took historical payor sources and projected changes based on the “*estimated numbers of underserved and impoverished patients and the potential effect of our Formal Charity, Poverty and Rural Outreach Program*”.

The projected payor mix is reasonable and adequately supported for the following reasons:

- The applicant bases projected payor mix on the historical payor mix.
- The applicant increases the underserved categories of payor sources based on the estimated numbers of underserved and impoverished patients and the potential effect of PSC’s formal outreach program in Exhibit C.3.b.
- The applicant provides revised percentages to total to 100.0% in supplemental information requested by the Agency.

The Agency reviewed the:

- Application
- Exhibits to the application
- Supplemental information requested by the Agency

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 67, the applicant adequately describes the range of means by which patients will have access to the proposed services.

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

In Section M, page 69, the applicant describes 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.2.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the applicant adequately demonstrates that the proposed services will accommodate the clinical needs of area health professional training programs, and therefore, the application is conforming to this criterion.

- (15) Repealed effective July 1, 1987.
(16) Repealed effective July 1, 1987.

- (17) Repealed effective July 1, 1987.
- (18) Repealed effective July 1, 1987.
- (18a) The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact upon the cost effectiveness, quality, and access to the services proposed; and in the case of applications for services where competition between providers will not have a favorable impact on cost-effectiveness, quality, and access to the services proposed, the applicant shall demonstrate that its application is for a service on which competition will not have a favorable impact.

C

The applicant proposes to convert PSC, a specialty ambulatory surgical program, to a multispecialty ambulatory surgical program.

On page 51, the 2020 SMFP states, “An operating room’s “service area” is the service area in which the operating room is located. The operating room service areas are the single or multicounty groupings shown in Figure 6.1.” In Figure 6.1, page 57 of the 2020 SMFP, Guilford and Caswell counties are shown as a multicounty operating room service area. Thus, the service area for this application is Guilford and Caswell counties. Facilities may also serve residents of counties not included in the service area.

The following table identifies the existing and approved inpatient, outpatient, and shared operating rooms located in Guilford County, and the inpatient and outpatient case volumes for each provider, from pages 62 and 74 of the 2020 SMFP. Caswell County has no ORs.

	IP ORs	OP ORs	Shared ORs	Excluded C-Section, Trauma, Burn	CON Adjustments	IP Surgery Cases	OP Surgery Cases	Group
Greensboro Specialty Surgical Center	0	3	0	0	0	0	1,304	6
Surgical Center of Greensboro	0	13	0	0	0	0	13,806	6
High Point Surgery Center	0	6	0	0	0	0	4,424	6
Premier Surgery Center	0	2	0	0	0	0	9	6
High Point Regional Health	3	0	8	-1	0	3,064	2,602	4
Valleygate Dental Surgery Ctr of the Triad	0	2	0				57	6
Surgical Eye Center	0	4	0				2,892	5
Piedmont Surgical Center	0	2	0				652	6
Kindred Hospital-Greensboro	0	0	1			261	16	4
Cone Health	4	13	33	-1	-4	13,289	15,957	2
Total Guilford County ORs	7	45	42	-2	-4			

Source: 2020SMFP, page 62 and 74

In Section N, pages 70-71, the applicant describes the expected effects of the proposed services on competition in the service area and discusses how any enhanced competition in the service

area will promote the cost-effectiveness, quality and access to the proposed services. On page 70, the applicant states:

“The expected effect of our proposed project will have a profoundly positive impact on cost effectiveness, quality and access to services in our service area.

Our proposed project will have little effect on competition but substantial impact on increased access. Our rates for the same services are lower than the lowest priced competition in the area, excluding Medicare and Medicaid rates which are set by CMS & the State. The positive impact we will have on self-pay and high deductible patients is huge. The following numbers of surgeries are taken from the SMFP 2020. Our surgery count was 652. There was a total of 41,719 ASC cases for Guilford County. Piedmont Surgical Center cases are only 1.6% of the total. Even if we triple that volume in 3 years as projected, which we expect will consist of largely otherwise unserved patients, we have a very small share of outpatient surgeries. We will not be a competitive detriment to other ASCs in the county.”

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

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

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Information which was 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.

C

In Section A.7, page 13, and Section Q Form A, the applicant identifies Piedmont Surgical Center as the only like facility owned or operated by the applicant.

In Section O, pages 73-74, the applicant states that during the 18 months immediately preceding the submittal of the application, there have been no incidents related to quality of care and resulting in a finding of immediate jeopardy at Piedmont Surgical Center. 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 have been no incidents related to quality of care at PSC. After reviewing and considering information provided by the applicant and by the Acute and Home Care Licensure and Certification Section and considering the quality of care provided at PSC, the applicant provides 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.

NA

The applicant does not propose to increase the number of operating rooms in the service area, therefore, the criteria and standards for surgical services and operating rooms do not apply.