

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: October 18, 2019

Findings Date: October 18, 2019

Project Analyst: Celia C. Inman

Team Leader: Gloria C. Hale

Project ID #: B-11750-19

Facility: Mission Hospital

FID #: 943349

County: Buncombe

Applicant: MH Mission Hospital, LLLP

Project: Acquire a third da Vinci Surgical System

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

C

MH Mission Hospital, LLLP (MHMH) or “the applicant,” proposes to acquire a third da Vinci Surgical System at Mission Hospital (Mission or MH). MHMH is an affiliate of HCA Healthcare, Inc (HCA).

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 2019 State Medical Facilities Plan (SMFP). Therefore, no need determinations are applicable to this review.

Policies

There is one policy in the 2019 SMFP which is applicable to this review: *Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities.*

Policy GEN-4, on page 31 of the 2019 SMFP, states:

“Any person proposing a capital expenditure greater than \$2 million to develop, replace, renovate, or add to a health service facility pursuant to G.S. 131E-178 shall include in its certificate of need application a written statement describing the project’s plan to assure improved energy efficiency and water conservation.

In approving a certificate of need proposing an expenditure greater than \$5 million to develop, replace, renovate, or add to a health service facility pursuant to G.S. 131E-178, Certificate of Need shall impose a condition requiring the applicant to develop and implement an Energy Efficiency and Sustainability Plan for the project that conforms to or exceeds energy efficiency and water conservation standards incorporated in the latest editions of the North Carolina State Building Codes. The plan must be consistent with the applicant’s representation in the written statement as described in paragraph one of Policy GEN-4.

Any person awarded a certificate of need for a project or an exemption from review pursuant to G.S. 131E-184 is required to submit a plan for energy efficiency and water conservation that conforms to the rules, codes and standards implemented by the Construction Section of the Division of Health Service Regulation. The plan must be consistent with the applicant’s representation in the written statement as described in paragraph one of Policy GEN-4. The plan shall not adversely affect patient or resident health, safety, or infection control.”

The proposed capital expenditure for this project is greater than \$2 million but less than \$5 million. In Section B.11, page 17, the applicant describes its plan to ensure energy efficiency and water conservation. The applicant adequately demonstrates that the application includes a written statement describing the applicant’s plans to assure improved energy efficiency and water conservation. Therefore, the application is consistent with Policy GEN-4.

Conclusion

The Agency reviewed the:

- application, and
- exhibits to the application.

Based on that review, the Agency concludes that the application is conforming to this criterion because the applicant includes 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, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.

C

The applicant proposes to acquire a third da Vinci Surgical System (da Vinci). In Section C.1, page 19, the applicant describes the da Vinci, stating:

“Robotic-assisted surgery with the da Vinci® Surgical System allows surgeons to perform complex minimally invasive surgical procedures with precision and accuracy. The system is an advanced robotic platform designed to expand the surgeon’s capabilities and offer an alternative to open surgery and laparoscopy. Because robotic surgery requires only a few tiny incisions and offers greater vision, precision, and control for the surgeon, patients often recover sooner, move on to additional treatments if needed, and get back to daily life more quickly.”

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 2019 SMFP does not define a service area for surgical equipment, nor are there any applicable rules adopted by the Department that define the service area for surgical equipment. In Section C.4, pages 23-24, the applicant states that Mission serves patients from a 15-county area as shown in Figures 1 and 2 on page 24. Facilities may also serve residents of counties not included in the service area.

In Section C.2, page 21, the applicant provides the actual patient origin for Mission’s da Vinci surgical services during the last full fiscal year (FY), FY2018, ending September 30, 2018, as summarized below.

**Patient Origin for MH da Vinci Surgical Services
 FY2018**

County	# Patients	% of Total Patients
Primary Service Area		
Buncombe	133	35.19%
Henderson	47	12.43%
Haywood	26	6.88%
McDowell	22	5.82%
Macon	17	4.5%
Burke	16	4.23%
Transylvania	16	4.23%
Jackson	15	3.97%
Madison	15	3.97%
Secondary Service Area		
Mitchell	12	3.17%
Cherokee	11	2.91%
Rutherford	11	2.91%
Yancey	11	2.91%
Clay	5	1.32%
Swain	4	1.06%
Other NC*	13	3.44%
Out of State**	4	1.03%
TOTAL	378	100.00%

Source: Table on page 21 of the application.

* "Other NC Counties" include Polk, Avery, Caldwell, Gaston, Cleveland, Graham, Lincoln, and Mecklenburg

**"Out of State" includes South Carolina and Tennessee

In Section C.3, page 22, the applicant provides the projected patient origin for da Vinci surgical services for what the applicant shows as the first three full fiscal years, as summarized below.

Projected Patient Origin for MH da Vinci Procedures

County	1 st Full FY 4/1/2020-3/31/2021		2nd Full FY 4/1/2021-3/31/2022		3rd Full FY 4/1/2022-3/31/2023	
	# Patients	% of Total Patients	# Patients	% of Total Patients	# Patients	% of Total Patients
Primary Service Area						
Buncombe	289	35.19%	344	35.19%	388	35.19%
Henderson	102	12.43%	122	12.43%	137	12.43%
Haywood	56	6.88%	67	6.88%	76	6.88%
McDowell	48	5.82%	57	5.82%	64	5.82%
Macon	37	4.5%	44	4.5%	50	4.5%
Burke	35	4.23%	41	4.23%	47	4.23%
Transylvania	35	4.23%	41	4.23%	47	4.23%
Jackson	33	3.97%	39	3.97%	44	3.97%
Madison	33	3.97%	39	3.97%	44	3.97%
Secondary Service Area						
Mitchell	26	3.17%	31	3.17%	35	3.17%
Cherokee	24	2.91%	28	2.91%	32	2.91%
Rutherford	24	2.91%	28	2.91%	32	2.91%
Yancey	24	2.91%	28	2.91%	32	2.91%
Clay	11	1.32%	13	1.32%	15	1.32%
Swain	9	1.06%	10	1.06%	12	1.06%
Other NC*	28	3.44%	34	3.44%	38	3.44%
Out of State**	9	1.03%	10	1.03%	12	1.03%
TOTAL	821	100.00%	978	100.00%	1,104	100.00%

Source: Table on page 21 of the application. Table indicates that the years, 4/1 - 3/31, represent full fiscal years; however, based upon the project beginning April 1, 2020 and MH's 2019 License Renewal Application (LRA), it is apparent that the years represent full operating years

* "Other NC Counties" include Polk, Avery, Caldwell, Gaston, Cleveland, Graham, Lincoln, and Mecklenburg

** "Out of State" includes South Carolina and Tennessee

In Section C.3, page 23, the applicant provides the assumptions and methodology used to project the number of patients by county of origin. The applicant states:

"Mission does not expect the patient origin for its surgery patients receiving robotic surgery to change as a result of this project. FY 2018 actual patient origin percentages by county for Mission's existing 2 da Vinci surgical robots were applied to the projected da Vinci robotic surgical volume in order to project patient origin."

The applicant's assumptions are reasonable and adequately supported.

Analysis of Need

In Section C.4, pages 23-33, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. The applicant discusses several factors supporting the need, including:

- Population trends in the service area (pages 24-26).
- Trends in need for Mission’s robotic surgery services (pages 26-28).
- Robotic surgery as the standard of care (pages 28-29).
- Growth in number of physicians trained in robotic surgery (pages 29-30).
- Service area patients leaving the service area for robotic-appropriate procedures (pages 31-32).

In reviewing the information, as outlined above, it became apparent that the population data as provided by the applicant was questionable. The applicant provides Figure 3, pages 25-26, showing population data, by age, that it states was obtained from the North Carolina Office of State Budget and Management (NCOSBM). The following table summarizes the data provided by the applicant in Figure 3 by county totals, without regard to age.

Total County Population Change
Figure 3, pages 25-26

County	2019	2024	Change	% Change	CAGR
Buncombe	267,800	283,474	15,674	5.85%	1.14%
Henderson	119,575	127,142	7,567	6.33%	1.23%
Haywood	63,286	65,808	2,522	3.99%	0.78%
McDowell	46,082	46,574	492	1.07%	0.21%
Macon	36,149	37,988	1,839	5.09%	1.00%
Burke	91,317	93,576	2,259	2.47%	0.49%
Transylvania	35,123	36,674	1,551	4.42%	0.87%
Jackson	44,206	46,926	2,720	6.15%	1.20%
Madison	22,769	24,092	1,323	5.81%	1.14%
PSA Total	726,307	762,254	35,947	4.95%	0.97%
Mitchell	15,199	15,169	(30)	-0.20%	-0.04%
Cherokee	30,434	32,679	2,245	7.38%	1.43%
Rutherford	67,953	68,189	236	0.35%	0.07%
Yancey	18,311	18,592	281	1.53%	0.31%
Clay	21,390	12,651	(8,739)	-40.86%	-9.97%
Swain	15,292	16,017	725	4.74%	0.93%
SSA Total	168,579	163,297	(5,282)	-3.13%	-0.63%
Total SA	894,886	925,551	30,665	3.43%	0.68%

As can quickly be seen in the table above and on pages 25-26, there is an issue with the population figures for Clay County in 2019, which of course creates an issue with the totals

for the secondary service area and for the total service area, particularly related to change and percent change. The applicant did not provide the raw data or the calculation of the difference between the 2019 and 2024 data, only the percent change. The Project Analyst could not discern the exact issue causing the error from the data provided by the applicant, therefore, the Analyst pulled population data by county total (not by age) from the NCOSBM website. The following table is composed of the county population data, as pulled by the Project Analyst from the NCOSBM.

**Total County Population Change Calculated by Analyst
 From NC OSBM Data**

County	2019	2024	Change	% Change	CAGR
Buncombe	265,586	281,109	15,523	5.84%	1.14%
Henderson	118,926	126,426	7,500	6.31%	1.23%
Haywood	63,455	65,929	2,474	3.90%	0.77%
McDowell	46,578	47,677	1,099	2.36%	0.47%
Macon	36,640	39,251	2,611	7.13%	1.39%
Burke	92,156	94,419	2,263	2.46%	0.49%
Transylvania	35,435	37,138	1,703	4.81%	0.94%
Jackson	44,909	48,086	3,177	7.07%	1.38%
Madison	22,794	24,158	1,364	5.98%	1.17%
PSA Total	726,479	764,193	37,714	5.19%	1.02%
Mitchell	15,239	15,252	13	0.09%	0.02%
Cherokee	29,621	31,093	1,472	4.97%	0.97%
Rutherford	69,251	71,448	2,197	3.17%	0.63%
Yancey	18,412	18,657	245	1.33%	0.26%
Clay	11,806	12,602	796	6.74%	1.31%
Swain	14,995	15,659	664	4.43%	0.87%
SSA Total	159,324	164,711	5,387	3.38%	0.67%
Total SA	885,803	928,904	43,101	4.87%	0.95%

Source: NCOSBM, pulled August 22, 2019, data last updated December 3, 2018
 2019 data - https://files.nc.gov/ncosbm/demog/statesingleage_2010_2019.html
 2024 data - https://files.nc.gov/ncosbm/demog/countytotals_2020_2029.html

Because the data pulled by the Project Analyst is by county total (not by age) and obtained on a different date, the county totals in the second table differ slightly from what the applicant provided in Figure 3; however, it clearly shows where the error is. The applicant's Figure 3 table shows Clay County with a total 2019 population of 21,390 and a total 2024 population of 12,651. The 2019 Clay County population in the applicant's table was nearly 10,000 more than it should have been and skewed any growth projections for the secondary service area and total service area accordingly. However, the percent change provided by the applicant is more conservative than that calculated by the Project Analyst and the compound annual growth rate (CAGR) was relatively constant in both tables at one percent for the primary and total service area. Therefore, the error in the data as reported, had no effect on the outcome of the supporting data.

As the applicant states on page 26, the 65 and older population shows the highest growth projections in the service area during the time period. The applicant states:

“This growth is significant due to the fact that the 65 and older population uses health care resources, including robotic surgery, at a much higher rate than any other age group.”

In Section G, page 55, the applicant states:

“It is imperative that Mission have sufficient robotic surgery capacity both to meet the standard of efficacious care and also to meet its duty as the regional tertiary provider that patients throughout western North Carolina rely on for their specialty care.”

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

- The population projections by the NCOSBM indicate MH’s total service area will grow almost 5% between 2019 and 2024, with a 5-year CAGR of 1.0% and that the population cohort Age 65+ will grow more significantly.
- The applicant provides data supporting the increased use of robotic surgery across the surgical continuum.
- The applicant provides data showing growth in overall robotic surgery utilization at MH, leaving limited availability for additional capacity as current Mission physicians become certified in robotic surgery and newly recruited physicians, who are certified, join the Mission surgical team.
- The applicant provides data supporting the increased use of robotic surgery at MH, with more existing Mission physicians training to use the da Vinci system, as well as the recruitment of additional physicians already da Vinci trained.
- The applicant provides information regarding the number of service area residents currently migrating out of the MH service area seeking minimally invasive surgical care, such as the da Vinci provides.

Projected Utilization

In Section Q, Form C, the applicant provides projected utilization for the proposed da Vinci equipment through the first three full operating years following completion of the project. Form C Utilization, page 79 of the application, uses the headings “full fiscal year” and states in the assumptions, Section Q, page 83, that the facility’s fiscal year runs October 1 - September 30. The data provided is based on the operating year (OY), April 1 through March 31, with the “Services Offered” date in Section P, being April 1, 2020; therefore, the information provided by the applicant is for the first three full operating years following project completion, as summarized in the following table.

Other Medical Equipment (da Vinci)

	Prior FY	Interim FY	Partial Interim FY	1 st Full OY	2 nd Full OY	3 rd Full OY
	FY2018	FY2019	FY2020	OY2021	OY2022	OY2023
	10/1/17-9/30/18	10/1/18-9/30/19	10/1/19-3/31/20	4/1/20-3/31/21	4/1/21-3/31/22	4/1/22-3/31/23
# of Units	2	2	2	3	3	3
# of Cases	378	411	261	821	978	1,104

Source: Section Q Form C Utilization, page 79

The applicant provides its assumptions and methodology for projecting utilization for its proposed services in Section Q Form C, page 81, and in Section C, pages 33-36. Each form in Section Q shows the first three full operating years as April 1-March 31. Each form also shows the third operating year as April 1, 2022 – March 31, 2022. Obviously, the ending date is a typographical error, with the third operating year ending March 31, 2023. The applicant’s methodology and assumptions are summarized as follows:

Methodology

Step 1: Determine historic base volume for the two existing da Vinci robots – The applicant states that historical MH data was used for FY2018 utilization. For FY2019, the applicant annualized actual data October 2018 through June 2019 for a total of 411 patients.

	Prior FY	Interim FY
	FY2018	FY2019
	10/1/17-9/30/18	10/1/18-9/30/19
Historical Base volume of Patients	378	411

Assumptions:

- volume is discussed using the terms patient, case, and procedure interchangeably throughout the application and in the methodology and utilization
- the fiscal year runs October 1-September 30

Step 2: Determine projected base volume for the two existing robots – The applicant states that based on the May and June 2019 total case volumes for the two existing da Vinci units, MH is on track to perform 522 robotic surgery cases annually.

	Prior FY	Interim FY	Partial Interim FY	1 st Full OY	2 nd Full OY	3 rd Full OY
	10/1/17-9/30/18	10/1/18-9/30/19	10/1/19-3/31/20	4/1/20-3/31/21	4/1/21-3/31/22	4/1/22-3/31/23
Historical Base	378	411	261	522	522	522

Assumptions:

- Established physicians will continue to perform 522 cases annually
- Volume for the partial interim year will be one half of 522 cases (261)
- The operating year runs April 1-March 31.

Step 3: Identify established physicians who will perform additional incremental volume – Drs. Ahearne, Bird and McCoy will perform additional incremental cases.

	Prior FY	Interim FY	Partial Interim FY	1 st Full OY	2 nd Full OY	3 rd Full OY
	10/1/17-9/30/18	10/1/18-9/30/19	10/1/19-3/31/20	4/1/20-3/31/21	4/1/21-3/31/22	4/1/22-3/31/23
Existing Physician Incremental Cases				45	57	69

Case totals may not sum due to rounding

Step 4: Determine incremental volume of new physicians and recruited physicians –

	Prior FY	Interim FY	Partial Interim FY	1 st Full OY	2 nd Full OY	3 rd Full OY
	10/1/17-9/30/18	10/1/18-9/30/19	10/1/19-3/31/20	4/1/20-3/31/21	4/1/21-3/31/22	4/1/22-3/31/23
New Physician Incremental Cases				254	399	513

Case totals may not sum due to rounding

Step 5: Add base volume to incremental volume of existing and new physicians for total utilization –

	Prior FY	Interim FY	Partial Interim FY	1 st Full OY	2 nd Full OY	3 rd Full OY
	10/1/17-9/30/18	10/1/18-9/30/19	10/1/19-3/31/20	4/1/20-3/31/21	4/1/21-3/31/22	4/1/22-3/31/23
<i>Historical Base</i>	378	411	261	522	522	522
<i>Existing Physician Incremental Cases</i>				45	57	69
<i>New Physician Incremental Cases</i>				254	399	513
Total Patients/Cases	378	411	261	821	978	1,104

Step 6: Calculate projected utilization as a percent of capacity –

Assumptions:

- Hours available: 240 days x 8 hours / day = 1,920 hours
- Case time: 3.45 hours per case + 0.69 hours turnover = 4.13 total hours per case
- Capacity: 1,920 hours / 4.13 hours per case = 465 cases per year per unit x 3 units = 1,395
- Target Utilization: 80% capacity (1,395 x 80%) = 1,115 cases = 372 cases / unit

	1 st Full OY	2 nd Full OY	3 rd Full OY
	4/1/20-3/31/21	4/1/21-3/31/22	4/1/22-3/31/23
Total Utilization	821	978	1,104
Capacity (3 units)	1,115	1,115	1,115
Percent of Target	74%	88%	99%

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

- The applicant’s utilization projections are supported by the historical utilization of the existing da Vinci surgical equipment at MH.
- The applicant provides adequate support for the increase in incremental projections.
- The applicant provides letters from physicians and surgeons expressing support for the proposed project and their intention to perform surgery using the da Vinci surgical equipment.

Access

In Section C.11, page 41, the applicant states:

“Mission already demonstrates its service to all patients, regardless of gender, race, or ability to pay, by being one of the leading providers of indigent and charity care to patients seeking services in the region. The approval of this project will allow Mission to continue serving all patient populations.”

In Section L.3, page 67, the applicant projects the following payor mix for the MH facility and its da Vinci services during the third year of operation following completion of the project, as summarized in the following table.

Payment Source	Percent of Total Facility	Percent of Total da Vinci Surgery
Self-Pay*	3.27%	4.29%
Medicare**	53.23%	36.93%
Medicaid**	14.66%	4.75%
Insurance**	24.94%	51.92%
Other (Workers Comp, TRICARE, Liability)	3.90%	2.11%
Total	100.00%	100.00%

Source: Table on page 67 of the application

*Including charity care

**Including any managed care plans

The projected payor mix is reasonable and adequately supported.

Conclusion

The Agency reviewed the:

- application,
- exhibits to the application, and
- information publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the application is conforming to this criterion for the 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 (payer mix) and adequately supports its assumptions.

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

NA

The applicant does not propose the reduction, elimination, or relocation of a 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 third da Vinci Surgical System.

In Section E.2, page 48, the applicant describes the alternatives it considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

- Maintain the status quo – The applicant states that the status quo is not an effective alternative because the existing equipment (one da Vinci Si system and one da Vinci Xi system) has utilization issues and presents scheduling difficulties. The applicant states that in order to meet demand for robotic surgery and reduce the risk of reaching a utilization breaking point, this option is not feasible.
- Update the da Vinci Si system to a da Vinci Xi robotic surgical system – The applicant states this was not an effective alternative because Mission ENT surgeons prefer using the da Vinci Si surgical system over the da Vinci Xi system. Additionally, replacing or updating the Si would not allow for the additional capacity needed to meet future demand for robotic surgery.
- Acquire a third da Vinci surgical system for a total of one da Vinci Si and two da Vinci Xi surgical systems - The applicant states that acquiring a third da Vinci will allow the Mission ENT surgeons to continue to use their preferred da Vinci Si

system, accommodate demand from patients and newly credentialed surgeons, provide access to robotic surgical capacity to new physician recruits, and improve MH's competitive position in western North Carolina.

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

- The application is conforming to all statutory and regulatory review criteria.
- The alternative will meet the need for additional capacity to perform robotic surgeries at MH.
- The alternative is more cost-effective and convenient for patients and medical staff.

Conclusion

The Agency reviewed the:

- application,
- exhibits to the application, and
- information publicly available during the review and used by the Agency.

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

- 1. MH Mission Hospital, LLLP shall materially comply with all representations made in the certificate of need application.**
- 2. MH Mission Hospital, LLLP shall acquire no more than one da Vinci Surgical System for a total of no more than three da Vinci Surgical Systems at Mission Hospital upon project completion.**
- 3. MH Mission Hospital, LLLP, as part of this project, shall not acquire 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.**
- 4. No later than three months after the last day of each of the first three full years of operation following initiation of the services authorized by this certificate of need, MH Mission Hospital, LLLP 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.

5. MH Mission Hospital, LLLP shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to insurance 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 third da Vinci Surgical System.

Capital and Working Capital Costs

In Section Q, Form F.1a, page 82, the applicant projects the total capital cost of the project as summarized in the table below.

Medical Equipment	\$2,261,311
Consultant Fees	\$47,000
Total	\$2,308,311

In Section Q, page 82, the applicant provides the assumptions used to project the capital costs, stating that the costs are based on the vendor quote for the equipment.

In Section F.3, pages 50-51, the applicant states the project represents the expansion of an existing service and there will be no start-up costs or initial operating expenses required.

Availability of Funds

In Section F, page 49, the applicant states that the capital cost will be funded as summarized in the table below.

Sources of Capital Cost Financing

Type	MH Mission Hospital, LLLP (by affiliation with HCA Healthcare)
Loans	\$0
Accumulated reserves or OE *	\$2,308,311
Bonds	\$0
Other (Specify)	\$0
Total Financing	\$2,308,311

* OE = Owner's Equity

Exhibit F-2.1 contains a letter dated August 2, 2019 from the CFO of HCA, an affiliate of MH, documenting its intention to provide an inter-company loan from accumulated reserves for the capital needs of the proposed project. Exhibit F-2.2 contains the audited consolidated financial statements of HCA, which show that as of December 31, 2018, HCA had \$502 million in cash and cash equivalents, \$39,207 million in total assets.

Financial Feasibility

The applicant provides pro forma financial statements for MH’s da Vinci surgical services for the first three full years of operation following completion of the project. In Form F.2, page 83, the applicant projects that revenues will exceed operating expenses in the first three operating years of the project, as summarized in the table below.

MH da Vinci Surgical Services			
	1st Full OY	2nd Full OY	3rd Full OY
	4/1/2020-3/31/2021	4/1/2021-3/31/2022	4/1/2022-3/31/2023
Total Cases	821	978	1,104
Total Gross Revenues (Charges)	\$49,677,876	\$59,769,564	\$68,144,637
Total Net Revenue	\$19,527,281	\$23,494,101	\$26,786,158
Average Net Revenue per Case	\$23,785	\$24,023	\$24,263
Total Operating Expenses (Costs)	\$8,438,349	\$9,370,292	\$10,119,548
Operating Expense per Case	\$10,278	\$9,581	\$9,166
Net Income	\$11,088,932	\$14,123,810	\$16,666,610

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

Conclusion

The Agency reviewed the:

- application, and
- exhibits to the application.

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

- The applicant adequately demonstrates that the capital costs are based on reasonable and adequately supported assumptions.
- The applicant adequately demonstrates availability of sufficient funds for the capital needs of the proposal.
- The applicant adequately demonstrates sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.

- (6) The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

C

The applicant proposes to acquire a third da Vinci Surgical 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 2019 SMFP does not define a service area for surgical equipment, nor are there any applicable rules adopted by the Department that define the service area for surgical equipment. In Section C.4, pages 23-24, the applicant states that MH serves patients from a 15-county area as shown in Figures 1 and 2 on page 24. Facilities may also serve residents of counties not included in the service area.

In Section G, page 55, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved robotic (da Vinci) surgical services in the service area. On page 55, the applicant states that there are no other existing robotic surgery providers in the service area. The applicant further states that the closest robotic surgery facilities are Franklin Woods Community Hospital and Johnson City Medical Center Hospital in Johnson City, Tennessee, and Atrium Health Cleveland in Cleveland County, all 50 to 60 miles away and not in the proposed service area.

In Section A, page 10, the applicant states that MH is located in Asheville and serves as the regional referral center for tertiary and quaternary care. In Section G, page 55, the applicant states:

“It is imperative that Mission have sufficient robotic surgery capacity both to meet the standard of efficacious care and also to meet its duty as the regional tertiary provider that patients throughout western North Carolina rely on for their specialty care.”

The applicant adequately demonstrates that the proposal would not result in an unnecessary duplication of existing or approved services in the service area because the applicant adequately demonstrates that the third da Vinci surgical system is needed in addition to the existing or approved services.

Conclusion

The Agency reviewed the:

- application, and
- exhibits to the application.

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

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

C

In Section Q, Form H, page 85, the applicant provides the current and projected staffing in full-time equivalent (FTE) positions for the first three full operating years for the da Vinci surgical service at MH.

**MH da Vinci Surgical System Services
Projected FTE Positions**

	Prior FY	1 st Full OY	2 nd Full OY	3 rd Full OY
	10/1/17-9/30/18	4/1/20-3/31/21	4/1/21-3/31/22	4/1/22-3/31/23
Registered Nurse	2	3	3	3
Surgical Technician	2	3	3	3
Surgical Assistant	2	3	3	3
Total	6	9	9	9

The assumptions and methodology used to project staffing are provided in Section Q, page 85. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form F.3, which is found in Section Q. In Sections H.2 and H.3, pages 56-57, the applicant describes the methods to be used to recruit or fill new positions and its proposed training and continuing education programs. In Exhibit I-3.1, the applicant provides a letter from Matthew Young, MD, the current medical director, confirming his intent to continue to serve in that capacity.

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

Conclusion

The Agency reviewed the:

- application, and
- exhibits to the application.

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

- (8) The applicant shall demonstrate that the provider of the proposed services will make available, or otherwise make arrangements for, the provision of the necessary ancillary and

support services. The applicant shall also demonstrate that the proposed service will be coordinated with the existing health care system.

C

In Section I.1, page 58, the applicant states MH is an existing quaternary and tertiary provider and, as such, the hospital currently has all necessary ancillary and support services in place, including but not limited to pharmacy, laboratory, medical supplies, and any subsequent diagnostic or therapeutic follow-up procedures required.

In Section I.2, pages 58-59, the applicant discusses its established relationships with other local health care and social service providers which will continue following completion of the proposed project. The applicant provides supporting documentation in Exhibit I.

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

Conclusion

The Agency reviewed the:

- application, and
- exhibits to the application.

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

- (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 HSA IV where 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 proposed project does not involve any construction or renovation.

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

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

C

In Section L.1, page 66, the applicant provides the historical payor mix for FY2018 for the hospital and for the da Vinci Surgical Systems at MH, as summarized in the table below.

Payment Source	Percent of Facility	Percent of Total da Vinci Surgical Services
Self-Pay*	4.95%	4.76%
Medicare**	52.39%	42.59%
Medicaid**	14.07%	5.03%
Insurance**	24.57%	45.77%
Other (Workers Comp, TRICARE, Liability)	4.02%	1.85%
Total	100.00%	100.00%

Source: Table on page 66 of the application.

*Includes Charity Care

** Includes any managed care plans

Totals may not foot due to rounding.

In Section L.1, page 65, the applicant provides the following comparison.

	Percentage of Total MH Patients Served FY2018	Percentage of the Population of the Service Area
Female	74.07%	51.43%
Male	25.93%	48.57%
Unknown	0.00%	0.00%
64 and Younger	64.81%	77.53%
65 and Older	35.19%	22.47%
American Indian	0.00%	1.37%
Asian	0.00%	1.27%
Black or African-American	3.70%	4.45%
Native Hawaiian or Pacific Islander	0.00%	0.12%
White or Caucasian	91.80%	87.77%
Other Race	1.06%	5.02%
Declined / Unavailable	3.44%	0.00%

The Agency reviewed the:

- application,
- exhibits to the application, and
- information publicly available during the review and used by the Agency.

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

- (b) Its past performance in meeting its obligation, if any, under any applicable regulations requiring provision of uncompensated care, community service, or access by minorities and handicapped persons to programs receiving federal

assistance, including the existence of any civil rights access complaints against the applicant;

C

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L.2, page 66, the applicant states MH has no obligation in regard to uncompensated care, community benefits and access to care by all persons, regardless of ability to pay or other factors.

In Section L.2, page 66, the applicant states that during the last five years, no patient civil rights access complaints have been filed against MH or a related entity located in North Carolina.

The Agency reviewed the:

- application, and
- exhibits to the application.

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

- (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.3, page 67, the applicant provides the projected payor mix for the third full operating year for the proposed project, as summarized in the table below.

Payment Source	Percent of Total da Vinci Surgical Services
Self-Pay*	4.29%
Medicare**	36.93%
Medicaid**	4.75%
Insurance**	51.92%
Other (Workers Comp, TRICARE, Liability)	2.11%
Total	100.00%

Source: Table on page 67 of the application

*Including charity care

**Including any managed care plans

As shown in the table above, during the third full year of operation, the applicant projects that 4% of the da Vinci surgical services will be provided to self-pay/charity care patients, 37 % to Medicare patients, and 5% to Medicaid patients.

In Section L.3, page 67, the applicant provides the assumptions and methodology used to project payor mix. The projected payor mix is reasonable and adequately supported because it is based on the applicant's historical experience.

The Agency reviewed the:

- application, and
- exhibits to the application.

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

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

The Agency reviewed the:

- application, and
- exhibits to the application.

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

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

C

In Section M.1, pages 69-70, the applicant describes the extent to which health professional training programs in the area have access to the facility for training purposes.

Conclusion

The Agency reviewed the:

- application, and
- exhibits to the application.

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

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

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

C

The applicant proposes to acquire a third da Vinci Surgical 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 2019 SMFP does not define a service area for surgical equipment, nor are there any applicable rules adopted by the Department that define the service area for surgical equipment. In Section C.4, pages 23-24, the applicant states that MH serves patients from a 15-county area as shown in Figures 1 and 2 on page 24. Facilities may also serve residents of counties not included in the service area.

In Section A, page 10, the applicant states that MH is located in Asheville, Buncombe County, and serves as the regional referral center for tertiary and quaternary care. In

Section G, page 55, the applicant states that there are no other existing robotic (da Vinci) surgery providers in the service area.

In Section N.2, page 71, the applicant describes the expected effects of the proposed services on competition in the service area and discusses how any enhanced competition in the service area will promote the cost-effectiveness, quality and access to the proposed services. On page 71, the applicant states:

“The proposed project will not impact competition in the proposed service area. Mission is the only surgical department to offer minimally invasive robotic surgical procedures in Buncombe County.

...

The proposed project will foster cost containment and improve quality of care through improved efficiency of robotic surgery with the proposed advanced technology. . . . Mission will continue to serve a large percentage of medically underserved patients based on its historical experience and existing policies and procedures.”

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

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

Conclusion

The Agency reviewed the:

- application, and
- exhibits to the application.

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

(19) Repealed effective July 1, 1987.

(20) An applicant already involved in the provision of health services shall provide evidence that quality care has been provided in the past.

C

In Section Q, page 77, the applicant provides a table listing eight hospitals owned or managed by HCA Healthcare, Inc., affiliate of the applicant. The table shows that MH is the only provider of da Vinci surgical services.

In Section O, page 74, the applicant states that, during the 18 months immediately preceding the submittal of the application, none of its affiliated hospitals had any incidents resulting in a finding of immediate jeopardy or operated out of compliance with the Medicare Conditions of Participation. According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, Mission Hospital is in compliance with all Medicare Conditions of Participation. 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 Mission, the applicant provides sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

(21) Repealed effective July 1, 1987.

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

NA

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