

REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: May 27, 2021

Findings Date: May 27, 2021

Project Analyst: Gregory F. Yakaboski

Team Leader: Fatimah Wilson

Project ID #: E-12021-21

Facility: Frye Regional Medical Center

FID #: 943182

County: Catawba

Applicant: DLP Frye Reginal Medical Center, LLC

Project: Acquire one new da Vinci Xi Robotics System

REVIEW CRITERIA

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

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

C

DLP Frye Regional Medical Center, LLC (DLP FRMC) hereinafter referred to as the applicant, proposes to acquire one da Vinci Xi Robotics System (da Vinci Xi) to assist with certain surgeries at Frye Regional Medical Center (FRMC), located at 420 North Center Street in Hickory, Catawba County.

Need Determinations

There are no need determinations in the 2021 State Medical Facilities Plan (SMFP) applicable to the proposed project.

Policies

There is one policy applicable to this review, Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities.

Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities 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 for energy efficiency and water conservation that conforms to the rules, codes and standards implemented by the Construction Section of the Division of Health Service Regulation. The plan must be consistent with the applicant’s representation in the written statement as described in paragraph one of Policy GEN-4. The plan shall not adversely affect patient or resident health, safety or infection control.”

The proposed capital expenditure for this project is greater than \$2 million but less than \$5 million. In Section B, page 25, the applicant describes its plan to assure improved energy efficiency and water conservation and states, *“The new da Vinci Xi model is designed with energy conservation in mind. See Exhibit B.2 [Da Vinci Xi Energy Efficiency Brochure] Generator and instruments enable rapid sealing while keeping temperatures low. ... The new sonic washer for the instruments has an energy efficient design and water conserving operation.”* Therefore, the application is consistent with Policy GEN-4.

Conclusion

The Agency reviewed the:

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

Based on that review, the Agency concludes that the application is conforming to this criterion because the applicant adequately demonstrates that the application is consistent with Policy GEN-4 by providing a written statement describing the project’s plan to assure improved energy efficiency and water conservation.

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

C

The applicant proposes to acquire a da Vinci Xi Robotics System at FRMC.

Patient Origin

N.C. Gen. Stat. §131E-176(24a) states, “*Service area means the area of the State, as defined in the State Medical Facilities Plan or in rules adopted by the Department, which receives services from a health service facility.*” The 2021 SMFP does not define a service area for major medical equipment, nor are there any applicable rules adopted by the Department that define the service area for major medical equipment. In Section C.4, page 33, the applicant defines the service area for the proposed project. The applicant states that FRMC’s da Vinci Xi surgical service area consists of five counties: Catawba, Alexander, Burke, Caldwell and Lincoln, as depicted in Figure C-1. Facilities may also serve residents of counties not included in the service area.

The following tables illustrate historical and projected patient origin. While FRMC does not currently have a da Vinci Xi Robotics system the historical patient origin for surgical services at FRMC is provided for reference as the da Vinci Xi Robotics system is proposed to be utilized for certain surgical services.

FRMC: Surgical Services

County	Historical (CY2020)	
	Patients	% of Total
Catawba	2,886	49.4%
Caldwell	999	17.1%
Burke	544	9.3%
Lincoln	467	8.0%
Alexander	449	7.7%
Other*	501	8.6%
Total	5,846	100.0%

Source: Table on page 28 of the application.

*Other includes all other North Carolina counties and other states.

FRMC: da Vinci Robotics System

County	1 st Full FY (CY2022)		2 nd Full FY (CY2023)		3 rd Full FY (CY2024)	
	Patients	% of Total	Patients	% of Total	Patients	% of Total
Catawba	116	46.7%	127	46.7%	133	46.7%
Caldwell	45	18.2%	50	18.2%	52	18.2%
Burke	25	9.9%	27	9.9%	28	9.9%
Lincoln	21	8.5%	23	8.5%	24	8.5%
Alexander	19	7.4%	20	7.4%	21	7.4%
Other*	23	9.4%	26	9.4%	27	9.4%
Total	249	100.0%	273	100.0%	285	100.0%

Source: Table on page 30 of the application.

*Other includes all other North Carolina counties and other states.

In Section C, page 30, and Section Q, the applicant provides the assumptions and methodology used to project its patient origin.

“FRMC assumed that patient distribution would remain constant through 2024, the proposed third year of operation. This is reasonable and conservative because FRMC surgeons proposing to use the da Vinci Xi equipment have an established presence in the service area.”

The applicant’s assumptions are reasonable and adequately supported based on the following reasons:

- Projections are based on surgical case data provided by Intuitive Surgical, Inc. (IMS Health) regarding da Vinci Xi appropriate surgical cases within the market for 2018. IMS Health produces da Vinci surgical robotics systems and their research group captures data within surgical markets evaluating all billed surgeries that were appropriate for robotic assistance, regardless of surgical technique billed. IMS Health provides its surgical data by site of service, ZIP code, and surgical type.; and
- Projections are based on historical surgical patterns of the hospital for 2017-2019.

Analysis of Need

In Section C, pages 33-41, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. On page 33, the applicant states the specific need for the project is comprised of several factors, including:

- Population growth in the five service area counties (pages 33-34);
- Health status of the population in the service area (pages 34-37);
- Outmigration from the service area for robotic appropriate procedures (pages 38-39);
- Benefits to patients (pages 39-40); and
- Physician interest and referrals (page 40).

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

- Use of a da Vinci Xi can provide multiple benefits to patients including lower complication rate due to increased visualization; shorter length of stay for inpatient procedures; less post-operative pain and discomfort; and mitigation of infection risk due to smaller incisions and more precise surgery.
- IMS Health, the research arm of Intuitive Surgical Services, Inc. determined that in 2018 alone over 585 FRMC cases were candidates for robotic-assisted surgery.
- Projected population growth and health status of the population in the five-county service area.
- The applicant’s belief that adding a da Vinci Xi robotics system to FRMC’s surgery service will allow patients to stay closer to home for care thus decreasing travel times and resulting in less stress on patients and caregivers.

Projected Utilization

In Section Q, Form C.2a, page 110, the applicant provides projected utilization for the first three full fiscal years, CY2022 – CY2024, illustrated in the following table.

FRMC: da Vinci Xi Robotic System Projected Utilization

	1st Full FY (CY2022)	2nd Full FY (CY2023)	3rd Full FY (CY2024)
# of Units	1	1	1
# of Procedures	249	273	285

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

Step 1: Determine the population growth rate of the five-county service area for 2018-2022.

The primary users of the da Vinci Xi appropriate surgery are the age group 50+. The table below reflects the 50+ population in the defined service area for 2018-2022

50+ Population for the da Vinci Xi Five County Service Area

County	2018	2019	2020	2021	2022	CAGR
Catawba	60,876	61,886	62,990	64,093	65,076	1.68%
Alexander	15,771	16,059	16,351	16,662	16,927	1.78%
Burke	37,982	38,466	38,796	39,130	39,472	0.97%
Caldwell	34,232	34,689	35,209	35,746	36,184	1.40%
Lincoln	34,131	35,304	36,547	37,691	38,658	3.16%
Total	182,992	186,404	189,893	193,322	196,317	1.77%

Source: North Carolina Office of State Budget and Management (NCOSBM)

- Applicant states that Catawba, Alexander, Burke, Caldwell and Lincoln counties represent at least 90 percent of FRMC’s historical surgical patients therefore it is reasonable to use these five counties as the da Vinci Xi surgical service area.

- Applicant states that the NCOSBM estimates reasonably reflect both calendar and state fiscal year population.

Step 2: Determine FRMC share of da Vinci Xi appropriate cases within the market (Service Area) for 2018.

Surgical Type	Total Market Cases (2018)	FRMC Cases (2018)	FRMC Market Share (2018)
Colorectal	336	52	15.5%
Hysterectomy, Benign	322	25	7.8%
Hysterectomy, Malignant	7	1	14.3%
Bariatric	272	59	21.7%
Ventral Hernia	598	75	12.5%
Inguinal Hernia	744	98	13.2%
Total	2,279	310	13.6%

Source: Table in Section Q.

- FRMC expects the majority of the surgical cases that are appropriate for the da Vinci Xi robotics system to be colorectal, hysterectomy, bariatric and hernia repair.
- The applicant relied on IMS Health research and data.

Step 3: Forecast the total number of da Vinci appropriate cases in the service area for 2018-2024.

2018	2019	2020	2021	2022	2023	2024
2,279	2,319	2,361	2,402	2,445	2,445	2,445
% growth rate	1.77%	1.77%	1.77%	1.77%	0.00%	0.00%

- Applicant projected a growth rate from 2018 through 2022 based on the CAGR of the 50+ population of the five-county service area calculated in Step 1.
- Applicant conservatively projected no growth in da Vinci Xi appropriate cases for 2023 and 2024.

Step 4: Forecast FRMC's market share of da Vinci Xi appropriate surgeries for 2022-2024.

	2022	2023	2024
Total da Vinci Xi appropriate surgical cases	2,445	2,445	2,445
FRMC's projected market share percentage	15.6%	15.6%	15.6%
Total projected FRMC da Vinci appropriate cases	381	381	381

- Based on IMS Health data, in 2018, 11.3% of the da Vinci Xi appropriate cases in the service area (market) were served by Lake Norman Regional Medical Center in Mooresville (Lake Norman), Iredell County. FRMC, with the addition of the da Vinci

Xi, projects to capture 2.0% or 49 da Vinci Xi appropriate cases [2,445 x 2.0% = 49] from Lake Norman.

- The applicant combined the 2.0% of market share of da Vinci Xi appropriate surgical cases from the service area projected to shift from Lake Norman to FRMC with FRMC’s historical market share of 13.6% as calculated in Step 2 for a projected 15.6% FRMC market share of da Vinci Xi appropriate cases.

Step 5: Determine the total number of FRMC da Vinci Xi appropriate cases performed on the da Vinci Xi by year, 2022-2024.

Metric	1 st Full FY (CY2022)	2 nd Full FY (CY2023)	3 rd Full FY (CY2024)
Projected FRMC da Vinci Xi appropriate cases	381	381	381
Annual percent of FRMC da Vinci Xi appropriate cases that use the da Vinci Xi	65%	72%	75%
Total FRMC da Vinci Xi cases	249	273	285

- According to FRMC surgical staff, approximately 20% to 25% of da Vinci Xi appropriate cases will not meet robotic-assisted criteria. Thus, the applicant projected 75% of FRMC da Vinci Xi appropriate cases will utilize the da Vinci Xi and utilized the first two full fiscal years as “ramp up” years.
- The applicant states that physician referral letters in Exhibit I.2 support the adjusted utilization forecast for the first full fiscal year (CY2022).
- The applicant states that the second and third full fiscal years (CY2023 and CY2024) allow for a reasonable proportion of cases that will not meet criteria and are based on conservative estimates of need and market share.

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

- The projected utilization is based on historical utilization of FRMC’s surgical services as well as physician letters of support.
- The number of da Vinci Xi appropriate cases in the five-county service area relied on historical cases from 2018 and then was projected through CY2022 based on the CAGR population growth rate for the service area.
- The applicant relied upon IMS Health data and market analysis in projecting da Vinci Xi appropriate cases in the service area already utilizing FRMC surgical services as well as historical and projected market share.
- The applicant conservatively held projections of da Vinci Xi appropriate cases at FRMC constant for the first three project years with no growth projected for the second and third project years.
- Actual surgical cases performed at FRMC utilizing the da Vinci Xi robotic system were conservatively projected at 75% of the number of da Vinci Xi appropriate cases at

FRMC with the first two project years projected as ramp up years at lower percentages relying on input from FRMC surgical staff.

Access to Medically Underserved Groups

In Section C.6, page 47 the applicant states, “*The facility does not restrict service based on age, gender, race, sexual orientation, ethnicity, or ability.*” The applicant provides the estimated percentage for each medically underserved group, as shown in the following table.

Medically Underserved Groups	Percentage of Total Patients
Low income persons	15.8%
Racial and ethnic minorities	12.9%
Women	54.0%
Persons with Disabilities	100.0%
The elderly (persons 65 and older)	38.0%
Medicare beneficiaries	39.6%
Medicaid recipients	14.9%

Source: Table on page 49 of the application.

The applicant adequately describes the extent to which all residents of the service area, including underserved groups, are likely to have access to the proposed services based on the following reasons:

- Relied on FRMC historical internal data for CY2021 for females and racial and ethnic minorities.
- The hospital makes provisions for persons for whom English is a second language.
- FRMC has business policies that provide care for low-income persons who may need charity or assistance covering deductible and copayments.
- FRMC is certified to provide services to both Medicaid and Medicare beneficiaries.
- The hospital can accommodate persons who have mental or physical impairments and is compliant with the Americans with Disabilities Act.

Conclusion

The Agency reviewed the:

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

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

- (3a) In the case of a reduction or elimination of a service, including the relocation of a facility or a service, the applicant shall demonstrate that the needs of the population presently served will be met adequately by the proposed relocation or by alternative arrangements, and the effect of

the reduction, elimination or relocation of the service on the ability of low income persons, racial and ethnic minorities, women, ... persons [with disabilities], and other underserved groups and the elderly to obtain needed health care.

NA

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

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

CA

The applicant proposes to acquire a da Vinci Xi Robotics System at FRMC.

In Section E, page 57, the applicant states that there are no alternatives available to meet the need described.

On page 57, the applicant states that its proposal is the most effective alternative because:

“For some surgical procedures, robotic assistance supports a less invasive technique with less bleeding, and more precision than traditional “open” procedure. Together these mean faster recovery, shorter hospital stays and quicker return to full function. ... The applicant also found that it could support the equipment cost with little or no increase in its existing surgical market share pattern.”

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

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

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- 1. DLP Frye Regional Medical Center, LLC (hereinafter certificate holder) shall materially comply with all representations made in the certificate of need application.**
- 2. The certificate holder shall acquire a da Vinci Xi Robotics System to be located at Frye Regional Medical Center.**
- 3. Upon completion of the project, Frye Regional Medical Center shall have no more than one da Vinci Xi Robotics System.**
- 4. Progress Reports:**
 - a. Pursuant to G.S. 131E-189(a), the certificate holder shall submit periodic reports on the progress being made to develop the project consistent with the timetable and representations made in the application on the Progress Report form provided by the Healthcare Planning and Certificate of Need Section. The form is available online at: <https://info.ncdhhs.gov/dhsr/coneed/progressreport.html>.**
 - b. The certificate holder shall complete all sections of the Progress Report form.**
 - c. The certificate holder shall describe in detail all steps taken to develop the project since the last progress report and should include documentation to substantiate each step taken as available.**
 - d. Progress reports shall be due on the first day of every third month. The first progress report shall be due on July 1, 2021. The second progress report shall be due on October 1, 2021 and so forth.**
- 5. The certificate holder shall not acquire as part of this project any equipment that is not included in the project's proposed capital expenditures in Section Q of the application and that would otherwise require a certificate of need.**
- 6. 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 certificate holder 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 certificate holder shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.**

- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

The applicant proposes to acquire a da Vinci Xi Robotics System at FRMC.

Capital and Working Capital Costs

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

Site Costs	\$0
Construction Costs	\$0
Miscellaneous Costs	\$2,643,563
Total	\$2,643,563

In Section Q, the applicant provides the assumptions used to project the capital cost. The applicant adequately demonstrates that the projected capital cost is based on reasonable and adequately supported assumptions based on the following reasons:

- Cost of equipment (see Exhibit F.1).
- Cost of consultants.
- Contingency fees equal to 5.34% of the medical equipment and consultant fees.

In Section F, pages 61-62, the applicant projects there will be no start-up or initial operating expenses for the project is an “ongoing operation” and does not involve working capital.

Availability of Funds

In Section F, page 59, the applicant states that the capital cost will be funded, as shown in the table below.

Sources of Capital Cost Financing

Type	DLP Frye Regional Medical Center, LLC	Total
Loans	\$0	\$0
Cash and Cash Equivalents Accumulated reserves or Owner’s Equity	\$2,643,563	\$2,643,563
Bonds	\$0	\$0
Other (Specify)	\$0	\$0
Total Financing	\$2,643,563	\$2,643,563

The applicant adequately demonstrates the availability of sufficient funds for the capital needs of the project based on the following reasons:

- Exhibit F.2 contains a letter from the Chief Accounting Officer of LifePoint Health, Inc. (LifePoint) stating that DLP FRMC is a majority owned subsidiary of LifePoint, that LifePoint commits approximately \$3.0 million from its cash reserves to fund the proposed project and that LifePoint has approximately 1.2 billion in available cash as of December 31, 2020.
- Exhibit F.2 also contains a letter from the Chief Executive Officer of DLP FRMC stating that he has the authority to commit funds to the proposed project and that up to \$3.0 million received from LifePoint will be committed to acquiring the da Vinci Xi robotics system at FRMC.

Financial Feasibility

The applicant provided pro forma financial statements for the first three full fiscal years of operation following completion of the project. In Form F.2b, 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.

	1 st FFY (CY2022)	2 nd FFY (CY2023)	3 rd FFY (CY2024)
Total da Vinci Xi Cases	249	273	285
Total Gross Revenues (Charges)	\$15,914,088	\$18,320,375	\$20,081,949
Total Net Revenue	\$2,391,514	\$2,681,387	\$2,864,425
Average Net Revenue per da Vinci Xi Case	\$9,604	\$9,822	\$10,051
Total Operating Expenses (Costs)	\$2,087,459	\$2,424,140	\$2,532,815
Average Operating Expense per da Vinci Xi Case	\$8.383	\$8.880	\$8,887
Net Income	\$304,055	\$257,247	\$331,610

The assumptions used by the applicant in preparation of the pro forma financial statements are provided in Section Q. The applicant adequately demonstrates that the financial feasibility of the proposal is reasonable and adequately supported based on the following reasons:

- The applicant based its average charge per surgical case on its historical average charge inflated annually at 5%.
- Projected utilization is based on reasonable and adequately supported assumptions. See the discussion regarding projected utilization in Criterion (3) which is incorporated herein by reference.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- The applicant adequately demonstrates that the capital costs are based on reasonable and adequately supported assumptions for all the reasons described above.
 - The applicant adequately demonstrates availability of sufficient funds for the capital needs of the proposal for all the reasons described above.
 - The applicant adequately demonstrates sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of revenues and operating expenses for all the reasons described above.
- (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 acquire a da Vinci Xi Robotics System at FRMC.

N.C. Gen. Stat. §131E-176(24a) states, “Service area means the area of the State, as defined in the State Medical Facilities Plan or in rules adopted by the Department, which receives services from a health service facility.” The 2021 SMFP does not define a service area for major medical equipment, nor are there any applicable rules adopted by the Department that define the service area for major medical equipment. In Section C.4, page 33, the applicant defines the service area for the proposed project. The applicant states that FRMC’s da Vinci Xi surgical service area consists of five counties: Catawba, Alexander, Burke, Caldwell and Lincoln, as depicted in Figure C-1. Facilities may also serve residents of counties not included in the service area.

In Section G, page 66, the applicant states that Catawba Valley Medical Center does have an earlier version of the da Vinci, the Si. However, the applicant notes that license renewal forms do not provide information on annual utilization of da Vinci robotic-assisted surgery equipment.

In Section G, page 66, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing da Vinci Xi robotic-assisted surgery services in the service area. The applicant states:

“The project will not result in unnecessary duplication. The forecast utilization represents little to no change in FRMC surgery market shares. ... The project involves replacement of open surgical technique with less invasive robotic surgery techniques. Less invasive means better patient outcomes.”

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

- The applicant adequately demonstrates that the proposed da Vinci Xi robotic system is needed in addition to the existing da Vinci robotic systems in the service area.

- The applicant adequately demonstrates that the proposed da Vinci Xi robotic system would mostly be used by existing FRMC open surgery cases where utilizing the da Vinci Xi robotic system to assist in surgery cases was appropriate.

Conclusion

The Agency reviewed the:

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

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

- (7) The applicant shall show evidence of the availability of resources, including health manpower and management personnel, for the provision of the services proposed to be provided.

C

The applicant proposes to acquire a da Vinci Xi Robotics System at FRMC.

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

Position	Projected FTE Staff		
	1 st Full Fiscal Year (CY2022)	2 nd Full Fiscal Year (CY2023)	3 rd Full Fiscal Year (CY2024)
Registered Nurses	4.5	5.0	5.2
TOTAL	4.5	5.0	5.2

The assumptions and methodology used to project staffing are provided in Section H, page 69, and Section Q. Adequate operating expenses for the health manpower and management positions proposed by the applicant are budgeted in Section Q, Form F.3b. In Section H.2 and H.3, page 69, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs.

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

- FMRC has historically been able to meet staffing needs of the facility utilizing a variety of means to both recruit and maintain staff.
- Some FRMC staff have been trained on the da Vinci Xi with the projected staffing identified in Section Q, Form H, adequate to provide time for other staff to be oriented to the new equipment.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (8) The applicant shall demonstrate that the provider of the proposed services will make available, or otherwise make arrangements for, the provision of the necessary ancillary and support services. The applicant shall also demonstrate that the proposed service will be coordinated with the existing health care system.

C

The applicant proposes to acquire a da Vinci Xi Robotics System at FRMC.

Ancillary and Support Services

In Section I.1, page 71, the applicant identifies the necessary ancillary and support services for the proposed services. On page 72, the applicant explains how each ancillary and support service is or will be made available and provides supporting documentation in Exhibit I.1. The applicant adequately demonstrates that the necessary ancillary and support services will be made available because FRMC is an existing facility that currently already provides all the identified ancillary and support services.

Coordination

In Section I.2, page 73, the applicant describes its existing and proposed relationships with other local health care and social service providers and provides supporting documentation in Exhibit I.2. The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system based on the following reasons:

- FRMC is an existing hospital with extensive working relationships with area healthcare providers.
- FRMS works with physicians, the post-acute care community, the Catawba County Department of Health and Social Services and partners with Guardian Home Health to provide home health services.

Conclusion

The Agency reviewed the:

- Application

- Exhibits to the application

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

- (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 does not propose to construct any new space or renovate any existing space.

Therefore, Criterion (12) is not applicable to this review.

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

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

C

The applicant proposes to acquire a da Vinci Xi Robotics System at FRMC. FRMC does not currently have a da Vinci Xi Robotics System.

For reference, in Section L, page 80, the applicant provides the historical payor mix during the last full FY (CY2020) for all services at FRMC, as shown in the table below.

FRMC: All Services

Payor Category	Percent of Total Patients Served
Self-Pay	6.93%
Charity Care	0.05%
Medicare*	48.46%
Medicaid*	10.36%
Insurance*	29.74%
Workers Compensation	0.79%
TRICARE	0.48%
Other	3.19%
Total	100.0%

Source: Table on page 80 of the application.

*Including any managed care plans.

Note: Other includes Federal and State Government insurance and undefined.

In Section L, page 81, the applicant provides the following comparison.

	Percentage of Total Patients Served by the Facility or Campus during the Last Full FY	Percentage of the Population of the Service Area
Female	54.00%	50.20%
Male	46.00%	49.80%
Unknown	--	--
64 and Younger	62.00%	80.46%
65 and Older	38.00%	19.54%
American Indian	0.20%	0.62%
Asian	Not available	2.14%
Black or African American	7.00%	6.54%
Native Hawaiian or Pacific Islander	0.70%	0.22%
White or Caucasian	87.12%	88.72%
Other Race	4.40%	1.80%
Declined / Unavailable	1.00%	--

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L, page 82, the applicant states,

“FMRC is a CMS certified hospital and therefore subject to EMTALA rules. FRMC is in full compliance with CMS certification for Medicare and Medicaid, and by extension in compliance with EMTALA requirements. ... Furthermore, FRMC is subject to compliance with Internal Revenue Services Section 501(r) and all requirements imposed by the Affordable Care Act. ... FMRC is in full compliance with these requirements.”

In Section L.2b, page 82, the applicant states that during the last 18 months no patient civil rights access complaints have been filed against the facility.

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (c) That the elderly and the medically underserved groups identified in this subdivision will be served by the applicant's proposed services and the extent to which each of these groups is expected to utilize the proposed services; and

C

In Section L, page 83, the applicant projects the following 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.

Da Vinci Xi Robotics System:

Payor Category	Percent of Total Patients Served
Self-Pay	2.97%
Charity Care	0.99%
Medicare*	39.60%
Medicaid*	14.85%
Insurance*	41.58%
Total	100.00%

Source: Table on page 83 of the application.

*Including any managed care plans.

As shown in the table above, during third full fiscal year of operation, the applicant projects that 2.97% of total services will be provided to self-pay patients, 0.99% to charity care patients, 39.60% to Medicare patients and 14.85% to Medicaid patients.

On page 83, the applicant provides 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 based on the following reasons:

- FRMC used the historical data from its CY2020 surgical volumes for surgery cases that are expected to transition to the da Vinci Xi robotics system.
- FRMC kept these assumed percentages constant through the third project year (CY2024).

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (d) That the applicant offers a range of means by which a person will have access to its services. Examples of a range of means are outpatient services, admission by house staff, and admission by personal physicians.

C

In Section L.5, page 84, 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

The applicant proposes to acquire a da Vinci Xi Robotics System at FRMC.

In Section M, page 86, the applicant describes the extent to which health professional training programs in the area have access to the facility for training purposes and provides supporting documentation in Exhibit M.1. The applicant adequately demonstrates that health professional training programs in the area have access to the facility for training purposes based on the following reasons:

- FRMC, an existing hospital, maintains collaborative relationships with training programs in the area including Appalachian State University and Catawba Valley Community and Technical Institute. A complete list is provided on page 86 of the application.
- FRMC provided copies of letters in Exhibit M.1 demonstrating both that FRMC reached out to its existing training partners regarding plans to acquire a da Vinci Xi and seeking collaboration and that area training college and programs expressed support for including the da Vinci Xi as part of clinical training.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (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 acquire a da Vinci Xi Robotics System at FRMC.

N.C. Gen. Stat. §131E-176(24a) states, “*Service area means the area of the State, as defined in the State Medical Facilities Plan or in rules adopted by the Department, which receives services from a health service facility.*” The 2021 SMFP does not define a service area for major medical equipment, nor are there any applicable rules adopted by the Department that define the service area for major medical equipment. In Section C.4, page 33, the applicant defines the service area for the proposed project. The applicant states that FRMC’s da Vinci Xi surgical service area consists of five counties: Catawba, Alexander, Burke, Caldwell and Lincoln, as depicted in Figure C-1. Facilities may also serve residents of counties not included in the service area.

In Section G, page 66, the applicant states no existing or approved health service facilities located in the proposed service area offer da Vinci Xi robotic-assisted surgery. The applicant notes that Catawba Valley Medical Center does have an earlier version of the da Vinci, the Si. Furthermore, the applicant notes that license renewal forms do not provide information on annual utilization of da Vinci robotic-assisted surgery equipment.

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 88, the applicant states:

“In the service area, only Catawba Valley Medical Center offers da Vinci robotic surgery. Catawba Valley’s equipment is an older model with fewer capabilities. ... Frye will offer a competitive alternative in the service area.”

Regarding the impact of the proposal on cost effectiveness, in Section N, page 88, the applicant states:

“The forecasts [Revenue and Expense] involve only surgical procedures currently offered at FRMC. The forecasts also assume no change in payor mix. ... Minimally invasive surgery also involves lower patient costs associated with recovery post-surgery because of small incisions. Surgery costs involve less blood loss. Care closer to home involves lower transportation costs.”

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

Regarding the impact of the proposal on quality, in Section N, page 89, the applicant states:

“FRMC is accredited and proposes to maintain accreditation by Joint Commission and maintains certification by Centers for Medicare and Medicaid Services. ... Furthermore, as a Duke LifePoint hospital, FRMC is a member of the Duke Quality Network. The Duke Quality Network connects Duke LifePoint hospitals to the quality and patient safety resources of Duke Health through a proven model focused on leadership, performance improvement, and a culture of safety.”

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

Regarding the impact of the proposal on access by medically underserved groups, in Section N, page 89, the applicant states:

“The payor mix includes service to beneficiaries of Medicare and Medicaid. Medicare cases are proportionally much higher than the percent of Medicare beneficiaries in the services area. ... The payor mix for proposed da Vinci Xi surgery at FRMC reflects equitable access to Medicaid beneficiaries.”

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

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

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

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- 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 based on all the reasons described above.

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

C

In Section Q, Form O, the applicant identifies the hospitals located in North Carolina owned, operated or managed by the applicant or a related entity. The applicant identifies a total of nine of this type of facility located in North Carolina.

In Section O.5, page 92, the applicant states that, during the 18 months immediately preceding the submittal of the application, incidents related to quality of care occurred in none of these facilities. However, after this application was submitted on February 12, 2021 CMS surveyors conducted a site visit on April 20, 2021. 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, incidents related to quality of care occurred in one of these facilities, Central Carolina Medical Center (CCMC). In supplemental information the applicant states that

*“On April 20, 2021, during a CMS site visit, surveyors found two instances of failure to follow CCMC’s written policies. **Neither instance put patients in immediate jeopardy.** They included:*

- a. In one of 24 observations, a nurse failed to use full Personal Protective Equipment while transporting a patient from the Emergency Department; and*
- b. In two instances, the process for cleaning blood glucose monitors did not follow the manufacturer’s instructions.*

... CCMC worked with CMS to develop a plan of correction which was submitted on May 20, 2021. CCMC expects full resolution of the issue by June 30, 2021. CCMC has not lost CMS certification.”

After reviewing and considering information provided by the applicant, the Acute and Home Care Licensure and Certification Section, DHSR, considering the quality of care provided at all nine facilities owned, operated or managed by the applicant or a related entity, and based on the applicant's statement provided in supplemental information that "**FRMC and CCMC operate as a [sic] different hospitals**. Each hospital has separate leadership, corporations, and quality departments", the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

(21) Repealed effective July 1, 1987.

G.S. 131E-183 (b): The Department is authorized to adopt rules for the review of particular types of applications that will be used in addition to those criteria outlined in subsection (a) of this section and may vary according to the purpose for which a particular review is being conducted or the type of health service reviewed. No such rule adopted by the Department shall require an academic medical center teaching hospital, as defined by the State Medical Facilities Plan, to demonstrate that any facility or service at another hospital is being appropriately utilized in order for that academic medical center teaching hospital to be approved for the issuance of a certificate of need to develop any similar facility or service.

NA

The applicant proposes to acquire a da Vinci Xi Robotics System. There are no administrative rules that are applicable to this proposal.