

REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: July 23, 2021

Findings Date: July 23, 2021

Project Analyst: Julie M. Faenza

Assistant Chief: Lisa Pittman

Project ID #: F-12064-21

Facility: Carolinas Imaging Services – Denver

FID #: 170522

County: Lincoln

Applicants: Carolinas Imaging Services, LLC

The Charlotte-Mecklenburg Hospital Authority

Project: Cost overrun and change of scope for Project ID #F-11440-17 (develop a new diagnostic center) to include CT scanner, MRI, x-ray, ultrasound, mammography and bone density services

REVIEW CRITERIA

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

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

NA

Union Medical Services, LLC (UMS) and The Charlotte-Mecklenburg Hospital Authority (CMHA) were issued a certificate of need for Project I.D. #F-11440-17 on April 3, 2018 to develop Carolinas Imaging Center – Denver (CIS-Denver), a freestanding MRI facility, by acquiring a fixed MRI scanner pursuant to a need determination in the 2017 State Medical Facilities Plan (SMFP). According to the application for Project I.D. #F-11440-17, UMS is a wholly owned subsidiary of CMHA. The capital expenditure for the approved project was \$3,881,400.

In this application, UMS is no longer an applicant and CMHA is joined by a different applicant – Carolinas Imaging Services, LLC (CIS), a different wholly owned subsidiary of CMHA. CIS and CMHA are hereinafter referred to collectively as “Atrium” or “the

applicant.” In this application, ownership of the fixed MRI scanner will transfer from UMS to CMHA, who will lease it to CIS, and the applicant proposes a change of scope to develop a diagnostic imaging center instead of a freestanding MRI facility. CIS will acquire diagnostic imaging equipment from CMHA, replace it, and relocate it to be developed together with the fixed MRI scanner at a new diagnostic center. The projected increase in capital cost is \$1,829,167.

The applicant does not propose to:

- develop any beds or services or acquire any medical equipment for which there is a need determination in the 2021 SMFP
- offer a new institutional health service for which there are any policies in the 2021 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, ... persons [with disabilities], the elderly, and other underserved groups are likely to have access to the services proposed.

C

The applicant proposes a cost overrun and change of scope to Project I.D. #F-11440-17. Instead of developing a freestanding MRI facility, the applicant proposes to develop a new diagnostic center by replacing and relocating diagnostic imaging equipment and developing the fixed MRI scanner all in the same location.

In Section C, page 27, the applicant states:

“Under the proposed project, UMS, which is wholly owned by CMHA, will transfer ownership of the previously approved but yet to be developed fixed MRI scanner to CMHA. CMHA will in turn lease the fixed MRI to CIS to be operated as part of the proposed diagnostic center.”

N.C.G.S. §131E-181(a) states:

“A certificate of need shall be valid only for the defined scope, physical location, and person named in the application. A certificate of need shall not be transferred or assigned except as provided in G.S. 131E-189(c).”

N.C.G.S. §131E-189(c) states:

“The Department may immediately withdraw any certificate of need if the holder of the certificate, before completion of the project or operation of the facility, transfers ownership or control of the facility, the project, or the certificate of need. Transfers resulting from...other good cause, as determined by the Department, shall not result in withdrawal if the Department receives prior written notice of the transfer and finds good cause.”

CMHA was an applicant for Project I.D. #F-11440-17 and is an applicant for this project; however, UMS is not an applicant for this project. To transfer ownership of a certificate of need, the Agency must receive prior written notice and find that good cause exists for the transfer. In Section C, page 42, the applicant states:

“..., ownership of the previously approved fixed MRI scanner will transfer from UMS to CMHA. CMHA and CIS believe that the change of ownership of the previously approved MRI scanner from UMS to CMHA is necessary because it will allow for a more streamlined and well-structured lease arrangement between CMHA and CIS as, upon approval of the proposed application, the previously approved fixed MRI scanner will be owned by CMHA and leased to CIS for use at the proposed diagnostic center.”

Based on the information provided in the application as submitted, the Agency finds that UMS, via CMHA, has provided prior written notice of its intent to transfer ownership of the certificate of need for Project I.D. #F-11440-17 and that good cause exists for the transfer.

Patient Origin

On page 344, the 2021 SMFP defines the service area for fixed MRIs as “...the same as an Acute Care Bed Service Area as defined in Chapter 5 and shown in Figure 5.1.” Figure 5.1 on page 36 of the 2021 SMFP shows Lincoln County as its own acute care bed service area. Thus, the service area for this project is Lincoln County. Facilities may also serve residents of counties not included in their service area.

CIS-Denver is not an existing facility; however, in Section C, the applicant provided the CY 2020 patient origin for the diagnostic imaging equipment that will be replaced and relocated as part of this change of scope application.

The following tables illustrate current and projected patient origin.

| Mammography – Current and Projected Patient Origin | | | | | | | | |
|---|----------------------|-------------------|-----------------------|-------------------|-----------------------|-------------------|-----------------------|-------------------|
| County | CY 2020 | | FY 1 – CY 2023 | | FY 2 – CY 2024 | | FY 3 – CY 2025 | |
| | # of Patients | % of Total | # of Patients | % of Total | # of Patients | % of Total | # of Patients | % of Total |
| Lincoln | 2,413 | 72.5% | 3,452 | 72.5% | 3,870 | 72.5% | 4,339 | 72.5% |
| Gaston | 452 | 13.6% | 647 | 13.6% | 725 | 13.6% | 813 | 13.6% |
| Catawba | 305 | 9.2% | 436 | 9.2% | 489 | 9.2% | 548 | 9.2% |
| Mecklenburg | 104 | 3.1% | 149 | 3.1% | 167 | 3.1% | 187 | 3.1% |
| Other* | 53 | 1.6% | 76 | 1.6% | 85 | 1.6% | 95 | 1.6% |
| Total | 3,327 | 100.0% | 4,759 | 100.0% | 5,336 | 100.0% | 5,983 | 100.0% |

Source: Section C, pages 28 and 31

*Other (for CY 2020) includes Lee, Moore, and Union counties, as well as other states. Other (for projected patient origin) includes Burke, Cabarrus, Cleveland, Forsyth, Iredell, Lee, Moore, Randolph, and Union counties, as well as other states.

| X-Ray – Current and Projected Patient Origin | | | | | | | | |
|---|----------------------|-------------------|-----------------------|-------------------|-----------------------|-------------------|-----------------------|-------------------|
| County | CY 2020 | | FY 1 – CY 2023 | | FY 2 – CY 2024 | | FY 3 – CY 2025 | |
| | # of Patients | % of Total | # of Patients | % of Total | # of Patients | % of Total | # of Patients | % of Total |
| Lincoln | 928 | 63.4% | 1,107 | 63.4% | 1,150 | 63.4% | 1,195 | 63.4% |
| Gaston | 252 | 17.2% | 301 | 17.2% | 312 | 17.2% | 325 | 17.2% |
| Catawba | 164 | 11.2% | 196 | 11.2% | 203 | 11.2% | 211 | 11.2% |
| Mecklenburg | 64 | 4.4% | 76 | 4.4% | 79 | 4.4% | 82 | 4.4% |
| Other* | 56 | 3.8% | 67 | 3.8% | 69 | 3.8% | 72 | 3.8% |
| Total | 1,464 | 100.0% | 1,746 | 100.0% | 1,814 | 100.0% | 1,886 | 100.0% |

Source: Section C, pages 29 and 32

*Other includes Alleghany, Burke, Cabarrus, Caldwell, Cleveland, Forsyth, Iredell, Rowan, Stanly, Union, Wake, Wayne, and Wilkes counties, as well as other states.

| Ultrasound – Current and Projected Patient Origin | | | | | | | | |
|--|----------------------|-------------------|-----------------------|-------------------|-----------------------|-------------------|-----------------------|-------------------|
| County | CY 2020 | | FY 1 – CY 2023 | | FY 2 – CY 2024 | | FY 3 – CY 2025 | |
| | # of Patients | % of Total | # of Patients | % of Total | # of Patients | % of Total | # of Patients | % of Total |
| Lincoln | 492 | 66.5% | 692 | 66.5% | 792 | 66.5% | 907 | 66.5% |
| Gaston | 119 | 16.1% | 167 | 16.1% | 192 | 16.1% | 219 | 16.1% |
| Catawba | 87 | 11.8% | 122 | 11.8% | 140 | 11.8% | 160 | 11.8% |
| Mecklenburg | 26 | 3.5% | 37 | 3.5% | 42 | 3.5% | 48 | 3.5% |
| Other* | 16 | 2.2% | 23 | 2.2% | 26 | 2.2% | 30 | 2.2% |
| Total | 740 | 100.0% | 1,041 | 100.0% | 1,192 | 100.0% | 1,364 | 100.0% |

Source: Section C, pages 29 and 32

*Other includes Caldwell, Cleveland, Iredell, Rowan, Rutherford, and Union counties, as well as other states.

| CT Scanner – Current and Projected Patient Origin | | | | | | | | |
|---|-----------------|---------------|-----------------|---------------|-----------------|---------------|-----------------|---------------|
| County | CY 2020 | | FY 1 – CY 2023 | | FY 2 – CY 2024 | | FY 3 – CY 2025 | |
| | # of HECT Units | % of Total | # of HECT Units | % of Total | # of HECT Units | % of Total | # of HECT Units | % of Total |
| Lincoln | 347 | 68.8% | 528 | 68.8% | 651 | 68.8% | 803 | 68.8% |
| Gaston | 73 | 14.4% | 111 | 14.4% | 137 | 14.4% | 168 | 14.4% |
| Catawba | 71 | 14.1% | 108 | 14.1% | 133 | 14.1% | 165 | 14.1% |
| Mecklenburg | 8 | 1.7% | 13 | 1.7% | 16 | 1.7% | 20 | 1.7% |
| Other* | 5 | 1.0% | 8 | 1.0% | 10 | 1.0% | 12 | 1.0% |
| Total | 504 | 100.0% | 767 | 100.0% | 947 | 100.0% | 1,168 | 100.0% |

Source: Section C, pages 29 and 32

*Other includes Caldwell and Cabarrus counties, as well as other states.

| Bone Density Scans – Current and Projected Patient Origin | | | | | | | | |
|---|---------------|---------------|----------------|---------------|----------------|---------------|----------------|---------------|
| County | CY 2020 | | FY 1 – CY 2023 | | FY 2 – CY 2024 | | FY 3 – CY 2025 | |
| | # of Patients | % of Total | # of Patients | % of Total | # of Patients | % of Total | # of Patients | % of Total |
| Lincoln | 292 | 74.1% | 446 | 74.1% | 534 | 74.1% | 641 | 74.1% |
| Gaston | 52 | 13.2% | 79 | 13.2% | 95 | 13.2% | 114 | 13.2% |
| Catawba | 32 | 8.1% | 49 | 8.1% | 59 | 8.1% | 70 | 8.1% |
| Mecklenburg | 15 | 3.8% | 23 | 3.8% | 27 | 3.8% | 33 | 3.8% |
| Other* | 3 | 0.8% | 5 | 0.8% | 5 | 0.8% | 7 | 0.8% |
| Total | 394 | 100.0% | 601 | 100.0% | 721 | 100.0% | 865 | 100.0% |

Source: Section C, pages 30 and 33

*Other includes Lee, Moore, and Union counties, as well as other states.

| MRI Scans (Weighted) – Projected Patient Origin | | | | | | |
|---|----------------|---------------|----------------|---------------|----------------|---------------|
| County | FY 1 – CY 2023 | | FY 2 – CY 2024 | | FY 3 – CY 2025 | |
| | # of Patients | % of Total | # of Patients | % of Total | # of Patients | % of Total |
| Lincoln | 1,954 | 75.0% | 2,613 | 75.0% | 2,957 | 75.0% |
| Gaston | 328 | 12.6% | 439 | 12.6% | 497 | 12.6% |
| Catawba | 208 | 8.0% | 279 | 8.0% | 315 | 8.0% |
| Mecklenburg | 18 | 0.7% | 24 | 0.7% | 28 | 0.7% |
| Other* | 96 | 3.7% | 129 | 3.7% | 146 | 3.7% |
| Total | 2,605 | 100.0% | 3,484 | 100.0% | 3,942 | 100.0% |

Source: Section C, page 31

*Other includes Alexander, Burke, Cabarrus, Caldwell, Cleveland, Davidson, Iredell, McDowell, Pender, Rutherford, Scotland, and Wilkes counties, as well as other states.

| CIS-Denver Entire Facility – Projected Patient Origin | | | | | | |
|--|-----------------------|-------------------|-----------------------|-------------------|-----------------------|-------------------|
| County | FY 1 – CY 2023 | | FY 2 – CY 2024 | | FY 3 – CY 2025 | |
| | # of Patients | % of Total | # of Patients | % of Total | # of Patients | % of Total |
| Lincoln | 8,178 | 71.0% | 9,611 | 71.2% | 10,843 | 71.3% |
| Gaston | 1,633 | 14.2% | 1,900 | 14.1% | 2,136 | 14.0% |
| Catawba | 1,120 | 9.7% | 1,303 | 9.7% | 1,470 | 9.7% |
| Mecklenburg | 316 | 2.7% | 356 | 2.6% | 398 | 2.6% |
| Other* | 274 | 2.4% | 324 | 2.4% | 361 | 2.4% |
| Total | 11,520 | 100.0% | 13,494 | 100.0% | 15,208 | 100.0% |

Source: Section C, page 33

*Other includes Alexander, Alleghany, Anson, Brunswick, Burke, Cabarrus, Caldwell, Cleveland, Forsyth, Iredell, Lee, McDowell, Mitchell, Moore, Polk, Randolph, Rowan, Rutherford, Stanly, Union, Wake, Wayne, and Wilkes counties, as well as other states.

In Section C, page 30, the applicant provides the assumptions and methodology used to project its patient origin. The applicant states its projected patient origin for all equipment except the fixed MRI scanner is based on historical patient origin and projected patient origin for the fixed MRI scanner is based on the projections in Project I.D. #F-11440-17. The applicant’s assumptions are reasonable and adequately supported based on the following:

- The applicant plans to offer the services being relocated within the same county and same health system.
- Despite minor discrepancies with the identification of counties for “Other” patients, the applicant uses the current patient origin of the equipment it proposes to relocate to project future patient origin and the projections are consistent with current patient origin.
- With regard to patient origin, Project I.D. #F-11440-17 was found conforming with this criterion and the applicant proposes no changes in the application as submitted which would affect that determination.

Analysis of Need

In Section C, pages 35-44, the applicant explains why it believes there is a need to change the scope of Project I.D. #F-11440-17 by developing a new diagnostic center instead of developing a freestanding MRI facility, as summarized below:

- Need for a Freestanding Diagnostic Center in Lincoln County: the applicant states there are no freestanding diagnostic centers in Lincoln County; the only option for diagnostic imaging for residents of eastern Lincoln County is at Atrium Health Lincoln Imaging Center (AH-LIC), where all equipment except the fixed MRI is currently located, and that facility uses a hospital-based billing structure. Developing a freestanding diagnostic center will result in lower out-of-pocket costs for patients. The applicant states that, despite only having access to hospital-based diagnostic imaging equipment, patients utilized the diagnostic imaging equipment at significant volumes.

- Need to Co-Locate Equipment at Link Landing: in a material compliance approval issued on May 21, 2020, CMHA was authorized to locate the new freestanding MRI facility at Link Landing, a medical office building, instead of at the site proposed in Project I.D. #F-11440-17. The applicant states it is also planning to develop physician offices at the same location. The applicant states locating all the diagnostic imaging equipment at the same site will be more convenient for patients and providers and help eliminate duplicative components like waiting rooms.
- Need for Newer Technology in Equipment and Facility: the applicant states the equipment being replaced is all at least 10 years old, and some units are older, and do not have the latest technology and features. The applicant states replacing the existing equipment will enhance the diagnostic imaging services it can provide to patients. The applicant also states that new technology may require upgraded electrical and HVAC systems, and the ability to upgrade that infrastructure is limited where the equipment is currently located.
- Population Growth in Lincoln County: the applicant states historical growth of the population age 65 and older in Lincoln County is more than twice the growth rate of Lincoln County as a whole, and that trend is projected to continue going forward.
- Need to Change Ownership of Fixed MRI and Other Equipment: the applicant states it believes it can develop the most optimal lease agreement for the proposed project if the fixed MRI is owned by CMHA instead of UMS. The applicant further states it believes transferring ownership of the other diagnostic imaging equipment to CIS is the most optimal way to develop the project as proposed.

On Form F.1b in Section Q, the applicant provides a summary of the capital cost approved in Project I.D. #F-11440-17, the changes proposed in this application, and the new projected capital cost, as shown in the table below.

| Comparison of Capital Expenditures | | | |
|---|---------------------------------|---------------------|--------------------|
| | Project I.D. #F-11440-17 | New Proposed | New Total |
| Construction/Renovation Contracts | \$1,174,000 | \$1,446,180 | \$2,620,180 |
| Architect/Engineering Fees | \$145,400 | -\$6,400 | \$139,000 |
| Medical Equipment | \$1,570,000 | \$737,720 | \$2,307,720 |
| Non-Medical Equipment/Furniture | \$207,000 | \$85,750 | \$292,750 |
| Consultant Fees | \$65,000 | \$60,587 | \$125,587 |
| Other | \$720,000 | -\$494,670 | \$225,330 |
| Total | \$3,881,400 | \$1,829,167 | \$5,710,567 |

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

- The applicant provides information about why the proposed changes to Project I.D. #F-11440-17 will benefit the residents of Lincoln County.
- The applicant explains why the equipment to be relocated should also be replaced.

- The applicant uses publicly available information to document the population increase in Lincoln County.

Projected Utilization

On Form C.2b in Section Q, the applicant projects utilization for the first three fiscal years of operation following project completion, as shown in the table below.

| CIS – Denver Projected Utilization – FYs 1-3 (CYs 2023-2025) | | | |
|---|-----------------------|-----------------------|-----------------------|
| Component | FY 1 (CY 2023) | FY 2 (CY 2024) | FY 3 (CY 2025) |
| CT Scanner – Units | 1 | 1 | 1 |
| CT Scanner – Scans | 454 | 560 | 691 |
| CT Scanner – HECT Units | 767 | 947 | 1,168 |
| Fixed X-Ray Machine – Units | 1 | 1 | 1 |
| Fixed X-Ray Machine – Tests | 1,746 | 1,814 | 1,886 |
| Mammography – Units | 1 | 1 | 1 |
| Mammography – Tests | 4,759 | 5,336 | 5,983 |
| Fixed MRI Scanner – Units | 1 | 1 | 1 |
| Fixed MRI Scanner – Scans | 2,344 | 3,135 | 3,547 |
| Fixed MRI Scanner – Weighted Procedures | 2,605 | 3,484 | 3,942 |
| Ultrasound Machines – Units | 1 | 1 | 1 |
| Ultrasound Machines – Tests | 1,041 | 1,192 | 1,364 |
| Bone Density Scanner – Units | 1 | 1 | 1 |
| Bone Density Scanner – Scans | 601 | 721 | 865 |
| Total Tests* | 10,945 | 12,758 | 14,336 |

*Does not include HECT Units or Weighted MRI Procedures

In Section C, pages 39-40, and in the Form C Utilization – Assumptions and Methodology subsection of Section Q, 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* |
| Mammography Unit | 1 | 4 | 8 | 250 | 8,000 |
| X-ray Unit | 1 | 4 | NA** | 250 | NA** |
| Ultrasound Unit | 1 | 2 | 8 | 250 | 4,000 |
| Bone Density Scanner | 1 | 3 | NA** | 250 | NA** |
| Fixed MRI Scanner*** | 1 | NA | NA | NA | 6,864 |
| CT Scanner (HECT Units)**** | 1 | NA | NA | NA | 5,100 |

Source: Section C, page 39; Form C Utilization – Assumptions and Methodology subsection of Section Q

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

**No dedicated staff, so no hours per day or maximum capacity

***Based on definition of capacity in Chapter 17 in the 2021 SMFP.

****Based on definition of capacity in 10A NCAC 14C .2701(2).

In the Form C Utilization – Assumptions and Methodology subsection of Section Q, the applicant provides the assumptions and methodology used to project utilization, as summarized below.

Except for the fixed MRI scanner approved in Project I.D. #F-11440-17, the applicant uses “normalized” CY 2020 data. The applicant explains the impact of the COVID-19 pandemic on utilization and describes how it calculated “normalized” CY 2020 data using historical data instead of annualizing data from months in CY 2020 where COVID-19 did not impact utilization as much as others. The applicant also explains why it believes the impact of COVID-19 on utilization is temporary and why utilization is expected to rebound.

Fixed MRI Scanner

- The applicant states the projections it made for utilization of a fixed MRI scanner in Project I.D. #F-11440-17 are still reasonable to use for this application.
- The applicant states the utilization projections were based on an average annual increase in MRI scanner utilization by Lincoln County residents, regardless of location, of 4.7 percent between FFYs 2011-2016. The applicant provides utilization data for MRI scanner utilization by Lincoln County residents for FFYs 2016-2019, Lincoln County patients at Atrium Health Lincoln for FFYs 2016-2019, and all patients at Atrium Health Lincoln for FFYs 2016-2019. All three sets of data have higher Compound Annual Growth Rates (CAGRs) than 4.7 percent.
- The Project Analyst also reviewed the License Renewal Applications (LRAs) for Atrium Health Lincoln for FFYs 2015-2019. The Project Analyst did not include inpatient MRI procedures in the analysis, since they will not be provided at the diagnostic center. The number of outpatient MRI procedures at Atrium Health Lincoln grew at 4-year CAGR of 6.2 percent – even with a slight decrease in utilization between FFY 2018 and 2019.
- The utilization projections in Project I.D. #F-11440-17 were found to be reasonable and adequately supported and nothing in the current application as submitted would affect that determination.

Mammography Unit

- The applicant states internal data from AH-LIC shows mammography utilization increased by 12.1 percent between CYs 2018-2019 and increased at a 2-year CAGR of 19.8 percent between CYs 2018-2020 normalized.
- The applicant states volume from a newly formed medical practice comprised 24 percent of utilization in CY 2020 normalized. The applicant further states that since the location of the diagnostic center will be in the same building as the medical practice it is reasonable to believe the medical practice will continue to contribute to growth of mammogram utilization.

- The applicant states it projects growth in mammogram utilization between CYs 2020-2022 at an annual growth rate of 1.2 percent, which is the projected growth rate of the Lincoln County population between 2021-2025. The applicant's data is from the North Carolina Office of State Budget and Management (NC OSBM).
- The applicant states it projects growth in mammogram utilization between CYs 2023-2025 at a rate of 12.1 percent, which is the lower of the two annual growth rates calculated by the applicant for historical mammogram utilization.
- The applicant projects to perform 5,983 mammograms at CIS-Denver in CY 2025. Based on the calculated maximum capacity of the mammography unit, the applicant projects the mammography unit will be utilized at 74.8 percent of capacity in CY 2025.

X-ray Machine

- The applicant states internal data from AH-LIC shows x-ray utilization increased by 9.9 percent between CYs 2018-2019 and increased at a 2-year CAGR of 3.9 percent between CYs 2018-2020 normalized.
- The applicant states volume from a newly formed medical practice has contributed to increases in utilization, though not at the same volume as with mammograms. The applicant further states that since the location of the diagnostic center will be in the same building as the medical practice it is reasonable to believe the medical practice will continue to contribute to growth of x-ray utilization.
- The applicant states that, based on the projected growth rate of the population of Lincoln County as published by NC OSBM, it projects growth in x-ray utilization at CIS-Denver at an annual growth rate of 1.2 percent between CYs 2020-2022.
- The applicant states it projects growth in x-ray utilization between CYs 2023-2025 at a rate of 3.9 percent, which is the lower of the two annual growth rates calculated by the applicant for historical x-ray utilization.
- The applicant projects to perform 1,886 x-rays at CIS-Denver in CY 2025. The applicant states the x-ray machine does not have dedicated staff and is utilized based on physician need; therefore, there is no maximum annual utilization calculated for the x-ray machine. While there is no maximum annual utilization calculated, the applicant states that if the x-ray machine was staffed eight hours per day, the maximum annual capacity of the x-ray machine would be 8,000 x-rays.

Ultrasound Machine

- The applicant states internal data from AH-LIC shows ultrasound utilization increased by 27.6 percent between CYs 2018-2019 and increased at a 2-year CAGR of 14.5 percent between CYs 2018-2020 normalized.

- The applicant states volume from a newly formed medical practice has contributed to increases in utilization, though not at the same volume as with mammograms. The applicant further states that since the location of the diagnostic center will be in the same building as the medical practice it is reasonable to believe the medical practice will continue to contribute to growth of ultrasound utilization.
- The applicant states that, based on the projected growth rate of the population of Lincoln County as published by NC OSBM, it projects growth in ultrasound utilization at CIS-Denver at an annual growth rate of 1.2 percent between CYs 2020-2022.
- The applicant states it projects growth in ultrasound utilization between CYs 2023-2025 at a rate of 14.5 percent, which is the lower of the two annual growth rates calculated by the applicant for historical ultrasound utilization.
- The applicant projects to perform 1,364 ultrasounds at CIS-Denver in CY 2025. Based on the calculated maximum capacity of the ultrasound machine, the applicant projects the ultrasound machine will be utilized at 34.1 percent of capacity in CY 2025.

CT Scanner

- The applicant states internal data from AH-LIC shows HECT units increased by 36.0 percent between CYs 2018-2019 and increased at a 2-year CAGR of 23.4 percent between CYs 2018-2020 normalized.
- The applicant states volume from a newly formed medical practice has contributed to increases in utilization, though not at the same volume as with mammograms. The applicant further states that since the location of the diagnostic center will be in the same building as the medical practice it is reasonable to believe the medical practice will continue to contribute to growth of CT scanner utilization.
- The applicant states that, based on the projected growth rate of the population of Lincoln County as published by NC OSBM, it projects HECT units from CT scanner utilization at CIS-Denver will increase at an annual growth rate of 1.2 percent between CYs 2020-2022.
- The applicant states it projects HECT units from CT scanner utilization will increase between CYs 2023-2025 at a rate of 23.4 percent, which is the lower of the two annual growth rates calculated by the applicant for historical HECT units from CT scanner utilization.
- The applicant projects to perform 1,168 HECT units on the CT scanner at CIS-Denver in CY 2025. Based on the calculated maximum capacity of the CT scanner, the applicant projects the CT scanner will be utilized at 22.9 percent of capacity in CY 2025.

Bone Density Scanner

- The applicant states internal data from AH-LIC shows bone density scanner utilization increased by 39.9 percent between CYs 2018-2019 and increased at a 2-year CAGR of 48.1 percent between CYs 2018-2020 normalized.
- The applicant states volume from a newly formed medical practice has contributed to increases in utilization, though not at the same volume as with mammograms. The applicant further states that since the location of the diagnostic center will be in the same building as the medical practice it is reasonable to believe the medical practice will continue to contribute to growth of bone density scanner utilization.
- The applicant states that, based on the projected growth rate of the population of Lincoln County as published by NC OSBM, it projects growth in bone density scanner utilization at CIS-Denver at an annual growth rate of 1.2 percent between CYs 2020-2022.
- The applicant states it projects growth in bone density scanner utilization between CYs 2023-2025 at a rate of 20 percent, which is one half of the lower of the two annual growth rates calculated by the applicant for historical bone density scanner utilization.
- The applicant projects to perform 865 bone density scans at CIS-Denver in CY 2025. The applicant states the bone density scanner does not have dedicated staff and is utilized based on physician need; therefore, there is no maximum annual utilization calculated for the bone density scanner. While there is no maximum annual utilization calculated, the applicant states that if the bone density scanner was staffed eight hours per day, the maximum annual capacity of the bone density scanner would be 6,000 scans.

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

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

Access to Medically Underserved Groups

In Section C, page 50, the applicant states:

“CMHA and CIS are committed to providing services to all patients regardless of income, racial/ethnic origin, gender, physical or mental conditions, age, ability to pay, or any other factor that would classify a patient as underserved. Diagnostic imaging services at CIS-Denver will be available to and accessible by any patient who has a clinical need for such services.”

In Section C, page 51, the applicant provides the estimated percentage of patients it projects to serve in CY 2025, its third full fiscal year of operation, for each medically underserved group, as shown in the following table.

| Medically Underserved Groups | Percentage of Total Patients |
|-------------------------------------|-------------------------------------|
| Racial and ethnic minorities | 23.2% |
| Women | 73.6% |
| Persons 65 and older | 43.4% |
| Medicare beneficiaries | 44.1% |
| Medicaid recipients | 5.0% |

The applicant states on page 51 that it does not keep records on the number of low-income persons or persons with disabilities that it serves, but that neither of those groups are denied access to the proposed services.

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

- The applicant provides a statement that it will provide access to the proposed services for underserved groups.
- The applicant provides a copy of the Non-Discrimination Policies it will use at CIS-Denver in Exhibit C.6-1 and a copy of the CIS Service Provision & Collection Policy in Exhibit C.6-2.

Conclusion

The Agency reviewed the:

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

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

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

C

The applicant proposes a cost overrun and change of scope to Project I.D. #F-11440-17. Instead of developing a freestanding MRI facility, the applicant proposes to develop a new diagnostic center by replacing and relocating diagnostic imaging equipment and developing the fixed MRI scanner all in the same location.

In Section D, page 59, 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:

“CMHA and CIS are fully committed to ensuring access to the utmost high quality healthcare services and offering patients with a seamless continuum of care. ...the replacement of one CT scanner, one X-ray unit, one ultrasound unit, and one bone density scanner included as part of the proposed project will result in up-to-date equipment with improved capabilities for optimal patient care, as well as a more modern and geographically and financially accessible diagnostic center than the existing Atrium Health Lincoln Imaging Center. Upon completion of the proposed project, Atrium Health Lincoln Imaging Center will cease to exist. At such time, CMHA and CMHA-affiliated physicians in the area that currently refer patients to Atrium Health Lincoln and Atrium Health Lincoln Imaging Center will begin referring outpatient diagnostic imaging patients to CIS-Denver, providing the residents of Lincoln County and the surrounding area with access to lower-cost, freestanding diagnostic imaging services and maintaining the continuity of their care.”

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

- The applicant projects to serve existing patients at the new facility.
- The applicant’s proposal will make costs of the services more affordable for the existing patients.

On Form D.2 in Section Q, the applicant provides projected utilization, as illustrated in the following table.

| AH-LIC Projected Utilization – CYs 2020 normalized through May 31, 2022 | | | |
|--|---------------------------|----------------|-------------------------|
| Component | CY 2020 normalized | CY 2021 | 1/1/22 – 5/31/22 |
| CT Scanner – Units | 1 | 1 | 1 |
| CT Scanner – Scans | 359 | 364 | 152 |
| CT Scanner – HECT Units | 608 | 615 | 257 |
| Fixed X-Ray Machine – Units | 1 | 1 | 1 |
| Fixed X-Ray Machine – Tests | 1,641 | 1,660 | 695 |
| Mammography – Units | 1 | 1 | 1 |
| Mammography – Tests | 4,145 | 4,195 | 1,756 |
| Ultrasound Machines – Units | 1 | 1 | 1 |
| Ultrasound Machines – Tests | 888 | 898 | 376 |
| Bone Density Scanner – Units | 1 | 1 | 1 |
| Bone Density Scanner – Scans | 489 | 495 | 207 |

In the Form C Utilization – Assumptions and Methodology subsection of Section Q, the applicant provides the assumptions and methodology used to project utilization, as summarized below.

- The applicant uses “normalized” CY 2020 data. The applicant explains the impact of the COVID-19 pandemic on utilization and describes how it calculated “normalized” CY 2020 data using historical data instead of annualizing data from months in CY 2020 where COVID-19 did not impact utilization as much as others. The applicant also explains why it believes the impact of COVID-19 on utilization is temporary and why utilization is expected to rebound.
- The applicant states that, according to NC OSBM, the projected annual growth rate of the Lincoln County population between 2021-2025 is 1.2 percent.
- The applicant projects utilization of the existing equipment will grow at an annual rate of 1.2 percent through the end of CY 2022. This growth rate is lower than the growth rate based on historical utilization of the equipment.
- CIS-Denver is projected to offer services on June 1, 2022. The applicant calculated utilization between January 1, 2022 and May 31, 2022 based on the percentage of days in that time period as compared with the entire year.

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

- Projected utilization is based on population growth and is lower than historical growth.
- The applicant uses conservative projected growth rates.
- The applicant uses data from reliable sources.

Access to Medically Underserved Groups

In Section D, page 60, the applicant states:

“...CMHA and CIS are committed to providing services to all patients regardless of income, racial/ethnic origin, gender, physical or mental conditions, age, ability to pay, or any other factor that would classify a patient as underserved. Diagnostic imaging services at CIS-Denver will be available to and accessible by any patient who has a clinical need for such services. As such, the proposed project, which includes the elimination of the existing service components at Atrium Health Lincoln Imaging Center, will have a positive impact on the ability for medically underserved populations to access to [sic] lower-cost, freestanding outpatient diagnostic imaging services while maintaining the continuity of their care.”

The applicant adequately demonstrates that the needs of medically underserved groups that will continue to use the equipment at AH-LIC and that will be relocated to CIS-Denver will be adequately met following completion of the project for the following reasons:

- The applicant provides a statement that it will provide access to the proposed services for underserved groups.
- The applicant provides a copy of the Non-Discrimination Policies it will use at CIS-Denver in Exhibit C.6-1 and a copy of the CIS Service Provision & Collection Policy in Exhibit C.6-2.

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 demonstrates that the needs of the population currently using the services to be reduced, eliminated or relocated will be adequately met following project completion for all the reasons described above.
 - The applicant adequately demonstrates that the project will not adversely impact the ability of underserved groups to access these services following project completion for all the reasons described above.
- (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 a cost overrun and change of scope to Project I.D. #F-11440-17. Instead of developing a freestanding MRI facility, the applicant proposes to develop a new diagnostic center by replacing and relocating diagnostic imaging equipment and developing the fixed MRI scanner all in the same location.

In Section E, pages 63-64, 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:

- Maintain the Status Quo: The applicant states maintaining the status quo would prevent the acquisition, relocation, and replacement of diagnostic imaging equipment and would leave residents of Lincoln County without any access to non-hospital based diagnostic imaging services within the county. The applicant determined this was not an effective alternative.
- Replace/Relocate a Different Combination of Equipment/Acquire New Equipment: The applicant states purchasing new diagnostic imaging equipment would result in an unnecessary duplication of resources in Lincoln County. The applicant also states that splitting up diagnostic imaging equipment between two locations is not cost-effective. The applicant determined these related alternatives were not effective alternatives.
- Develop CIS-Denver at a Different Location: The applicant states developing the diagnostic center on the campus of Atrium Health Lincoln, on the site of the existing Atrium Health Lincoln Imaging Center, would not be an effective alternative due to space constraints and its location on a smaller and less traveled road. The applicant states developing the diagnostic center where originally proposed is also less effective because the site chosen in Project I.D. #F-11440-17 is also on a smaller and less traveled road. The applicant determined these alternative sites were not effective alternatives.

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

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

- 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 Imaging Services, LLC and The Charlotte-Mecklenburg Hospital Authority (hereinafter certificate holder) shall materially comply with the representations in this application, the representations in Project I.D. #F-11440-17, and any supplemental information. Where representations conflict, the certificate holder shall materially comply with the last made representation.**
- 2. The certificate holder shall develop a new diagnostic center, Carolinas Imaging Services – Denver, by developing the fixed MRI scanner approved in Project I.D. #F-11440-17 and relocating and replacing a CT scanner, mammography unit, X-ray machine, ultrasound machine, and bone density scanner from Atrium Health Lincoln Imaging Center.**
- 3. Upon completion of the project, Carolinas Imaging Center – Denver will have no more than one fixed MRI scanner.**
- 4. The approved combined capital expenditure for both Project I.D. #F-11440-17 and this project is \$5,710,567, an increase of \$1,829,167 over the previously approved capital expenditure of \$3,881,400 in Project I.D. #F-11440-17.**
- 5. The certificate holder shall not acquire as part of this project any equipment that is not included in the project’s proposed capital expenditures in Section Q of the application and that would otherwise require a certificate of need.**
- 6. Progress Reports:**
 - a. Pursuant to G.S. 131E-189(a), the certificate holder shall submit periodic reports on the progress being made to develop the project consistent with the timetable and representations made in the application on the Progress Report form provided by the Healthcare Planning and Certificate of Need Section. The form is available online at <https://info.ncdhhs.gov/dhsr/coneed/progressreport.html>.**
 - b. The certificate holder shall complete all sections of the Progress Report form.**
 - c. The certificate holder shall describe in detail all steps taken to develop the project since the last progress report and should include documentation to substantiate each step taken as available.**

- d. Progress reports shall be due on the first day of every third month. The first progress report shall be due on November 1, 2021. The second progress report shall be due on February 1, 2022 and so forth.**

 - 7. 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 certificate holders 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.**

 - 8. The certificate holder shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Certificate of Need Section in writing prior to issuance of the certificate of need.**
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

The applicant proposes a cost overrun and change of scope to Project I.D. #F-11440-17. Instead of developing a freestanding MRI facility, the applicant proposes to develop a new diagnostic center by replacing and relocating diagnostic imaging equipment and developing the fixed MRI scanner all in the same location.

Capital and Working Capital Costs

On Form F.1b in Section Q, the applicant provides a summary of the capital cost approved in Project I.D. #F-11440-17, the changes proposed in this application, and the new projected capital cost, as shown in the table below.

| Comparison of Capital Expenditures | | | |
|---|---------------------------------|---------------------|--------------------|
| | Project I.D. #F-11440-17 | New Proposed | New Total |
| Construction/Renovation Contracts | \$1,174,000 | \$1,446,180 | \$2,620,180 |
| Architect/Engineering Fees | \$145,400 | -\$6,400 | \$139,000 |
| Medical Equipment | \$1,570,000 | \$737,720 | \$2,307,720 |
| Non-Medical Equipment/Furniture | \$207,000 | \$85,750 | \$292,750 |
| Consultant Fees | \$65,000 | \$60,587 | \$125,587 |
| Other | \$720,000 | -\$494,670 | \$225,330 |
| Total | \$3,881,400 | \$1,829,167 | \$5,710,567 |

Immediately following Form F.1b in Section Q, in Section C, pages 54-55, and in supplemental information, the applicant provides the assumptions used to project the capital cost. The applicant adequately demonstrates that the projected capital cost is based on reasonable and adequately supported assumptions based on the following:

- The applicant explains in detail the items in each category projecting an increase from the originally approved capital expenditure.
- The applicant provides a quote for the MRI which reflects the lower cost than proposed in Project I.D. #F-11440-17.
- The applicant provides floor plans showing updated designs in Exhibit C.1-5.
- The applicant provides vendor quotes for the replacement equipment in Exhibit C.4-1.
- The applicant provides a certified cost estimate signed by an architect in Exhibit F.1.

In Section F, page 69, the applicant projects start-up costs of \$306,747 and initial operating costs of \$417,176 for a total projected working capital cost of \$723,923, an increase of \$595,985 over the total projected working capital cost of \$127,938 approved in Project I.D. #F-11440-17. In Section F, pages 69 and 74-75, the applicant provides the assumptions and methodology used to project the working capital needs of the project. The applicant adequately demonstrates that the projected working capital needs of the project are based on reasonable and adequately supported assumptions based on the following:

- The applicant explains the factors used in projecting the estimated start-up costs and the time period involved.
- The applicant explains the factors used in projecting the initial operating costs.
- The applicant’s explanation for the increase in projected total working capital costs is reasonable and adequately supported.

Availability of Funds

In Section F, pages 67-68, the applicant states the capital costs will be funded with accumulated reserves and divided as shown in the table below.

| Capital Costs | |
|---------------------------------|--------------------|
| CMHA (via accumulated reserves) | \$3,000,000 |
| CIS (via accumulated reserves) | \$2,710,567 |
| Total | \$5,710,567 |

In Section F, page 70, the applicant states the \$723,923 in working capital costs will be funded with the accumulated reserves of CIS.

In Exhibit F.2-1, the applicant provides the funding letter from CMHA included with Project I.D. #F-11440-17, which committed to funding the original capital cost of \$3,881,400. In Exhibit F.2-2, the applicant provides a letter signed by a Board Manager for CIS, committing to funding the difference in cost between the two projects (\$1,829,167) in addition to up to \$1 million in working capital costs. In supplemental information, the applicant provided an additional letter from the same Board Manager for CIS, clarifying that while the overall difference in cost between the two projects is \$1,829,167, CIS will commit to funding up to \$2,710,567 of the capital cost.

Publicly available information – the application and exhibits for Project I.D. #F-12025-21 – contains a copy of Atrium’s Basic Financial Statements and Other Financial Information for the year ending December 31, 2019. According to the Basic Financial Statements, as of December 31, 2019, Atrium had adequate cash and assets to fund its share of the capital needs of the proposed project. Exhibit F.2-3 contains a balance sheet for CIS as of February 28, 2021. According to the balance sheet, as of February 28, 2021, CIS had adequate cash and assets to fund its share of the capital needs and all the working capital needs of the proposed project.

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

- The applicant provides documentation from Project I.D. #F-11440-17 to demonstrate the availability of funding for Atrium’s share of the capital costs.
- The applicant provides documentation of the commitment of CIS to fund its share of the capital costs and all of the working capital costs.
- Between publicly available information and information provided by the applicant in Exhibit F.2-3, the applicant provides adequate documentation of the accumulated reserves it proposes to use to fund the capital needs of the project.

Financial Feasibility

The applicant provided pro forma financial statements for the first three full fiscal years of operation following project completion. In Form F.2b, the applicant projects revenues will exceed operating expenses in the second and third full fiscal years following project completion, as shown in the table below.

| Revenues and Operating Expenses – CIS-Denver | | | |
|---|---|---|---|
| | 1st Full FY CY 2023 | 2nd Full FY CY 2024 | 3rd Full FY CY 2025 |
| Total Tests/Procedures | 10,945 | 12,758 | 14,336 |
| Total Gross Revenues (Charges) | \$7,911,721 | \$10,107,023 | \$11,820,859 |
| Total Net Revenue | \$2,567,304 | \$3,266,140 | \$3,818,785 |
| Total Net Revenue per Test | \$235 | \$256 | \$266 |
| Total Operating Expenses (Costs) | \$2,814,346 | \$3,134,613 | \$3,398,013 |
| Total Operating Expenses per Test | \$257 | \$246 | \$237 |
| Net Income/(Loss) | (\$247,041) | \$131,527 | \$420,772 |

The assumptions used by the applicant in preparation of the pro forma financial statements are provided immediately following Form F.3b in Section Q. The applicant adequately demonstrates that the financial feasibility of the proposal is reasonable and adequately supported based on the following:

- The applicant clearly details the sources of data used to project revenues and expenses.
- The applicant based its projections on its own historical experience.
- Projected utilization is based on reasonable and adequately supported assumptions. See the discussion regarding projected utilization in Criterion (3) which is incorporated herein by reference.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- 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 demonstrates that the capital and working capital costs are based on reasonable and adequately supported assumptions for all the reasons described above.

- The applicant adequately demonstrates availability of sufficient funds for the capital and working capital needs of the proposal for all the reasons described above.
 - The applicant adequately demonstrates sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of revenues and operating expenses for all the reasons described above.
- (6) The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

C

The applicant proposes a cost overrun and change of scope to Project I.D. #F-11440-17. Instead of developing a freestanding MRI facility, the applicant proposes to develop a new diagnostic center by replacing and relocating diagnostic imaging equipment and developing the fixed MRI scanner all in the same location.

On page 344, the 2021 SMFP defines the service area for fixed MRIs as “...*the same as an Acute Care Bed Service Area as defined in Chapter 5 and shown in Figure 5.1.*” Figure 5.1 on page 36 of the 2021 SMFP shows Lincoln County as its own acute care bed service area. Thus, the service area for this project is Lincoln County. Facilities may also serve residents of counties not included in their service area.

Table 17E-1 on page 355 of the 2021 SMFP shows the only fixed MRI scanner currently operational in Lincoln County is located at Atrium Health Lincoln.

In Section G, page 76, the applicant states its service area for CIS-Denver’s other modalities includes Lincoln, Gaston, Catawba, and Mecklenburg counties. The applicant lists the existing hospitals in those counties, and states that while the hospitals may provide the same kind of diagnostic imaging services, they would be hospital-based and not done in a freestanding diagnostic imaging center. The applicant further states it is not aware of an existing public data source that would provide the inventory of the non-MRI equipment that are part of this application. On page 77, the applicant lists the existing and approved diagnostic centers owned or operated by the applicant or a related entity.

In Section G, page 77, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved diagnostic center services in Lincoln County. The applicant states:

“...there are currently no freestanding outpatient diagnostic centers in Lincoln County. Upon approval of the proposed project, CIS-Denver will serve as a low-cost, convenient, outpatient alternative to hospital-based imaging services. While the proposed project does not include any new services, the proposed project will provide patients and staff with improved geographic and financial access to the only freestanding imaging services in Lincoln County, namely X-ray, ultrasound, mammography, CT, MRI and bone density. As such, the proposed project will not

result in an unnecessary duplication of the existing or approved health service facilities located in the proposed service area.”

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 CT scanners, ultrasounds, x-ray machines, mammography units, or bone density scanners in Lincoln County.
- There are not currently any existing or approved freestanding diagnostic imaging centers in Lincoln County.
- Project I.D. #F-11440-17 was found conforming with this criterion and there is nothing in the application as submitted which would affect that determination.

Conclusion

The Agency reviewed the:

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

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

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

C

The applicant proposes a cost overrun and change of scope to Project I.D. #F-11440-17. Instead of developing a freestanding MRI facility, the applicant proposes to develop a new diagnostic center by replacing and relocating diagnostic imaging equipment and developing the fixed MRI scanner all in the same location.

On Form H in Section Q, the applicant provides projected full-time equivalent (FTE) staffing for the proposed services. The applicant projects to have four FTE radiology technologists and one FTE for clerical for a total of five FTEs for each of the first three operating years. In Section H, page 81, the applicant states the projected FTE staffing is different than that projected in Project I.D. #F-11440-17 because the proposed project involves additional service components.

The assumptions and methodology used to project staffing are provided immediately following Form H in Section Q. Adequate operating expenses for the health manpower and

management positions proposed by the applicant are budgeted on Form F.3b in Section Q. In Section H, pages 79-80, the applicant describes the methods to be used to recruit or fill new positions and its proposed training and continuing education programs.

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

- The applicant projects staffing based on its own experience operating diagnostic centers.
- The applicant adequately explains the need for additional staffing compared with projections in Project I.D. #F-11440-17.
- The applicant projects adequate operating expenses for the staff it proposes on Form H.
- Project I.D. #F-11440-17 was conforming with this criterion and the applicant proposes no changes in the application as submitted which would affect that determination.

Conclusion

The Agency reviewed the:

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

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

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

C

The applicant proposes a cost overrun and change of scope to Project I.D. #F-11440-17. Instead of developing a freestanding MRI facility, the applicant proposes to develop a new diagnostic center by replacing and relocating diagnostic imaging equipment and developing the fixed MRI scanner all in the same location.

Ancillary and Support Services

In Section I, page 82, the applicant identifies the necessary ancillary and support services for the proposed services. In Section I, pages 82-83, the applicant explains how each ancillary and support service is or will be made available and provides supporting documentation in

Exhibit I.1. The applicant adequately demonstrates that the necessary ancillary and support services will be made available based on the following:

- The applicant provides documentation of the availability of the necessary ancillary and support services.
- The applicant operates other diagnostic imaging centers and has experience in providing the necessary ancillary and support services.

Coordination

In Section I, pages 83-84, the applicant describes its existing and proposed relationships with other local health care and social service providers and provides supporting documentation in Exhibit I.2. The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system based on the following:

- While CIS-Denver is not an existing facility, the applicant has existing relationships with other local health care and service providers.
- The applicant provides documentation of its existing relationships with other local health care and service providers.

Conclusion

The Agency reviewed the:

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

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

- (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

The applicant proposes a cost overrun and change of scope to Project I.D. #F-11440-17. Instead of developing a freestanding MRI facility, the applicant proposes to develop a new diagnostic center by replacing and relocating diagnostic imaging equipment and developing the fixed MRI scanner all in the same location.

In Section K, page 86, the applicant states the proposed project involves the upfitting and renovation of 7,647 square feet of space in a medical office building currently under development. Line drawings are provided in Exhibit C.1-5.

While the proposed project does involve the development of a new facility, the location of the facility within a medical office building was approved in a request for a determination of material compliance issued by the Agency on May 21, 2020. The applicant also provides the proposed lease agreement in Exhibit C.1-2. The site appears to be suitable for the proposed diagnostic center based on the applicant's representations and supporting documentation.

On page 87, the applicant adequately explains how the cost, design, and means of construction represent the most reasonable alternative for the proposal based on the following:

- Developing the diagnostic center in a medical office building being constructed by a third party allows the construction costs to be paid over time via a lease agreement.
- The upfit and renovation is taking place at the same time the medical office building is being constructed which allows for the design to better fit the proposed diagnostic center and is more cost-effective than upfitting and renovating existing space.
- The applicant is utilizing accumulated reserves to develop the proposed project which will not result in an increase in costs or charges.

On page 87, 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 based on the following:

- The applicant is utilizing accumulated reserves to develop the proposed project which will not result in an increase in costs or charges.
- The proposed project will put the diagnostic imaging equipment in the same building as the providers who order the tests and will save patients travel time.
- The proposed project will lower the costs and charges to the public by creating a freestanding diagnostic center instead of keeping the existing hospital-based diagnostic center.

On pages 87-88, 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
- Information publicly available during the review and used by the Agency

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

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

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

C

CIS-Denver is not an existing facility. However, there are existing assets that will be relocated from AH-LIC to CIS-Denver.

In Section L, page 93, the applicant provides the historical payor mix during CY 2020 for the existing services at AH-LIC, as shown in the table below.

| AH-LIC Historical Payor Mix CY 2020 | |
|--|----------------------------|
| Payment Source | % of Total Patients |
| Self-Pay | 2.0% |
| Medicare* | 39.9% |
| Medicaid* | 3.9% |
| Insurance* | 52.0% |
| Other (Other gov't, workers comp) | 2.2% |
| Total | 100.0% |

*Including any managed care plans

In Section L, page 94, the applicant provides the following comparison.

| | % of Total Patients Served by AH-LIC during CY 2020 | % of the Population of Lincoln County |
|-------------------------------------|--|--|
| Female | 78.9% | 50.4% |
| Male | 21.1% | 49.6% |
| Unknown | 0.0% | 0.0% |
| 64 and Younger | 61.1% | 82.1% |
| 65 and Older | 38.9% | 17.9% |
| American Indian | 0.2% | 0.5% |
| Asian | 0.5% | 0.8% |
| Black or African-American | 3.5% | 5.8% |
| Native Hawaiian or Pacific Islander | 0.1% | 0.1% |
| White or Caucasian | 80.3% | 91.3% |
| Other Race | 0.0% | 1.5% |
| Declined / Unavailable | 15.4% | 0.0% |

Sources: Atrium Internal Data, US Census Bureau

On page 94, the applicant states that two of its services are provided predominantly to women, which is the reason for the difference between the population by gender and patients served.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

CIS-Denver is not an existing facility. However, there are existing assets that will be relocated from AH-LIC to CIS-Denver.

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L, page 95, the applicant states AH-LIC has no such obligation.

In Section L, page 95, the applicant states that during the 18 months immediately preceding the application deadline, no patient civil rights access complaints have been filed against AH-LIC.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (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 95, the applicant projects the following payor mix for the proposed services during the third full fiscal year of operation following completion of the project, as shown in the table below.

| CIS-Denver Projected Payor Mix CY 2025 | |
|---|----------------------------|
| Payment Source | % of Total Patients |
| Self-Pay | 3.0% |
| Medicare* | 44.1% |
| Medicaid* | 5.0% |
| Insurance* | 45.8% |
| Other (Other gov't, workers comp) | 2.1% |
| Total | 100.0% |

*Including any managed care plans

As shown in the table above, during the third full fiscal year of operation, the applicant projects that 3.0 percent of total services will be provided to self-pay patients, 44.1 percent to Medicare patients, and 5.0 percent to Medicaid patients.

In Section L, page 95, the applicant states that its internal data does not include charity care as a payor source but that patients in any category can and do receive charity care.

On pages 96-98, the applicant provides the assumptions and methodology used to project payor mix during the third full fiscal year of operation following completion of the project. The projected payor mix is reasonable and adequately supported based on the following:

- The applicant projects payor mix based on its own historical experience.
- The applicant accounts for the differing payor mixes by type of test and equipment in projecting payor mix.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (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 99, 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

The applicant proposes a cost overrun and change of scope to Project I.D. #F-11440-17. Instead of developing a freestanding MRI facility, the applicant proposes to develop a new diagnostic center by replacing and relocating diagnostic imaging equipment and developing the fixed MRI scanner all in the same location.

In Section M, page 101, the applicant describes the extent to which health professional training programs in the area will have access to the facility for training purposes and provides supporting documentation in Exhibit M.1. The applicant adequately demonstrates that health professional training programs in the area will have access to the facility for training purposes based on the following:

- The applicant has numerous existing relationships with health professional training programs through other established facilities.
- The applicant provides documentation of its existing relationships with health professional training programs.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (15) Repealed effective July 1, 1987.
 - (16) Repealed effective July 1, 1987.
 - (17) Repealed effective July 1, 1987.
 - (18) Repealed effective July 1, 1987.
- (18a) The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact upon the cost effectiveness, quality, and access to the services proposed; and in the case of applications for services where competition between providers will not have a favorable impact on cost-effectiveness, quality, and access to the services proposed, the applicant shall demonstrate that its application is for a service on which competition will not have a favorable impact.

C

The applicant proposes a cost overrun and change of scope to Project I.D. #F-11440-17. Instead of developing a freestanding MRI facility, the applicant proposes to develop a new diagnostic center by replacing and relocating diagnostic imaging equipment and developing the fixed MRI scanner all in the same location.

On page 344, the 2021 SMFP defines the service area for fixed MRIs as “...*the same as an Acute Care Bed Service Area as defined in Chapter 5 and shown in Figure 5.1.*” Figure 5.1 on page 36 of the 2021 SMFP shows Lincoln County as its own acute care bed service area. Thus, the service area for this project is Lincoln County. Facilities may also serve residents of counties not included in their service area.

Table 17E-1 on page 355 of the 2021 SMFP shows the only fixed MRI scanner currently operational in Lincoln County is located at Atrium Health Lincoln.

In Section G, page 76, the applicant states its service area for CIS-Denver’s other modalities includes Lincoln, Gaston, Catawba, and Mecklenburg counties. The applicant lists the existing hospitals in those counties, and states that while the hospitals may provide the same kind of diagnostic imaging services, they would be hospital-based and not done in a freestanding diagnostic imaging center. The applicant further states it is not aware of an existing public data source that would provide the inventory of the non-MRI equipment that are part of this application. On page 77, the applicant lists the existing and approved diagnostic centers owned or operated by the applicant or a related entity.

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 103, the applicant states:

“...there are currently no existing freestanding outpatient diagnostic centers in Lincoln County. The closest option for outpatient diagnostic imaging services for residents of Lincoln County is currently Atrium Health Lincoln Imaging Center, which provides hospital-based outpatient diagnostic imaging services as a campus of Atrium Health Lincoln. ... Given that Lincoln County already offers hospital-based MRI services at Atrium Health Lincoln, and that there are currently no freestanding

outpatient diagnostic centers in the county, CMHA and CIS believe that the best alternative to enhance competition by reducing the necessity for Lincoln County diagnostic imaging patients seeking freestanding services to travel out of the county is to develop the proposed CIS-Denver, which will result in convenient, cost-effective, and local freestanding access for Lincoln County patients.”

Regarding the impact of the proposal on cost effectiveness, in Section N, pages 103-104, the applicant states:

“.... The development of CIS-Denver as a freestanding outpatient diagnostic center will result in lower out-of-pocket expenses for patients. Most insurance companies tier out-of-pocket requirements depending on the type of facility where patients receive care. Insurance companies categorize hospital-based services in a higher out-of-pocket tier than they do freestanding outpatient services, meaning that the patient’s out of-pocket expenses are higher when receiving hospital-based care, regardless of whether the service is classified as inpatient or outpatient care. Since freestanding facilities are categorized in a lower tier, patients benefit from lower out-of-pocket expenses. ...

..., the single location for these services will allow use of the same support and administrative staff rather than duplicating between two facilities. Rather than separate facilities for MRI and the other diagnostic equipment, the proposed project will reduce duplicative common areas that would ensue otherwise, such as waiting areas, registration, and staff offices.”

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

Regarding the impact of the proposal on quality, in Section N, page 104, the applicant states:

“The proposed project will serve to improve the quality of diagnostic imaging services through the acquisition and replacement of existing diagnostic equipment from Atrium Health Lincoln Imaging Center to CIS-Denver. The proposed equipment will provide enhanced technology that allows for more efficient exams and improved patient and staff work-flow. It features innovative technologies geared towards improving the quality of the diagnostic scans, while increasing patient comfort.”

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

Regarding the impact of the proposal on access by medically underserved groups, in Section N, pages 104-105, the applicant states:

“..., CIS is committed to providing services to all patients regardless of income, racial/ethnic origin, gender, physical or mental conditions, age, ability to pay, or any other factor that would classify a patient as underserved. Diagnostic imaging services at CIS-Denver will be available to and accessible by any patient who has a clinical need for such services.

CIS has historically provided substantial care and services to all of the groups mentioned above. ... Low income and medically underserved persons will continue to have access to all diagnostic services provided by CIS. Specifically, upon completion of the proposed project CIS-Denver will perform diagnostic outpatient procedures for the uninsured and underserved population of Lincoln County.

As an example of this commitment, Charlotte Radiology, which will staff the proposed diagnostic facility, developed Project Pink to provide local uninsured women over the age of 40 with access to essential breast cancer screening services. The Project Pink program provides free screening mammograms, as well as diagnostic breast imaging, related procedures, and diagnostic follow-up care. Through this program, Charlotte Radiology has provided over 1,000 uninsured and underinsured women in the region with vital breast cancer services and have identified more than 60 cases of breast cancer since the program began in 2011.”

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

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

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

Conclusion

The Agency reviewed the:

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

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

- (19) Repealed effective July 1, 1987.

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

C

The applicant proposes a cost overrun and change of scope to Project I.D. #F-11440-17. Instead of developing a freestanding MRI facility, the applicant proposes to develop a new diagnostic center by replacing and relocating diagnostic imaging equipment and developing the fixed MRI scanner all in the same location.

On Form O in Section Q, the applicant identifies diagnostic centers and hospitals with imaging equipment located in North Carolina owned, operated, or managed by the applicant or a related entity. The applicant identified 17 existing and approved diagnostic centers and 13 hospitals in North Carolina.

In Section O, pages 108-109, the applicant states that during the 18 months immediately preceding the submittal of the application, there was a single incident related to quality of care at Atrium Health Cleveland which resulted in a finding of immediate jeopardy and a termination action. The applicant states that it submitted documentation and at a subsequent review, the deficiency was determined to be corrected and The Centers for Medicare and Medicaid Services withdrew the immediate jeopardy termination action. Supporting documentation is provided in Exhibit O.4. After reviewing and considering information provided by the applicant and considering the quality of care provided at all 30 diagnostic centers and hospitals, the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

- (21) Repealed effective July 1, 1987.

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

NA

The Criteria and Standards for Magnetic Resonance Imaging Scanner promulgated in 10A NCAC 14C .2700 were applicable to Project I.D. #F-11440-17, and that project was conforming with all applicable administrative rules. There is nothing in the current application which would affect the previous determination of conformity with the applicable administrative rules and nothing proposed which would make any additional administrative rules applicable to this review. Therefore, there are no administrative rules applicable to this review.