

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: April 24, 2020

Findings Date: April 24, 2020

Project Analyst: Ena Lightbourne

Team Leader: Fatimah Wilson

Project ID #: G-11859-20

Facility: Cone Health Women's Outpatient Center

FID #: 200138

County: Guilford

Applicant(s): The Moses H. Cone Memorial Hospital

The Moses H. Cone Memorial Hospital Operating Corporation

Project: Develop a new off-site hospital-based outpatient campus for maternal-fetal medicine and outpatient rehabilitation

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

The applicants, The Moses H. Cone Memorial Hospital and The Moses H. Cone Memorial Hospital Operating Corporation, hereinafter referred to as the "applicant", proposes to develop a new off-site hospital-based outpatient campus and relocate maternal-fetal medicine and outpatient rehabilitation services from the current location, Cone Health Women's Hospital to the proposed site, Cone Health Women's Outpatient Center in Greensboro, North Carolina.

Need Determination

The proposed project does not involve the addition of any new health service facility beds, services, or equipment for which there is a need determination in the 2020 State Medical Facilities Plan (SMFP). Therefore, no need determinations are applicable to this review.

Policies

There is one policy in the 2020 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 2020 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, pages 18-19, 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 develop a new off-site hospital-based outpatient campus by relocating maternal-fetal medicine and outpatient rehabilitation services from the existing Cone Health Women’s Hospital to the proposed Cone Health Women’s Outpatient Center.

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 rules adopted by the Department, which receives services from a health service facility.*” The 2020 SMFP does not define a service area for hospital-based outpatient clinics nor are there any applicable rules adopted by the Department that define the service area for hospital-based outpatient clinics. Thus, the service area in this review is as defined by the applicant. The service area for this facility consists of Guilford County. Facilities may also serve residents of counties not included in their service area.

The following tables illustrates current and projected patient origin.

Maternal-Fetal Medicine				
County	Current Patient Origin Last FFY, FY 2019		Projected Patient Origin 3rd FFY, FY 2024	
	Patients	% of Total	Patients	% of Total
Guilford	7,453	82.1%	7,756	82.1%
Randolph	406	4.5%	422	4.5%
Rockingham	329	3.6%	343	3.6%
Forsyth	322	3.5%	335	3.5%
Alamance	236	2.6%	245	2.6%
Virginia State	125	1.4%	130	1.4%
Davidson	98	1.1%	102	1.1%
Other States and Counties	113	1.2%	117	1.2%
Total	9,082	100.0%	9,451	100.0%

Source: Section Q, Exhibit C.2 and C.3

Outpatient Rehabilitation				
County	Current Patient Origin Last FFY, FY 2019		Projected Patient Origin 3rd FFY, FY 2024	
	Patients	% of Total	Patients	% of Total
Guilford	1,490	88.9%	1,101	88.9%
Randolph	54	3.2%	40	3.2%
Rockingham	50	3.0%	37	3.0%
Forsyth	50	3.0%	37	3.0%
Other States and Counties	32	1.9%	24	1.9%
Total	1,676	100.0%	1,239	100.0%

Source: Section Q, Exhibit C.2 and C.3

In Section C, page 27, the applicant provides the assumptions and methodology used to project its patient origin. The applicant states:

“Both maternal-fetal medicine and outpatient rehabilitation services are well established existing services offered by Cone Health. Patient origin for maternal-fetal medicine is based on existing patients at the maternal-fetal medicine clinic and outpatient rehabilitation is based on patients likely to use the outpatient rehabilitation site at the proposed project.”

The applicant’s assumptions are reasonable and adequately supported because the patient origin is based on the current patient origin of maternal-fetal medicine and outpatient rehabilitation services offered at Cone Health.

Analysis of Need

In Section C, pages 27-34, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. On page 28, the applicant states that the services are needed based on the following factors:

Historical and Projected Service Area Population Growth (pages 28-30)

The applicant states that the service area for the proposed services consists of Guilford, Alamance, Randolph, Rockingham, and eastern Forsyth counties. The projected patient origin is based on the historical patient origin of the proposed services at Cone Health. The applicant states that the historical payor origin is used as a basis for determining need. Based on ESRI data, a “*mapping and spatial analytics software*”, the applicant demonstrates the projected growth rate of the relevant female population between 2019 and 2024, as shown in the table below.

Projected Female Population 2019-2024					
Age Cohort	2019 Population	2024 Population	# Change	% Change	CAGR
0-17	106,019	108,492	2,473	2.3%	0.5%
18-44	184,196	188,459	4,263	2.3%	0.5%
45-64	140,611	139,369	-1,242	-0.9%	-0.2%
65+	97,229	112,837	15,608	16.1%	3.0%
Total	528,055	549,157	21,102	4.0%	0.8%

Source: Section C, page 29

The table above demonstrates an overall projected growth of 4.0% over five years. Women 65+ is projected to grow at 16.1% while females age 18-44 is expected to grow at 2.3%.

Using data from Cone Health Financial Systems, the applicant demonstrates the change in the average age of high-risk birth patients at the Women's Hospital over the last five years. The applicant states that this data is consistent with the Advisory Board Company's, "a *Healthcare Intelligence firm*", conclusion that the obstetric population is getting older and sicker and projects higher rates of utilization for maternal-fetal medicine.

Average Age of a High-Risk Obstetric Patient 2019-2024							
Year	FY 2014	FY 2015	FY 2016	FY 2017	FY 2018	FY 2019	% of Change
Average Age	27.0	27.9	28.0	27.9	28.1	29.1	2.1

Source: Section C, page 29

Growing Demand for Maternal-Fetal Medicine and Rehabilitation Services (pages 30-32)

The applicant states that based on data from the Advisory Board, maternal-fetal medicine is projected to grow nationally 15% between 2017 and 2022. The applicant states that although gynecologic oncology is projected to have the highest percentage of growth, the volume of cases is significantly lower than the volume of cases of maternal-fetal medicine. Gynecologic Oncology is projected to have an overall volume of 2,900 cases, while maternal-fetal medicine is projected to have over 3 million cases.

In addition to maternal-fetal medicine, the Advisory Board projects that rehabilitation services is projected to grow by 23% nationally between 2018 and 2028. The applicant states that this data is consistent with the growth in the existing utilization of outpatient rehabilitation services at Cone Health.

Increasing Prevalence of Chronic Conditions in the Population (pages 32-33)

The applicant states that the growth in the presence of chronic and comorbid conditions in women indicates that the female population is less healthy and at high risk for complication

during pregnancy. The applicant states that higher risks pregnancies lead to higher need for maternal-fetal medicine services.

Historical Utilization of Maternal-Fetal Medicine and Outpatient Rehabilitation at Existing Cone Health Locations (pages 33-34)

The applicant states that maternal-fetal medicine and outpatient rehabilitation services at Cone Health facilities in Guilford County have experienced a significant growth from 2015 to 2019. The applicant projects that these services will continue grow in the future. The tables below demonstrate the historical growth for each service component.

Maternal-Fetal Medicine Clinic Visits FY 2015 – FY 2019							
	FY 2015	FY 2016	FY 2017	FY 2018	FY 2019	# Change	% of Change
Visits	3,081	4,566	8,165	8,688	9,082	6,064	200.9%

Source: Section C, page 33

Note: The percent change as calculated by the Project Analyst is 194.8%. Also, the # change as calculated by the Project Analyst is 6,001.

Outpatient Rehabilitation Visits FY 2015 – FY 2019							
	FY 2015	FY 2016	FY 2017	FY 2018	FY 2019	# Change	% of Change
Visits	51,313	53,182	59,266	61,998	65,519	14,206	27.7%

Source: Section C, page 34

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

- The applicant provides information regarding the growth in the female population in the service area.
- The applicant provides information regarding the growing demand for maternal-fetal medicine and outpatient rehabilitation services.
- The applicant provides historical utilization data supporting it utilization projections.

Projected Utilization

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

Historical and Projected Utilization						
	Prior FFY FY 2019	Interim FFY FY 2020	Interim FFY FY 2021	1ST FFY FY 2022	2nd FFY FY 2023	3rd FFY FY 2024
Maternal -Fetal Medicine	9,082	9,082	9,173	9,265	9,357	9,451
Outpatient Rehabilitation	0	0	0	350	1,024	1,239

Source: Section Q, page 97

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

Maternal-Fetal Medicine

- The applicant reviewed historical utilization of maternal-fetal medicine services at Cone Health and determined a 31.7% Compound Annual Growth Rate (CAGR) between FY 2015 and FY 2019. The applicant states that this growth rate is possibly due to the addition of physicians and the changes in the staffing model so other growth rates were reviewed.
- The applicant reviewed the data from the Advisory Board indicating an overall CAGR of 2.8% in maternal-fetal medicine volumes in the service area from FY 2017 to FY 2022.
- The applicant reviewed ESRI data which projects a 0.8% CAGR in the female population in the proposed service area from FY 2019 to FY 2024.
- The applicant selected a conservative projected growth rate of 1.0% based on the overall female population projected growth and the historical growth in maternal-fetal medicine volumes at Cone Health.

Outpatient Rehabilitation

- The applicant estimates the existing outpatient rehabilitation volumes at all Cone Health Outpatient Rehabilitation Centers.
- The applicant excludes the volume of patients that are not candidates to receive services related to gynecologic and obstetric conditions.
- The applicant estimates that 1,676 visits in FY 2019 were potentially related to gynecologic or obstetric conditions.
- The applicant projects a conservative growth rate of 1% in volumes between FY 2019- FY 2020. The applicant states that this yields a baseline of 1,693 cases in FY 2020.

- The applicant assumes 50% of the volume will shift to the proposed location based on the hiring of a physical therapist focused solely on treating gynecologic and obstetric conditions, the convenience of the location and lower wait times associated with a new site.
- The applicant projects a 10% growth rate beginning FY 2021 at the new location, based on the unique focus of this location and the integration of therapy services with the other clinical services provided in the Women's Outpatient Center.
- The applicant projects the volumes for outpatient rehabilitation for the first three years of operation, based on the expected volume shift to the location and the projected growth rates outlined in this Section.

Outpatient Rehabilitation Projected Volumes FY 2022- FY 2024	
Years	Visits
FY 2022	1,024
FY 2023	1,127
FY 2024	1,239

Source: Section Q, page 102

- The applicant assumes a ramp-up period during the interim year, FY 2021, since the services provided at the Women's Outpatient Center are not currently consolidated at the Women's Hospital.

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

- The applicant's utilization projections are supported by the projected population growth rates for the proposed service area.
- The applicant's utilization projections are supported by the historical growth in utilization for maternal-fetal medicine and outpatient rehabilitation at the current location.

Access

In Section C, pages 40-41, the applicant states:

“Cone Health is a private, not-for-profit organization established to serve the community by providing high quality, affordable, and comprehensive healthcare services to all patients, regardless of their economic status. Cone Health does not discriminate against low-income persons, racial and ethnic minorities, women, handicapped persons, the elderly, or other underserved persons, including the medically indigent, the uninsured and the underinsured. In general, the health services of Cone Health are available to any patient in need without restriction of any kind. Access to hospital services for disadvantaged groups is provided in an organized setting through Cone Health's hospital-based outpatient clinics, including the maternal-fetal medicine clinic.”

In Exhibit L.3, the applicant projects the following payor mix during the second full fiscal year of operation following completion of the project, as illustrated in the following table.

Cone Health Women's Outpatient Center Projected Payor Mix 2nd FFY, FY 2023		
Payor Category	Maternal-Fetal Medicine Services as percent of Total	Outpatient Rehabilitation Services as Percent of Total
Self-Pay	6.7%	3.4%
Medicare*	0.8%	38.7%
Medicaid*	58.8%	12.5%
Insurance*	32.6%	43.1%
Other	1.1%	2.3%
Total	100.0%	100.0%

Source: Section Q, Exhibit L.3
 *Including managed care plans

In Exhibit L.3, the applicant provides the assumptions and methodology used to project payor mix during the second full fiscal year of operation following completion of the project. The projected payor mix is reasonable and adequately supported because it is based on the current payor mix at Cone Health's Women's Hospital.

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 (payor mix) and adequately supports its assumptions.

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

racial and ethnic minorities, women, handicapped persons, and other underserved groups and the elderly to obtain needed health care.

C

The applicant proposes to develop a new off-site hospital-based outpatient campus by relocating maternal-fetal medicine and outpatient rehabilitation services from the existing Cone Health Women's Hospital to the proposed Cone Health Women's Outpatient Center.

In Section D, page 46, the applicant explains why it believes the needs of the population presently utilizing the services to be reduced, eliminated or relocated will be adequately met following completion of the project. On page 46, the applicant states:

"The entire remaining campus will be relocated from Women's Hospital to the Women's Outpatient Center. This new campus will serve the same patients that are currently served at the existing location."

In Section D, page 48, the applicant states that the once the maternal-fetal medicine and outpatient rehabilitation services are relocated to the proposed facility, there will be no remaining services at the Women's Hospital campus.

In Section D, page 49, the applicant states:

"Cone Health will serve the same, existing patient population at the proposed Women's Outpatient Center. No changes to access will occur as part of this project."

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 following reasons:

- The applicant adequately demonstrates that the needs of the population currently using the services to be reduced, eliminated or relocated will be adequately met following project completion.
- The applicant adequately demonstrates that the project will not adversely impact the ability of underserved groups to access these services following project completion.

- (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 develop a new off-site hospital-based outpatient campus by relocating maternal-fetal medicine and outpatient rehabilitation services from the existing Cone Health Women's Hospital to the proposed Cone Health Women's Outpatient Center.

In Section E, pages 50-51, 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 this was not an effective alternative because it would require Cone Health to continue to support the entire existing infrastructure of Women's Hospital that will be mostly vacated upon the relocation of the acute care beds and operating rooms to Moses Cone Hospital. In addition, it would prevent Cone Health or another party from fully redeveloping the site since outpatient services are located in the existing property.

Co-locate the Services with the Acute Care Services at the Women's and Children's Center: The applicant states that acute care services will be moving to a new tower at the Moses Cone Hospital. The applicant states that this would not be an effective alternative because it would require a capital cost for a new floor. The applicant states that this does not support Cone Health's strategy to providing patient value and this alternative is not the best use of financial resources.

In supplemental information requested by the Agency, the applicant states that its proposal is the most effective alternative because patients will not have to travel to a busy hospital campus for outpatient services that often require multiple visits during pregnancy. In addition, the applicant states that the proposed project will allow Cone Health to minimize operating expenses in a non-hospital setting for a relatively low capital outlay.

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

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

Conclusion

The Agency reviewed the:

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

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

- 1. The Moses H. Cone Memorial Hospital and The Moses H. Cone Memorial Hospital Operating Corporation shall materially comply with all representations made in the certificate of need application and any supplemental responses. In the event that representations conflict, The Moses H. Cone Memorial Hospital and The Moses H. Cone Memorial Hospital Operating Corporation shall materially comply with the last made representation.**
 - 2. The Moses H. Cone Memorial Hospital and The Moses H. Cone Memorial Hospital Operating Corporation shall develop a new off-site hospital-based outpatient campus by relocating maternal-fetal medicine and outpatient rehabilitation services from the existing Cone Health Women's Hospital to the proposed Cone Health Women's Outpatient Center.**
 - 3. The Moses H. Cone Memorial Hospital and The Moses H. Cone Memorial Hospital Operating Corporation, 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, The Moses H. Cone Memorial Hospital and The Moses H. Cone Memorial Hospital Operating Corporation 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. The Moses H. Cone Memorial Hospital and The Moses H. Cone Memorial Hospital Operating Corporation 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.

The applicant proposes to develop a new off-site hospital-based outpatient campus by relocating maternal-fetal medicine and outpatient rehabilitation services from the existing Cone Health Women's Hospital to the proposed Cone Health Women's Outpatient Center.

Capital and Working Capital Costs

In Section Q, page 103, the applicant projects the total capital cost of the project, as shown in the table below.

Capital Costs	
Site Preparation	\$278,735
Construction/Renovation Contract (s)	\$1,471,121
Architecture/Engineering Fees	\$126,328
Medical Equipment	\$174,651
Non-Medical Equipment	\$262,304
Furniture	\$68,584
Total	\$2,381,723

In Section Q, page 104, the applicant provides the assumptions used to project the capital cost.

In Section F, page 56, the applicant states that there are no start-up or initial operating expenses since all services currently exist and the proposed project involves relocation.

Availability of Funds

In Section F, page 53, the applicant states that the capital cost will be funded, as shown in the table below.

Sources of Capital Cost Financing			
Type	The Moses. H. Cone Memorial Hospital	The Moses. H. Cone Memorial Hospital Operating Corporation	Total
Loans	\$	\$	\$
Accumulated reserves or OE *	\$ 2,381,723	\$	\$ 2,381,723
Bonds	\$	\$	\$
Other (Specify)	\$	\$	\$
Total Financing	\$ 2,381,723	\$	\$ 2,381,723

* OE = Owner's Equity

Exhibit F.2-1 contains a letter dated February 12, 2020, from the Chief Financial Officer of Cone Health documenting its intention to provide accumulated reserves for the capital needs of the proposed project. Exhibit F.2-2 contains the audited financial statements of The Moses H. Cone Memorial Hospital and its affiliates, which show that as of December 31, 2019, the

applicant had over \$43 million in cash and cash equivalents, \$2.8 billion in total assets, and \$1.7 billion in net assets (total assets less total liabilities).

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.2, the applicant projects that operating expenses will exceed revenues in the first three operating years of the project for maternal-fetal medicine and the first two operating years for outpatient rehabilitation services. However, The Moses H. Cone Memorial Hospital overall revenues are projected to exceed operating expenses for the first three operating years, as illustrated in the tables below.

Maternal Fetal Medicine	1st FFY FY 2022	2nd FFY FY 2023	3rd FFY FY 2024
Total Visits	9,265	9,357	9,451
Total Gross Revenues (Charges)	\$10,364,417	\$10,886,02	\$11,435,204
Total Net Revenue	\$3,598,895	\$3,675,201	\$3,754,303
Average Net Revenue per Visit	\$388.43	\$393.77	\$397.23
Total Operating Expenses (Costs)	\$3,927,620	\$4,070,955	\$4,222,577
Average Operating Expense per Visit	\$423.92	\$435.07	\$446.78
Net Income	(\$328,725)	(\$395,754)	(\$468,275)

Outpatient Rehabilitation	1st FFY FY 2022	2nd FFY FY 2023	3rd FFY FY 2024
Total Visits	350	1,024	1,239
Total Gross Revenues (Charges)	\$381,423	\$436,580	\$499,165
Total Net Revenue	\$141,077	\$158,476	\$177,833
Average Net Revenue per Visit	\$403.07	\$154.76	\$143.52
Total Operating Expenses (Costs)	\$154,356	\$160,938	\$167,976
Average Operating Expense per Visit	\$441.01	\$157.16	\$135.57
Net Income	(\$13,279)	(\$2,462)	\$9,857

The Moses H. Cone Memorial Hospital	1st FFY FY 2022	2nd FFY FY 2023	3rd FFY FY 2024
Total Gross Revenues (Charges)	\$5,594,817,000	\$5,781,257,000	\$5,979,089,000
Total Net Revenue	\$2,432,190,000	\$2,514,019,000	\$2,612,186,000
Total Operating Expenses (Costs)	\$2,372,270,000	\$2,453,046,000	\$2,549,554,000
Net Income	\$59,920,000	\$60,973,000	\$62,632,000

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
- 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.
 - 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 develop a new off-site hospital-based outpatient campus by relocating maternal-fetal medicine and outpatient rehabilitation services from the existing Cone Health Women's Hospital to the proposed Cone Health Women's Outpatient Center.

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 rules adopted by the Department, which receives services from a health service facility.*" The 2020 SMFP does not define a service area for hospital-based outpatient clinics nor are there any applicable rules adopted by the Department that define the service area for hospital-based outpatient clinics. Thus, the service area in this review is as defined by the applicant. The service area for this facility consists of Guilford County. Facilities may also serve residents of counties not included in their service area.

In Section G, page 60, the applicant states that Wake Forest Baptist Health is the only other provider of maternal-fetal medicine in Guilford County, however, it is not a hospital-based clinic. The applicant states that Cone Health is the only provider of hospital-based outpatient rehabilitation in the service area.

In Section G, page 61, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved maternal-fetal medicine and outpatient rehabilitation services in Guilford County. The applicant states:

"The proposed project will relocate existing services from Women's Hospital to a new outpatient campus due to the move of acute care beds and operating rooms from Women's Hospital to Moses Cone Hospital. This project will not result in unnecessary

duplication as the proposed services exist today and will continue to be offered in the future in a different location.”

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:

- The proposal would not result in an increase in maternal-fetal medicine and outpatient rehabilitation services.
- The applicant is the only hospital-based provider of maternal-fetal medicine and outpatient rehabilitation services in Guilford County.

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 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, page 112, the applicant provides current and projected full-time equivalent (FTE) staffing for the maternal-fetal medicine services, as illustrated in the following table.

Maternal-Fetal Medicine		
Position	Current FTE Staff	Projected FTE Staff
	As of 9/30/2018	2nd FFY FY 2023
Physician	0.33	2.50
Non-Clinical Professional	0.42	1.00
Radiology	6.33	6.00
Admin Support	4.79	4.50
Registered Nurse	2.13	2.50
TOTAL	14.00	16.50

In Section Q, page 115, the applicant provides current and projected full-time equivalent (FTE) staffing for outpatient rehabilitation services, as illustrated in the following table.

Outpatient Rehabilitation		
Position	Current FTE Staff	Projected FTE Staff
	As of 9/30/2018	2nd FFY FY 2023
Rehabilitation Specialist	1.00	1.00
TOTAL	1.00	1.00

The assumptions and methodology used to project staffing are provided in Section Q, pages 116-117. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form F.3, which is found in Section Q. In Section H.2 and H.3, pages 63 and 64, respectively, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs. In Section I, page 68, the applicant identifies the current medical directors. In Exhibit I-3, the applicant provides letters from the medical directors indicating their interest in continuing to serve as medical directors for the proposed services.

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

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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.

In Section I, page 65, the applicant states that the ancillary and support services for maternal-fetal medicine and outpatient rehabilitation include registration, medical records, administration, environmental services, laboratory, pharmacy, biomedical engineering, and security.

On page 65, the applicant adequately explains how each ancillary and support service is or will be made available and provides supporting documentation in Exhibit I-1.

In Section I, pages 65-66, the applicant describes its existing and proposed relationships with other local health care and social service providers and provides supporting documentation in Exhibit I-1.

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.

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

NA

The applicant does not project to provide the proposed services to a substantial number of persons residing in Health Service Areas (HSAs) that are not adjacent to the HSA in which the services will be offered. Furthermore, the applicant does not project to provide the proposed services to a substantial number of persons residing in other states that are not adjacent to the North Carolina county in which the services will be offered. Therefore, Criterion (9) is not applicable to this review.

- (10) When applicable, the applicant shall show that the special needs of health maintenance organizations will be fulfilled by the project. Specifically, the applicant shall show that the project accommodates: (a) The needs of enrolled members and reasonably anticipated new members of the HMO for the health service to be provided by the organization; and (b) The availability of new health services from non-HMO providers or other HMOs in a reasonable and cost-effective manner which is consistent with the basic method of operation of the HMO. In assessing the availability of these health services from these providers, the applicant shall consider only whether the services from these providers:
- (i) would be available under a contract of at least 5 years duration;

- (ii) would be available and conveniently accessible through physicians and other health professionals associated with the HMO;
- (iii) would cost no more than if the services were provided by the HMO; and
- (iv) would be available in a manner which is administratively feasible to the HMO.

NA

The applicant is not an HMO. Therefore, Criterion (10) is not applicable to this review.

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

C

In Section K, page 72, the applicant states that the project involves constructing 4,757 square feet of new space. Line drawings are provided in Exhibit C.1-2.

On page 73, the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal.

On pages 73-74, the applicant adequately explains why the proposal will not unduly increase the costs to the applicant of providing the proposed services or the costs and charges to the public for the proposed services.

On page 74, the applicant identifies any applicable energy saving features that will be incorporated into the construction plans.

On pages 75-76, the applicant identifies the proposed site and provides information about the current owner, zoning and special use permits for the site, and the availability of water, sewer and waste disposal and power at the site.

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.

- (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 Exhibit L.1 the applicant provides the historical payor mix during last full fiscal year for the proposed services, as shown in the table below.

Cone Health Women's Outpatient Center Historical Payor Mix Last FFY, FY 2019		
Payor Category	Maternal-Fetal Medicine Services as percent of Total	Outpatient Rehabilitation Services as Percent of Total
Self-Pay	6.7%	3.4%
Medicare*	0.8%	38.7%
Medicaid*	58.8%	12.5%
Insurance*	32.6%	43.1%
Other	1.1%	2.3%
Total	100.0%	100.0%

Source: Section Q, Exhibit L.3
 *Including managed care plan

In Exhibit L.1 the applicant states that charity care is not a separate payor class for Cone Health, which is offered to qualified patients based on Cone Health's Financial Assistance Program Policy.

In Section L, page 79, the applicant provides the following comparison.

Cone Health Women's Outpatient Center	Percentage of Total Patients Served by the Facility or Campus during the Last Full FY	Percentage of the Population of the Service Area
Female	97.5%	51.8%
Male	2.5%	48.2%
Unknown	0.0%	0.0%

64 and Younger	99.0%	83.2%
65 and Older	1.0%	16.8%
American Indian	0.3%	0.6%
Asian	2.6%	3.6%
Black or African-American	49.8%	25.0%
Native Hawaiian or Pacific Islander	0.1%	0.0%
White or Caucasian	33.9%	63.2%
Other Race	12.1%	7.5%
Declined / Unavailable	1.2%	0.0%

Sources: Cone Health Financial Systems (facility data), ESRI (service area data)

The Agency reviewed the:

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

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

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

C

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L, page 80, the applicant states:

“Cone Health has no obligation under applicable federal regulations to provide uncompensated care, community service, or access to care by minorities and handicapped persons.”

In Section L, page 81, the applicant states that during the last five years one patient civil rights access complaint has been filed against the facility or any similar facilities owned by the applicant or a related entity and located in North Carolina. On page 81, the applicant states that the Office of Civil Rights closed the case without any request for additional information or remediation.

The Agency reviewed the:

- Application

- Exhibits to the application

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

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

C

In Exhibit L.3, the applicant projects the following payor mix for the proposed services during the second full fiscal year of operation following completion of the project, as shown in the table below.

Cone Health Women's Outpatient Center Projected Payor Mix 2nd FFY, FFY 2023		
Payor Category	Maternal-Fetal Medicine Services as percent of Total	Outpatient Rehabilitation Services as Percent of Total
Self-Pay	6.7%	3.4%
Medicare*	0.8%	38.7%
Medicaid*	58.8%	12.5%
Insurance*	32.6%	43.1%
Other	1.1%	2.3%
Total	100.0%	100.0%

Source: Section C, Exhibit L.3

*Including managed care plan

In Exhibit L.3 the applicant states that charity care is not a separate payor class for Cone Health, which is offered to qualified patients based on Cone Health's Financial Assistance Program Policy.

As shown in the table above, during the second full fiscal year of operation for maternal-fetal medicine services, the applicant projects that 6.7% of total services will be provided to self-pay patients, 0.8% to Medicare patients and 58.8% to Medicaid patients.

As shown in the table above, during the second full fiscal year of operation for outpatient rehabilitation services, the applicant projects that 3.4% of total services will be provided to self-pay patients, 38.7% to Medicare patients and 12.5% to Medicaid patients.

In Exhibit L.3, the applicant provides the assumptions and methodology used to project payor mix during the second full fiscal year of operation following completion of the project. The projected payor mix is reasonable and adequately supported because it is based on the current payor mix at Cone Health's Women's Hospital.

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

In Section L, page 83, the applicant adequately describes the range of means by which patients will have access to the proposed services.

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

In Section M, pages 84-85, 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
- 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 develop a new off-site hospital-based outpatient campus by relocating maternal-fetal medicine and outpatient rehabilitation services from the existing Cone Health Women's Hospital to the proposed Cone Health Women's Outpatient Center.

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 rules adopted by the Department, which receives services from a health service facility.*" The 2020 SMFP does not define a service area for hospital-based outpatient clinics nor are there any applicable rules adopted by the Department that define the service area for hospital-based outpatient clinics. Thus, the service area in this review is as defined by the applicant. The service area for this facility consists of Guilford County. Facilities may also serve residents of counties not included in their service area.

In Section G, page 60, the applicant states that Wake Forest Baptist Health is the only other provider of maternal-fetal medicine in Guilford County, however, it is not a hospital-based clinic. The applicant states that Cone Health is the only provider of hospital-based outpatient rehabilitation.

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 87, the applicant states:

"The proposed project will relocate two hospital-based services into a new medical office building alongside other non-CON reviewable services to create a comprehensive site of care for women's healthcare services in Greensboro. Since Cone Health is simply relocating existing services from their current location at Women's Hospital, the proposed project is not expected to have a significant impact on competition in the proposed service area."

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

"The relocation of these services to a new outpatient facility will allow Cone Health to design new space by incorporating Lean design principles and add additional services that are not currently available at Women's Hospital that are not subject to

CON review. This integration of women's healthcare services across the ambulatory continuum of care will allow Cone Health to operate these services more efficiently, thereby increasing cost effectiveness."

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

"The incorporation of Lean design principles will also allow staff input on the layout of the facility which will increase safety and quality, as staff will be familiar with the new space prior to opening."

Regarding the impact of the proposal on access by medically underserved groups, in Section N, pages 88-89, the applicant states:

"Additionally, Cone Health has a longstanding, demonstrated commitment to the underserved residents of its communities...Cone Health expects to provide 59.6% of maternal-fetal medicine services to Medicare and Medicaid beneficiaries with another 6.7% to self pay patients while 63.0% of outpatient rehabilitation services will be provided to Medicare and Medicaid patients and 51.2% of outpatient rehabilitation patients are projected to be Medicare and Medicaid beneficiaries with an additional 3.4% of patient projected to be self pay. As such, the proposed project will have a favorable impact on cost effectiveness, quality, and access."

Considering all the information in the application, 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 (see Sections C, F, N and Q of the application and any exhibits)
- Quality (see Sections C, N and O of the application and any exhibits)
- Access to medically underserved groups (see Sections C, L and N of the application and any exhibits)

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 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 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 three of this type of facility located in North Carolina.

In Section O, page 93, the applicant states that, during the 18 months immediately preceding the submittal of the application, incidents related to quality of care has not occurred in any of these facilities. According to the files in the Acute Care 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 has occurred in all three of these facilities. However, one facility was back in compliance on September 26, 2019. After reviewing and considering information provided by the applicant and by the Acute Care and Home Care Licensure and Certification Section and considering the quality of care provided at all three 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.
- (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 develop a new off-site hospital-based outpatient campus for maternal medicine and outpatient rehabilitation. There are no administrative rules that are applicable to proposals to develop hospital-based outpatient clinics.