

REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: September 23, 2022

Findings Date: September 23, 2022

Project Analyst: Donna Donihi

Co-Signer: Mike Mckillip

Project ID #: L-12229-22

Facility: DLP Wilson Medical Center

FID #: 923569

County: Wilson

Applicant: DLP Wilson Medical Center, LLC

Project: Acquire no more than one da Vinci 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.

NA

DLP Wilson Medical Center, LLC., (WMC), referred to hereinafter as “the applicant,” proposes to acquire no more than one da Vinci robotics system.

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 2022 State Medical Facilities Plan (SMFP). Also, no policies in the 2022 SMFP are applicable to this review.

Therefore, Criterion (1) 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- (2) Repealed effective July 1, 1987.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, ... persons [with disabilities], the elderly, and other underserved groups are likely to have access to the services proposed.

C

DLP Wilson Medical Center proposes to acquire no more than one da Vinci robotics system.

DLP Wilson Medical Center, LLC is affiliated with all Life Point Hospitals In North Carolina. The applicant and its affiliates operate 9 facilities in North Carolina.

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 2022 SMFP does not define a service area for a da Vinci robotics system, nor are there any applicable rules adopted by the Department that define the service area for a da Vinci robotics system.

In Section C.3, pages 29-32, the applicant defines the service area for the proposed services consisting of Wilson, Nash, Johnston, Wayne, Edgecombe, Wake, and Pitt counties.

The following tables illustrate historical and projected patient origin for the facility, surgical procedures, and da Vinci robotics system at WMC.

County	Entire Facility Historical CY2021		Third Full FY of Operation following Project Completion CY2026	
	# of Patients	% of Total	# of Patients	% of Total
Wilson	75,960	79.0%	76,403	79.5%
Nash	8,705	9.1%	8,616	8.9%
Johnston	3,240	3.4%	3,429	3.6%
Wayne	2,369	2.5%	2,318	2.4%
Edgecombe	1,521	1.2%	1,409	1.5%
Pitt	1,013	1.1%	934	1.0%
Wake	769	0.8%	716	0.7%
Other*	2,524	2.6%	2,373	2.5%
Total	96,102	100.0%	96,329	100.0%

Source: Section C, Tables on pages 29-32

County	Historical Surgical Services CY2021		Third Full FY of da Vinci robotics system following project completion CY2026	
	# of Patients	% of Total	# of Patients	% of Total
Wilson	2,586	72.5%	124	72.7%
Nash	417	11.7%	19	11.4%
Johnston	143	4.0%	7	4.4%
Wayne	113	3.2%	6	3.7%
Edgecombe	104	2.9%	4	2.5%
Pitt	46	1.3%	2	1.1%
Wake	33	0.9%	2	1.1%
Other*	128	3.6%	5	3.2%
Total	3,569	100.0%	170	100.0%

Source: Section C, Tables on pages 29-32

In Section C.3, the applicant states projected patient origin is based on the historical (FY2021) patient origin for the proposed services, which is shown in a table on page 32 of the application. The applicant's assumptions are reasonable and adequately supported.

Analysis of Need

In Section C.4, page 34 -46, the applicant explains why it believes the population projected to utilize the proposed equipment needs the proposed services, including:

- Intuitive Surgical, Inc. ("IMS Health") provided market share data based on four zip codes: 27822, 27893, 27896, and 27883. These four zip codes house 88.7 percent of the Wilson County population (see Exhibit C.4). IMS Health also sampled from six hospitals serving the WMC service area. WMC assumes that the IMS Health analysis provides a reasonable estimate of the number of cases available for da Vinci robotic-assisted surgery in a market (page 33).
- The applicant reviewed patient origin for all existing surgical services. As an established community hospital, WMC has consistent patient patterns.
- The applicant used population growth of the primary user group (people age 45+) of Wilson County as estimated by North Carolina Office of State Budget and Management (NCOSBM), and the number da Vinci-appropriate surgeries performed in 2021 in the WMC market, as basis for forecasting need.
- To forecast utilization, the applicant evaluated its current market share of surgeries performed in 2021 that were da Vinci-appropriate and applied that to IMS Health's estimated number of da Vinci appropriate cases in the market.

The information provided by the applicant in the pages referenced above is reasonable and adequately supported for the following reasons:

- The applicant provides information regarding the historical utilization of its existing surgical patients.
- The applicant provides data supporting its utilization projections and projected population growth in the primary and secondary service areas.

Projected Utilization

In Section Q, form C.2b, the applicant provides projected utilization for the proposed da Vinci robotics system through one partial year and three full fiscal years (FY2023-FY2026) as summarized in the following table:

Projected Utilization da Vinci robotics system	Partial FY 04/01/2023 12/31/2023	Projected FY 1 2024	Projected FY 2 2025	Projected FY3 2026
Procedures	105	154	162	170
# of Units	1	1	1	1

Source: Section Q, Form C Utilization.

In Section Q, pages 106-111, the applicant describes its assumptions as follow:

- The applicant applied the compound annual population growth rate of persons 45 and older, for the service area determined the total number of da Vinci -appropriate cases, to estimate the total annual number of cases in the WMC market by year through 2026, the third year of operation.
- IMS estimates of cases in 2021 will increase annually at the rate of population increase in the population 45 and older.
- Forecasting five years forward (2022 through 2026) on the basis of the service area’s annual population growth rate for persons 45 and older during that same period. The primary patient user group is age 45 and older.
- The applicant used IMS’s 2021 data to determine the number of da Vinci -appropriate cases within its market. See Exhibit C.4.
- In Section C.1 and C.4 the applicant explains procedure types which are appropriate for the da Vinci robotics system. WMC expects many of its cases will be from five disciplines, prostatectomy, hysterectomy, colorectal, cholecystectomy, and hernia repair.
- WMC’s historical cases of da Vinci robotics which are appropriate surgeries in the five surgical types compared to the WMC market as reported by IMS Health. WMC’s market share for 2021 was 7.8 percent.

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

- The applicant’s utilization projections are supported by the projected population growth rates for the proposed primary and secondary service area.

- The applicant used seven county service area as both WMC historical surgical data and IMS Health market study data represent patients from these counties.
- The applicant’s utilization projections for the da Vinci robotics system are supported by its historical surgery utilization.

Access to Medically Underserved Groups

In Section C, page 52, the applicant states,

“WMC accepts patients regardless of gender, gender preference, race, ethnicity, age, or income, it can and does also serve most people who have disabilities. WMC has Medicare and Medicaid certification and provides services to both populations. Patients may access WMC care through the emergency room, through private physicians or through WMC supported primary care clinics. Many complex-care and low-income patients originate from the WMC clinics that are located throughout Wilson County.”

In Section C.6, page 54, the applicant provides the following table:

GROUP	ESTIMATED PERCENTAGE OF TOTAL PATIENTS DURING THE THIRD FULL FISCAL YEAR
Low income persons	12.80%
Racial and ethnic minorities	47.12%
Women	57.57%
Persons with disabilities	100.00%
Persons 65 and older	47.96%
Medicare beneficiaries	46.00%
Medicaid recipients	12.20%

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:

- The applicant provides estimated percentages of patients from underserved groups.
- The applicant provides written statements about offering access to all residents of the service area, including underserved groups.

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 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 and adequately support their assumptions.

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

C

DLP Wilson Medical Center proposes to acquire no more than one da Vinci robotics system.

In Section E, page 61, the applicant states that there are no alternatives available to meet the need described.

On page 61, 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” procedures. Together, these mean faster recovery, shorter hospital stays and quicker return to full function. Most such procedures involve internal organs. Open procedures require incisions through muscle and connective membranes to reach the affected organ. With the most successful surgery, these tissues require repair, protection, and time to heal. Pain levels are higher with open than with robotic surgery because more tissue is subject to injury. DaVinci is the leader in this type of robotic surgery and has now released a more precise model, the xi. The applicant understands that the nearest hospitals offering the xi model are in Raleigh, Wake County, Greenville, Pitt County, and Smithfield, Johnston County. (See Figure 1 on page 35) Each of these locations is 45-minutes, or more, away from work and from most of the WMC primary surgical service

area, depending on traffic. None of those is a desirable solution for a person getting surgery who will need support getting to and from the hospital. The better alternative proposed here is having the surgery done close to home by qualified surgeons. The applicant also found that it could support the equipment cost with little or no increase in its existing surgical market share pattern. See the need and utilization methodology with Form C.2b in Section Q of this application for detail. The applicant does not own da Vinci or other surgical robotic alternatives capable of these surgeries. To use the robot, surgeons must be trained and develop skills. Four surgeons on the WMC medical staff have proficiency and two others have committed to developing the required skills. Thus, to provide state of the art surgery in the community, WMC has no other alternative than this proposed equipment acquisition.”

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 Wilson 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 no more than one da Vinci robotics system to be located at Wilson Medical Center.**
- 3. Upon completion of the project, the applicant shall have no more than one da Vinci 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. The first progress report shall be due on January 1, 2022.**
- 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

DLP Wilson Medical Center proposes to acquire no more than one da Vinci robotics system.

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.

Medical Equipment	\$2,222,033
Consultant Fees	\$60,000
Contingency	\$228,203
Total	\$2,510,237

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 documentation provided in Exhibit F.1.

In Section F, page 66, the applicant projects there will be no start-up or initial operating expenses for the project because the project is an “ongoing operation” and does not involve working capital.

Availability of Funds

In Section F, page 65, the applicant states that the capital cost will be funded, as shown in the table below.

Type	DLP Wilson Medical Center, LLC
Cash and Cash Equivalents Accumulated reserves or Owner's Equity	\$2,510,237
Total Financing	\$2,510,237

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 Senior Vice President/Chief Accounting Officer of LifePoint Health, Inc. (LifePoint) stating that DLP WMC 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 WMC 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 robotics system at WMC.

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 (CY2024)	2 nd FFY (CY2025)	3 rd FFY (CY2026)
Total da Vinci Cases	154	162	170
Total Gross Revenues (Charges)	\$8,269,180	\$9,133,722	\$10,064,000
Total Net Revenue	\$1,685,520	\$1,852,659	\$2,011,334
Average Net Revenue per da Vinci Case	\$10,944	\$11,436	\$11,831
Total Operating Expenses (Costs)	\$1,601,231	\$1,752,508	\$1,850,679
Average Operating Expense per da Vinci Case	\$8,383	\$8,880	\$8,887
Net Income	\$84,289	\$100,150	\$160,655

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

DLP Wilson Medical Center proposes to acquire no more than one da Vinci robotics system.

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 2022 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 31-36, the applicant defines the service area for the proposed project. The applicant states that WMC da Vinci surgical service area consists of six counties, Wilson, Edgecombe, Johnston, Nash, Pitt, Wake, and Wayne as depicted in Figure C-4. Facilities may also serve residents of counties not included in the service area.

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

“No existing or approved health service facilities located in the proposed four-zip code primary service area offer da Vinci xi robotic-assisted surgery. Four providers in the seven-county WMC surgical service area provide da Vinci xi robotic surgery. However, each location is more than 30-minutes away from WMC.

The forecast utilization represents little or no change in WMC 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 proposes to acquire three instrument sets to make efficient use of surgeon time and assure maximum infection control. Parts of the robot which come in contact with patients must be completely processed through the hospital’s central sterile processing after each surgery. Normal turnaround time would be 24 hours. Having multiple sets permits scheduling more than one case a day. Having one set in reserve permits cases to continue if an instrument is unusable at any time during the case.”

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 robotic system is needed in addition to the existing services in the service area.
- The applicant adequately demonstrates that the proposed da Vinci robotic system would mostly be used by existing WMC open surgery cases where utilizing the da Vinci 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

DLP Wilson Medical Center proposes to acquire no more than one da Vinci robotics system.

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 (CY2024)	2 nd Full Fiscal Year (CY2025)	3 rd Full Fiscal Year (CY2026)
Registered Nurses	2.65	2.93	3.15

The assumptions and methodology used to project staffing are provided in Section H, page 118, 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 74-75, 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:

- WMC has historically been able to meet staffing needs of the facility utilizing a variety of means to both recruit and maintain staff.
- Some staff have been trained on the da Vinci 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 decide 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

DLP Wilson Medical Center proposes to acquire no more than one da Vinci robotics system.

Ancillary and Support Services

In Section I.1, page 76, the applicant identifies the necessary ancillary and support services for the proposed services. On page 77, 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 WMC is an existing facility that currently already provides all the identified ancillary and support services.

Coordination

In Section I.2, pages 78-79, 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:

- WMC is an existing hospital with extensive working relationships with area healthcare providers.
- WMC works with physicians, the post-acute care community, the County Department of Health and Social 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.

N/A

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

- (10) When applicable, the applicant shall show that the special needs of health maintenance organizations will be fulfilled by the project. Specifically, the applicant shall show that the project accommodates: (a) The needs of enrolled members and reasonably anticipated new members of the HMO for the health service to be provided by the organization; and (b) The availability of new health services from non-HMO providers or other HMOs in a reasonable and cost-effective manner which is consistent with the basic method of operation of the HMO. In assessing the availability of these health services from these providers, the applicant shall consider only whether the services from these providers:
- (i) would be available under a contract of at least 5 years duration;
 - (ii) would be available and conveniently accessible through physicians and other health professionals associated with the HMO;
 - (iii) would cost no more than if the services were provided by the HMO; and
 - (iv) would be available in a manner which is administratively feasible to the HMO.

N/A

- (11) Repealed effective July 1, 1987.
- (12) Applications involving construction shall demonstrate that the cost, design, and means of construction proposed represent the most reasonable alternative, and that the construction project will not unduly increase the costs of providing health services by the person proposing the construction project or the costs and charges to the public of providing health services by other persons, and that applicable energy saving features have been incorporated into the construction plans.

C

DLP Wilson Medical Center proposes to acquire no more than one da Vinci robotics system. 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

DLP Wilson Medical Center proposes to acquire no more than one da Vinci robotics system.

In Section L, page 84, the applicant provides the historical payor mix during the last full FY (CY2021) for all services at WMC, as shown in the table below.

WMC: All Services

Payor Category	Percent of Total Patients Served
Self-Pay	15.5%
Charity Care	0.5%
Medicare	39.5%
Medicaid	11.8%
Insurance	23.0%
Workers Compensation	0.3%
TRICARE	0.6%
Other	8.8%
Total	100.0%

Source: Table on page 84 of the application.

In Section L, page 85, 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	61.30%	52.40%
Male	38.80%	47.60%
64 and Younger	64.70%	79.60%
65 and Older	35.30%	20.40%
American Indian	0.05%	0.80%
Asian	0.12%	1.60%
Black or African American	47.50%	38.50%
Hawaiian or Pacific Islander	0.70%	0.50%
White or Caucasian	45.4%	49.10%
Other Race	7.00%	9.50%

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;

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L, page 88, the applicant states,

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

In Section L.2b, page 88, 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

In section L, page 89, 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 Robotics System: CY 2026

Payor Category	Percent of Total Patients Served
Self-Pay	8.90%
Charity Care	0.60%
Medicare*	46.00%
Medicaid*	12.20%
Insurance*	32.20%
Total	100.00%

Source: Table on page 89 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 8.9% of total services will be provided to self-pay patients, 0.60% to charity care patients, 46% to Medicare patients and 12.2% to Medicaid patients.

On page 89, 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:

- WMC used the historical data from its CY2021 surgical volumes for surgery cases that are expected to transition to the da Vinci robotics system.
- WMC kept these assumed percentages constant through the third project year (CY2026).

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

DLP Wilson Medical Center proposes to acquire no more than one da Vinci robotics system.

In Section L.5, page 88, 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

DLP Wilson Medical Center proposes to acquire no more than one da Vinci robotics system.

In Section M, page 92, 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 fact that WMC is an existing hospital and maintains collaborative relationships with training programs in the area.

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

DLP Wilson Medical Center proposes to acquire no more than one da Vinci robotics system.

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 2022 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 31-36, the applicant defines the service area for the proposed project. The applicant states that WMC da Vinci surgical service area consists of six counties, Wilson, Edgecombe, Johnston, Nash, Pitt, Wake, and Wayne as depicted in Figure C-4. Facilities may also serve residents of counties not included in the service area.

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 94, the applicant states:

“In the primary service area, no other provider offers da Vinci robotics surgical services. Within the other six service area counties, five hospitals have da Vinci robotics. However, none within a 30- minute drive time. The project involves no change in WMC market share. It will make WMC competitive with others, so it can retain current market share.”

Regarding the impact of the proposal on cost effectiveness, in Section N, page 94, the applicant states:

“As demonstrated in Form F.2b, Revenue and Expense forecast, the applicant can profitably offer the robotic surgery with fewer than 200 cases per year. The forecasts involve only surgical procedures currently offered at WMC. The forecasts also assume no change in payor mix. the current payor mix includes beneficiaries of Medicare and Medicaid programs, as well as charity patients, medically underserved individuals will have access to the program. Financial assumptions also include an allowance for bad debt. Minimally invasive surgery also involves lower patient costs associated with recovery post-surgery because of smaller incisions. It also involves less blood loss which represents significant cost reduction. 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, pages 94-95, the applicant states:

“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. The Quality Network team works with organizations to build on strengths and successes by guiding and supporting

hospital leadership and engaging staff and providers in quality and patient safety activities”

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 95, 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 service area. In 2022, for example, 20 percent of Wilson County residents are age 65+ and Medicare Disability is about 2 percent of a population. A payer mix of 46.0 percent Medicare for the da Vinci Xi compares well. In May 2022, Wilson County has 30,091 Medicaid and CHIP Enrollees.²² According to NCDMA, Catawba County has 20,014 Medicaid beneficiaries who are not infants and children or family planning. This is 26 percent of the population (20,014 / 78,096 = 0.256). Some of the Medicaid Old Age Beneficiaries will also have Medicare. At 12.2 percent Medicaid, the payor-mix for proposed da Vinci Xi surgery at WMC 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) In Section O, page 96, 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 hospitals located in North Carolina.

In Section O, page 99, the applicant states that, during the 18 months immediately preceding the submittal of the application, incidents related to quality of care occurred in one of these facilities: Wilson Medical Center. The applicant states that a plan of correction is being prepared and that the finding has not resulted in a loss of CMS Medicare certification. 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: Wilson Medical Center. Wilson Medical Center was surveyed by the Acute and Home Care Licensure and Certification Section on July 14, 2022, and remains out of compliance pending submission of a plan of correction. 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 all nine facilities, 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 robotics system. There are no administrative rules that are applicable to this proposal.