ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS
C = Conforming
CA = Conditional
NC = Nonconforming
NA = Not Applicable

| | |
|---|---|
| Decision Date: | August 26, 2019 |
| Findings Date: | August 26, 2019 |
| Project Analyst: | Julie M. Faenza |
| Assistant Chief: | Lisa Pittman |
| Project ID #: | F-11722-19 |
| Facility: | Atrium Health Kenilworth Diagnostic Center #2 |
| FID #: | 190278 |
| County: | Mecklenburg |
| Applicant: | Carolinas Physicians Network, Inc. |
| Project: | Develop a new diagnostic center in MOB #2 by relocating existing GI, neurology, and urology equipment and adding a fluoroscopy unit, prostate biopsy unit, and two bladder scanners |

**REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES**

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

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

NA

Carolinas Physicians Network, Inc. (hereinafter referred to as CPN or "the applicant") proposes to develop a new diagnostic center, Atrium Health Kenilworth Diagnostic Center #2 (AH Kenilworth #2), in a medical office building (MOB #2) being developed at 1225 Harding Place, in Charlotte. The combined value of the medical diagnostic equipment costing $10,000 or more exceeds the statutory threshold of $500,000 and therefore qualifies as a diagnostic center, which is a new institutional heath service, and which requires a certificate of need.

The applicant does not propose to acquire any medical equipment or offer new institutional health services for which there are any need determinations or applicable policies in the 2019 State Medical Facilities Plan (SMFP). Therefore, Criterion (1) is not applicable to this review.

(2) Repealed effective July 1, 1987.

(3) The applicant shall identify the population to be served by the proposed project, and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and, in particular, low income persons, racial and ethnic minorities, women, 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 diagnostic center in Mecklenburg County as part of relocating physician office practices away from the Carolinas Medical Center (CMC) campus and consolidating various physician office practices affiliated with CPN. In Section C, page 21, the applicant states that an unrelated third-party developer is building two medical office buildings (MOB #1 and MOB #2) and associated parking as part of a new medical campus in Charlotte, also called Atrium Health Kenilworth, which will serve as a site to consolidate physician practices that are part of CPN. MOB #1 is located at 1237 Harding Place and MOB #2 is located at 1225 Harding Place. The Agency, in letters sent June 15, 2018 and November 7, 2018, determined that development of these medical office buildings, to the extent the development was not part of projects requiring a certificate of need, was exempt from review.

In Section A, page 6, the applicant provides an explanation of its corporate ownership structure. CPN's parent company (and sole owner of CPN) is Carolinas Health Network, Inc. The parent company of Carolinas Health Network, Inc. (and sole owner of Carolinas Health Network, Inc.) is The Charlotte-Mecklenburg Hospital Authority (CMHA). CMHA does business as Atrium Health. Thus, while the applicant for this project is CPN, the applicant and the facility are ultimately affiliated with and are part of CMHA and the Atrium Health system.

Designation as a Diagnostic Center

In Section C, pages 22-23, the applicant states the proposed diagnostic center will feature physician offices and related medical diagnostic equipment on multiple floors of the medical office building. The applicant states the proposed diagnostic center will include the following pieces of new and existing medical diagnostic equipment, each of which is worth $10,000 or more:

| AH Kenilworth #2 Type and Location of Medical Diagnostic Equipment | | |
|---|---|---|
| **Equipment** | **Number of Units** | **New or Existing/Relocated** |
| **UROLOGY – SECOND FLOOR** | | |
| Fluoroscopy Systems | 1 | New |
| Prostate Biopsy Systems | 1 | New |
| Prostate Biopsy Systems | 1 | Existing/Relocated |
| Cystoscopy Systems* | 5 | Existing/Relocated |
| Bladder Scanners | 2 | New |
| Bladder Scanners | 3 | Existing/Relocated |
| **GENERAL NEUROLOGY – FOURTH FLOOR** | | |
| EMG Machines** | 3 | Existing/Relocated |
| **GASTROENTEROLOGY – FIFTH FLOOR** | | |
| Capsule Endoscopy Systems | 2 | Existing/Relocated |

*The applicant states three of the five existing cystoscopy units will be replaced and relocated to AH Kenilworth #2 and the remaining two units will be relocated without being replaced.

****Note:** EMG = Electromyography. The applicant states two of the three existing EMG machines will be replaced and relocated to AH Kenilworth #2 and the remaining EMG machine will be relocated without being replaced.

On pages 21-22, the applicant states the existing equipment will be relocated from physician practices in different locations. The applicant states that the combined cost of the pieces of equipment listed above is more than $500,000; therefore, a certificate of need is required to develop a diagnostic center. In Form F.1a, the applicant lists the cost of medical equipment as $1,365,494.

Patient Origin

N.C.G.S. §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 2019 SMFP does not define a service area for diagnostic centers, nor are there any applicable rules adopted by the Department that define the service area for diagnostic centers. Thus, the service area in this review is as defined by the applicant.

In supplemental information, the applicant defines the service area as Mecklenburg, Gaston, and Union counties in North Carolina and York County in South Carolina. Facilities may also serve residents of counties not included in their service area.

The following table illustrates projected patient origin during the first three full fiscal years following project completion.

| AH Kenilworth #2 Projected Patient Origin – FYs 1-3 (CYs 2021-2023) | | | | | | |
|---|---|---|---|---|---|---|
| County | FY 1 – CY 2021 | | FY 2 – CY 2022 | | FY 3 – CY 2023 | |
| | # of Patients | % of Total | # of Patients | % of Total | # of Patients | % of Total |
| Mecklenburg | 5,073 | 66.2% | 5,427 | 66.4% | 5,815 | 66.5% |
| Union | 507 | 6.6% | 543 | 6.6% | 581 | 6.6% |
| York (SC) | 487 | 6.4% | 521 | 6.4% | 558 | 6.4% |
| Gaston | 387 | 5.0% | 410 | 5.0% | 436 | 5.0% |
| Other* | 1,205 | 15.7% | 1,278 | 15.6% | 1,357 | 15.5% |
| **Total** | **7,660** | **100.0%** | **8,179** | **100.0%** | **8,748** | **100.0%** |

*Other includes Alamance, Alexander, Anson, Ashe, Avery, Beaufort, Brunswick, Buncombe, Burke, Cabarrus, Caldwell, Carteret, Caswell, Catawba, Clay, Cleveland, Cumberland, Durham, Edgecombe, Forsyth, Guilford, Haywood, Henderson, Iredell, Jackson, Lincoln, Macon, Madison, McDowell, Mitchell, Montgomery, Moore, New Hanover, Pitt, Polk, Randolph, Richmond, Robeson, Rowan, Rutherford, Scotland, Stanly, Stokes, Transylvania, Wake, Watauga, Wayne, Wilkes, Yadkin, and Yancey counties, as well as other states. In supplemental information, the applicant states that Cabarrus County patients represent 2.3 percent of total projected patients and it is the county with the highest percent of projected patients in the "Other" category.
**Source:** Section C, page 26

In Section C, pages 24-26, the applicant provides the assumptions and methodology used to project its patient origin. The applicant's assumptions are reasonable and adequately supported.

Analysis of Need

In Section C, pages 27-30, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. The applicant states:

- The physician offices that will be located at AH Kenilworth #2 are currently located in multiple buildings across multiple locations in Charlotte, which makes in-person consultations between physicians difficult, and which requires patients to go to multiple locations for related services.

- By consolidating physician office locations with medical diagnostic equipment, AH Kenilworth #2 allows patients to receive medical diagnostic services at the same location they see their providers. Consolidation also allows patients to schedule multiple appointments for the same day (when schedules permit) at a single location.

- Relocating the medical diagnostic equipment with the physician offices allows physicians to avoid referring patients needing medical diagnostic services to a different location with potentially higher charges. Additionally, as a physician-based practice, AH Kenilworth #2 will provide patients with an opportunity to lower their out-of-pocket medical costs.

- Shifting services that can be provided in physician-based offices away from outpatient facilities or other locations on hospital campuses results in greater capacity to treat emergency, inpatient, or outpatient cases that cannot be treated in office-based settings.

- According to the North Carolina Office of State Budget and Management (NC OSBM), the Mecklenburg County population is projected to grow at a Compound Annual Growth

Rate (CAGR) of 1.9 percent through 2023, and the population of Mecklenburg County residents age 65 and older will increase from 11.6 percent in 2019 to 13 percent in 2023. The applicant states the increase in the percent of the population age 65 and older is significant because older residents utilize healthcare services at a higher rate than younger residents.

The information is reasonable and adequately supported for the following reasons:

- The applicant provides reasonable and adequately supported information to support its assertion that the relocation of physician offices and medical diagnostic equipment will better serve patients.

- Reliable data sources are used to support assertions about population growth.

*Projected Utilization*

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

| AH Kenilworth #2 Projected Utilization – FYs 1-3 (CYs 2021-2023) | | | |
|---|---|---|---|
| **Component** | **FY 1 (CY 2021)** | **FY 2 (CY 2022)** | **FY 3 (CY 2023)** |
| Capsule Endoscopy System – Units | 2 | 2 | 2 |
| Capsule Endoscopy System – Tests | 155 | 192 | 240 |
| EMG Machines – Units | 3 | 3 | 3 |
| EMG Machines – Tests | 514 | 524 | 534 |
| Fluoroscopy System – Rooms | 1 | 1 | 1 |
| Fluoroscopy System – Tests | 674 | 687 | 700 |
| Prostate Biopsy Machines – Units | 2 | 2 | 2 |
| Prostate Biopsy Machines – Tests | 501 | 570 | 648 |
| Cystoscopy Systems – Units | 5 | 5 | 5 |
| Cystoscopy Systems – Tests | 1,945 | 1,998 | 2,052 |
| Bladder Scanners – Units | 5 | 5 | 5 |
| Bladder Scanners – Tests | 3,871 | 4,207 | 4,573 |
| **Total Tests** | **7,660** | **8,178** | **8,747** |

In Section C, pages 31-35, the applicant provides the annual maximum capacity per unit for each type of medical diagnostic equipment proposed in this application, as well as the assumptions and methodology used to project the annual maximum capacities. The annual maximum capacity for each type of medical diagnostic equipment proposed in this application is shown in the table below.

| Annual Maximum Capacity for Each Type of Medical Diagnostic Equipment Proposed | | | | | |
|---|---|---|---|---|---|
| **Equipment Type** | **# Units** | **Patients/Hour** | **Hours/Day** | **Days/Year** | **Maximum Annual Capacity*** |
| Capsule Endoscopy Systems | 2 | 0.143 | 7 | 200** | 400 |
| EMG Machines | 2*** | 1.000 | 7 | 100 | 1,400 |
| Fluoroscopy Systems | 1 | 1.000 | 7 | 250 | 1,750 |
| **Equipment Used in Urology Treatment Rooms**** | | | | | |
| Prostate Biopsy Machines | 2 | 0.500 | NA | 200** | NA |
| Cystoscopy Systems | 5 | 0.570 | NA | 250 | NA |
| Bladder Scanners | 5 | 6.000 | NA | 250 | NA |
| Treatment Rooms | 5 | -- | 7 | 250 | 8,750 |

**Source:** Section C, page 31; Section Q

***Maximum Annual Capacity = (Units X Patients X Hours X Days) or (Units X Hours X Days)

****The applicant states procedures are not performed on Fridays due to associated risk factors.

*****The applicant states one of the machines is used as backup and not routinely scheduled for procedures.

******The applicant states the pieces of equipment are used in the five treatment rooms in the urology clinic, and the time is split between patients needing one or more types of tests/procedures on the equipment. The applicant states each room is available seven hours per day and the combined capacity of the equipment is the capacity of the treatment rooms.

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

The applicant states the projected utilization is based on the historical utilization of the physicians who will have offices at AH Kenilworth #2. The applicant further states that historical and interim utilization is not provided specifically for AH Kenilworth #2 because the physicians are currently located in many different locations and the proposed facility is not an existing facility.

The applicant further states that, except for the fluoroscopy room and the EMG machines, none of the equipment has dedicated staff and is used by physicians as needed for their diagnostic requirements. The applicant states the equipment proposed is intended to maximize the efficiency of the physicians using the equipment and efficiency of care to patients rather than to maximize utilization of the equipment.

*Capsule Endoscopy Systems*

- The applicant states internal data shows capsule endoscopy system utilization grew at a CAGR of 49.1 percent between CY 2016 and CY 2018.

- The applicant states it projects growth in the utilization of capsule endoscopy systems at AH Kenilworth #2 at half the historical CAGR, 24.5 percent, for CY 2019 through CY 2023.

- Based on the calculated maximum capacity of the capsule endoscopy systems, the applicant projects the capsule endoscopy systems will be utilized at 60 percent of capacity in CY 2023.

*Electromyography (EMG) Machines*

- The applicant states internal data shows EMG machine utilization decreased at a CAGR of -8.2 percent between CY 2016 and CY 2018. The applicant states this is due to a lack of EMG-trained technicians.

- The applicant states it assumes utilization will increase going forward due to planned recruitment of additional providers trained in the use of EMG machines.

- The applicant states that, based on the projected growth rate of the population of Mecklenburg County as published by NC OSBM, it projects growth in EMG machine utilization at AH Kenilworth #2 at an annual growth rate of 1.9 percent for CY 2019 through CY 2023.

- Based on the calculated maximum capacity of the EMG machines, and assuming one EMG machine is constantly offline and serving as backup, the applicant projects the EMG machines will operate at 38 percent of capacity in CY 2023.

*Fluoroscopy Room*

- The applicant states internal data shows fluoroscopy room utilization decreased at a CAGR of -1.6 percent between CY 2016 and CY 2018. The applicant states this is due to the lack of fluoroscopy services available at existing physician practices which necessitates patient referrals to hospitals with limited capacity.

- The applicant states it assumes utilization will increase going forward due to the availability of fluoroscopy services in a convenient and lower-cost setting.

- The applicant states that, based on the projected growth rate of the population of Mecklenburg County as published by NC OSBM, it projects growth in fluoroscopy room utilization at AH Kenilworth #2 at an annual growth rate of 1.9 percent for CY 2019 through CY 2023.

- Based on the calculated maximum capacity of the fluoroscopy room, the applicant projects the fluoroscopy room will be utilized at 40 percent of capacity in CY 2023.

*Prostate Biopsy Machines*

- The applicant states internal data shows prostate biopsies increased at a CAGR of 27.5 percent between CY 2016 and CY 2018.

- The applicant states it projects growth in the utilization of prostate biopsy systems at AH Kenilworth #2 at half the historical CAGR, 13.8 percent, for CY 2019 through CY 2023.

- The applicant projects to perform 648 prostate biopsies at AH Kenilworth #2 in CY 2023. As discussed further below, the prostate biopsy machines, along with other related medical

diagnostic equipment, are in five urology treatment rooms which are utilized based on physician need. The applicant calculates a maximum capacity for its five urology treatment rooms, based on its historical utilization trends, which includes utilization of the prostate biopsy machines.

*Cystoscopy Systems*

- The applicant states internal data shows cystoscopies increased grew at a CAGR of 5.4 percent between CY 2016 and CY 2018.

- The applicant states it projects growth in the utilization of cystoscopy systems at AH Kenilworth #2 at half the historical CAGR, 2.7 percent, for CY 2019 through CY 2023.

- The applicant projects to perform 2,052 cystoscopies at AH Kenilworth #2 in CY 2023. As discussed further below, the cystoscopy machines, along with other related medical diagnostic equipment, are in five urology treatment rooms which are utilized based on physician need. The applicant calculates a maximum capacity for its five urology treatment rooms, based on its historical utilization trends, which includes utilization of the cystoscopy machines.

*Bladder Scanners*

- The applicant states internal data shows bladder scanner utilization grew at a CAGR of 17.4 percent between CY 2016 and CY 2018.

- The applicant states it projects growth in the utilization of bladder scanners at AH Kenilworth #2 at half the historical CAGR, 8.7 percent, for CY 2019 through CY 2023.

- The applicant projects to perform 4,573 bladder scans at AH Kenilworth #2 in CY 2023. As discussed further below, the bladder scanners, along with other related medical diagnostic equipment, are in five urology treatment rooms which are utilized based on physician need. The applicant calculates a maximum capacity for its five urology treatment rooms, based on its historical utilization trends, which includes utilization of the bladder scanners.

*Urology Treatment Room Utilization*

- The applicant provides average procedure time for each of the three types of equipment – prostate biopsy machines, cystoscopy systems, and bladder scanners – located in the five urology treatment rooms, as shown in the table below.

| AH Kenilworth #2 – Average Procedure Time by Type of Equipment | | |
|---|---|---|
| **Equipment** | **Procedures per Hour** | **Procedure Time in Hours** |
| Prostate Biopsy Machines | 0.50 | 2.00 |
| Cystoscopy Systems | 0.57 | 1.75 |
| Bladder Scanners | 6.00 | 0.17 |

- The applicant projects total utilization in hours for the five urology treatment rooms by equipment type based on each piece of equipment's projected utilization, as shown in the table below.

| AH Kenilworth #2 – Projected Annual Procedure Hours by Type of Equipment | | | | | |
|---|---|---|---|---|---|
| **Equipment** | **CY 2019** | **CY 2020** | **CY 2021** | **CY 2022** | **CY 2023** |
| Prostate Biopsy Machines | 774 | 880 | 1,001 | 1,139 | 1,296 |
| Cystoscopy Systems | 3,226 | 3,314 | 3,404 | 3,496 | 3,591 |
| Bladder Scanners | 546 | 594 | 645 | 701 | 762 |
| **Total Hours** | **4,546** | **4,788** | **5,050** | **5,337** | **5,650** |

- Based on the calculated maximum capacity of the urology treatment rooms, the applicant projects the five urology treatment rooms will be utilized at 65 percent of capacity in CY 2023.

A summary of the applicant's historical utilization, details of assumptions and methodology, and projected utilization for each type of equipment is shown in the table below.

| AH Kenilworth #2 Utilization Assumptions, Methodology, and Projections – CY 2016 through CY 2023 | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| **Component** | **CY 2016** | **CY 2017** | **CY 2018** | **CY 2019** | **CY 2020** | **FY 1 (CY 2021)** | **FY 2 (CY 2022)** | **FY 3 (CY 2023)** | **Max. Capacity** | **% of Max. Capacity** |
| Capsule Endoscopy System – Units | -- | -- | -- | -- | -- | 2 | 2 | 2 | -- | -- |
| Capsule Endoscopy System – Tests | 36 | 41 | 80 | 100 | 124 | 155 | 192 | 240 | 400 | 60% |
| Growth Rate | 49.1% | | | 24.5% | 24.5% | 24.5% | 24.5% | 24.5% | -- | -- |
| EMG Machines – Units* | -- | -- | -- | -- | -- | 2 | 2 | 2 | -- | -- |
| EMG Machines – Tests | 577 | 543 | 486 | 495 | 505 | 514 | 524 | 534 | 1,400 | 38% |
| Growth Rate | -8.2% | | | 1.9% | 1.9% | 1.9% | 1.9% | 1.9% | -- | -- |
| Fluoroscopy Systems – Rooms | -- | -- | -- | -- | -- | 1 | 1 | 1 | -- | -- |
| Fluoroscopy Systems – Tests | 658 | 545 | 637 | 649 | 662 | 674 | 687 | 700 | 1,750 | 40% |
| Growth Rate | -1.6% | | | 1.9% | 1.9% | 1.9% | 1.9% | 1.9% | -- | -- |
| Prostate Biopsy Machines – Units | -- | -- | -- | -- | -- | 2 | 2 | 2 | -- | -- |
| Prostate Biopsy Machines – Tests | 209 | 238 | 340 | 387 | 440 | 501 | 570 | 648 | NA | NA |
| Growth Rate | 27.5% | | | 13.8% | 13.8% | 13.8% | 13.8% | 13.8% | -- | -- |
| Hours per Test | 2.0 hours | | | | | | | | -- | -- |
| Total Hours per Year | -- | -- | -- | 774 | 880 | 1,001 | 1,139 | 1,296 | -- | -- |
| Cystoscopy Systems – Units | -- | -- | -- | -- | -- | 5 | 5 | 5 | -- | -- |
| Cystoscopy Systems – Tests | 1,615 | 1,685 | 1,795 | 1,844 | 1,894 | 1,945 | 1,998 | 2,052 | NA | NA |
| Growth Rate | 5.4% | | | 2.7% | 2.7% | 2.7% | 2.7% | 2.7% | -- | -- |
| Hours per Test | 1.75 hours | | | | | | | | -- | -- |
| Total Hours per Year | -- | -- | -- | 3,226 | 3,314 | 3,404 | 3,496 | 3,591 | -- | -- |
| Bladder Scanners – Units | -- | -- | -- | -- | -- | 5 | 5 | 5 | -- | -- |
| Bladder Scanners – Tests | 2,187 | 2,802 | 3,014 | 3,276 | 3,561 | 3,871 | 4,207 | 4,573 | NA | NA |
| Growth Rate | 17.4% | | | 8.7% | 8.7% | 8.7% | 8.7% | 8.7% | -- | -- |
| Hours per Test | 0.17 hours | | | | | | | | -- | -- |
| Total Hours per Year | -- | -- | -- | 546 | 594 | 645 | 701 | 762 | -- | -- |
| Urology Treatment Rooms | -- | -- | -- | -- | -- | 5 | 5 | 5 | -- | -- |
| **Total Hours Urology Treatment Rooms** | **--** | **--** | **--** | **4,546** | **4,788** | **5,050** | **5,337** | **5,650** | **8,750** | **65%** |
| **Total Tests** | -- | -- | -- | -- | -- | **7,660** | **8,178** | **8,747** | -- | -- |

*In Section C, page 31, the applicant states one of the machines is used as backup and not routinely scheduled for procedures.

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

- Projected utilization is based on historical data.
- The applicant uses conservative projected growth rates.
- The applicant provides reasonable and adequately supported information to justify the need for equipment which is projected to be utilized at lower rates.

Access

In Section C, page 39, the applicant states:

> *"…Atrium Health's system-wide policies and procedures with regard to access to care will apply to the proposed diagnostic center at Atrium Health Kenilworth. Please see Exhibit C.11-1 for Atrium Health's Non-Discrimination policies. As noted in Atrium*

*Health's Non-Discrimination Policy Statement, '[n]o individual shall be subject to discrimination or denied the benefits of the services, programs, or activities of* [Atrium Health] *on the basis of race, color, religion, national origin, sex, age, disability or source of payment.' Atrium Health will continue to serve this population as dictated by the mission of Atrium Health, which is the foundation for every action taken. The mission is simple, but unique: To improve health, elevate hope, and advance healing – for all. This includes the medically underserved."*

In Section L, page 71, 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.

| **AH Kenilworth #2 Payor Mix – FY 2 (CY 2022)** | |
|---|---|
| **Payor Source** | **Percent of Services** |
| Self-Pay | 3.6% |
| Medicare* | 51.1% |
| Medicaid* | 4.0% |
| Insurance* | 40.1% |
| Other** | 1.3% |
| **Total** | **100.0%** |

**Note:** The applicant states that it does not have charity care as a payor source, and that patients in every payor category receive charity care.
*Including any managed care plans
**"Other" includes Worker's Compensation and TRICARE

The projected payor mix is reasonable and adequately supported.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Supplemental information requested by the Agency
- 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 diagnostic center in Mecklenburg County as part of relocating physician office practices away from the CMC campus and consolidating various physician office practices affiliated with CPN.

As part of the proposed project, the applicant proposes to relocate two capsule endoscopy systems, three EMG machines, one prostate biopsy machine, five cystoscopy systems, and three bladder scanners from their current locations to AH Kenilworth #2. The equipment and services being relocated will no longer be offered at their current locations.

In Section D, pages 44-45, the applicant explains why it believes the needs of the population presently utilizing the services to be relocated will be adequately met following completion of the project. The applicant states:

- The proposed facility will be more accessible than the current locations of offices. Current offices are in multiple locations and many are on the campus of CMC. The proposed facility will consolidate the offices into a single location, which will be accessible from major roads; it will be located close to CMC but will be more accessible, without having to navigate a busy hospital campus; and it will offer substantially more parking options.

- Patients needing to see multiple providers can do so in one location and on the same day, as scheduling permits, without having to navigate the campus of CMC.

- Locating the physician offices together allows physicians to collaborate and discuss cases and care more frequently, which allows for higher quality care.

In Section D, page 47, the applicant states:

> *"…given the relocation and consolidation of the physician practices to Atrium Health Kenilworth, the patients historically served by the equipment to be relocated are also expected to relocate to the proposed diagnostic center. As such, the proposed project will not have any negative impact on the ability of low income persons, racial and ethnic minorities, women, handicapped persons, the elderly, or other underserved groups to obtain needed healthcare."*

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the applicant adequately demonstrates that:

- The needs of the population currently using the services to be relocated will be adequately met following project completion.

- 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 diagnostic center in Mecklenburg County as part of relocating physician office practices away from the CMC campus and consolidating various physician office practices affiliated with CPN.

In Section E, 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 this option would not allow enhanced and more convenient access to care by patients and would not free up capacity and space at CMC. Therefore, this is not an effective alternative.

Relocate Physicians Without Medical Diagnostic Equipment: The applicant states this option is not feasible because the equipment being relocated with the physicians is currently in use at the same location as the physicians. Relocating the physicians without the equipment would require physicians to send patients to a different location for medical diagnostic tests that patients currently receive at the same location they see their physicians. Therefore, this is not an effective alternative.

On page 48, the applicant states that its proposal is the most effective alternative because it provides enhanced and more convenient access to patients, frees up capacity at CMC, and maintains the ability of patients to receive medical diagnostic tests at the same location they see their physicians.

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 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
- 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. **Carolinas Physicians Network, Inc. shall materially comply with all representations made in the certificate of need application and any supplemental responses. In the event that representations conflict, Carolinas Physicians Network, Inc. shall materially comply with the last made representation.**

2. **Carolinas Physicians Network, Inc. shall develop a diagnostic center in MOB #2 at 1225 Harding Place in Charlotte by relocating two capsule endoscopy systems, three electromyography machines, one prostate biopsy machine, five cystoscopy systems, and three bladder scanners, and adding a second prostate biopsy machine, two additional bladder scanners, and one fluoroscopy system.**

3. **Carolinas Physicians Network, Inc., as part of this project, shall not acquire any equipment that is not included in the project's proposed capital expenditures in Sections F and Q of the application or 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, Carolinas Physicians Network, Inc. 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. Carolinas Physicians Network, Inc. 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 develop a new diagnostic center in Mecklenburg County as part of relocating physician office practices away from the CMC campus and consolidating various physician office practices affiliated with CPN.

Capital and Working Capital Costs

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

| | |
|---|---|
| Construction Costs | $286,834 |
| Medical Equipment Costs | $1,365,494 |
| Non-Medical Equipment/Furniture | $65,952 |
| Consultant/A&E Fees | $92,911 |
| Miscellaneous Costs/Contingency | $45,112 |
| **Total** | **$1,856,303** |

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

In Section F, page 52, the applicant projects that start-up costs will be $40,624 and initial operating expenses will be $61,782 for a total working capital cost of $102,406. On page 52, the applicant provides the assumptions and methodology used to project the working capital needs of the project.

Availability of Funds

In Sections F.2 and F.3, pages 50 and 52, respectively, the applicant states the capital and working capital costs of the project will be funded via accumulated reserves of CMHA/Atrium Health. Exhibit F.2-1 contains a letter from the Executive Vice President and Chief Financial Officer of Atrium Health, who also serves as the Treasurer of CPN, stating CPN will fully commit the funding costs provided to it by CMHA to develop the proposed project.

Exhibit F.2-2 contains financial statements for CMHA/Atrium Health for the years ending December 31, 2018 and 2017. As of December 31, 2018, CMHA/Atrium Health had adequate cash and cash equivalents to fund the proposed project.

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 revenues will exceed operating expenses in the first three fiscal years of the project, as shown in the table below.

| AH Kenilworth #2 Revenue and Expenses – FYs 1-3 (CYs 2021-2023) | | | |
|---|---|---|---|
| | FY 1 (CY 2021) | FY 2 (CY 2022) | FY 3 (CY 2023) |
| Total Tests/Procedures | 7,660 | 8,178 | 8,747 |
| Total Gross Revenues (Charges) | $2,766,414 | $3,021,622 | $3,314,273 |
| Total Net Revenue | $1,007,241 | $1,107,309 | $1,223,147 |
| Average Net Revenue per Test | $131 | $135 | $140 |
| Total Operating Expenses (Costs) | $712,910 | $746,348 | $784,757 |
| Average Operating Expense per Test | $93 | $91 | $90 |
| Net Income / (Loss) | $294,331 | $360,961 | $438,390 |

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 for the following reasons:

- The applicant adequately demonstrates that the capital and working capital costs are based on reasonable and adequately supported assumptions.

- The applicant adequately demonstrates availability of sufficient funds for the capital and working capital needs of the proposal.

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

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

C

The applicant proposes to develop a new diagnostic center in Mecklenburg County as part of relocating physician office practices away from the CMC campus and consolidating various physician office practices affiliated with CPN.

N.C.G.S. §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 2019 SMFP does not define a service area for diagnostic centers, nor are there any applicable rules adopted by the Department that define the service area for diagnostic centers. Thus, the service area in this review is as defined by the applicant.

In supplemental information, the applicant defines the service area as Mecklenburg, Gaston, and Union counties in North Carolina and York County in South Carolina. Facilities may also serve residents of counties not included in their service area.

In Section G, page 56, and supplemental information, the applicant states it is unaware of any publicly available data to show inventory and utilization of existing and approved non-hospital-based facilities and equipment providing services like those proposed in this application. In Exhibit G.2, and in supplemental information, the applicant provides copies of pages from 2019 License Renewal Applications (LRAs) and the 2017 South Carolina Joint Annual Reports, the most recent data available for South Carolina, for facilities in Mecklenburg, Gaston, Union, and York counties with equipment and services like those proposed in this application.

In Section G, pages 56-57, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved diagnostic center services in Mecklenburg, Gaston, Union, and York counties. The applicant states:

> *"The need for the proposed project is based on the need for CPN to provide convenient access to diagnostic services to support the physician services proposed to relocate to Atrium Health Kenilworth. Atrium Health Kenilworth will serve as a destination center with access to CPN physician clinics as well as the diagnostic services that comprise the proposed diagnostic center. No other provider can meet the identified need. Further, though other imaging and diagnostic services may be available in the service area, they are not reasonably available to the patients of the CPN physicians, who will be located at Atrium Health Kenilworth."*

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 proposed diagnostic center is needed in addition to the existing or approved diagnostic centers.

Conclusion

The Agency reviewed the:

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

(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, the applicant provides projected staffing for the proposed services as illustrated in the following table. Also, in Section Q, in its assumptions and methodology for projecting utilization of the proposed facility, the applicant states that there are no dedicated staff for any pieces of equipment except for EMG machines and the fluoroscopy system.

| **AH Kenilworth #2 Projected Staffing – All FYs (CYs 2021, 2022, 2023)** | |
|---|---|
| **Position** | **FTEs** |
| EMG Technicians | 0.49 |
| Fluoroscopy Technicians | 1.00 |
| **Total** | **1.49** |

**Source:** Form H in Section Q of the application.

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, pages 58-59, 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.2-2, the applicant provides letters from three proposed medical directors, one for each type of medical service, each indicating an interest in serving as a medical director for the proposed services. In Section I, page 61, the applicant describes its physician recruitment plans.

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.

C

In Section I, page 60, the applicant states the following ancillary and support services are necessary for the proposed diagnostic center:

- Housekeeping
- Security
- Maintenance
- Registration
- Administration
- Other Ancillary and Support Services

On page 60, the applicant adequately explains how each ancillary and support service will be made available.

In Section I, page 60, the applicant describes its efforts to develop relationships with other local health care and social service providers. The applicant states:

> *"As part of Atrium Health, CPN has established relationships with area healthcare providers. Atrium Health's and CPN's relationships with other local healthcare and social service providers are well established and will continue following completion of the proposed project."*

The applicant provides supporting documentation in Exhibit I.2-1.

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

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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 64, the applicant states that the project involves renovating 1,658 square feet of leased space in a medical office building being developed by an unrelated third-party developer. Line drawings are provided in Exhibit C.1-1.

In Section K, pages 64-65, the applicant adequately explains how the cost, design, and means of construction represent the most reasonable alternative for the proposal.

In Section K, page 65, 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. The applicant states development of the building by a third-party developer while the applicant leases and renovates the space is a more cost-effective option for the proposed project, and consolidation of services allows for economies of scale.

In Section K, pages 65-66, the applicant identifies any applicable energy saving features that will be incorporated into the construction plans.

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 supplemental information, the applicant provides the historical payor mix for CY 2018 at existing facilities where diagnostic equipment that is part of the proposed project is currently located, as shown in the table below.

| Historical Payor Mix at Existing Facilities – CY 2018 | | | | |
|---|---|---|---|---|
| | Atrium Health Digestive Center Medical Plaza | Carolina Neurological Clinic Randolph | Myers Park Urology | McKay Urology |
| **Payor Source** | **% of Services** | **% of Services** | **% of Services** | **% of Services** |
| Self-Pay | 1.3% | 3.9% | 13.8% | 2.0% |
| Medicare* | 43.8% | 42.9% | 45.9% | 52.7% |
| Medicaid* | 3.8% | 6.7% | 16.3% | 1.2% |
| Insurance* | 51.3% | 45.3% | 21.3% | 43.0% |
| Other** | 0.0% | 1.3% | 2.7% | 1.0% |
| **Total** | **100.0%** | **100.0%** | **100.0%** | **100.0%** |

**Source:** Atrium Health internal data
**Note:** The applicant states that it does not have charity care as a payor source, and that patients in every payor category receive charity care.
*Including any managed care plans
**"Other" includes Worker's Compensation and TRICARE

In supplemental information, the applicant provides the following comparison.

| Percent of Patients Served During CY 2018 (by Facility) | | | | |
|---|---|---|---|---|
| | Atrium Health Digestive Center Medical Plaza | Carolina Neurological Clinic Randolph | Myers Park Urology | McKay Urology |
| Female | 58.8% | 65.3% | 37.7% | 27.5% |
| Male | 41.3% | 34.7% | 62.3% | 72.5% |
| Unknown | 0.0% | 0.0% | 0.0% | 0.0% |
| 64 and Younger | 53.8% | 65.1% | 67.3% | 48.0% |
| 65 and Older | 46.3% | 34.9% | 32.7% | 52.0% |
| American Indian | 0.0% | 0.2% | 0.3% | 0.2% |
| Asian | 1.3% | 1.1% | 0.8% | 1.4% |
| Black or African-American | 22.5% | 36.2% | 37.8% | 22.8% |
| Native Hawaiian or Pacific Islander | 0.0% | 0.0% | 0.0% | 0.0% |
| White or Caucasian | 67.5% | 55.6% | 47.5% | 67.3% |
| Other Race | 2.5% | 3.7% | 10.7% | 4.7% |
| Declined / Unavailable | 6.3% | 3.2% | 2.9% | 3.6% |

**Source:** Atrium Health Internal Data

| Percent of Population in CY 2018 (by County) | | | | |
|---|---|---|---|---|
| | Gaston | Mecklenburg | Union | York |
| Female | 51.8% | 51.9% | 50.8% | 51.8% |
| Male | 48.2% | 48.1% | 49.2% | 48.2% |
| Unknown | 0.0% | 0.0% | 0.0% | 0.0% |
| 64 and Younger | 83.9% | 88.8% | 87.3% | 85.7% |
| 65 and Older | 16.1% | 11.2% | 12.7% | 14.3% |
| American Indian | 0.6% | 0.8% | 0.6% | 0.9% |
| Asian | 1.6% | 6.4% | 3.4% | 2.5% |
| Black or African-American | 17.6% | 32.9% | 12.3% | 19.4% |
| Native Hawaiian or Pacific Islander | 0.1% | 0.1% | 0.1% | 0.1% |
| White or Caucasian | 78.0% | 57.5% | 81.6% | 75.0% |
| Other Race | 2.1% | 2.4% | 2.0% | 2.2% |
| Declined / Unavailable | 0.0% | 0.0% | 0.0% | 0.0% |

**Source:** US Census Bureau QuickFacts

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 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 70, the applicant states that it has no such obligations.

In Section L, page 70, the applicant states that during the last five years no patient civil rights access complaints have been filed against the facility or any similar facilities owned by the applicant or a related entity and located in North Carolina.

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.

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

C

In Section L, page 71, 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.

| AH Kenilworth #2 Payor Mix – FY 2 (CY 2022) | |
|---|---|
| **Payor Source** | **Percent of Services** |
| Self-Pay | 3.6% |
| Medicare* | 51.1% |
| Medicaid* | 4.0% |
| Insurance* | 40.1% |
| Other** | 1.3% |
| **Total** | **100.0%** |

**Note:** The applicant states that it does not have charity care as a payor source, and that patients in every payor category receive charity care.
*Including any managed care plans
**"Other" includes Worker's Compensation and TRICARE

As shown in the table above, during the second full fiscal year of operation, the applicant projects that 3.6 percent of total services will be provided to self-pay patients, 51.1 percent to Medicare patients, and 4.0 percent to Medicaid patients.

In Section L, page 71, 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 for the following reasons:

- Projected payor mix is based on CPN's historical experience in providing the proposed services.

- The applicant provides reasonable and adequately supported information to explain why there are no changes to the projected payor mix in future years.

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.

(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 72, the applicant adequately describes the range of means by which patients will have access to 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.

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

C

In Section M, page 73, the applicant describes the extent to which health professional training programs in the area will 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 diagnostic center in Mecklenburg County as part of relocating physician office practices away from the CMC campus and consolidating various physician office practices affiliated with CPN.

N.C.G.S. §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 2019 SMFP does not define a service area for diagnostic centers, nor are there any applicable rules adopted by the Department that define the service area for diagnostic centers. Thus, the service area in this review is as defined by the applicant.

In supplemental information, the applicant defines the service area as Mecklenburg, Gaston, and Union counties in North Carolina and York County in South Carolina. Facilities may also serve residents of counties not included in their service area.

In Section N, pages 75-76, 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. The applicant states the proposed project will positively impact cost effectiveness due to consolidation of existing resources, freeing up capacity of other resources, and cost savings from economies of scale. The applicant states the services to be relocated to the proposed diagnostic center are accredited by top industry associations, which will positively impact quality. The applicant states access will improve with the development of the proposed project because it will allow patients more convenient and efficient access to providers as well as provide services at a lower out-of-pocket cost to patients.

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 Sections C, D, and L of the application and any exhibits).

Conclusion

The Agency reviewed the:

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

(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, the applicant identifies all other diagnostic centers in North Carolina owned, operated, or managed by the applicant or a related entity. The applicant identifies a total of eight diagnostic centers located in North Carolina.

In Section O, page 78, the applicant states,

> "*Each of the facilities identified…has continually maintained all relevant licensure, certification, and accreditation…for the 18 months preceding the submission of this application.*"

After reviewing and considering information provided by the applicant regarding the quality of care provided at all eight diagnostic centers, 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 diagnostic center. There are no administrative rules that are applicable to proposals to develop new diagnostic centers.