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STATE OF NORTH CAROLINA

COUNTY OF WAKE

IN THE OFFICE OF
ADMINISTRATIVE HEARINGS
22 DHR 00415

WR Imaging LLC and Wake Radiology Diagnostic Imaging Inc, Petitioner, v. North Carolina Department of Health and Human Services, Division of Health Service Regulation, Health Care Planning & Certificate of Need Section, Respondent, and Raleigh Radiology, LLC, Respondent-Intervenor.	**FINAL DECISION**

THIS MATTER came on for hearing before Michael C. Byrne, Administrative Law Judge, on November 8-10, November 18-19, 2021, and January 5, 25-26, 2022 at the Office of Administrative Hearings in Raleigh, North Carolina.

APPEARANCES

For Petitioners WR Imaging, LLC, and Wake Radiology Diagnostic Imaging, Inc. ("Wake Radiology"):

Frank Kirschbaum
Charles George
Wyrick, Robbins,Yates & Ponton LLP
4101 Lake Boone Trail,
Suite 300
Raleigh, NC 27607

For Respondent North Carolina Department of Health and Human Services Division of Health Service Regulation, Certificate of Need Section (the "Agency"):

Joshua Stein
Attorney General
By: Derek Hunter, Assistant Attorney General
North Carolina Department of Justice
114 West Edenton Street (27603)

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For Respondent-Intervenor Raleigh Radiology, LLC d/b/a Raleigh Radiology Cary ("Raleigh Radiology-Cary"):

James C. Adams, II
Katarina K. Wong
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230 North Elm Street (27401)
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Greensboro, North Carolina 27420-6000

APPLICABLE LAW

1. The procedural statutory law applicable to this contested case hearing is the North Carolina Administrative Procedure Act (APA), N.C.G.S. 150B, et seq.

2. The substantive statutory law applicable to this contested case hearing is the North Carolina Certificate of Need Law, N.C.G.S. 131E-175, et seq.

3. The administrative rules applicable to this contested case hearing are the North Carolina Certificate of Need administrative rules, 10A NCAC 14C.0100, et seq., and the Office of Administrative Hearings Expedited Hearing Procedures for Complex Contested Cases, 26 NCAC 3.0100, et seq.

4. "The fundamental purpose of the certificate of need law is to limit the construction of health care facilities in this state to those that the public needs and that can be operated efficiently and economically for their benefit." Hope-A Women's Cancer Ctr., P.A. v. N.C. Dep't of Health & Human Servs., 203 N.C. App. 276, 281, 691 S.E.2d 421, 424 (2010); AH N.C. Owner LLC v. N.C. HHS, 240 N.C. App. 92, 97, 771 S.E.2d 537, 540 (2015).

ISSUES

1. Whether WR Imaging, LLC and Wake Radiology Diagnostic Imaging, Inc. were substantially prejudiced in their rights as a result of one or more of the foregoing errors by the Agency's Decision.

2. Whether the Agency exceeded its authority or jurisdiction, acted erroneously, failed to use proper procedure, acted arbitrarily or capriciously, or failed to act as required by law or rule in finding that the Wake Radiology Application was conforming with respect to N.C. Gen. Stat. 131E-183(a)(1) ("Criterion 1").

3. Whether the Agency exceeded its authority or jurisdiction, acted erroneously, failed to use proper procedure, acted arbitrarily or capriciously, or failed to act as required by law

or rule in finding that the Wake Radiology Application was nonconforming with respect to N.C. Gen. Stat. 131E-183(a)(3) ("Criterion 3").

4. Whether the Agency exceeded its authority or jurisdiction, acted erroneously, failed to use proper procedure, acted arbitrarily or capriciously, or failed to act as required by law or rule in finding that the Wake Radiology Application was nonconforming with respect to N.C. Gen. Stat. 131E-183(a)(4) ("Criterion 4").

5. Whether the Agency exceeded its authority or jurisdiction, acted erroneously, failed to use proper procedure, acted arbitrarily or capriciously, or failed to act as required by law or rule in finding that the Wake Radiology Application was nonconforming with respect to N.C. Gen. Stat. 131E-183(a)(5) ("Criterion 5").

6. Whether the Agency exceeded its authority or jurisdiction, acted erroneously, failed to use proper procedure, acted arbitrarily or capriciously, or failed to act as required by law or rule in finding that the Wake Radiology Application was conforming with respect to N.C. Gen. Stat. 131E-183(a)(6) ("Criterion 6").

7. Whether the Agency exceeded its authority or jurisdiction, acted erroneously, failed to use proper procedure, acted arbitrarily or capriciously, or failed to act as required by law or rule in finding that the Wake Radiology Application was nonconforming with respect to 10A NCAC 14C .2703(b)(1).

8. Whether the Agency exceeded its authority or jurisdiction, acted erroneously, failed to use proper procedure, acted arbitrarily or capriciously, or failed to act as required by law or rule in finding that the Wake Radiology Application was nonconforming with respect to 10A NCAC 14C .2703(b)(2).

9. Whether the Agency exceeded its authority or jurisdiction, acted erroneously, failed to use proper procedure, acted arbitrarily or capriciously, or failed to act as required by law or rule in finding that the Wake Radiology Application was nonconforming with respect to 10A NCAC 14C .2703(b)(3)(E).

10. Whether the Agency exceeded its authority or jurisdiction, acted erroneously, failed to use proper procedure, acted arbitrarily or capriciously, or failed to act as required by law or rule in finding that the Wake Radiology Application was nonconforming with respect to 10A NCAC 14C .2703(b)(4)(E).

11. Whether the Agency exceeded its authority or jurisdiction, acted erroneously, failed to use proper procedure, acted arbitrarily or capriciously, or failed to act as required by law or rule in finding that the Wake Radiology Application was nonconforming with respect to 10A NCAC 14C .2703(b)(5).

12. Whether the Agency exceeded its authority or jurisdiction, acted erroneously, failed to use proper procedure, acted arbitrarily or capriciously, or failed to act as required by law or rule in finding that the Wake Radiology Application was nonconforming with respect to 10A NCAC 14C .2703(b)(6).

13. Whether the Agency exceeded its authority or jurisdiction, acted erroneously, failed to use proper procedure, acted arbitrarily or capriciously, or failed to act as required by law or rule in finding that the Raleigh Radiology application was conforming with respect to N.C. Gen. Stat. 131E-183(a)(1) ("Criterion 1").

14. Whether the Agency exceeded its authority or jurisdiction, acted erroneously, failed to use proper procedure, acted arbitrarily or capriciously, or failed to act as required by law or rule in finding that the Raleigh Radiology Application was conforming with respect to N.C. Gen. Stat. 131E-183(a)(3) ("Criterion 3").

15. Whether the Agency exceeded its authority or jurisdiction, acted erroneously, failed to use proper procedure, acted arbitrarily or capriciously, or failed to act as required by law or rule in finding that the Raleigh Radiology Application was conforming with respect to N.C. Gen. Stat. 131E-183(a)(4) ("Criterion 4").

16. Whether the Agency exceeded its authority or jurisdiction, acted erroneously, failed to use proper procedure, acted arbitrarily or capriciously, or failed to act as required by law or rule in finding that the Raleigh Radiology application was conforming with respect to N.C. Gen. Stat. 131E-183(a)(5) ("Criterion 5").

17. Whether the Agency exceeded its authority or jurisdiction, acted erroneously, failed to use proper procedure, acted arbitrarily or capriciously, or failed to act as required by law or rule in finding that the Raleigh Radiology application was conforming with respect to N.C. Gen. Stat. 131E-183(a)(6) ("Criterion 6").

18. Whether the Agency exceeded its authority or jurisdiction, acted erroneously, failed to use proper procedure, acted arbitrarily or capriciously, or failed to act as required by law or rule in finding that the Raleigh Radiology application was conforming with respect to N.C. Gen. Stat. 131E-183(a)(6) ("Criterion 7").

19. Whether the Agency exceeded its authority or jurisdiction, acted erroneously, failed to use proper procedure, acted arbitrarily or capriciously, or failed to act as required by law or rule in finding that the Raleigh Radiology application was conforming with respect to N.C. Gen. Stat. 131E-183(a)(13) ("Criterion 13").

20. Whether the Agency exceeded its authority or jurisdiction, acted erroneously, failed to use proper procedure, acted arbitrarily or capriciously, or failed to act as required by law or rule in finding that the Raleigh Radiology application was conforming with respect to N.C. Gen. Stat. 131E-183(a)(14) ("Criterion 14").

21. Whether the Agency exceeded its authority or jurisdiction, acted erroneously, failed to use proper procedure, acted arbitrarily or capriciously, or failed to act as required by law or rule in finding that the Raleigh Radiology application was conforming with respect to N.C. Gen. Stat. 131E-183(a)(18a) ("Criterion 18a").

22. Whether the Agency exceeded its authority or jurisdiction, acted erroneously, failed to use proper procedure, acted arbitrarily or capriciously, or failed to act as required by law

or rule in finding that the Raleigh Radiology application was conforming with respect to N.C. Gen. Stat. 131E-183(a)(20) ("Criterion 20").

23. Whether the Agency exceeded its authority or jurisdiction, acted erroneously, failed to use proper procedure, acted arbitrarily or capriciously, or failed to act as required by law or rule in finding that the Raleigh Radiology application was conforming with respect to 10A NCAC 14C .2103.

24. Whether the Agency exceeded its authority or jurisdiction, acted erroneously, failed to use proper procedure, acted arbitrarily or capriciously, or failed to act as required by law or rule in conducting the comparative analysis and finding that the Raleigh Radiology Application was the most effective alternative of the applications in the review.

25. Whether the Agency exceeded its authority or jurisdiction, acted erroneously, failed to use proper procedure, acted arbitrarily or capriciously, or failed to act as required by law or rule in awarding a certificate of need to Raleigh Radiology-Cary.

26. Whether the Agency exceeded its authority or jurisdiction, acted erroneously, failed to use proper procedure, acted arbitrarily or capriciously, or failed to act as required by law or rule in not awarding a certificate of need to Wake Radiology.

WITNESSES

For Petitioner WR Imaging, LLC, and Wake Radiology Diagnostic Imaging, Inc.:

Dr. Lyndon B. Jordan
Daniel Carter
Elisabeth Pittman
Gregory Yakaboski
Dr. Laura Thomas
Joanne Watson
Dr. Satish Mathan

For Respondent North Carolina Department of Health and Human Services Division of Health Service Regulation, Certificate of Need Section:

None

For Respondent-Intervenor Raleigh Radiology LLC d/b/a Raleigh Radiology Cary:

Elisabeth Pittman
Nancy Lane

EXHIBITS

Exhibits submitted by all Parties and admitted are set forth in the transcript of the hearing and the Order and Stipulation Regarding Admission of Hearing Exhibits. The Agency file, the

Raleigh Radiology Application (for Certificate of Need) and the Wake Radiology Application (same) were admitted into evidence as Joint Exhibits 1, 2 and 3, respectively.

Exhibit 1, Agency File – November 15, 2019 Agency File Wake County MRI Review;

Exhibit 2, November 15, 2019 Raleigh Radiology Application;

Exhibit 3, November 15, 2019 Wake Radiology Application;

Exhibit 4, November 12, 2018, MRI Standards;

Exhibit 5, November 12, 2019 Duke University Health System Application;

Exhibit 8, Raleigh Radiology Resumes Mammography Services at Blue Ridge;

Exhibit 9, June 20, 2018, Incident Report by Halos;

Exhibit 17, CON MRI Data Pull 2019 09 10 – Volumes;

Exhibit 18, September 12, 2019, e-mail from Marvelle to King;

Exhibit 32, 2016-2019 UNC Rex MRI Data;

Exhibit 34, Mammography Facility Adverse Event and Action Report, February 11, 2020; Raleigh Radiology – Blue Ridge;

Exhibit 35, November 25, 2019, e-mail chain from Ivey to Lane and Mathan;

Exhibit 39, March 3, 2017, WR Rex Exemption for MRI;

Exhibit 41, Browning Mobile MRI CON;

Exhibit 42, Redacted Asset Contribution Agreement between WR Imaging and WRS;

Exhibit 43, Redacted Asset Contribution Agreement between WR Imaging and Rex;

Exhibit 44, Redacted WRS Distribution Agreement;

Exhibit 55, December 19, 2019, Margaret King Public Hearing Presentation;

Exhibit 62, WR Imaging Form C Worksheet;

Exhibit 66, Ascendient Engagement Letter;

Exhibit 67, Daniel Carter C.V.;

Exhibit 68, Expert Opinion of Daniel Carter;

Exhibit 69: Expert Opinion of Nancy Lane;

Exhibit 120: Meeting Agenda 1/9/2020;

Exhibit 125: Accredited Facility Search;

Exhibit 141, Status of mammography services at Raleigh Radiology - Blue Ridge;

Exhibit 143, E-mail from Frannie Joseph re Image Loss 7/25/2018;

Exhibit 146, Raleigh Radiology Resumes Mammography Services at Blue Ridge;

Exhibit 147, Video Script – Raleigh Radiology, Blue Ridge;

Exhibit 153: Letter re Intent to Revoke Accreditation;

Exhibit 169, 2019 SMFP MRI;

Exhibit 172, Excel - Pro forma, Equipment Staff Costs, Payer/Mix/Charge Adjust, Assumptions;

Exhibit 177, Raleigh Radiology Application;

Exhibit 180, Guilford County MRI Findings (Aug. 26, 2016);

Exhibit 181, Mecklenburg County MRI Findings (Nov. 4, 2014);

Exhibit 185, New Hanover County OR Findings (May 4, 2018);

Exhibit 190, Mecklenburg County MRI Findings (Nov. 1, 2016);

Exhibit 191: Pre-Application Conference Agenda (October 24, 2019);

Exhibit 193, Additional Mammography Review Report (October 23, 2019);

Exhibit 194, Letter from Laura Thomas (Raleigh Radiology) to Daphany Branch (December 11, 2019);

Exhibit 196, Letter from David Lee (FDA) to Satish Mathan, M.D. (November 12, 2019);

Exhibit 198, Template Patient Letter - Important Information About Your Mammography;

Exhibit 200, Fuquay-Varina Findings (March 26, 2020);

Exhibit 202, Affidavit of Elisabeth Pittman;

Exhibit 203, Declaration of Laura Thomas, M.D.;

Exhibit 204, Affidavit of Satish Mathan, M.D.;

Exhibit 300, Temporary ACR Accreditation;

Exhibit 301, Full ACR Accreditation;

Exhibit 304, Satish Mathan CV;

Exhibit 305, Laura Thomas CV;

Exhibit 306, Hayward, et al., "Improving Screening Mammography Outcomes Through Comparison with Multiple Prior Mammograms";

Exhibit 307: Excel Version of Attachment to Nancy Lane's Expert Report;

Exhibit 312, July 6, 2018, e-mails from Joanne Watson to Frannie Joseph, Ryan Halos, and Satish Mathan and attachment;

Exhibit 314, Status of Mammography Services at Raleigh Radiology - Blue Ridge;

Exhibit 316, A Message to Our Patients and Community from Raleigh Radiology (February 12, 2020 Legal Approved);

Exhibit 319, January 2020 Registration and Inventory of Medical Equipment of Grandfathered Fixed MRI;

Exhibit 321, Subpoena to Lyndon Jordan and documents produced pursuant to the subpoena;

Exhibit 334, Chapter 131E - Article 19;

Exhibit 351, 2019 UNCH Agency Findings;

Exhibit 354, 2016 Wake MRI Agency Findings;

Exhibit 357-A Petition filed by WR Imaging;

Exhibit 357-B Prehearing statement of WR Imaging;

Exhibit 357-C Petitioner's Motion for Partial Relief from Consent Protective Order;

Exhibit 400, 10 NCAC 14C (Certificate of Need Regulations);

Exhibit 401, 2010 Duke University Hospital MRI Findings;

Exhibit 402, 2017 Bio-Medical Application of North Carolina, Inc. ESRD Findings;

Exhibit 403, 2019 UNC Hospitals Orange County OR Findings;

Exhibit 404, 2020 Liberty Commons of Kernersville, LLC Nursing Home Findings;

Exhibit 405, 2020 DVA Renal Healthcare, Inc. ESRD Findings;

Exhibit 406, State Agency Findings Dated January 28, 2020

BASED UPON careful consideration of the sworn testimony of the witnesses presented at the hearing, the documents and exhibits received and admitted into evidence, and the entire record in this proceeding, the Tribunal makes the following Findings of Fact. In making the Findings of Fact, the Tribunal has weighed all the evidence and has assessed the credibility of the witnesses by taking into account the appropriate factors for judging credibility, including but not limited to the demeanor of the witness, any interests, bias, or prejudice the witness may have, the opportunity of the witness to see, hear, know, or remember the facts or occurrences about which the witness testified, whether the testimony of the witness is reasonable, and whether the testimony is consistent with all other believable evidence in the case.

FINDINGS OF FACT

PARTIES

1. Petitioner Wake Radiology Diagnostic Imaging, Inc. ("WRDI") is a professional corporation organized and existing under the laws of the State of North Carolina that operates diagnostic equipment and diagnostic centers within Wake County and surrounding counties. (Ex. 357A, ¶ 1; Jt. Ex. 3, pp. 13-14, 133-135). WRDI operates facilities in these locations offering MRI and other diagnostic imaging services. (Ex. 357A, ¶ 1).

2. Petitioner WR Imaging, LLC ("WR Imaging") is a limited liability company organized and existing under the laws of the State of North Carolina and is a joint venture between UNC Rex Hospital and Wake Radiology. WR Imaging owns imaging equipment and provides imaging services, including MRI and other diagnostic imaging services, within Wake County and surrounding counties. (Ex. 357A, ¶ 2). WR Imaging operates facilities in these locations offering MRI and other diagnostic imaging services.

3. Together, "WR Imaging" and "WRDI" are referred to as "Wake Radiology."

4. Respondent North Carolina Department of Health and Human Services, Division of Health Regulation, Certificate of Need Section (the "Agency") is the state agency responsible for the administration of North Carolina's certificate of need ("CON") law.

5. Respondent-Intervenor Raleigh Radiology, LLC ("Raleigh Radiology-Cary") is a patient-centric radiology medical practice that operates diagnostic equipment and diagnostic centers within Wake County and surrounding counties. (Watson, Vol. 5, p. 1123; Mathan, Vol, 5. p. 1208). At the time of the hearing, Raleigh Radiology had four diagnostic centers where it conducted its practice: Cary, Blue Ridge, Knightdale, and Fuquay Varina. (Mathan, Vol. 6, p. 1274-75). Raleigh Radiology does not currently own any magnetic resonance imaging ("MRI") scanners. (Mathan, Vol. 6, p. 1283). It provides MRI services through an MRI lease with Alliance Imaging, LLC. (Id., p. 1284).

PROCEDURAL HISTORY

6. The 2019 State Medical Facilities Plan ("SPMF") recognized the need for one additional fixed MRI scanner in Wake County. ("SMFP Need Determination").

7. On or around November 15, 2019, the Agency received six applications for a certificate of need for the fixed MRI, including applications from Raleigh Radiology-Cary ("the Raleigh Radiology Application," Raleigh Radiology-Knightdale, Pinnacle Health Services of North Carolina ("PHSNC"), EmergeOrtho, Wake Radiology, and the Duke University Health System ("DUHS"). (Jt. Ex. 1, pp. 818-19).

8. The Agency considered all of the applications to be competitive and batched them together for consideration, pursuant to N.C.G.S. 131E-182. Agency review of the applications began on or about December 1, 2019 (the "Review"). The comment period for the applications was from December 1, 2019 to December 31, 2019, with the public hearing taking place on January 10, 2020. (Jt. Ex. 1, pp. 314-15).

9. On April 28, 2020, the Agency, through the CON Section, issued a preliminary decision that the Raleigh Radiology Application was conditionally approved, that Raleigh Radiology-Cary would be awarded the certificate of need for the fixed MRI for Wake County, and that the Wake Radiology Application had been disapproved. (Jt. Ex. 1, pp. 14-15). On May 5, 2020, the Agency issued its statutorily required Findings which found the Raleigh Radiology Application conforming or conditionally conforming with all applicable statutory criteria and rules, found it to be the most effective alternative, and awarded the certificate of need to Raleigh Radiology. (Jt Ex. 1, p. 818). The Findings also stated that the Wake Radiology Application was nonconforming with Criteria 3, 4, and 5 under N.C.G.S. 131E-183(a) and the required MRI Performance Standards under 10A NCAC 14C .2703. (Id., pp. 827, 853, 860, 922-30).

10. On May 28, 2020, Wake Radiology timely filed a Petition for a contested case hearing challenging the Agency decision. On the same day, DUHS timely filed a Petition for a contested case hearing challenging the Agency decision. On July 7, 2020, Raleigh Radiology-Cary was allowed to intervene in all cases as a respondent with full rights as a party, and DUHS and Wake Radiology were allowed to intervene in the other's respective cases. The Contested Cases were consolidated for all purposes.

11. On August 12, 2020, DUHS voluntarily dismissed its contested case.

12. On September 8, 2020, pursuant to a Consent Order, Wake Radiology voluntarily dismissed their Petition without prejudice to allow it to refile the case within five (5) business days. Wake Radiology timely refiled their Petition for a Contested Case Hearing in the above captioned contested case on September 15, 2020, in Case No. 20 DHR 3611.

13. On May 5, 2021, pursuant to a Consent Order, Wake Radiology voluntarily dismissed their Petition without prejudice to allow it to refile the case within five (5) business days. Wake Radiology timely refiled their Petition for a Contested Case Hearing in the above captioned contested case on May 7, 2021, in Case No. 20 DHR 3611.

14. On August 13, 2021, the Agency and Raleigh Radiology-Cary moved for summary judgment asserting that there was no genuine dispute of material fact that (1) Wake Radiology could not show that their application was conforming with the required MRI Performance Standards, 10A NCAC 14C .2704(b)(1) and 14C .2703(b)(2), and (2) Wake Radiology could not show that the Agency's decision to approve the Raleigh Radiology Application and deny the Wake Radiology Application caused substantial prejudice to Wake Radiology.

15. On August 17, 2021, Wake Radiology moved for summary judgment asserting that there was no genuine dispute of material fact that the Agency improperly approved the Raleigh Radiology Application as a matter of law because the Raleigh Radiology Application failed to comply with N.C.G.S. 131E-183(a)(20), and that Wake Radiology had established substantial prejudice as a matter of law.

16. On October 18, 2021, the Tribunal heard argument on the parties' respective motions for summary judgment. The Tribunal denied both motions.

17. This contested case was heard November 8-10, 2021, November 18-19, 2021, January 5, 2022, and January 25-26, 2022.

18. On January 25, 2022, the Agency and Raleigh Radiology-Cary moved for involuntary dismissal under N.C.G.S. 1A-1, Rule 41(b). The Tribunal denied the motion.

19. On January 27, 2022, pursuant to a Consent Order, Wake Radiology voluntarily dismissed their Petition without prejudice to allow it to refile the case within 5 business days. Wake Radiology timely refiled their Petition for a Contested Case Hearing in the above captioned contested case on February 3, 2022, in Case No. 22 DHR 0415.

20. WRDI is one of three entities comprising a single medical practice with common physician ownership. (Jt. Ex. 3, p. 13; Jordan, Vol. 1, p. 20). The first entity, WRDI, provides and bills for imaging services. (Jt. Ex. 3, p. 13). The second entity, Wake Radiology Consultants, PA provides professional services. (Id.) The third entity, Wake Radiology Services ("WRS"), provides management services for all of the Wake Radiology entities including WR Imaging. (Id.) WRS manages and maintains the data for WRDI, WRC, and WR Imaging. (Jordan, Vol. 1, p. 37).

21. WR Imaging is a provider of technical imaging services – the acquisition, storage, and distribution of images. (Jordan, Vol. 1, p. 22). It is also an applicant in this Review and a party to this Contested Case.

22. Wake Radiology physicians also have partial ownership of WR Imaging. (Jt. Ex. 3, p. 13; Jordan, Vol. 1, p. 23). The current physician owners of WR Imaging are, in part, the same owners of WRS, WRC, and WRDI. (Jordan, Vol. 1, pp. 56-58).

23. WRS used to be the sole owner of an entity called Browning Equipment SPE, LLC ("Browning"). (Id., pp. 42-44). Browning became a legal entity on October 24, 2016. (Jordan, Vol. 1, p. 41; Jt. Ex. 3., p. 127). On June 21, 2017, Browning amended its articles of organization and changed its name to WR Imaging, LLC. (Jordan Vol. 1, pp 41-43; Jt. Ex. 3, p. 128).

24. In 1988, WRS acquired a free-standing, fixed magnetic resonance imaging ("MRI") scanner – which was grandfathered under the certificate of need law. (Jt. Ex. 39, p. 6). On October 9, 1998, WRS received a certificate of need for a second fixed MRI scanner (J-5783-97). (Id., pp. 6, 8). Both of these scanners were located at Wake Radiology's Raleigh MRI Center. (Id., p. 6).

25. The fixed scanners at the Raleigh MRI Center were replaced with newer fixed MRI scanners in 2004 and 2006 respectively. (Jt. Ex. 1, p. 539).

26. On September 1, 2004, WRS received a certificate of need for a mobile MRI scanner ("Mobile MRI 1"). (Jt. Ex. 39, p. 14; Jordan, Vol. 1, pp. 49-50). On August 4, 2006, Rex Hospital, Inc. ("Rex") acquired a mobile MRI for use in Wake County ("Mobile MRI 2"). (2017 Browning Mobile MRI CON Review Agency Findings at 8).

27. On January 18, 2017, WRS and Browning submitted an exemption and/or no-review request for a proposed joint venture between Rex and WRS pertaining to the various diagnostic centers owned and operated by WRS. (Jordan, Vol. 1, pp. 47-50; Jt. Ex. 39, pp. 3-5). The request stated that Browning would be the joint venture entity, would be owned by WRS and Rex, and that imaging equipment, including two fixed MRI machines and Mobile MRI 1, would be redesignated to Browning's ownership. (Jordan, Vol. 1, pp. 47-50). The request stated that the redesignation was "anticipated to occur within a short time frame and prior to the planned joint venture of Browning with Rex." (Id., p. 51). On March 3, 2017, the Agency granted WRS and Browning the requested exemption to permit the imaging equipment, including the two fixed MRIs and Mobile MRI 1 to be redesignated as being owned by Browning. Jt. Ex. 39, pp. 1, 3, 6-8, 14-15).

28. Also on January 18, 2017, Rex, WRS, and Browning submitted an exemption and/or no-review request related to the same proposed joint venture seeking to redesignate the owner of Rex's Cary Outpatient Imaging Site to Browning. (Ex. 40, pp. 3-5). The request stated that Browning would be the joint venture entity and that imaging equipment, including a fixed MRI machine, would be redesignated to Browning's ownership. (Id., p. 4.). On March 3, 2017, the Agency issued the requested exemption to permit the imaging equipment, including the fixed MRI, to be redesignated as being owned by Browning. (Id., p. 1).

29. When WRS and Browning submitted an exemption and/or no review request for the redesignation of the two fixed MRI machines and Mobile MRI 1, WRS and Browning represented that "[t]he ultimate ownership and control of the service does not change" and "[a]ll of the assets being redesignated from WRS to Browning already exist and are already being

operated by WRS at the same location of which they will remain after the redesignation." (Jt. Ex. 39, p. 4).

30. In the exemption and/or no review request seeking to redesignate the owner of Rex's Cary Outpatient Imaging Site to Browning, Rex, Browning and WRS states "[o]nce Browning obtains full ownership, the same equipment will be used to provide the exact same radiology services, in the same location, with Rex still participating in the ownership." (Jt. Ex. 40 at 5).

31. In 2017, Rex and Browning filed an application for a CON seeking permission for Rex to contribute certain imaging assets, including Mobile MRI 2, to Browning for the development of a new freestanding diagnostic center. (2017 Browning Mobile MRI CON Review Agency Findings at 1). Like the prior exemption/no-review requests, Rex and Browning represented that Browning would be a joint venture between Rex and WRS. Id. On May 20, 2017, the Agency issued the requested CON to Browning and Rex for the development of a new freestanding diagnostic center through Rex's contribution of Mobile MRI 2 to Browning. (Jt. Ex. 41).

32. On June 21, 2017, after receipt of the two exemptions and the CON, Browning changed its name to WR Imaging, LLC. (Jt. Ex. 3., p. 128). Thereafter, WRS and Rex continued to separately own and operate the outpatient MRI scanners which were to be contributed to Browning pursuant to the exemptions and CON. (See Jt. Ex. 40, p. 5).

33. Nearly two years later, on February 23, 2019, WR Imaging and Rex finally consummated the joint venture. (Jordan, Vol. 1, p. 29-30). WR Imaging, WRS, and Rex entered into Asset Contribution Agreements. (Id., pp. 53-54; see also Jt. Exs. 42, 43). Pursuant to those Agreements, WRS transferred its two fixed MRI scanners and Mobile MRI 1 to WR Imaging, and Rex transferred Mobile MRI 2 to WR Imaging. (Id.). Rex did not transfer any of the assets referenced in the January 18, 2017, exemption and/or no review request related to the Cary Outpatient Imaging site.

34. On the same date, WRS entered into a Distribution Agreement with its 39 physician members. (Jt. Ex. 44) Pursuant to this Agreement, WRS distributed its ownership in WR Imaging to these physician members, making the physicians owners of WR Imaging, along with Rex. (Jordan, Vol. 1, pp. 56-57) Rex owns 44% of WR Imaging and the physician members own 56% of WR Imaging. (Id., p. 47). All of these physician members also had ownership interest in WRDI, WRS, and WRC. (Id.; pp. 56-57)

35. Rex, WRS, WRC, WRDI, and WR Imaging were all related entities.

36. When the joint venture was formed, none of the equipment previously owned by WRS or Rex changed locations. (Jordan, Vol. 1, p. 54). WRS billed for MRI services for the equipment before the joint venture was formed, and WRS continued to bill for MRI services for the same equipment after the joint venture's formation. (Id., pp. 60-61). From the patient's perspective, the only change that occurred was the name on the building and name of the health provider. (Id., pp. 54-55). From WRS's perspective, the only thing that changed was the name and the billing number. WRS employees managed and updated the equipment before the joint venture was formed and after.

37. At the time the Wake Radiology Application was filed, WR Imaging had access to years of historical volume data relating to the MRI scanners it owned. (Jordan, Vol. 1, pp. 30, 37, 106; see also Jt. Exs. 17; Ex. 319; Jt. Ex. 1., pp. 534-65). All of the data created by WRC, WRDI, and WR Imaging is maintained by WRS as it had been long before the joint venture began. (Jordan, Vol. 1, p. 37).

The Agency Review Process

Requirements for the CON Review Process

38. Under the CON Law, the Agency must conduct its review of CON applications within 90 days, with a possible extension of the review period of up to an additional 60 days. N.C.G.S. 131E-185(a1) and (c).

39. Within the review period, the Agency must issue a decision to approve, approve with conditions, or deny a CON application to develop a new institutional health service. N.C.G.S. 131E-186(a).

40. Within five business days of issuing its decision, the Agency must "provide written notice of all the findings and conclusions upon which it based its decision, including the criteria used . . . in making its decision, to the applicant." N.C.G.S. 131E-186(b). This written notice is the Required State Agency Findings ("Agency Findings").

41. When conducting a review, the Agency must issue findings and conclusions that are consistent with the CON Law, CON rules, and applicable Tribunal opinions. (Yakaboski, Vol. 4, p. 871). The Agency reviews an application to determine whether it demonstrates conformity with applicable statutory and regulatory review criteria. (Id.; see also N.C.G.S. 131E-183(a)).

42. The Agency conducts a "competitive review" of applications when two or more applications are submitted to develop the same or similar services and the Agency determines that the approval of one or more of the applications may result in the denial of another application submitted in the same review.

43. During a competitive review, the Agency reviews each application independently and individually against the review criteria in the CON Law and any applicable CON rules. (Yakaboski, Vol. 4, pp. 812, 871). The Agency then conducts a comparative analysis of the applications to determine which application or applications to approve. (Yakaboski, Vol. 4, p. 890).

44. The Agency has authority to decide which factors to use during the comparative analysis. WakeMed v. N. Carolina Dep't of Health & Hum. Servs., Div. of Health Serv. Regul., 222 N.C. App. 755, 770, 750 S.E.2d 186, 196 (2012). No statute, regulation, or North Carolina judicial opinion requires the Agency to use any specific factors. Id. Nor, in reviewing the Agency decision, may the Tribunal substitute or use different factors than those used by the Agency.

45. The Agency Findings summarize the Agency's analysis of how a particular application or set of applications conforms (or does not) to the applicable statutory and

regulatory review criteria. Accordingly, the Agency views each set of Agency findings as unique and fact specific.

46. The Agency analyzes each individual application's conformity or non-conformity with applicable statutory and regulatory review criteria. (Yakaboski, Vol. 4, p. 871). It is common for the Agency to rely upon the same facts when analyzing an application's conformity or nonconformity with different criteria. To prevent unnecessary repetition, and for the sake of brevity and clarity, the Agency will at times incorporate the facts and determinations from its analysis under one criterion under the analysis of another criterion in its findings. (See id., pp. 823-824). Despite this practice, in each case the Agency performs a separate analysis of the application's conformity or non-conformity with each criterion. (Id.)

47. Nothing in the CON Law or rules requires the Agency to ensure that Agency findings are consistent with prior Agency findings. The Agency is required to look at the specific facts and circumstances of the application or applications currently before it in a review and to apply the CON criteria to those facts and circumstances. The Agency may not, however, act in an arbitrary and capricious manner with respect to its findings.

Yakaboski's Background and Process

48. As a Project Analyst, Gregory Yakaboski is responsible for reviewing CON applications and drafting Agency findings. (Yakaboski, Vol 4, p. 718-19). Yakaboski has been a Project Analyst for nearly fourteen years and has reviewed CON Applications in that capacity. (Id.)

49. Yakaboski reviewed the entirety of all the applications submitted in the Review, the comments in opposition submitted by the applicants and others, and the responses to public comments in opposition submitted by the applicants. (Yakaboski, Vol. 4, p. 721-22). Yakaboski conducted the public hearings where both Raleigh Radiology-Cary and Wake Radiology representatives made presentations. (Jt. Ex. 1, pp. 317-18).

50. Yakaboski was responsible for drafting the Agency Findings. (Yakaboski, Vol. 4, p. 719). Yakaboski approaches every application he reviews with the intention to approve it until it is impossible for him to do so. (Id., pp. 833-34).

51. When conducting a competitive review, Yakaboski first reviews applications individually by each criterion to determine whether the application is conforming with all applicable statutory and regulatory review criteria. (Yakaboski, Vol. 4, pp. 730-31, 812, 820, 823-24, 871).

52. Yakaboski also reviews the comments in opposition and responses to comments in opposition that have been submitted for the review as he is preparing their proposed findings. (Yakaboski, Vol. 4, pp. 721-22). He also consults with his co-signer regarding his findings on each application and his intentions regarding the outcome of the review at issue. (Id., pp. 720-21).

53. A co-signer to a set of Agency findings is a senior member of Agency management who would review each of the applications for consistency and co-sign the findings.

(Pittman, Vol. 1, p. 151-52; Pittman, Vol. 2, p. 396). Lisa Pittman, the Assistant Chief of the CON Section, was the co-signer in the present case. (Pittman, Vol. 1, pp. 150-52).

54. Only after reviewing each application individually and determining whether the applications conform to the applicable statutory and regulatory review criteria does Yakaboski conduct a comparative analysis of the applications. (Jt. Ex. 1, p. 932).

55. When Yakaboski had questions or concerns about the review, he discussed them with Pittman. (Yakaboski, Vol 4, pp. 778-789).

56. Yakaboski prepared drafts of the findings he submitted to Pittman in order to gain Pittman's concurrence that he was applying the law correctly. (Pittman, Vol. 1, pp. 157-58). Pittman edited drafts of the Agency Findings but made no substantive changes. (Id., p. 158).

57. Yakaboski and Pittman had no disagreements regarding the review of the applications submitted in the Review. (See Pittman, Vol. 2, p. 251).

The Agency File

58. Yakaboski assembled the Agency File, which is the official record of the Review. (Yakaboski, Vol. 4, pp. 720-21). The Agency File includes general correspondence related to the CON applications, written comments, public hearing documents, working papers, other Agency findings considered during the Review, as well as the Agency Findings in the Review. (Jt. Ex. 1).

59. Tab 1 of the Agency File contains correspondence between the Agency and the applicants related to their applications and the review process. (Jt. Ex. 1, pp. 1-47).

60. Tab 2 of the Agency File contains the Written Comments. (Jt. Ex. 1, pp. 48-310). After a review begins, there is a thirty-day period during which the Agency accepts written comments from the public. In this Review, Raleigh Radiology, Wake Radiology, Alliance Healthcare Services, Pinnacle Health, EmergeOrtho, and Maria Parham Medical Center submitted comments. (Jt. Ex. 1, pp. 48-310).

61. Tab 3 of the Agency File contains the Public Hearing Documents and Responses to Comments. (Jt. Ex. 1, pp. 311-565). The Agency must conduct a public hearing on competitive CON reviews. See N.C.G.S. 131E-185(a1)(2) a. to c. Each applicant has fifteen minutes to present an overview of its project. Following each presentation, members of the public have the opportunity to speak for or against the applications. After that, each applicant has five minutes to respond to any concerns or provide closing comments. Here, Raleigh Radiology-Cary, Wake Radiology, Pinnacle Health, and EmergeOrtho made presentations at the Public Hearing. (Jt. Ex. 1, pp. 311-565).

62. Responses to comments are also presented to the project analyst at the public hearing. The Agency must consider all responses to comments submitted but is not required to agree with any of the responses or to explain why it agrees or disagrees with any responses. In this Review, Raleigh Radiology-Cary and Wake Radiology both submitted responses to

comments. Yakaboski considered all the responses to comments submitted. (Yakaboski, Vol. 4, pp. 721-22).

63. Tab 4 of the Agency File contains the Project Analyst's Working Papers. (Jt. Ex. 1, pp. 509-65). These are the documents that Yakaboski referred to, used, or developed himself during the course of the Review. (Yakaboski, Vol. 4, pp. 722-23).

64. Tab 5 of the Agency File contains Other Agency Findings, which are the findings that Yakaboski looked at in preparation of the Agency Findings in the Review. (Jt. Ex. 1, pp. 566-815; Yakaboski, Vol. 4, p. 723). The Agency File contains the following Agency Findings: 2019 Forsyth County MRI Review; 2019 Mecklenburg County MRI Review; 2019 Wake County Operating Room Review. (Jt. Ex. 1, pp. 566-815).

65. Tab 6 of the Agency File contains the Agency Findings for the Review. (Id., pp. 816-945).

The Wake Radiology Application

66. The Wake Radiology Application proposed that WR Imaging would acquire a fixed 1.5 Tesla MRI scanner to be installed at its existing offices in Cary. (Jt. Ex. 3, pp. 15-16; Jordan, Vol. 1, p. 70). WR Imaging leases a fixed MRI scanner from Alliance Imaging. (Jt. Ex. 3, p. 29; Jordan, Vol. 1, p. 71). The new 1.5T MRI would be installed in the same space as the leased scanner. (Jt. Ex. 3, p. 29; Jordan, Vol. 1, pp. 71).

67. The Wake Radiology Application was prepared by Ascendient Healthcare Advisors ("Ascendient"). (Carter, Vol. 2, p. 428). Daniel Carter, Vice President of Ascendient and Wake Radiology's expert, oversaw the preparation of the Application. (Id., pp. 418, 428-29).

Wake Radiology's Alleged Substantial Prejudice

68. A petitioner in a CON contested case is required to prove both Agency error and substantial prejudice to its legal rights due to the Agency's decision. N.C.G.S. 150B-23(a).

69. Wake Radiology first put forth its theory of substantial prejudice in their Petition. In their Petition, it alleges that the Agency's decision to disapprove Wake Radiology's Application, which "preclude[d] [Wake Radiology] from developing its proposed project," substantially prejudiced Wake Radiology's rights. (Ex. 357A, ¶ 7).

70. Additionally, Wake Radiology alleges that the Agency's decision to approve the Raleigh Radiology Application unfairly prejudices Wake Radiology by preventing it "from carrying out the project that is the subject of Petitioner's Application." (Ex. 357A ¶ 14).

71. Wake Radiology's witnesses did not provide evidence showing by a preponderance of the evidence that the Agency's decision substantially prejudiced Wake Radiology.

72. Wake Radiology's expert, Carter, testified that if the Agency had found all applications for this review nonconforming, the placeholder need for a fixed MRI Machine in the 2019 SMFP would return to the Plan for the following year. (Carter Vol. 2, pp. 426-28). On cross-examination, Carter agreed that the actual effect of such a finding would be a reduction of the denominator by one in the need methodology calculation. Applying that result to the 2022 SMFP, would yield no additional need for a fixed MRI in Wake County. (Carter Vol. 3, pp. 663-68). Thus, even if the Raleigh Radiology Application were found nonconforming, the standard SMFP methodology would not trigger a need for an additional fixed MRI machine in Wake County. (Id.).

The Agency Correctly Found the Wake Radiology Application Nonconforming with Criterion 3

73. Criterion 3 applied to the Wake Radiology Application. Criterion 3 provides:

> 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.

N.C.G.S. 131E-183(a)(3).

74. Criterion 3 is broken up into multiple components. (Pittman, Vol. 2, p. 345). First, the applicant must show a need for the service. (Id.) Then, the applicant must show that there is a population that has the need for the service. (Id.) Then, the applicant must show that its application proposes to meet the need. (Id.)

75. In order to find an application conforming with Criterion 3, the Agency requires an applicant to meet four requirements: (1) the applicant must identify the population proposed to be served; (2) the applicant must demonstrate the need that this population has for the services proposed; (3) the applicant must demonstrate that the projected utilization of the project is reasonable and adequately supported; and (4) the applicant must demonstrate the extent to which all residents of the area, and in particular, medically underserved groups, are likely to have access to the services proposed. (Pittman, Vol. 2, pp. 345-46; Jt. Ex. 1, pp. 846-53).

76. The Agency has long interpreted Criterion 3 to include a showing of need and a showing of how the applicant's proposed project will meet the proposed need. (Yakaboski, Vol. 4, pp. 912-13).

77. The Agency determined that the Wake Radiology Application met the first, second, and fourth requirements. The Agency found that the Wake Radiology Application did not demonstrate that the projected utilization of the project was reasonable and adequately supported.

A. Population Proposed to be Served

78. The first element under Criterion 3 requires the applicant to identify from where the proposed patients projected to be served by the proposed project will originate. See N.C.G.S. 131E-183(a)(3).

79. Wake Radiology states that its projected patient origin was based on its historical patient origin for MRI services at its Cary location. (Jt. Ex. 3, p. 28; Jt. Ex. 1, p. 847).

80. The Agency determined that Wake Radiology adequately identified the patient origin for the population it proposed to serve.

B. Demonstration of Need

81. The second element of the analysis under Criterion 3 – the "demonstration of need" – evaluates whether the applicant demonstrates the patients it proposes to serve need those services in the location proposed by the applicant. See N.C.G.S. 131E-183(a)(3).

82. In the Wake Radiology Application, Wake Radiology proposed to acquire one fixed MRI scanner to be located at Wake Radiology, an existing freestanding diagnostic center. (Jt. Ex. 3, p. 31.) This proposed scanner would replace an existing grandfathered MRI unit leased by Alliance. (Id.)

83. In this Review, Yakaboski analyzed whether Wake Radiology demonstrated the need for the Wake Radiology project at the location proposed. (Jt. Ex. 1, pp. 847-48). The Agency determined that the Wake Radiology Application had demonstrated that the patients it proposed to serve needed those services in the location proposed by the applicant.

C. Projected Utilization

84. The third element of the Criterion 3 analysis evaluates the reasonableness and adequacy of the support for the applicant's projected utilization. In addition, the projected utilization in the third year of operation after the project's completion must meet any applicable performance standards for the services proposed. See N.C.G.S. 131E-183(a)(3).

85. The Agency does not tell applicants which assumptions and methodology to use to develop the utilization projections in their CON applications. Instead, the Agency requires only that the assumptions and methodology used to project the utilization of the proposed project be reasonable and adequately supported.

86. The Wake Radiology Application failed to show that its proposed project would meet the need. (Pittman, Vol. 2, p. 346). The Agency found that Wake Radiology's projected utilization was not reasonable and adequately supported. (Jt. Ex. 1, p. 849).

87. The need methodology and projected utilization for the Wake Radiology Application were contained in Form C and Utilization – Methodology and Assumptions. (Jt. Ex. 3, pp. 106-07).

88. To project utilization, Wake Radiology created a forecast based on a manipulated representation of its own history. (Jt. Ex. 3, pp. 106-07). Wake Radiology calculated a three-year compound annual growth rate ("CAGR") for weighted MRI scans based on historical data from 2016 through 2019 for the Wake Radiology facility.

Wake Radiology Cary Fixed MRI Historical Utilization

	CY16	CY17	CY18	CY19*	CAGR^
Outpatient No Contrast	2,207	2,201	2,479	2,326	1.8%
Outpatient With Contrast	1,198	1,138	1,132	1,458	6.8%
Total	3,405	3,339	3,611	3,784	3.6%
Total Adjusted Scans**	**3,884**	**3,794**	**4,064**	**4,367**	**4.0%**
Adjusted Scans Annual Growth	**NA**	**-2.3%**	**7.1%**	**7.5%**	

*CY 2019 data based on March to August utilization annualized.
^Compound annual growth rate.
**Adjusted scans based on 1.0 weight for outpatient no contrast and 1.4 weight for outpatient with contrast.
Note: Wake Radiology Cary Fixed MRI utilization shown above does not include MRI scans performed on mobile MRI units at Wake Radiology Cary.
Source: Wake Radiology internal data.

(Jt. Ex. 3, p. 106).

89. Wake Radiology used actual historical data for years 2016 through 2018. (Jt. Ex. 3, p. 106). However, for year 2019, Wake Radiology annualized the number of scans from March 2019 through August 2019 – or multiplied the number of scans from March 2019 through August 2019 by two. (See id.) Wake Radiology did not use data reflecting the number of scans performed by the fixed scanner at its Cary location in January 2019, February 2019, or September 2019. (Id.; see also Lane, Vol. 8, pp. 1576-78).

90. Wake Radiology calculated a growth rate from a pre-joint-venture number of scans in 2016 to a post-joint-venture number of scans in 2019 to calculate its compound annual growth rate of four (4) percent for the fixed scanner at Cary. (Carter, Vol. 3, pp. 641-43; Jt. Ex. 3, p. 106),

91. In its Application, Wake Radiology explained that its joint venture with Rex began in February 2019. (Jt. Ex. 3, p. 106). It asserted that in the months after the joint venture began, fixed MRI utilization at Wake Radiology facilities, including the Cary location, had increased since February 2019 and was expected to increase into the future. (Id.) This was because patients were directed from in-patient centers to out-patient centers operated by the joint venture. (Id.; Jordan, Vol. 1, p. 25).

92. Carter testified that the need methodology, namely, excluding data from January and February 2019, and annualizing data from six months, was reasonable because it would represent Wake Radiology's increased utilization post-joint venture. (Carter, Vol. 2, pp. 432-35).

93. The Agency found the exclusion of this data was unreasonable. (Jt. Ex. 1, p. 849). Yakaboski was concerned that, although Wake Radiology had actual historic data for January and February 2019, Wake Radiology used the more advantageous numbers from March 2019

through August 2019 and substituted them for January and February. (Yakaboski, Vol. 4, pp. 856-87; see also Lane, Vol. 8, p. 1581). This artificially inflated number for 2019 was critically important to generating Wake Radiology's projected compound annual growth rate. (Yakaboski, Vol. 4, pp. 857-58). Wake Radiology was obligated to demonstrate a reasonable, annualized number for 2019 to generate a reasonable growth rate. (Id., p. 857). Otherwise, the overstated numbers for 2019 could result in an overstated growth rate for the future utilization projections. (Jt. Ex. 1, p. 850).

94. In fact, the scanner at Cary, which was owned by Alliance and operated by the same staff in the same location before and after the joint venture began, performed fewer scans in March 2019 through August 2019 than it did in March 2018 through August 2018. (Jordan, Vol. 1, pp. 98-99; Carter, Vol. 3, p. 628; Jt. Ex. 17). From March 2018 to August 2018, before the joint venture began, the scanner at Cary performed 1911 scans. (Jordan, Vol. 1, p. 98; Jt. Ex. 17). From March 2019 to August 2019, after the joint venture began, the scanner at Cary only performed 1,892 scans. (Jordan, Vol. 1, p. 99; Jt. Ex. 17). Wake Radiology's data actually shows that the joint venture's performance was either flat or down in its Cary location from 2018 to 2019. (Id.)

95. Moreover, most of Wake Radiology's highest performing months in 2018 occurred in March through August. (Jordan, Vol. 1, pp. 95-96; Jt. Ex. 17). Wake Radiology's lower performing months were January, February, September, November, and December. (Jordan, Vol. 1, p. 96; Jt. Ex. 17). Thus, Wake Radiology excluded data from its lowest performing months to annualize utilization for 2019. (Jordan, Vol. 1, pp. 96-97; Jt. Ex. 17).

96. By annualizing the March to August 2019, Wake Radiology assumed that the fixed scanner at Cary had performed an average of 315 scans per month and would continue to perform an average of 315 scans per month in 2019. (Carter, Vol. 3, pp. 624-27). However, the Alliance fixed scanner at Cary never performed a monthly average of 315 scans from September 2018 through February 2019, except for October 2018. (Id., pp. 624-27; Jt. Ex. 17).

97. The Agency also considered Wake Radiology's failure to satisfy the MRI Performance Standards under NCAC 14C .2703(b) as evidence that Wake Radiology could not show that its projected utilizations were reasonable and adequately supported. (Jt Ex. 1, pp. 850-52) The Agency's analysis of the MRI Performance Standards are discussed later in this Tribunal's analysis of the Wake Radiology Application's nonconformity with the MRI Performance Standards.

98. Moreover, Wake Radiology's utilization projections failed to show how its continuing contract with Alliance would impact its forecast utilization patterns. Wake Radiology has a contract with Alliance that requires it to lease and operate the fixed scanner currently located at its Cary location throughout the term of the contract for approximately $1.1 million per year. (Jordan, Vol. 1, pp. 73-75). Wake Radiology is bound to relocate and operate the scanner within the Wake County service area. (Id., p. 74). In order to pay the yearly lease amount for the Alliance scanner, Wake Radiology would have to perform an additional 3858 scans. (Jordan, Vol. 1, p. 113). The Wake Radiology Application did not account for these scans in its utilization projections. (Id.)

99. Based on the foregoing reasons, the Agency did not err in determining that the Wake Radiology Application was nonconforming with Criterion 3 because its projected utilization was not reasonable and adequately supported.

D. Access to Services Proposed

100. The last component under Criterion 3 evaluates whether the application demonstrates the extent to which residents of the service area are likely to have access to the proposed project, particularly with respect to medically underserved groups. See N.C.G.S. 131E-183(a)(3).

101. The Agency determined that the projected payor mix was reasonable and adequately supported because it was based on the historical experience of the facility in providing MRI services. (Jt. Ex. 1, p. 852).

The Agency Correctly Found the Wake Radiology Application Nonconforming with Criterion 4

102. Criterion 4 applied to the Wake Radiology Application. Criterion 4 provides:

> 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.

N.C.G.S. 131E-183(a)(4).

103. The Wake Radiology Application stated that it considered other alternatives, including maintaining the status quo and developing the MRI at another location. (Jt. Ex. 3, pp. 67-68). Wake Radiology concluded that maintaining the status quo did not allow it the ability to secure adequate fixed MRI capacity to meet demand as the Wake Radiology and Rex joint venture grew and more patients were directed to freestanding outpatient diagnostic imaging centers operated by Wake Radiology. (Id., p. 67). Wake Radiology also rejected developing the MRI at another location because Wake Radiology cannot guarantee permanent access to the MRI scanner at its Cary location since the MRI scanner was owned by Alliance. (Id., p. 68).

104. The Agency found the Wake Radiology Application non-conforming with Criterion 4. (Jt. Ex. 1, p. 860).

105. In analyzing the Wake Radiology Application's conformity with Criterion 4, the Agency first reviewed the alternatives the applicant considered and the reasons why Wake Radiology believed those alternatives were not effective. (Jt. Ex. 1, p. 859).

106. The Agency then evaluated whether the applicant had adequately demonstrated that projected utilization is based on reasonable and adequately supported assumptions. (Jt. Ex. 1, p. 859). The Agency found that Wake Radiology had not done so based upon the same facts considered under Criterion 3. (Id.)

107. The Agency next reviewed whether Wake Radiology demonstrated compliance with the MRI Performance Standards promulgated in 10A NCAC 14C .2703. (Jt. Ex. 1, p. 859) The Agency concluded that Wake Radiology had not done so based upon the same facts considered under the MRI Performance Standards.

108. In evaluating the conformity of the application with Criterion 4, the Agency also considered that the application was not conforming to all statutory and regulatory criteria. (Jt. Ex. 1, p. 859). The Agency found that "an application that cannot be approved cannot be the most effective alternative." (Id.)

109. Wake Radiology also failed to demonstrate that acquiring a new fixed scanner was the least costly or more effective alternative because it did not provide information about its $1.1 million lease of an Alliance fixed scanner, including where the scanner would be relocated to and how the maintenance of this scanner would impact the utilization, costs, and profitability of the proposed project. (See Lane, Vol. 8, pp. 1612-13).

110. Wake Radiology also failed to demonstrate that acquiring a new fixed scanner was the least costly or more effective alternative compared with the alternative of expanding hours and capacity for the Alliance fixed scanner at Cary. (Lane, Vol. 8, pp. 1613-14).

111. Wake Radiology argued that its application should have been found conforming because its methodology to project future utilization by annualizing six months of 2019 data was reasonable and because the MRI Performance Standards did not apply to it. (Jt. Ex. 68, p. 1).

112. As discussed under Criterion 3, the Agency properly concluded that the Wake Radiology Application was nonconforming with Criterion 3 because its projected utilization was not reasonable and adequately supported.

113. As discussed later under the Performance Standards for MRI scanners under 10A NCAC 14C .2703, the Agency properly determined that the Performance Standards applied to Wake Radiology and the Wake Radiology was nonconforming with them.

114. For the foregoing reasons, the Agency did not err in determining that Wake Radiology could not demonstrate that its proposed project was the least costly or most effective alternative.

The Agency Correctly Found the Wake Radiology Application Nonconforming with Criterion 5

115. Criterion 5 applied to the Wake Radiology Application. (Jt. Ex. 1, p. 860) Criterion 5 provides:

> Financial and operating 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.

116. The Agency considers several factors under Criterion 5. The first factor is capital and working capital costs. The total capital costs of Wake Radiology's project are projected to be $2,482,448. (Jt. Ex. 1, p. 871). Wake Radiology projected that there would be no start-up or initial operating expenses for the project because it currently staffs and operates the facility's existing mobile MRI service. (Id.)

117. The second factor is availability of funds. The Agency determined that Wake Radiology had adequate cash and assets to fund its portion of the capital cost of the proposed project. (Jt. Ex. 1, p. 871).

118. The third factor is financial feasibility of the project. Feasibility is usually evaluated by whether the project as proposed will generate a profit. (Yakaboski, Vol. 4, pp. 762-64, Pittman, Vol. 2, p. 257). Not every component of the project must be profitable in order for the project to be financially feasible. If a project will not be profitable, an applicant must demonstrate that it has the financial resources available to offset the costs.

119. The Agency concluded that the assumptions used by Wake Radiology in preparation of its pro forma financial statements were not reasonable and adequately supported because the projected utilization was questionable. (Jt. Ex. 1, p. 872). The projected revenues and expenses were based, in part, on the projected utilization, and as a result, the issues with the projected utilization also made the projected revenues and expenses questionable. (Id.) It thus found that the Wake Radiology Application was nonconforming with Criterion 5. (Id.)

120. In making these findings, the Agency incorporated by reference its discussion of the facts in Criterion 3. (Jt. Ex. 1, p. 872). The Agency referenced and relied upon the same facts that were considered under other criteria but conducted a separate analysis of the conformity of the application with Criterion 5.

121. Wake Radiology contends that the Wake Radiology Application should have been found conforming with Criterion 5 because its methodology to project future utilization by annualizing six months of 2019 data was reasonable. (Jt. Ex. 68, p. 1).

122. As discussed under Criterion 3, the Agency properly concluded that the Wake Radiology Application was nonconforming with Criterion 3 because its projected utilization was not reasonable and adequately supported.

123. Lane demonstrated that Wake Radiology's methodology for its pro formas is unreasonable. First, Form F.2 pro forma income statements show no change in year-to-year payor mix, but utilization forecasts rely on an aging population. (Jt. Ex. 69, p. 10, Lane, Vol. 8, pp. 1619-20). The assumptions on page 117 indicate that Wake Radiology expects payor mix to change, but the actual pro formas show no such change. (Jt. Ex. 69, p. 10). Ultimately, because each payor reimburses the provider at a different amount, Wake Radiology did not provide sufficient information to accurately calculate revenue. (Lane, Vol. 8, pp. 1619-20).

124. With regard to profit, the Form F.2 Revenue and Expense pro formas also show an unexplained three-fold increase in net income between the current and the first year of project operations. (Jt. Ex. 69, p. 10). Given the errors in the projected utilization forecasts, this increase in income is unsupported and unreasonable.

125. For the foregoing reasons, the Agency did not err in determining that Wake Radiology could not demonstrate that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.

MRI Performance Standards

The Agency Correctly Found the Wake Radiology Application Nonconforming with the 10A NCAC 14C .2703 (b)(1)

126. Under 10 NCAC 14C.2703(b)(1), Wake Radiology was required to:

> demonstrate that the existing fixed MRI scanners which the applicant or a related entity owns a controlling interest in and locates in the proposed MRI service area performed an average of 3,328 weighted MRI procedures in the most recent 12 month period for which the applicant has data . . .

127. The Agency correctly found that the Rule applied to Wake Radiology. (Jt. Ex. 1, p. 924). According to the Agency's interpretation, for the Rule to apply, (1) the applicant must be proposing to "acquire a fixed magnetic resonance imaging (MRI) scanner," and (2) own a fixed MRI scanner in the service area. (Id.) WR Imaging is proposing to acquire a fixed MRI scanner and it also owns two fixed MRI scanners in the service area. (Id.) Pursuant to the Agency's interpretation, Wake Radiology must satisfy the performance standards required by the Rule. (Yakaboski, Vol. 4, pp. 910-11; Pittman, Vol. 2, pp. 339-40).

128. Wake Radiology contended that the Rule did not apply. (Jt. Ex. 3, p. 57). Wake Radiology argued that the two fixed MRI scanners were transferred to WR Imaging in February 2019, when the joint venture began, and therefore WR Imaging did not own the scanners for a 12-month period. (Id.) This interpretation is not supported by plain reading of the rule. Of equal or greater importance, the Agency has applied this Rule continuously in every MRI review since 1993. (Pittman, Vol. 2, p. 343). The Agency has also consistently interpreted these MRI standards according to the above interpretation. (Pittman, Vol. 8, pp. 1470) The Agency's interpretation of the Rule is reasonable and the Tribunal thus defers to the Agency's interpretation of the Rule. Craven Reg'l Med. Auth. v. N.C. Dep't of Health & Human Servs., 176 N.C. App. 46, 58, 625 S.E.2d 837, 844 (2006); Total Renal Care of N. Carolina, LLC v. N. Carolina Dep't of Health & Hum. Servs., 242 N.C. App. 666, 674, 776 S.E.2d 322, 327 (2015).

129. Next, according to the Agency's interpretation, the applicant must then demonstrate that that the MRI scanners it owns in the service area performed an average of 3,328 weighted MRI procedure in the most recent 12-month period for which the applicant has data. (Jt. Ex. 1, p. 924; Yakaboski, Vol. 4, pp. 910-11; Pittman, Vol. 2, pp. 339-40).

130. The Agency correctly found that Wake Radiology Application was nonconforming with this Rule. (Jt. Ex. 1, pp. 923-24). The Agency recognized that Wake Radiology did not provide any data for the two fixed scanners to comply with the Rule (Pittman, Vol. 2, pp. 316-17; Jt. Ex. 1, p. 924). If an applicant does not provide any data, it is the applicant's burden to demonstrate that it did not have access to data for the most recent 12 month-period. (Pittman, Vol. 2, p. 312). Wake Radiology failed to meet that burden, so it failed to satisfy the Rule. (Jt. Ex. 1, p. 924).

131. Moreover, Wake Radiology did, in fact, possess data for the most recent 12-month period relating to the two fixed scanners. Wake Radiology admitted that WR Imaging possessed the relevant data. (See Jordan, Vol. 1, pp. 30, 37, 106). The Wake Radiology Application also states that the source of data from 2016-2019 for the fixed scanners was "Wake Radiology internal data." (Jt. Ex. 3, p. 188).

132. Because Wake Radiology failed to submit any data relating to its two fixed MRI scanners, and it possessed data for the most recent 12-month period, Wake Radiology failed to comply with the Rule. The Wake Radiology Application is therefore nonconforming as a matter of law.

The Agency Correctly Found the Wake Radiology Application Nonconforming with the 10A NCAC 14C .2703 (b)(2)

133. Under 10 NCAC 14C.2703(b)(2), Wake Radiology was required to

> demonstrate that each existing mobile MRI scanner which the applicant or a related entity owns a controlling interest in and operates in the proposed MRI service area except temporary MRI scanners, performed 3,328 weighed MRI procedures in the most recent 12-month period for which the applicant has data.

134. The Agency correctly found that the Rule applied to Wake Radiology. (Jt. Ex. 1, pp. 925-26). According to the Agency's interpretation, for the Rule to apply, (1) the applicant must be proposing to "acquire a fixed magnetic resonance imaging (MRI) scanner," and (2) own a mobile MRI scanner in the service area. (Id., p. 926). Wake Radiology is proposing to acquire a fixed MRI scanner and it also owns two mobile MRI scanners in the service area. (Id.) Pursuant to the Agency's interpretation, Wake Radiology must satisfy the performance standards required by the Rule. (Yakaboski, Vol. 4, pp. 911-12; Pittman, Vol. 2, p. 339).

135. In its Application, Wake Radiology contended that the Rule did not apply. (Jt. Ex. 3, p. 58). Wake Radiology argued that the two mobile MRI scanners were transferred to WR Imaging in February 2019, when the joint venture began, and therefore WR Imaging did not own the scanners for a 12-month period and did not have 12 months of its own data. (Id.) Yakaboski understood that Wake Radiology had taken the position that because ownership of Mobile MRI 1 and Mobile MRI 2 had changed within the last 12 months, Wake Radiology did not have to show conformity with the performance standard. (Yakaboski, Vol. 4, pp. 829-30). Yakaboski, on behalf of the Agency, did not find that Wake Radiology's position was an accurate interpretation of the rule. (Id., p. 830). Yakaboski confirmed his conclusion with Ms. Pittman. (Id., pp. 830, 850).

136. The Agency has consistently interpreted these MRI standards according to the above interpretation. (Pittman, Vol. 8, pp. 1470). The Agency's interpretation of the Rule is reasonable, and the Tribunal thus defers to the Agency's interpretation of the Rule. Craven Reg'l Med. Auth. v. N.C. Dep't of Health & Human Servs., 176 N.C. App. 46, 58, 625 S.E.2d 837, 844 (2006); Total Renal Care of N. Carolina, LLC v. N. Carolina Dep't of Health & Hum. Servs., 242 N.C. App. 666, 674, 776 S.E.2d 322, 327 (2015).

137. In sum, Wake Radiology's position that the Rule does not apply to them is not reasonable. This interpretation would allow applicants to simply create new entities and transfer ownership of its MRI scanners to those new entities, thus avoiding the need for compliance with the MRI Performance Standards. Whether a rule requiring a certain number of scans per year makes sense is not for the Tribunal to determine.

138. Next, according to the Agency's interpretation, the applicant must then demonstrate that that the mobile MRI scanners it owns in the service area performed 3,328 weighted MRI procedures in the most recent 12-month period for which the applicant has data. (Jt. Ex. 1, p. 926; Yakaboski, Vol. 4, pp. 848-49, 911-12; Pittman, Vol. 2, p. 339). Put simply, if the applicant has data for the relevant MRI machines, the applicant must provide the information. (Yakaboski, Vol. 4, p. 848). The Agency has applied this Rule continuously in every MRI review since 1993. (Pittman, Vol. 2, p. 343).

139. The Agency did not err in finding that the Wake Radiology Application was nonconforming with this Rule. (Jt. Ex. 1, pp. 925-26). The Agency recognized that Wake Radiology did not provide any data for the two mobile scanners to comply with the Rule (Pittman, Vol. 2, p. 319; Jt. Ex. 1, p. 926). If the applicant does not have data, it is the applicant's burden to demonstrate that it did not have access to data for the most recent 12-month period. (Pittman, Vol. 2, p. 312). Wake Radiology failed to meet that burden, so it failed to satisfy the Rule. (Jt. Ex. 1, p. 926)

140. Wake Radiology did possess data for the most recent 12-month period relating to the two mobile scanners. (Jt. Ex. 17). WR Imaging possessed the relevant data. (Jordan, Vol. 1, pp. 30, 37, 106). The Wake Radiology Application states that the source of data from 2016-2019 relating to its mobile MRI scanners was "Wake Radiology internal data." (Jt. Ex. 3, pp. 199, 200; Yakaboski, Vol. 4, p. 849; Pittman, Vol. 2, pp. 328-32).

141. Moreover, the two mobile MRI scanners failed to perform 3,328 scans in the most recent 12-month period. (Jordan, Vol. 1, pp. 102-04). During the Review, Yakaboski attempted to determine whether the Wake Radiology Application was conforming with the Rule according to publicly available data. (Yakaboski, Vol. 4, p. 830) Yakaboski looked up the Registration & Inventory (R&I) forms for each mobile scanner to see if each mobile scanner met the performance threshold. (Id., pp. 831-33). Neither scanner performed the minimum required number of scans under the Rule. (Id.)

142. Under these facts, the Agency had no discretion in determining whether an application was conforming with the Rule (Yakaboski, Vol. 4, p. 829). If the mobile scanners did not meet the performance threshold, it must find the application nonconforming. (Id.) As previously noted, whether a rule requiring a certain minimum number of scans makes practical sense is not for the Tribunal to determine.

143. Because Wake Radiology failed to submit conforming data relating to its two mobile MRI scanners, and because the data showed that the mobile scanners did not meet the minimum performance threshold, Wake Radiology failed to comply with the Rule. The Wake Radiology Application is therefore nonconforming with 10 NCAC 14C.2703(b)(2) as a matter of law.

The Agency Correctly Found the Wake Radiology Application Nonconforming with the 10A NCAC 14C .2703 (b)(3)(E)

144. Under 10 NCAC 14C.2703(b)(3)(E), Wake Radiology was required to

> demonstrate that the average annual utilization of the existing, approved and proposed fixed MRI scanners which the applicant or a related entity owns a controlling interest in and locates in the proposed MRI service area are reasonably expected to perform the following number of weighted MRI procedures, whichever is applicable, in the third year of operation following completion of the proposed project: 4,805 . . .

145. The Wake Radiology Application calculated a compound annual growth rate ("CAGR") of 4% based on annualized data from March 2019 through August 2019. (Jt. Ex. 3, p. 107) The exclusion of the number of actual scans performed in January and February 2019 created an inaccurately overstated CAGR. (Id.) Using the overstated CAGR, Wake Radiology calculated that the fixed scanner at Cary would perform 5,106 weighted scans in the third year of operation following completion of the proposed project:

Wake Radiology Cary Fixed MRI Projected Utilization

	CY20	CY21	CY22	CY23	CAGR
Outpatient No Contrast	2,419	2,515	2,615	2,719	4.0%
Outpatient With Contrast	1,516	1,576	1,639	1,705	4.0%
Total	3,935	4,092	4,255	4,424	4.0%
Total Adjusted Scans*	**4,541**	**4,722**	**4,910**	**5,106**	**4.0%**

*Adjusted scans based on 1.0 weight for outpatient no contrast and 1.4 weight for outpatient with contrast.

(Id.)

146. The Wake Radiology Application used the overstated 5,106 number to calculate its average annual utilization of all of its existing fixed MRI scanners in the service area. (Jt. Ex. 3, p. 191) Wake Radiology was able to show that the average annual utilization of all its and related entity Rex's fixed scanners was projected to exceed 4,805 scans in the third year of operation after the completion of the project:

Projected Total Adjusted Scans

	CY23	Fixed Magnet	Total Average
Wake Radiology Cary	5,106	1	
Wake Radiology Raleigh	11,411	2	
UNC REX Hospital	10,968	2	
UNC REX Holly Springs Hospital	1,455	1	
Total	**28,940**	**6**	**4,823**

(Jt. Ex. 3, p. 191). However, if any or all of the calculations in the column labeled CY23 were the result of a calculation using an overstated CAGR, then the total average is overstated. (Lane, Vol. 8, pp. 1592-93).

147. Moreover, Wake Radiology also excluded data from January 2019 and February 2019 to calculate its CAGR for its fixed scanner at Wake Radiology Raleigh. (Jt. Ex. 3, p. 188; Lane, Vol. 8, p. 1592). This exclusion of data could have also resulted in an overinflated CAGR, and thus, an overinflated projection for how many scans the fixed scanner at Wake Radiology Raleigh would perform during the third year of completion after the proposed project. (Lane, Vol. 8, p. 1592).

148. The Agency found that because the projected utilization for all fixed MRI scanners for CY23 relied on the overstated data from CY19, the projected utilization was not reasonable and adequately supported. (Jt. Ex. 1, p. 851). The Agency noted that to be conforming with this Rule, Wake Radiology's and Rex's scanners, together, needed to perform at least 28,830 scans in the third year of operation after the completion of the project [4,805 x 6 =28,830] (Id.) According to Wake Radiology's projections, the scanners were projected perform a total of 28,940 scans. (Id.) The Agency found that if the fixed MRI scanners performed, in total, just 78 fewer weighted scans, Wake Radiology would fail to comply with the rule. (Id.) Thus, a slightly inflated calculation would mean the difference between conformity and nonconformity.

149. Based on Wake Radiology's actual data, had the Wake Radiology Application used data from January 2019 and February 2019 in its calculations, it would not have satisfied the Rule. (Lane, Vol. 8, p. 1590).

150. Wake Radiology's actual data showed that in January 2019, the fixed scanner at Wake Radiology performed 202 scans. (Jt. Ex. 17). Wake Radiology's actual data shows that in February 2019, the fixed scanner at Wake Radiology performed 159 scans. (Id.) Wake Radiology's actual data shows that from September 1, 2019, to September 9, 2019, the fixed scanner at Wake Radiology performed 16 scans. (Id.)

151. Using these numbers, Ms. Lane calculated Wake Radiology's actual CAGR, annualizing the data from January 1, 2019, through September 9, 2019 (8.3 months of data).

Table 2 ***Wake Radiology Cary Fixed MRI Historical Utilization with 8.3 CY19 months of data annualized***

	CY16	CY17	CY18	CY19*	CAGR^
Outpatient No Contrast	2,207	2,201	2,479	2,227	0.29%
Outpatient with Contrast	1,198	1,138	1,132	1,343	3.89%
Total	3,405	3,339	3,611	3,570	1.59%
Total Adjusted Scans**	**3,884**	**3,794**	**4,064**	4,107	1.88%
Adjusted Scans Annual Growth	**NA**	**2.30%**	**7.10%**	**1.06%**	

(Lane, Vol. 8, pp. 1580-86; Jt. Ex. 69, p. 13; see also Ex. 307). The calculated number of annualized scans for 2019 using 8.3 months of data (4,107) resulted in a number 260 less than the calculated number of annualized scans for 2019 using 6 months of data (4,367). (Lane, Vol. 8, p. 1587).

152. According to Lane's calculation, including the utilization data from January 1, 201,9 to September 9, 2019 would have produced a CAGR of 1.88%. (Lane, Vol. 8, pp. 1584-87; Jt. Ex. 69, p. 13; Ex. 307).

153. Using the actual CAGR of 1.88%, Lane calculated Wake Radiology's projected utilization for the first three years of the proposed project:

Table 3 ***Wake Radiology Cary Fixed MRI Forecast Utilization Forecast with Adjusted CAGR***

	CY20	CY21	CY22	CY23	CAGR^
Outpatient No Contrast	2,233	2,240	2,246	2,253	0.29%
Outpatient With Contrast	1,395	1,450	1,506	1,564	3.89%
Total	3,626	3,684	3,742	3,802	1.59%
Total Adjusted Scans*	**4,184**	**4,263**	**4,343**	**4,424**	**1.88%**

** Forecast using CAGR of 1.88%; multiply the prior year by 1+CAGR*

(Lane, Vol. 8, p. 1593; Jt. Ex. 69, p. 13).

154. According to Lane's calculation, the scanner at Wake Radiology's Cary location would have only performed 4,424 scans in the third year of operation following completion of the proposed project. (Lane, Vol. 8, p. 1593; Jt. Ex. 69, p. 13).

155. Using the 4,424 number would have meant that Wake Radiology's and UNC Rex's four fixed scanners were projected to perform 28,258 (4,424+11,411+10,968+1,455=28,258) total scans in the third year of operation following completion of the proposed project. (See Jt. Ex. 3, p. 191; Lane, Vol. 8, p. 1593). To be conforming with the Rule, the scanners need to perform at least 28,830 scans in total. (Jt. Ex. 1, p. 851). Thus, Wake Radiology's inflated CAGR based on the exclusion of data from January and February 2019 did mean the difference between conformity and nonconformity with the Rule.

156. For the foregoing reasons, the Agency did not err in determining that Wake Radiology was nonconforming with 10 NCAC 14C.2703(b)(3)(E).

The Agency Correctly Found the Wake Radiology Application Nonconforming with the 10A NCAC 14C .2703 (b)(4)(E)

157. Under 10 NCAC 14C.2703(b)(4)(E), if the proposed MRI scanner will be located at a different site from any of the existing or approved MRI scanners owned by the applicant or a related entity, the applicant must

> demonstrate that the annual utilization of the proposed fixed MRI scanner is reasonably expected to perform the following number of weighted MRI procedures, whichever is applicable, in the third year of operation following completion of the proposed project: . . . 4,805 . . .

158. The Agency determined that the Rule applied because the proposed MRI scanner would be located at a different site from any of the existing or approved MRI scanners owned by Wake Radiology or a related entity. (Jt. Ex. 1, p. 929).

159. The Agency found that while Wake Radiology projected that the proposed MRI scanner would perform 5,106 weighted MRI procedures in the third year of operation, Wake Radiology did not adequately demonstrate that projected utilization was reasonable and adequately supported. (Jt. Ex. 1, p. 929).

160. In making these findings, the Agency incorporated by reference its discussion found in Criterion 3. (Jt. Ex. 1, p. 929). The Agency referenced and relied upon the same facts that were previously considered under Criterion 3 but conducted a separate analysis of the conformity of the application with 10 NCAC 14C.2703(b)(4)(E).

161. The Agency correctly found that the Wake Radiology Application was nonconforming with 10 NCAC 14C.2703(b)(4)(E) for the reasons stated under 10 NCAC 14C.2703(b)(3)(E). Wake Radiology's methodology to project utilization was not reasonable and adequately supported. Moreover, had Wake Radiology used all of the available 2019 data relating to the grandfathered fixed scanner at its Cary location in its utilization projections, the scanner at Wake Radiology's Cary location would have only performed 4,424 scans in the third year of operation following completion of the proposed project and would have failed to comply with the Rule. (Lane, Vol. 8, p. 1593; Jt. Ex. 69, p. 13).

The Agency Correctly Found the Wake Radiology Application Nonconforming with the 10A NCAC 14C .2703 (b)(5)

162. Under 10 NCAC 14C.2703(b)(5), the applicant must

> demonstrate that annual utilization of each existing, approved and proposed mobile MRI scanner which the applicant or a related entity owns a controlling interest in and locates in the proposed MRI service area is reasonably expected to perform 3,328 weighted MRI procedures in the third year of operation following completion of the proposed project . . .

163. The Agency noted that Wake Radiology owned a controlling interest in two mobile MRI scanners. (Jt. Ex. 1, p. 929). The Agency found that while Wake Radiology projected that Mobile MRI 1 would perform 3,500 weighted MRI scans, and MRI Mobile 2 would perform 3,971 weighted scans in 2023, Wake Radiology did not adequately demonstrate that projected utilization was reasonable and adequately supported. (Id., p. 930). The Agency

noted in order to project utilization for MRI Mobile 1 and MRI Mobile 2, Wake Radiology did not utilize the actual historical data for January 2019 and February 2019. (Jt. Ex. 1, p. 852).

164. In making these findings, the Agency incorporated by reference its discussion found in Criterion 3. (Jt. Ex. 1, p. 930). The Agency referenced and relied upon the same facts that were previously considered under Criterion 3 but conducted a separate analysis of the conformity of the application with 10 NCAC 14C.2703(b)(4)(E).

165. Wake Radiology calculated a growth rate from a pre-joint venture number of scans in 2016 to a post-venture number of scans in 2019 to calculate its compound annual growth rate of 10.7 percent for MRI Mobile 1 and 23.8 percent for MRI Mobile 2. (Carter, Vol. 3, pp. 644-45). Wake Radiology halved both of these calculated growth rates to create a more "conservative" estimate. (Jt. Ex. 1, pp. 199-201).

166. Wake Radiology's methodology for projecting the utilization of its mobile MRI scanners was consistent with its methodology for projecting the utilization of its fixed MRI scanners. (See Jt. Ex 3, pp. 187-91, 199-201). Because Wake Radiology relied on this methodology to calculate an overinflated CAGR to comply with 10A NCAC 14C .2703 (b)(3)(E), 10 NCAC 14C.2703(b)(4)(E), and Criterion 3, Wake Radiology had to apply the same unreasonable methodology, here.

167. For the foregoing reasons, the Agency did not err in determining that Wake Radiology was nonconforming with 10 NCAC 14C.2703(b)(5).

The Agency Correctly Found the Wake Radiology Application Nonconforming with the 10A NCAC 14C .2703 (b)(6)

168. Under 10 NCAC 14C.2703(b)(6), the applicant must "document the assumptions and provide data supporting the methodology used for each projection required in this Rule."

169. The Agency found that while Wake Radiology provided its assumptions and data supporting the methodology used for each project required by the Rule, the applicant did not adequately demonstrate that its projected utilization was reasonable and adequately supported. (Jt. Ex. 1, p. 930).

170. In making these findings, the Agency incorporated by reference its discussion found in Criterion 3. (Jt. Ex. 1, p. 930). The Agency referenced and relied upon the same facts that were previously considered under Criterion 3 but conducted a separate analysis of the conformity of the application with 10 NCAC 14C.2703(b)(6). (See id.)

171. For the reasons stated under Criterion 3 and the MRI Performance Standards, the Agency did not err in determining that the Wake Radiology Application was nonconforming with 10 NCAC 14C.2703(b)(6).

The Raleigh Radiology Application

172. The Raleigh Radiology Application proposed that Raleigh Radiology-Cary would acquire a 3.0 Tesla MRI scanner to be installed at its existing offices in Cary. (Jt. Ex. 1, p. 822).

Raleigh Radiology-Cary leases a 1.5T MRI scanner from Alliance Imaging. (Ex. 177, p. 44). The new 3T MRI would be installed in the same space as the leased scanner. (Id., p. 36).

173. The Raleigh Radiology Application was prepared by Nancy Lane, President of PDA, Inc. (Lane, Vol. 8, pp. 1546, 1564). Lane also prepared comments and responses to comments on behalf of Raleigh Radiology-Cary. (Id., p. 1568). Lane also issued an opinion and testified as an expert on behalf of Raleigh Radiology-Cary. (Id., p. 1571).

The Agency Correctly Found the Raleigh Radiology Application Conforming with Criterion 1

174. The Agency found the Raleigh Radiology Application conforming with Criterion 1. (Jt. Ex. 1, p. 823).

175. Criterion 1 has two distinct elements: (1) is the project consistent with the need determination in the SMFP; and (2) is the project consistent with the applicable policies in the SMFP. See N.C.G.S. 131E-183(a)(1).

176. The Agency began its analysis of Criterion 1 by analyzing the need determination in the SMFP. The 2019 SMFP contained a need determination for a fixed MRI scanner in Wake County. (Jt. Ex. 1, p. 823).

177. The Raleigh Radiology Application proposed to acquire one fixed MRI scanner to be located at Raleigh Radiology Cary, an existing non-hospital licensed diagnostic center. (Jt. Ex. 1, p. 822). Raleigh Radiology leases a mobile MRI scanner that is termed a "grandfathered fixed MRI scanner" from Alliance. (Id.) The proposed fixed MRI scanner would replace the existing Alliance leased "grandfathered fixed" MRI service. (Id.) Therefore, the Agency determined that the Raleigh Radiology Application was consistent with the 2019 SMFP need determination for Wake County. (Id., p. 823).

178. The Agency next analyzed the first applicable policy in the SMFP, Policy GEN-3. (Jt. Ex. 1, p. 823). Policy GEN-3 provides:

> A certificate of need applicant applying to develop or offer a new institutional health service for which there is a need determination in the North Carolina State Medical Facilities Plan shall demonstrate how the project will promote safety and quality in the delivery of health care services while promoting equitable access and maximizing healthcare value for the resources expended. A certificate of need applicant shall document its plans for providing access to services for patients with limited financial resources and demonstrate the availability of capacity to provide these services. A certificate of need applicant shall also document how its projected volumes incorporate these concepts in meeting the need identified in the State Medical Facilities Plan as well as addressing the needs of all residents in the proposed service area.

Policy GEN-3, 2019 SMFP.

179. Policy GEN-3 contains four distinct elements: (1) does the project promote safety and quality; (2) does the project promote equitable access; (3) does the project maximize healthcare value; and (4) does the project document how its projected volumes incorporate these concepts in meeting the need identified in the SMFP. Policy GEN-3, 2019 SMFP.

180. The Agency found that Raleigh Radiology-Cary adequately documented (1) how the project would promote safety and quality in the delivery of MRI services in Wake County; (2) how the project would promote equitable access to MRI services in Wake County; and (3) how the project will maximize healthcare value for the resources expended. (Jt. Ex. 1, p. 823).

181. The Agency next analyzed the second applicable policy in the SMFP, Policy GEN-4. (Jt. Ex. 1, p. 823). Policy GEN-4 provides:

> Any person proposing a capital expenditure greater than $2 million to develop, replace, renovate or add to a health service facility pursuant to N.C.G.S. 131E-178 shall include in its certificate of need application a written statement describing the project's plan to assure improved energy efficiency and water conservation.
>
> In approving a certificate of need proposing an expenditure greater than $5 million to develop, replace, renovate or add to a health service facility pursuant to N.C.G.S. 131E-178, Certificate of Need shall impose a condition requiring the applicant to develop and implement an Energy Efficiency and Sustainability Plan for the project that conforms to or exceeds energy efficiency and water conservation standards incorporated in the latest editions of the North Carolina State Building Codes. The plan must be consistent with the applicant's representation in the written statement as described in paragraph one of Policy GEN-4.
>
> Any person awarded a certificate of need for a project or an exemption from review pursuant to N.C.G.S. 131E-184 is required to submit a plan for energy efficiency and water conservation that conforms to the rules, codes and standards implemented by the Construction Section of the Division of Health Service Regulation. The plan must be consistent with the applicant's representation in the written statement as described in paragraph one of Policy GEN-4. The plan shall not adversely affect patient or resident health, safety or infection control.

Policy GEN-4, 2019 SMFP.

182. The Agency found that Raleigh Radiology-Cary demonstrates adequately that the application included a written statement describing the project's plan to assure improved energy efficiency and water conservation, and the Raleigh Radiology Application was therefore consistent with Policy GEN-4. (Jt. Ex. 1, p. 823).

183. In summary, the Agency concluded that the Raleigh Radiology Application was consistent with the need determination in the SMFP and Policy Gen-3, and Policy GEN-4. Thus, the Agency determined that the Raleigh Radiology Application was conforming with Criterion 1. (Jt. Ex. 1, p. 823).

184. In his report, Carter opined that the Agency erred in finding the Raleigh Radiology Application conforming with Criterion 1. (Jt. Ex. 68, p. 2). Wake Radiology asserted that the Raleigh Radiology Application did not demonstrate that its proposed project would promote safety and equality, equitable access, and the maximization of healthcare value under Policy GEN-3. (Id.)

185. Carter first contends that Raleigh Radiology-Cary's utilization projections were unreasonable. (Jt. Ex. 68, p. 2).

186. Carter also contends that Raleigh Radiology-Cary presented erroneous and inconsistent financial projections. (Jt. Ex. 68, p. 2).

187. Carter also contends that Raleigh Radiology-Cary's proposal to replace the Alliance grandfathered fixed MRI scanner, rather than increasing the number of MRI scanners in the area, renders the Raleigh Radiology Application nonconforming with Criterion 1. (Jt. Ex. 68, p. 2)

188. One of the basic assumptions of the 2019 SMFP Methodology states that an applicant may propose to acquire and operate an MRI scanner to replace a contracted service. (Lane, Vol. 8, pp. 1624-26). It provides:

> A facility that offers MRI services on a full-time basis pursuant to a service agreement with an MRI provider is not precluded from applying for a need determination in the North Carolina 2019 State Medical Facilities Plan to replace the existing contracted service with a fixed MRI scanner under the applicant's ownership and control. It is consistent with the purposes of the Certificate of Need law and the State Medical Facilities Plan for a facility to acquire and operate an MRI scanner to replace such a contracted service, if the acquisition and operation of the facility's own MRI scanner will allow the facility to reduce the cost of providing the MRI service at that facility

(Ex. 169, p. 4; Pittman, Vol. 2, pp. 350-51). The Agency is obligated to follow the methodology in the 2019 SMFP. (Pittman, Vol. 2, pp. 350-51). Thus, the proposal to acquire and operate an MRI scanner to replace a contracted service, standing alone, does not render an application nonconforming with Criterion 1.

189. Moreover, replacing the Alliance grandfathered MRI scanner with a fixed scanner owned wholly by Raleigh Radiology-Cary is more efficient and cost-effective, based on the

evidence. (Id.; Mathan, Vol. 6, pp. 1283-84; Lane, Vol. 8, pp. 1628-29). Raleigh Radiology-Cary would be able to hire its own technologists to run the equipment rather than paying for Alliance's technologists. (Watson, Vol. 5, pp. 1153-54). Raleigh Radiology-Cary would be able to manage the hours of the staff and have more flexibility in providing services and scheduling patients. (Id.)

190. Further, upon installation of the new 3T MRI scanner Alliance is free to place the leased grandfathered scanner at any location, including in Wake County. Therefore, it is possible that the overall inventory in Wake County would increase.

191. Ultimately, Raleigh Radiology-Cary needed to show that the "the acquisition and operation of the facility's own MRI scanner will allow the facility to reduce the cost of providing the MRI service at that facility." (Ex. 169, p. 4; Lane, Vol. 8, p. 1627). Raleigh Radiology-Cary's calculation of the savings of owning the 3T MRI versus leaning from Alliance is $1,379.138. (Watson, Vol. 5, p. 1158; Lane, Vol. 8, p. 1627). Raleigh Radiology-Cary was thus able to satisfy the assumptions stated in the 2019 SMFP.

192. For the foregoing reasons, the Agency did not err in determining the Raleigh Radiology Application was conforming with Criterion 1.

The Agency Correctly Found the Raleigh Radiology Application Conforming with Criterion 3

193. The Agency found the Raleigh Radiology Application conforming with Criterion 3. (Jt. Ex. 1, p. 836)

194. Criterion 3 requires the following:

> 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.

A. Population to Be Served

195. The first element under Criterion 3 requires the applicant to identify from where the proposed patients projected to be served by the proposed project will originate. See N.C.G.S. 131E-183(a)(3).

196. Raleigh Radiology-Cary provided historical data relating to the origin of its patients receiving services at its Cary location:

Table C. 1 - Actual Patient Origin for Each Service Component: MRI Services RRCary

County	Last Full FY* 10/1/18 to 9/30/19	
	Number of Patients	% of Total
Wake	4,756	85.4%
Harnett	134	2.4%
Chatham	114	2.0%
Lee	114	2.0%
Johnston	100	1.8%
Durham	61	1.1%
Orange	54	1.0%
Nash	15	0.3%
Other NC Counties	153	2.7%
Other States	31	0.6%
Unknown	34	0.6%
Total	***5,556***	***100.0%***

**Federal Fiscal Year;*

Exhibit C.2 has detail of the 41 other NC counties. Data provided are RRCary internal data, unique patients by zip code, converted to county, for October 1, 2018 through September 30, 2019.

(Jt. Ex. 177, p. 40).

197. Based on its historical data, Raleigh Radiology-Cary projected where the patients to be served by the proposed project would originate. (Jt. Ex. 177, pp. 41, 138-39). Raleigh Radiology-Cary projected the following patient origin:

Table C. 2 - Projected Patient Origin: Patients RRCary MRI for RRCary Fiscal Years

County or other geographic area such as ZIP code	1st Full FY 01/01/2021 to 12/31/2021		2nd Full FY 01/01/2022 to 12/31/2022		3rd Full FY 01/01/2023 to 12/31/2023	
	No. of Patients	% of Total	No. of Patients	% of Total	No. of Patients	% of Total
Wake	5,035	86.50%	5,133	86.50%	5,232	86.50%
Harnett	102	1.75%	104	1.75%	106	1.75%
Chatham	146	2.50%	148	2.50%	151	2.50%
Lee	105	1.80%	107	1.80%	109	1.80%
Johnston	70	1.20%	71	1.20%	73	1.20%
Durham	66	1.14%	68	1.14%	69	1.14%
Orange	60	1.03%	61	1.03%	62	1.03%
Nash	15	0.27%	16	0.27%	16	0.27%
Other NC Counties	156	2.68%	159	2.68%	162	2.68%
Other States	66	1.13%	67	1.13%	68	1.13%
Unknown	0	0.00%	0	0.00%	0	0.00%
Total	5,821	100.00%	5,934	100.00%	6,049	100.00%

Patient origin for MRI patients include patients in the core counties. Other includes patients from other North Carolina counties, and from other states. This small number of patients will distribute differently from year to year and is a function of patient physician preference, patient travel to stay with relatives, and the high concentration of specialist physicians in Wake County.

(Jt. Ex. 177, p. 41). Raleigh Radiology-Cary's projections accounted for annual changes in populations. (Jt. Ex. 177, p. 139-40).

198. For the foregoing reasons, the Agency did not err in determining that Raleigh Radiology-Cary adequately identified the patient origin for the population it proposed to serve.

B. Demonstration of Need

199. The second element of the analysis under Criterion 3 – the "demonstration of need" – evaluates whether the applicant demonstrates the patients it proposes to serve need those services in the location proposed by the applicant. See N.C.G.S. 131E-183(a)(3).

200. In the Raleigh Radiology Application, Raleigh Radiology-Cary proposed to acquire one fixed MRI scanner to be located at Raleigh Radiology Cary, an existing non-hospital licensed diagnostic center. (Jt. Ex. 1, p. 836).

201. In this Review, the Agency analyzed whether Raleigh Radiology-Cary demonstrated the need for the project at the location proposed. (Jt. Ex. 1, p. 836). The Agency determined that the information Raleigh Radiology-Cary provided was reasonable and adequately supported. (Jt. Ex. 1, p. 837; Jt. Ex. 177, pp. 42-51; Yakaboski, Vol. 4, pp. 873-74).

202. For the foregoing reasons, the Agency did not err in determining that Raleigh Radiology-Cary demonstrated that the patients it proposed to serve needed those services in the location proposed by the applicant.

C. Projected Utilization

203. The third element of the Criterion 3 analysis evaluates the reasonableness and adequacy of the support for the applicant's projected utilization. N.C.G.S. 131E-183(a)(3). In addition, the projected utilization in the third year of operation after the project's completion must meet any applicable performance standards for the services proposed. (Id.)

204. The Agency noted that Raleigh Radiology-Cary projected that the proposed scanner would perform 8,030 scans in the third year of operation following project completion. (Jt. Ex. 1, p. 838; Ex. 177, p. 147). Additionally, in 2019, the scanner at Raleigh Radiology's Cary location performed 7,427 weighted scans. (Jt. Ex. 1, p. 839). Raleigh Radiology-Cary's growth rate was derived from the population growth rate for Wake County, which the Agency determined was reasonable. (Id., pp. 837-38). The Agency also noted Raleigh Radiology-Cary was already conforming with both the historical and future-looking MRI Performance Standards and showed that it would continue to meet the MRI Performance Standards in the third year after completion of the project. (See id., pp. 839-40).

205. Raleigh Radiology-Cary provided its methodology for projecting utilization in Section Q of its application. (Ex. 177, pp. 132-53). The Agency determined that Raleigh Radiology's projected utilization was reasonable and adequately supported because it was based on the historical experience of the facility in providing MRI services and expected population growth data. (Jt. Ex. 1, p. 838).

206. Joanne Watson, Chief Operating Officer of Raleigh Radiology (Watson, Vol. 5, p. 1033), confirmed that the projected utilization was based on Raleigh Radiology's history. (Watson, Vol. 5, pp. 1162-63).

207. In his report, Carter opined that there were several identified issues with Raleigh Radiology-Cary's utilization projections that he found to be unreasonable and unreliable. None of these issues render the Raleigh Radiology Application nonconforming with Criterion 3.

208. First, Carter opined that the Raleigh Radiology Application's utilization methodology had several errors relating to how Raleigh Radiology-Cary's calculated need – specifically with respect to Steps 3 and 4. (Jt. Ex. 68, pp. 2-3). However, Steps 3 and 4 are focused on an analysis of the need of the population to be served for fixed MRI scanners and

were separate steps from Raleigh Radiology-Cary's methods for forecasting utilization. (Jt. Ex. 69, p. 2). Raleigh Radiology-Cary used Steps 3 and 4 to simply establish population need but used other data relating to historical use trends to forecast utilization at Raleigh Radiology-Cary. (Jt. Ex. 69, p. 2; Ex. 177, p. 149-52). Any alleged error relating to Steps 3 and 4 had no impact on the reasonableness on Raleigh Radiology-Cary's utilization projections.

209. With respect to Steps 6 and 9 of Raleigh Radiology-Cary's utilization methodology, Carter argued that it was unreasonable for Raleigh Radiology-Cary to predict growth where there was "historical decline" resulting from the initiation of another MRI service in Fuquay-Varina. (Jt. Ex. 68, p. 3; Jt. Ex. 1, p. 432). However, the number of MRI scans at Raleigh Radiology Cary decreased in 2019 only:

Table C. 3 - Annual MRI Procedures at RRCary by Federal Fiscal Year

	FY 2016	FY 2017	FY 2018	FY 2019	CAGR
Procedures	6,212	6,664	6,742	6,392	**0.96%**
Annual Change		452	78	(350)	

Note: FY refers to Oct. 1 through Sept. 30
Source: 2018 and Proposed 2020 SMFP and Raleigh Radiology internal data

(Ex. 177, p. 43). That one-year decline was caused by the opening of leased MRI services at Raleigh Radiology-Fuquay Varina. Moreover, Raleigh Radiology-Cary has reasonably assumed that: with more scheduling capacity at Raleigh Radiology-Cary, increased population growth in Wake County, a new fixed scanner, increased capabilities of the 3T equipment, aging of the population, and stabilization at Raleigh Radiology's Fuquay-Varina location, growth related only to increases in population is both reasonable and conservative. Raleigh Radiology-Cary also tested the reasonableness of its patient origin and market share data from core counties and Wake County in Steps 8-11 of its methodology to support its projected increases in population. (Ex. 177, pp. 150-51).

210. In his report, Carter opined that Raleigh Radiology-Cary used incorrect or inconsistent data in Steps 10 and 11 of its utilization methodology. (Jt. Ex. 68, p. 3). However, any alleged error in Steps 10 and 11 did not impact Raleigh Radiology-Cary's utilization projections. Steps 10 and 11 examines and tests the reasonableness of the total need for fixed MRI scanners in the Wake County area. (Ex. 177, p. 151). Any alleged error relating to Steps 10 and 11 had no impact on the reasonableness on Raleigh Radiology-Cary's utilization projections.

211. Raleigh Radiology Application relied on annualized data to project utilization. (Carter, Vol. 2, pp. 446-47). However, Raleigh Radiology-Cary's utilization projections were based on full *fiscal* years of data, rather than *calendar* years of data. (Lane, Vol. 9, pp. 1763-66; Ex. 177, p. 153). Raleigh Radiology-Cary then converted twelve months of utilization data for fiscal year 2019 into data for calendar year 2019 by multiplying the current fiscal year data by

0.75 and multiplying the following year's forecast data by 0.25. (Lane, Vol. 9, p. 1765; Ex. 177, p. 153).

212. Ultimately, identified errors in the utilization methodology did not result in Raleigh Radiology- Cary failing to demonstrate that the projected utilization in the third year of operation after the project's completion meets applicable performance standards for the services proposed based on reasonable and adequate support. Raleigh Radiology-Cary was already conforming with the projected MRI Performance Standards in 2019 and showed that it would continue to conform with them. (See Jt. Ex. 1, pp. 838-39).

213. For the foregoing reasons, the Agency did not err in determining that Raleigh Radiology-Cary demonstrated the projected utilization in the third year of operation after the project's completion must meet any applicable performance standards for the services proposed based on reasonable and adequate support.

D. Access to Services Proposed

214. The last component under Criterion 3 evaluates whether the application demonstrates the extent to which residents of the service area are likely to have access to the proposed project, particularly with respect to medically underserved groups. See N.C.G.S. 131E-183(a)(3).

215. The Agency determined that the projected payor mix was reasonable and adequately supported because it was based on the historical experience of the facility in providing MRI services. (Jt. Ex. 1, p. 839).

216. Based on Raleigh Radiology-Cary's history, the chart on page 116 of the Raleigh Radiology Application accurately reflects Raleigh Radiology-Cary's payor mix from 2017 through 2019:

Table L. 2 – RRCary Historic Payor Mix, FY2017-FY2019

Payor Class	FY17		FY18		FY19	
	Procedures	% of Total	Procedures	% of Total	Procedures	% of Total
Self-Pay	30	0.45%	77	1.14%	74	1.16%
Insurance	4,719	70.82%	4,596	68.23%	4,395	69.08%
Medicare	1,603	24.06%	1,651	24.51%	1,568	24.65%
Medicaid	65	0.98%	108	1.60%	109	1.71%
Other	241	3.62%	294	4.36%	209	3.29%
Charity	5	0.08%	10	0.15%	7	0.11%
Total	**6,663**	**100.00%**	**6,736**	**100.00%**	**6,362**	**100.00%**

Source: Raleigh Radiology internal data;
Other includes TriCare, VA, Government, MedSolutions, worker's comp, and railroad

(Watson, Vol. 5, p. 1176; Ex. 177, p. 116). The projected payor mixes for fiscal years 2020 through 2024 were reasonable based on Raleigh Radiology-Cary's experience and history. (Watson, Vol. 5, p. 1176). Raleigh Radiology-Cary provided the following projected payor mix based on its experience and history:

Table L. 3 – Forecast RRCary MRI Payor Mix through FY2024

Payor Class	FY2020	FY2021	FY2022	FY2023	FY2024
Self-Pay	1.63%	1.99%	2.34%	2.70%	3.06%
Insurance	67.64%	66.77%	65.89%	65.02%	64.15%
Medicare	24.99%	25.29%	25.58%	25.88%	26.17%
Medicaid	2.17%	2.54%	2.91%	3.28%	3.64%
Other	3.42%	3.26%	3.09%	2.93%	2.76%
Charity	0.15%	0.16%	0.18%	0.20%	0.22%
Total	**100.00%**	**100.00%**	**100.00%**	**100.00%**	**100.00%**

(Ex. 177, p. 116).

217. For the forgoing reasons, the Agency did not err in determining that Raleigh Radiology-Cary demonstrated the extent to which residents of the service area are likely to have access to the proposed project, particularly with respect to medically underserved groups.

The Agency Correctly Found the Raleigh Radiology Application Conforming With Criterion 4

218. The Agency found the Raleigh Radiology Application to be conforming with Criterion 4. (Jt. Ex. 1, p. 857). Criterion 4 provides:

> 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.

N.C.G.S. 131E-183(a)(4).

219. The Raleigh Radiology Application proposed to purchase a 3T scanner for its Cary location. (Ex. 177, p. 81).

220. The Raleigh Radiology Application stated that it considered other alternatives, including (1) maintaining the status quo; (2) purchasing a 1.5T scanner; (3) replacing the MRI scanner at its Blue Ridge location; (4) developing the project in a different area of Wake County; and (5) purchasing the Alliance grandfathered fixed scanner. (Ex. 177, pp. 79-81).

221. In analyzing the Raleigh Radiology Application's conformity with Criterion 4, the Agency first reviewed the alternatives the applicant considered and the reasons why Raleigh

Radiology-Cary believed those alternatives were not effective. (Jt. Ex. 1, pp. 856-57). The Agency found that Raleigh Radiology-Cary provided credible information to explain why it believed the proposed project was the most effective alternative. (Id., p. 856).

222. In his report, Carter opined that the Raleigh Radiology Application was nonconforming with Criterion 4 because its utilization projections are unreasonable, Raleigh Radiology-Cary failed to demonstrate the need for the project, and the proposed project was not the more effective or least costly alternative. (Jt. Ex. 68, p. 3).

223. As discussed under Criterion 3, Raleigh Radiology's utilization projections are reasonable and adequately supported.

224. Wake Radiology provided no other evidence or testimony to support its contention that Raleigh Radiology Cary failed to demonstrate the need for the project and that the proposed project was not the most effective or least costly alternative.

225. For the forgoing reasons, the Agency did not err in determining that the Raleigh Radiology Application demonstrated that the least costly or most effective alternative has been proposed.

The Agency Correctly Found the Raleigh Radiology Application Conforming With Criterion 5

226. The Agency found the Raleigh Radiology Application to be conforming with Criterion 5. (Jt. Ex. 1, p. 866). Criterion 5 provides:

> Financial and operating 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.

N.C.G.S. 131E-183(a)(5).

227. The Agency considers several factors under Criterion 5. The first factor is capital and working capital costs. N.C.G.S. 131E-183(a)(5). The total capital costs of Raleigh Radiology Cary's project were projected to be $2,904,152. (Jt. Ex. 1, p. 864).

228. The second factor is availability of funds. N.C.G.S. 131E-183(a)(5). The Agency determined that Raleigh Radiology had adequate cash and assets to fund its portion of the capital cost of the proposed project. (Jt. Ex. 1, p. 865).

229. The third factor is financial feasibility of the project. N.C.G.S. 131E-183(a)(5). If by the third project year, an applicant show that its project has a positive net income, the Agency deems the project financially feasible. (Yakaboski, Vol. 4, pp. 762-64, Pittman, Vol. 2, p. 257). The Agency may find an application conforming with Criterion 5, even if its financial projections include errors, as long as the applicant can still show that the project is financially feasible. (Yakaboski, Vol. 4 pp. 762-64).

230. The Agency concluded that Raleigh Radiology's project was financially feasible because Raleigh Radiology projected that revenues would exceed operating expenses in the first three operating years of the project. (Jt. Ex. 1, p. 865). Raleigh Radiology provided the following table:

	1st Full Fiscal Year	2nd Full Fiscal Year	3rd Full Fiscal Year
Total Procedures*	6,684	6,815	6,946
Total Gross Revenues (Charges)	$10,381,190	$10,584,462	$10,788,293
Total Net Revenue	$3,045,344	$2,993,012	$2,935,153
Average Net Revenue per Procedure*	$456	$439	$423
Total Operating Expenses (Costs)	$1,878,831	$2,032,935	$2,021,044
Average Operating Expense per Procedure*	$281	$298	$291
Net Income	**$1,166,513**	**$960,077**	**$914,109**

*Unweighted procedures

(Jt. Ex. 1, p. 865).

231. Wake Radiology argued that the Raleigh Radiology Application was nonconforming with Criterion 5 because Raleigh Radiology-Cary provided costs and charges that were so unreasonable such that the applicant could not establish the financial feasibility of the project. (Carter, Vol. 3, pp. 513-14; Carter, Vol. 7, p. 1314).

232. The charge is what the insurance company or payor is contractually obligated to pay the provider for that particular service. (Watson, Vol. 5, p. 1124).

233. First, Carter noted that Raleigh Radiology-Cary had provided the incorrect historical charge in its pro forma financial projections relating to Criterion 5. (Carter, Vol. 5, pp. 515-146). Carter opined that Raleigh Radiology-Cary failed to explain the difference and the error ultimately impacted revenue. (Id., p. 516).

234. During the drafting of the Raleigh Radiology Application, Ms. Watson accidentally provided PDA, its CON application preparer, with the wrong number for the average charge per procedure – $1,553. (Watson, Vol. 5, p. 1167). When Raleigh Radiology-Cary became aware of the error during the comments, it provided the Agency with the correct average charge per procedure – $1,887 – during its responses. (Id., p. 1168; Jt. Ex. 1, p. 433). Raleigh Radiology also disclosed the error ultimately increased the overall net revenue of Raleigh Radiology Cary's proposed project by $90 per procedure in the third year of operation. (Jt. Ex. 1, p. 433).

235. Ultimately, what mattered was that Raleigh Radiology-Cary had shown historically that its net income for its MRI services was positive and the project was financially feasible. (Yakaboski, Vol. 4. pp. 755-57, 873-74). The Agency thus found that Raleigh Radiology Cary's explanation of its error was reasonable because the correction would have increased the financial viability of the project. (Id., pp. 757-58).

236. Second, Carter opined that Raleigh Radiology-Cary provided inaccurate costs and expenses in its application. (Carter, Vol. 3, pp. 519-22; Jt. Ex. 68, pp. 6-9). Carter opined that if the costs and expenses were tied back to gross revenue, and the stated gross revenue in the Application was inaccurate, then all of the expenses were inaccurate. (Id.)

237. Based on Raleigh Radiology's history, certain expenses were pegged to revenue as a percentage such as professional fees paid to radiologists who interpret scans, filing fees, and medical supplies. (Watson, Vol. 5, pp. 1172-76; Lane, Vol. 8, p. 1632).

238. Errors stating these costs and expenses would not have eliminated Raleigh Radiology-Cary's ability to show the immediate and long-term financial feasibility of the proposal because costs were only a percentage of the increased net revenue. As Raleigh Radiology-Cary's expenses were tied to its revenue, the Agency could have determined the correct amount of expenses based on the numbers provided in the Raleigh Radiology Application. (See Carter, Vol. 7, pp. 1330-32; Lane, Vol. 8, pp. 1632-35).

239. To illustrate, the Agency knew that the total operating expense for the Raleigh Radiology-Cary Application in the third year of operation of the proposed project - $2,021,044. (Ex. 177, p. 865). Had the Agency divided the total operating expense by the total net revenue ($2,935,153), it would have calculated that the operating expenses were approximately 68.86% of the total net revenue. (Yakaboski, Vol. 4, p. 901).

240. Accounting for correct charge of $1,887 and the additional revenue of $90 per scan, the Agency had enough information to determine the correct total net revenue. (Yakaboski, Vol. 4, p. 901). First, the Agency would have simply needed to multiply $90 by the number of unweighted scans that the proposed scanner was projected to perform in the third year of operation following project completion – 6,946 – resulting in an additional revenue of $625,140. (Id.; see also Jt. Ex. 1, p. 940). Adding this amount to the prior total revenue of $2,935,153, the correct total revenue would have been $3,560,293 (Yakaboski, Vol. 4, pp. 901-02). Since costs were approximately 68.86% of revenue, multiplying the new total revenue by 68.86% would have resulted in the correct total operating expense: approximately $2,451,618. (Id., p. 902).

241. If the Agency had compared the correct total operating expense ($2,451,618) with the correct total revenue ($3,560,293), it would have found that total revenue exceeded total operating expenses by $1,108,675. Since Raleigh Radiology-Cary's net income would have still been positive, it would have still been able to show that its project was financially feasible. (Yakaboski, Vol. 4, pp. 755-57, 879-80).

242. Moreover, Raleigh Radiology-Cary was an existing facility that provided existing MRI services prior to filing the Raleigh Radiology Application. (Yakaboski, Vol. 4, p. 755). It was reasonable the Agency to determine that since Raleigh Radiology-Cary submitted historical data that it earned net-positive income in the past, it would continue to be financially feasible. (Id., pp. 755-57).

243. Third, Carter also opined that it was unreasonable for Raleigh Radiology-Cary to project that there would be annual changes in its charges and that its charges would decrease over the next three years. (Carter, Vol. 3, pp. 519-21; Jt. Ex. 68, p. 4).

244. Based on Raleigh Radiology's history of contractual adjustments with insurers, it was reasonable to expect that contractual allowances increased over time and that in turn, Raleigh Radiology-Cary's overall revenue decreased on a per-scan basis. (Watson, Vol. 5, 1170-71; Lane, Vol. 8, p. 1637; Jt. Ex. 69, p. 4). Even Carter admitted that generally speaking, projections based on historical trends or historical data are more reliable and reasonable. (Carter, Vol. 7, pp. 1326-27).

245. Carter also opined that several other expenses that were not tied to revenue were understated. (Jt. Ex. 68, pp. 6-8). Notably, Carter did not raise any of these issues before the Agency when Wake Radiology submitted its comments relating to the Raleigh Radiology Application. (Carter, Vol. 7, pp. 1318-23). Ultimately, any alleged error in understating these expenses would not have impacted the Agency's finding that Raleigh Radiology-Cary's proposed project was financially feasibility because the alleged errors were not significant enough to cause Raleigh Radiology-Cary's net income to become negative. (See Jt. Ex. 68, p. 6-8; Yakaboski, Vol. 4, pp. 868-69; Pittman, Vol. 2, pp. 403-04).

246. For the foregoing reasons, the Agency did not err in determining that the Raleigh Radiology Application showed immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services.

The Agency Correctly Found the Raleigh Radiology Application Conforming With Criterion 6

247. The Agency found the Raleigh Radiology Application conforming with Criterion 6. Criterion 6 provides:

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

N.C.G.S. 131E-183(a)(6).

248. The Agency found that the proposal would not result in the unnecessary duplication of existing or approved MRI services in Wake County because Raleigh Radiology-Cary stated that it would discontinue any MRI lease for its Cary location. (Jt. Ex. 1, p. 876).

249. The Agency did not err in determining the Raleigh Radiology Application was conforming with Criterion 6.

The Agency Correctly Found the Raleigh Radiology Application Conforming With Criterion 7

250. The Agency found the Raleigh Radiology Application conforming with Criterion 7. (Jt. Ex. 1, p. 881). Criterion 7 provides:

> 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.

N.C.G.S. 131E-183(a)(7).

251. The Agency reviewed the assumptions and methodology Raleigh Radiology-Cary used to project staffing. (Jt. Ex. 1, p. 880). The Agency found that Raleigh Radiology-Cary provided adequate costs for the health manpower and management positions. (Id.)

252. For the foregoing reasons, the Agency did not err in determining that Raleigh Radiology-Cary demonstrated the availability of sufficient health manpower and management personnel to provide the proposed services.

The Agency Correctly Found the Raleigh Radiology Application Conforming With Criterion 13

253. The Agency found the Raleigh Radiology Application to be conforming with Criterion 13. (Jt. Ex. 1, p. 897). Criterion 13 provides:

> 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;
> b. Its past performance in meeting its obligation, if any, under any applicable rules 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. 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
> 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.

N.C.G.S. 131E-183(a)(13).

254. First, the applicant must show 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. N.C.G.S. 131E-183(a)(13).

255. The Raleigh Radiology Application provided its historical payor mix during 2018 for the MRI services at its existing facility. It also provided a comparison between the percentage of total patients served by the facility or campus from October 1, 2018 to September 30, 2019 and the percentage of the population of the service area. (Jt. Ex. 1, p. 896).

256. The Agency found that Raleigh Radiology-Cary adequately documented the extent to which medically underserved populations currently use its existing services in comparison to the percentage of the population in its service area which is medically underserved. (Jt. Ex. 1, p. 897)

257. In his report, Carter opined that the Raleigh Radiology Application was nonconforming with Criterion 13(c). (Jt. Ex. 68, p. 9). He contended that the Raleigh Radiology Application made unreasonable assumptions regarding the projected payor mix for the project. (Id.) Raleigh Radiology-Cary's projected payor mix was reasonable and adequately supported for the reasons stated under Criterion 3.

258. Raleigh Radiology-Cary's projected payor mix was reasonable and adequately supported because it was based on the historical experience of the facility in providing MRI services. (Watson, Vol. 5, p. 1176, Ex. 177, p. 116; Jt. Ex. 1, p. 904).

259. The Agency did not err in determining that the Raleigh Radiology Application was conforming with Criterion 13(c).

The Agency Correctly Found the Raleigh Radiology Application Conforming With Criterion 14

260. The Agency found the Raleigh Radiology Application to be conforming with Criterion 14. (Jt. Ex. 1, p. 909). Criterion 14 provides:

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

N.C.G.S. 131E-183(a)(14).

261. The Raleigh Radiology Application stated that it maintains ongoing relationships with schools and training programs to support training programs and facilitate staff recruiting. (Jt. Ex. 177, p. 120). Raleigh Radiology-Cary provided letters to area programs introducing itself and inviting each to reach out to it for collaboration on MRI-related training. (Id.) Additionally, Raleigh Radiology-Cary provided letters of interest from various area programs communicating interest in working with and establishing relationships at Raleigh Radiology-Cary related to MRI training.

262. Wake Radiology contended that the Raleigh Radiology Application failed to document that the proposed project will actually enhance accessibility for professional training programs. (Jt. Ex. 68, p. 9). Wake Radiology contends that Raleigh Radiology-Cary has failed to show a history of providing training programs relating to MRI services.

263. Raleigh Radiology-Cary has not been able to provide training in MRI services because it leases the scanner from Alliance and Alliance operates the scanner. (Mathan, Vol. 6, p. 1289). However, if Raleigh Radiology-Cary owned its own MRI machine, it would offer professional health training programs for MRI imaging services. (Id.)

264. Moreover, Raleigh Radiology-Cary has documented its history providing training relating to other services. (Mathan, Vol. 6, pp. 1288-89). Raleigh Radiology-Cary has trained students in ultrasound and x-ray imaging services. (Id., p. 1289). Raleigh Radiology-Cary has also provided training for Wake Tech and Johnston County students in the past.

265. The Agency found that Raleigh Radiology-Cary adequately described the extent to which health professional training programs in the area have or will have access to the facility for training purposes and provide supporting documentation in the referenced exhibits. (Jt. Ex. 1, p. 910). The Agency found that Raleigh Radiology-Cary provided answers that satisfied the statutory criteria. (Yakaboski, Vol. 4, p. 881).

266. For the foregoing reasons, the Agency did not err in determining that the Raleigh Radiology Application was conforming with Criterion 14.

The Agency Correctly Found the Raleigh Radiology Application Conforming With Criterion 18a

267. The Agency found the Raleigh Radiology Application to be conforming with Criterion 18a. (Jt. Ex. 1, p. 915).

> 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.

N.C.G.S. 131E-183(a)(18a).

268. When reviewing conformity with Criterion 18a, the Agency considers what effect, if any, the proposed project would have on competition and whether any enhanced competition would have a positive impact on cost-effectiveness, quality, and access to the services provided. N.C.G.S. 131E-183(a)(18a).

269. With respect to the expected effects of the proposal on competition in the service area, the Agency found that Raleigh Radiology-Cary provided information that it would be able to keep out-of-pocket costs to the patients low if it owned its own MRI scanner. (Jt. Ex. 1, p. 914; Ex. 177, p. 121).

270. With respect to the expected effects of the proposal on cost-effectiveness, the Agency found that Raleigh Radiology provided information that it would be able to replace high

payments for a leased older scanner with lower operating costs for a new scanner that has more capabilities. (Jt. Ex. 1, p. 914; Ex. 177, pp. 121-22).

271. With respect to the expected effects of the proposal on quality, the Agency found that Raleigh Radiology provided information relating to its MRI accreditation for Raleigh Radiology Cary and board-certifications for its radiologists. (Jt. Ex. 1, p. 915; Ex. 177, p. 122).

272. With respect to the expected effects of the proposal on access by medically underserved groups, the Agency found that Raleigh Radiology-Cary provided information relating to Raleigh Radiology's commitment to accept patients without regard to source of payment and its plans to provide charity for medical facility. (Jt. Ex. 1, p. 915; Ex. 177, p. 123).

273. The Agency found that Raleigh Radiology-Cary adequately described the expected effects of the proposed services on competition in the service area and adequately demonstrated that the proposal would have a positive impact on cost-effectiveness, quality, and access to medically underserved groups. (Jt. Ex. 1, p. 915).

274. In his report, Carter opined that the Raleigh Radiology Application failed to demonstrate that it would enhance competition by having a positive impact on cost-effectiveness, quality and access to services. (Jt. Ex. 68, p. 10).

275. Carter first contended that Raleigh Radiology-Cary's utilization projections were unreasonable. (Jt. Ex. 68, p. 10). The Tribunal disagrees with Carter for the same reasons stated under Criterion 3.

276. Carter also opined that Raleigh Radiology-Cary presented erroneous and inconsistent financial projections. (Jt. Ex. 68, p. 10). The Tribunal disagrees that any error in Raleigh Radiology Cary's financial projections cause the Raleigh Radiology Application to be nonconforming with Criterion 18a for the same reasons stated under Criterion 5.

277. Carter also opined that Raleigh Radiology-Cary's proposal to replace the Alliance grandfathered fixed MRI scanner, rather than increasing the number of MRI scanners in the area, renders the Raleigh Radiology Application nonconforming with Criterion 18a. (Jt. Ex. 68, p. 10). The Tribunal disagrees that this proposal causes the Raleigh Radiology Application to be nonconforming with Criterion 18a for the reasons stated under Criterion 1.

278. Finally, Carter contended that Raleigh Radiology-Cary's failure to demonstrate quality of care renders the Raleigh Radiology Application nonconforming with Criterion 18a. The Tribunal disagrees with Wake Radiology Application for the reasons stated later under Criterion 20.

279. The Agency did not err in determining that the Raleigh Radiology Application was conforming with Criterion 18a.

The Agency Correctly Found the Raleigh Radiology Application Conforming With Criterion 20

280. The Agency found the Raleigh Radiology Application to be conforming with Criterion 20. (Jt. Ex. 1, p. 921). Criterion 20 requires the following:

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

N.C.G.S. 131E-183(a)(20). The time period set for application form for evaluation of Criterion 20 is 18-months from the date of submission of the application. (Pittman, Vol. 2, p. 276-77). However, the Agency considers quality care issues up until it makes its final decision. (Id.) 47. Under Section O, paragraph 3(a) of the Raleigh Radiology Application (and all applications submitted by applicants for CONs), the application requires the applicant to "Document that the facilities identified in response to Section A, Question 7, Form A Facilities, have provided quality care during the 18 months immediately preceding submission of the application (18 month look -back period)." The Agency agrees that this paragraph is not limited to the service for which an applicant is seeking a CON, but for all services provided by the applicant. (Yakaboski Vol. 4, p. 775; Pittman Vol. 2, p. 229);

281. Pursuant to its statutory authority, the Agency has developed standards that it uses in evaluating an applicant's conformity or nonconformity with Criterion 20. (Pittman, Vol. 2, pp. 260-61, 361-62). The Agency reviews issues of quality care holistically, taking all facts and circumstances on a case-by-case basis. (Id., p. 274). The Agency is not in the business of evaluating quality of care; it generally relies on other entities to make determinations about quality of care. (Pittman, Vol. 2, pp. 384-86, 392-93; Pittman, Vol. 8, pp. 1467, 1480, 1486).

282. The Raleigh Radiology Application submitted evidence of quality care in the 18 months prior to filing the Application, including information relating to its accredited facilities and modalities, quality oversight and review programs, physicians' good standing with Medicare, Medicaid, and the North Carolina Medical Board, communication with its patients and referring physicians, maintenance of equipment, internal quality standards, sub-specialization, and continuous training. (See Pittman, Vol. 2, pp. 262-70, 271-74, 362-65; Watson, Vol. 5, pp. 1134-35; Ex. 177, pp. 27, 52-53, 55, 121-25, 548-51; Lane, Vol. 8, pp. 1655-58).

283. However, Raleigh Radiology was aware that it had lost accreditation for mammography at its Blue Ridge facility prior to filing its application. (Watson, Vol. 5, p. 1045).

284. Raleigh Radiology was notified on October 23, 2019, that it failed the Additional Mammography Review conducted by the American College of Radiology and that the FDA intended to revoke the accreditation for mammography at the Blue Ridge Facility on November 5, 2019. (Mathan, Vol. 5, p. 1226; Exh. 193, Exh. 196).

285. Yakaboski testified that the only information he would have had about the loss of mammography accreditation by Raleigh Radiology was what was said about it on the Raleigh Radiology website and what was in the Raleigh Radiology Application, but there was **nothing in the Raleigh Radiology Application concerning the loss of mammography accredit**ation. (Yakaboski Vol. 4, pp. 769-773; Exh. 1, pp. 920-21, Exh, 2 and Exh. 177). This is significant as the Agency relies on the Applicant to identify any quality issues, including incidents involving

a lack of non-quality care, if the applicant is not subject to licensure requirements. (Pittman, Vol. 1, pp. 161, 229).

286. Yakaboski did not know at the time he found that Raleigh Radiology was conforming with Criterion (20), what the quality of issues were that led to Raleigh Radiology having its accreditation for mammography revoked by the American College of Radiology (at times, "ACR"). (Yakaboski Vol. 4, pp. 792-93, 796).

287. All that Ms. Pittman knew about the quality of care issues at Raleigh Radiology's Blue Ridge facility was what was in the newspaper, and according to Ms. Pittman the Agency doesn't traditionally make findings based upon what is in the newspaper. (Pittman Vol. 2, pp. 228-229).

288. When Wake Radiology filed its Petition and Prehearing Statement in this case, Wake Radiology did not raise any issue that the Raleigh Radiology Application was nonconforming with Criterion 20. (Jordan, Vol. 1, pp. 130-32; Ex. 357-A, 357-B). Wake Radiology also failed to raise any issue relating to Criterion 20 when it refiled its Petitions on September 8, 2020 and May 7, 2021.

289. However, Raleigh Radiology and the Agency were on notice that Wake Radiology was challenging whether the Agency erred in determining that Raleigh Radiology was in compliance with Criterion (20), as evidenced among other things, by the inclusion in the report of Raleigh Radiology's expert, Nancy Lane, a discussion about Criterion (20). (Ex. 69, pp. 5-6).

290. The Tribunal finds the Agency's comparative lack of concern regarding Raleigh Radiology's loss of accreditation, and its failure to disclose that issue in its application, to be troubling. Simply put, this is something that should have been disclosed to the Agency, and the Agency should have undertaken greater diligence investigating this issue than it did.

291. However, the Agency has, as is well-established, considerable leeway, to which this Tribunal owes considerable deference, in interpreting the statutory criteria at issue. Moreover, even to the extent the Agency may have erred on this issue, at bottom that error lacks legal significance – Wake Radiology's own application was un-approvable as a matter of law. Wake Radiology is thus in the position of the racing team who accurately demonstrates problems with both the race winner's product and the race's governing body – but whose own car was unable to complete the contest in its own right.

A. Mammography Accreditation Issue

292. The Mammography Quality Standards Act ("MQSA") regulates facilities that provide mammography to the public. (Thomas, Vol. 5, p. 983). For a facility to be able to perform mammograms, it must be certified and accredited. (Id.) One the major accrediting organizations is the American College of Radiology ("ACR"). (Id.) The ACR accredits physicians, technologists, medical physicists, mammography equipment, and quality assurance programs. (Id., pp. 983-984).

293. Dr. Laura Thomas, the Breast Imaging Division Chief at Raleigh Radiology, oversees the ACR accreditation process for mammography at Raleigh Radiology. (Thomas, Vol. 4, p. 933).

294. In 2017, Raleigh Radiology acquired a 3D mammography machine for its Blue Ridge facility. (Thomas, Vol. 5, p. 994). The manager of Raleigh Radiology-Blue Ridge at the time submitted accreditation paperwork to the ACR accidentally indicating that Raleigh Radiology-Blue Ridge owned a 2D mammography machine. (Id.) When a new manager began her position with Raleigh Radiology-Blue Ridge, she realized that the error and notified the ACR. (Id.) The ACR then required Raleigh Radiology-Blue Ridge to undergo an Additional Mammography Review ("AMR"). (Id.)

295. On August 27, 2019, when Raleigh Radiology-Blue Ridge was notified that it had to participate in an AMR, it did not know or believe that it would lose accreditation for mammography at Blue Ridge. (Watson, Vol. 5, pp. 1040-41). However, as previously found, Raleigh Radiology was well aware of this issue at the time it applied for the CON in this case.

296. The ACR typically allows radiology practices to submit its best images when applying for reaccreditation. (Thomas, Vol. 4, pp. 953-54). However, during an AMR, the ACR randomly selects images and interpretations for review. (Thomas, Vol. 5, p. 953).

297. The ACR reviewed 30 random images. (Thomas, Vol. 5, pp. 993-94). The ACR found one set of images – Case 26 -where the positioning was "severely deficient." (Id. p. 994; Ex. 193, p. 16). The patient was short and heavy-set and technically challenging to position. (Thomas, Vol. 5, pp. 994-95).

298. Dr. Thomas affirmed that the patient in Case 26 received quality medical care, even though it may not have been the best quality medical care. (Thomas, Vol. 4, pp. 944-45). Raleigh Radiology ultimately contacted the patient and notified her about the positioning issue. (Thomas, Vol. 5, p. 995) Raleigh Radiology-Blue Ridge invited her to come back for repeat imaging. (Id.) Dr. Thomas worked with the patient and technologist to capture acceptable images and Dr. Thomas also provided the interpretation. (Id.)

299. The ACR reviewers considers other factors besides positioning for the purpose of accreditation. These factors include exposure level, artifacts, noise, sharpness, compression, and patients' levels. (Thomas, Vol. 5, p. 996-97; see also Ex. 193). During the AMR, the ACR only identified issues with positioning relating to Raleigh Radiology-Blue Ridge's images. (Thomas, Vol. 5, p. 996; see also Ex. 193). None of the issues identified by the ACR impacted Raleigh Radiology-Blue Ridge's ability to make a diagnosis, monitor disease, or provide quality care. (Thomas, Vol. 5, pp. 996). None of the issues identified by the ACR led to any missed cancers. (Thomas, Vol. 4, pp. 964, 967; Thomas, Vol. 5, p. 996). The ACR did not find any issues relating to Raleigh Radiology's physicians, technologists, medical physicists, or equipment. (Thomas, Vol. 5, pp. 996-97).

300. On or around November 6, 2019, Raleigh Radiology-Blue Ridge received notice that Raleigh Radiology-Blue Ridge's mammography accreditation for its Blue Ridge facility was being revoked. (Watson, Vol. 5, p. 1045). The ACR told Raleigh Radiology that it was Case 26 that ultimately triggered the loss of accreditation. (Thomas, Vol. 4, pp. 955-56; see also Jt. Ex.

8, p. 2). None of these issues at Raleigh Radiology-Blue Ridge impacted the quality of care provided at Raleigh Radiology-Cary or Raleigh Radiology's other locations. (See Thomas, Vol. 5, pp. 982, 1007-08).

301. To receive reaccreditation, Raleigh Radiology created and implemented a corrective action plan that had to be approved by the ACR. (Thomas, Vol. 5, pp. 998-1001). The ACR required Raleigh Radiology-Blue Ridge to send from letters to all patients from the prior two years. (Id., p. 1000) The form letter included the FDA's standard language that stated that Raleigh Radiology-Blue Ridge was notifying its patients about a "serious risk to human health." (Id., pp. 1001-02; Ex. 193). Raleigh Radiology-Blue Ridge disputed the language in the letter and set up a conference call with the FDA to discuss the wording of the letter. (Id., p. 1002). The FDA told Raleigh Radiology-Blue Ridge that it could not change the standard form language but allowed Raleigh Radiology-Blue Ridge to send a separate letter to its patients explaining what happened in the AMR in more detail. (Id., pp. 999-1002; see also Exs. 194, 196).

302. Raleigh Radiology-Blue Ridge also posted several news updates on its website about the status of its mammography services and accreditation. (Thomas, Vol. 5, p. 1003-04; Jt. Ex. 8). The releases explained that there were only positioning issues relating to the technical quality of the mammography images and that the ACR identified issues with one image set in its review. (Id., 1003-05; Jt. Ex. 8, p. 2).

303. As part of the corrective action plan, all of Raleigh Radiology-Blue Ridge's technologists took a course on positioning and the physicians also took a course. (Thomas, Vol. 5, p. 1005). The technologists and physicians also reviewed the cases from the AMR. (Id.)

304. Raleigh Radiology-Blue Ridge received temporary accreditation in approximately six weeks on February 11, 2020. (Thomas, Vol. 5, pp. 1005-06; Ex. 300, p. 1). Raleigh Radiology-Blue Ridge was fully re-accredited on April 9, 2020. (Thomas, Vol. 5, p. 1005-06; Ex. 301, p. 1). Since then, Raleigh Radiology has been continuously accredited in mammography and all other modalities. (Thomas, Vol. 5. p. 1007).

305. After Raleigh Radiology-Blue Ridge facility was reaccredited for mammography, Raleigh Radiology issued a statement on its website that reaccreditation had been issued. (Watson, Vol. 5, p. 1151).

306. Significantly, Raleigh Radiology was continuously certified in all other modalities in the 18-month lookback period at all other locations and facilities. (Watson, Vol. 5, p. 1137-38).

307. The CON Application form does not ask applicants to disclose information relating to the loss of accreditation. (Pittman, Vol. 2, p. 275). It likewise does not ask applicants to disclose any number of troubling or potentially disqualifying things. Raleigh Radiology should have disclosed the accreditation issue and the Agency should have been more inquisitive about the issue when the Agency discovered it. Both of these actions poorly served the public.

308. In response to question 3(c), Raleigh Radiology-Cary stated, "Raleigh Radiology maintains American College of Radiology accreditation for all of its facilities." (Ex. 177, p. 125). This response strikes the Tribunal as word salad, neatly sidestepping a serious issue which should

have been disclosed. If a hypothetical physician employed by a CON applicant was found to have been butchering and dismembering patients, a response, "This practice maintains physicians who do not butcher and dismember their patients" fails to state the relevant facts – which is that one of them *did* – and (worse) works to conceal that problem from both the Agency and, ultimately, the State and the public.

309. The Agency was aware of the Mammography Accreditation Issue. (Yakaboski Vol. 4, pp. 769-70; Pittman, Vol. 8, p. 1466; see also Jt. Ex. 55, pp. 6-12). Yakaboski analyzed the applications for conformity with Criterion 20 towards the end of the review. (Yakaboski, Vol. 4, pp. 893-84) During the review, Yakaboski checked Raleigh Radiology's website and saw an announcement that Raleigh Radiology had all of its certifications and accreditations. (Yakaboski, Vol. 4, pp. 769-70). Yakaboski communicated the information he learned from Raleigh Radiology's website to Ms. Pittman. (Yakaboski, Vol. 4, pp. 779, 792). Pittman, using the discretion provided to the Agency under law, concluded that the temporary loss of mammography accreditation at Blue Ridge did not make Raleigh Radiology nonconforming with Criterion 20. (Id., pp. 792-93).

310. Applicants are not required to be perfect in order to show conformity with Criterion 20 (Pittman, Vol. 2, p. 371; Pittman, Vol. 8, pp. 1463, 1479). For example, the Agency contemplates that a finding of immediate jeopardy does not automatically render an applicant nonconforming with Criterion 20. (Pittman, Vol. 2, p. 274). An applicant can bring the facility back into compliance after it submits its application. (Id.; Pittman, Vol. 8, p. 1467). There were numerous reviews where applicants had resolved issues of immediate jeopardy by the time the decision was rendered and were still found conforming with Criterion 20. (Pittman, Vol. 2, p. 277; see also Ex. 401, p. 21; Ex. 402, p. 20, Ex. 403, p. 43; Ex. 404, p. 23; Ex. 405, pp. 21-22; 2019 Wake County OR Review Agency Findings, p. 91; 2018 Orange County OR Review Agency Findings, p. 74; 2018 Union County MRI Agency Findings, p. 23; 2018 Forsyth County OR Review Agency Findings, pp. 158-60; 2017 Union County OR Review Agency Findings, p. 35; 2016 Guilford County MRI Scanner Review Agency Findings, pp. 58-59).

311. It the Agency's position, again in its discretion, that even if an issue has not yet been resolved by the date of its decision, the applicant can still conform with Criterion 20 by showing that it has provided quality care in the past. (Pittman, Vol. 8, p. 1479). The Agency has also previously found applications conforming with Criterion 20 even where there were pending immediate jeopardy issues that had not been fully addressed by the date of the Agency's decision. (2017 New Hanover County OR Review Agency Findings, p. 91; 2016 Mecklenburg County MRI Scanner Review Agency Findings, p. 46).

312. Moreover, it is consistent with Agency practice to find an applicant conforming with Criterion 20 where the Agency identifies issues of quality care that the Applicant did not disclose. (Pittman, Vol. 2, p. 297). For example, in the 2017 New Hanover County OR Review, the Agency found Wilmington ASC conforming with Criterion 20 even though in its application, it failed to identify four incidents relating to quality care that were reported to the Acute and Home Care Licensure and Certification Section and DHSR in the 18-month lookback period. (2017 New Hanover County OR Review Agency Findings, p. 91).

313. Ultimately, a failure to disclose information relating to a possible quality issue does not automatically render an applicant nonconforming with Criterion 20. (Pittman, Vol. 8, pp. 1487-88). However, it should cause the Agency to undertake far more diligence than demonstrated in this case, again for the protection of both patient and public.

314. The Agency does not inquire into the reasons why an applicant may lose their accreditation or other quality-related issues. (Pittman, Vol. 2, pp. 384-86, 392-93). The Agency's position is that other entities are better qualified to evaluate quality and what matters is that the applicant is back in compliance with its accreditation. (Id.; Pittman, Vol. 8, pp. 1467, 1480, 1486). The Tribunal believes this practice and position to be unwise, erroneous, and a dereliction of the Agency's duty to find a history of quality care on the part of every applicant. An Agency decision is erroneous where the Agency fails to require the applicant to provide support for its assertions and assumptions, or where the Agency overlooks errors and omissions in an application. See Bio-Med'l Applications of N.C., Inc. v. N.C. Dep't of Health & Human Serv., 2004 WL 2148389, Case No. 03 DHR 1553, Conclusions of Law ¶ 19 (N.C.O.A.H. June 2, 2004) (Chess, J.); Native Angels Home Care Agency, Inc. v. N.C. Dep't of Health & Human Serv., 2004 WL 1091431, Case No. 03 DHR 0903, Conclusions of Law ¶ 9 (N.C.O.A.H. Feb. 20, 2004) (Conner, J.).

315. The Agency confirmed that it relies on the reaccreditation process to signal that an issue has been corrected with respect to quality care. (Pittman, Vol. 8, p. 1479). The Tribunal believes this practice and position to be unwise, erroneous, and a dereliction of the Agency's duty to find a history of quality care on the part of every applicant.

316. After hearing testimony from Dr. Laura Thomas, Dr. Satish Mathan, Joanne Watson, and Daniel Carter about the Mammography Accreditation Issue, the Agency testified that even if it had known all of the facts about the Mammography Accreditation Issue that it did not know during the review, it would have still found the Raleigh Radiology Application conforming with Criterion 20. (Pittman, Vol. 8, pp. 1463-67, 1508). The Tribunal believes this position to be highly questionable, even with all deference to the Agency's discretion and expertise. However, it does not rise to the level of arbitrary and capricious behavior.

317. However, for the foregoing reasons, the temporary loss of mammography accreditation at Raleigh Radiology-Blue Ridge did not render the Raleigh Radiology Application nonconforming with Criterion 20 as a matter of law. Most particularly, the Agency error discussed above does not demonstrate substantial prejudice for the part of Wake Radiology, whose own application was un-approvable due to its inability to meet MRI performance standard rules.

B. Image Loss Issue

318. On May 23, 2018, the Raleigh Radiology's image storage system, PACS, stopped functioning. (Watson, Vol. 5, p. 1086-87). The PACS was a server that was connected to a back-up server, and both were located at a separate data center. (Id., pp. 1086, 1116). Typically, if one server failed, the other server would maintain a copy of the images. (Id., p. 1086-87). However, sometime around February 13, 2018, an engineer from a third-party company did some work on the back-up server. (Id., p. 1087). The third-party engineer did not turn the back-up server on

after completing his work. (Id.) When the primary server had a hardware failure and stopped storing images, there was no back-up to capture the images. When the issue was discovered there had been a three-month period of time where neither server maintained images. (Id., pp. 1087-88).

319. Raleigh Radiology did not lose any written interpretations for any of its patients. (Watson, Vol. 5, p. 1093; Thomas, Vol. 5, p. 987).

320. Raleigh Radiology was able to recover at least 60% of the images that were lost by requesting copies of images from other health providers and patients and by retrieving images stored on certain machines. (Watson, Vol. 5, pp. 1088-89, 1127-31). Raleigh Radiology recovered many of the images that were lost in May in the two weeks prior to the PACS failure because the most recent images were stored in the memory of the imaging equipment. (Mathan, Vol. 6, pp. 1269-70, 1290-91).

321. Raleigh Radiology also developed a protocol for addressing patients whose mammograms were lost. For patients with interpretations where an abnormality was recorded, those patients were called back to evaluate the abnormality according to standard practice. (Thomas, Vol. 5, pp. 987-88.) For patients who had received a baseline examination or their first mammographic study during the three-month period, Raleigh Radiology called them back at no charge to make a new baseline study. (Id., p. 988) This baseline study could then be used in future studies. (Id.) Finally, for patients whose images did not show abnormalities and Raleigh Radiology still maintained their prior exams from 2015-2017, Raleigh Radiology did not notify those patients of the loss. (Id.) Ultimately, this protocol ensured that all patients with abnormalities received follow-up examinations and all patients had baseline examinations that could be used for comparisons in the future. (Id., pp. 987-99).

322. A radiologist takes several steps when interpreting a mammogram. First, the radiologist simply reviews the image, itself, and interprets it, looking for any abnormality without bias. (Thomas, Vol. 5, p. 984). Next, the radiologist assesses whether there are baseline examinations and/or prior mammograms for comparison and to evaluate whether there is a change or if an abnormality has been stable. (Id., p. 985). Dr. Thomas testified that she typically compares a new mammogram with older studies that are at least two or three-years old. (Id., pp. 985-86). It can be advantageous to compare the new image with older studies, particularly to determine whether a cancer has been stable for many years. (Id., p. 987).

323. Dr. Thomas testified without contradiction that it is commonplace for physicians to interpret mammograms without prior images for comparison. (Thomas, Vol. 5, p. 985). A patient who has a prior study available for comparison does not receive better quality care than one without a prior study. (Id., p. 987). The most likely impact of not having a prior study would be a false positive where a radiologist would detect a potential abnormality and request additional imaging studies to evaluate the observed abnormality. (Id., p. 986). The existence of a prior image could allow the radiologist to determine that the potential abnormality had been previously present and was not a concern.

324. The loss of images did not eliminate Raleigh Radiology's ability to provide patients with quality care. (Thomas, Vol. 5, p. 989). Moreover, Raleigh Radiology reported the

loss of images to the MQSA/FDA. (Thomas, Vol. 5, p. 990; Watson, Vol. 5, p. 1132). The FDA did not require Raleigh Radiology to take any further action. (Id.) However, the loss of images was a quality of care issue – simply put, massive loss of thousands of patient images does not help to demonstrate quality care, even if it does not automatically demonstrate its lack.

325. Lane, Raleigh Radiology-Cary's CON preparer, was not aware of the Image Loss issue at the time the Raleigh Radiology Application was drafted and submitted. (Lane, Vol. 8, p. 1645). Had Lane been aware of the facts relating to the Image Loss, she likely would not have included information about the Image Loss in the Raleigh Radiology Application because it did not raise concerns relating to Criterion 20. (Lane, Vol. 9, pp. 1645-46). The Tribunal specifically finds Lane's testimony on this issue to lack credibility for the reasons discussed above on the general disclosure issue of loss of accreditation.

326. After hearing testimony from Dr. Thomas, Dr. Mathan, Watson, and Carter about the Image Loss Issue, the Agency testified at the hearing that even if it had known all of the facts about the Image Loss Issue that it did not know during the review, it would have still found the Raleigh Radiology Application conforming with Criterion 20. (Pittman, Vol. 8, pp. 1461-63) The Agency testified that based on the available information relating to the Image Loss Issue, the image loss did not create any quality of care issues. (Id., p. 1463).

327. As with the accreditation issue, the Tribunal finds this conclusion highly questionable, but not so much that it meets the standard of arbitrary and capricious behavior. An Agency decision is erroneous where the Agency fails to require the applicant to provide support for its assertions and assumptions, or where the Agency overlooks errors and omissions in an application. See Bio-Med'l Applications of N.C., Inc. v. N.C. Dep't of Health & Human Serv., 2004 WL 2148389, Case No. 03 DHR 1553, Conclusions of Law ¶ 19 (N.C.O.A.H. June 2, 2004) (Chess, J.); Native Angels Home Care Agency, Inc. v. N.C. Dep't of Health & Human Serv., 2004 WL 1091431, Case No. 03 DHR 0903, Conclusions of Law ¶ 9 (N.C.O.A.H. Feb. 20, 2004) (Conner, J.).

328. For the foregoing reasons, the loss of three months of images caused by a third-party vendor error did not render the Raleigh Radiology Application nonconforming with Criterion 20 as a matter of law.

The Agency Correctly Found the Raleigh Radiology Application Conforming with 10A NCAC 14C .2103

329. The Agency found the Raleigh Radiology Application to be conforming with 10 NCAC 14C .2103 (the "MRI Performance Standards"). (Jt. Ex. 1, pp. 923-30).

330. In its Petition, Wake Radiology alleged that the Agency erred in finding the Raleigh Radiology Application conforming with the MRI Performance Standards because Raleigh Radiology had unreasonable and contradictory utilization projections. (Ex. 357-A ¶ 28). Wake Radiology submitted no other evidence at hearing.

331. As discussed under Criterion 3, Raleigh Radiology's utilization projections are reasonable.

332. For the foregoing reasons, the Agency did not err in determining that the Raleigh Radiology Application was conforming with all applicable MRI Performance Standards.

COMPARATIVE ANALYSIS OF ALL APPLICATIONS

333. The Agency performed a comparative analysis of all competing applications in this review to determine which application was the most effective. The Agency's Findings state that "after considering all of the information in each application and reviewing each application individually against all applicable criteria, the Project Analyst conducted a comparative analysis of the proposals to decide which proposal should be approved." (Joint Ex. 1, p. 932).

334. In simple terms, an application has to pass "Test 1" of conforming to all applicable statutory/review criteria. Atrium Health Lake Norman v. N.C. Dep't of Health & Human Servs., 20 DHR 03986, 80 (N.C.O.A.H. 2021). The practical effect of failing "Test 1" is the necessary failure of "Test 2," the comparative factors analysis: an application that fails to meet the statutory/review criteria cannot be deemed "comparable" with an application that does meet them. Id.

335. Despite the practical elimination of applications failing Test 1 from Test 2, the Agency includes these applications in the text of the comparative analysis to ensure completeness of the record. Atrium Health Lake Norman v. N.C. Dep't of Health & Human Servs., 20 DHR 03986, 80 (N.C.O.A.H. 2021).

336. There is no North Carolina statute, rule, or appellate opinion that compels the Agency to use particular comparative factors in any given competitive CON review. WakeMed v. N. Carolina Dep't of Health & Hum. Servs., Div. of Health Serv. Regul., 222 N.C. App. 755, 770, 750 S.E.2d 186, 196 (2012). Atrium Health Lake Norman v. N.C. Dep't of Health & Human Servs., 20 DHR 03986, at 80-81 (N.C.O.A.H. 2021). Nor is it required to use the same comparative factors in every competitive MRI review. Instead, which comparative factors to use in any competitive review are left to the Agency's discretion.

337. The comparative factors used in this Review are shown in the chart on page 125 of the Agency findings:

- (1) Conformity with Statutory and Regulatory Review Criteria
- (2) Scope of Services
- (3) Historical Utilization
- (4) Geographic Accessibility
- (5) Access by Service Area Residents
    - Number of Residents
    - Percentage of Residents
- (6) Access by Charity Care as a percent of net revenue
    - Charity Care per MRI scan
    - Access by Medicare: highest dollar amount
    - Access by Medicare as a % of Gross Revenue
    - Access by Medicaid: highest dollar amount
    - Access by Medicaid as a % of Gross Revenue

- (7) Competition (Access to New or Alternative Provider)
- (8) Projected Average Net Revenue per MRI procedure
- (9) Projected Average Operating Expense per MRI procedure

(Jt. Ex. 1, p. 942).

338. The Raleigh Radiology Application was the most effective alternative on the factors of (1) Access by Service Area Residents: Number of Residents; (2) Access by Service Area Residents: Percentage of Residents; (3) Access by Medicare: highest dollar amount; (4) Access by Medicaid; highest dollar amount; and (5) Projected Average Net Revenue per MRI Procedure. (Jt. Ex. 1, p. 943) The DUHS Application was the most effective alternative on the factors of (1) Charity Care per MRI Scan; and (2) Access by Medicare as a % of Gross Revenue. (Id.) The Raleigh Radiology Application and DUHS Application were determined to be equally effective alternatives on the factors of (1) Geographic Accessibility; (2) Scope of Services; and (3) Competition (Access to New or Alternative Provider. (Id.) The Wake Radiology Application would have been the most effective on the factors of (1) Access by Medicare: highest dollar amount; and (2) Access by Medicare as a % of Gross Revenue, but it was not approvable. (Jt. Ex. 1, p. 939).

339. The Agency conducted a comparative analysis to determine which application was the most effective alternative. The Agency found the Raleigh Radiology Application to be the most effective alternative. (Jt. Ex. 1, p. 944).

340. Carter opined that the Agency failed to conduct a comparative analysis. That opinion appears to have been offered for the first time very late in this case. (Carter, Vol. 3, pp. 539-43). Carter challenged Yakaboski 's drafting of a chart on page 125 (the "Summary Chart") in the Agency Findings. (See Jt. Ex. 1, p. 942). Carter testified that because Yakaboski wrote "Not Approvable" for almost every factor in Wake Radiology's column, the Agency did not conduct a comparative analysis.

341. Yakaboski did, however, conduct a comparative analysis. The Comparative Analysis in Agency Findings explicitly references the Wake Radiology Application and where it stands in comparison with other applications on specific factors. (Jt. Ex. 1, pp. 933, 936-41). The Comparative Analysis also compares the Wake Radiology Application with the other applications in a series of factor-specific charts. (Id., pp. 936-41). Yakaboski also testified that he analyzed each and every factor independently. (Yakaboski, Vol. 4, p. 890). The Tribunal finds no reason to disbelieve him, even if his testimony on this point was not particularly convincing.

Conformity with Review Criteria

342. The Agency reviewed the applications with respect to the factor of conformity with the review criteria. (Jt. Ex. 1, pp. 933, 942).

343. With respect to this factor, the Agency does not decide that an applicant is "more conforming" or "less conforming" with a review criterion. Instead, any application that is conforming to all applicable review criteria is considered "more effective" or "equally effective," and any application that is not is "less effective." (Jt. Ex. 1, pp. 933, 942).

344. The Agency found the Wake Radiology Application and the Raleigh Radiology-Knightdale Application to be less effective alternatives regarding this factor because these applications were not conforming with all applicable statutory and regulatory criteria. (Jt. Ex. 1, p. 933). The Agency found that the Raleigh Radiology-Cary Application, PHSNC Application, EmergeOrtho Application, and DUHS Application were equally effective alternatives and more effective than the applications submitted by Wake Radiology and Raleigh-Radiology Knightdale. (Id.)

Scope of Services

345. The Agency compared the applications with respect to the scope of services. (Jt. Ex. 1, pp. 933, 942).

346. The Agency noted that all applicants proposed to acquire a fixed MRI scanner in a freestanding outpatient setting. (Jt. Ex. 1, p. 933). However, the Agency determined that the Wake Radiology Application and Raleigh Radiology-Knightdale Application were less effective alternatives regarding this factor because these applications were not conforming with all applicable statutory and regulatory criteria. (Id.)

Historical Utilization

347. The Agency compared the applications with respect to historical utilization. (Jt. Ex. 1, pp. 934, 942).

348. The Agency noted that two of the applications, Raleigh Radiology Knightdale and DUHS, both propose to provide MRI services at new facilities and thus have no historical utilization. (Jt. Ex. 1, p. 934). The Agency ultimately found that its analysis was inconclusive. (Id.)

Geographic Accessibility

349. The Agency compared the applications with respect to the factor of geographic accessibility. (Jt. Ex. 1, pp. 934, 942).

350. The Agency reviewed the Wake County population estimates as of July 1, 2018 and the number of people using freestanding fixed MRI scanners in Raleigh, Cary, Wake Forest, Knightdale, Holly Springs, and Garner on a per capital basis. (Jt. Ex. 1, p. 935). The Agency determined that 81,160 people were using the freestanding fixed MRI scanner located in Cary on a per capital basis as opposed to only 66,350 in Raleigh. (Id., p. 936). The Agency noted that the populations in Wake Forest and Knightdale were smaller and that no application proposed to locate a fixed scanner in Holly Springs or Garner. (Id.) The Agency ultimately found that the geographic location of the MRI scanner in Cary was a better option for MRI services in Wake County.

351. The Agency noted that the Raleigh Radiology-Cary Application, DUHS Application, and Wake Radiology Application all proposed to locate the additional fixed MRI scanner in Cary, Wake County. (Jt. Ex. 1, p. 936). However, the Agency determined that because Wake Radiology did not comply with all applicable statutory and regulatory criteria, the Wake

Radiology Application was not approvable. The Agency found that the Raleigh Radiology-Cary Application and DUHS Applications were equally effective and more effective than the other Applications.

Access by Service Area Residents

352. The Agency also compared the applications with respect to the comparative factor of access by service area residents. (Jt. Ex. 1, pp. 936, 942).

353. The Agency reviewed how many patients the projects proposed to provide access to during the third full fiscal year following project completion:

Applicant	Wake County Residents Served	Wake County Residents per Scanner	Wake County Residents Served as a % of Total
PHSNC	2,942	2,942	62.79%
EmergeOrtho	3,840	3,840	75.62%
Raleigh Radiology-Cary	5,232	5,232	86.49%
Raleigh Radiology-Knightdale	3,640	3,640	98.00%
DUHS	3,086	3,086	70.00%
Wake Radiology	3,937	3,937	88.99%

(Jt. Ex. 1, p. 937).

354. The Agency first considered the number of residents served per scanner. The Agency noted that Raleigh Radiology-Cary projected to serve the highest total number of service area residents. (Jt. Ex. 1, p. 937). The Agency found that the Raleigh Radiology Application was the more effective alternative. The Agency next considered the percentage of residents served per scanner. The Agency noted that the Raleigh Radiology-Knightdale projects to serve the highest percentage of service area residents and that Wake Radiology Application projected to serve the next highest percentage of service area residents. (Jt. Ex. 1, p. 937). However, because Raleigh Radiology-Knightdale and Wake Radiology failed to comply with all applicable statutory and regulatory criteria, the Raleigh Radiology-Knightdale Application and Wake Radiology Application were not approvable. The Agency thus found that Raleigh Radiology-Cary was the more effective alternative, as it served the next highest percentage of service area residents.

Access by Underserved Groups

355. The Agency also compared the applications with respect to the comparative factor of access by underserved groups. (Jt. Ex. 1, pp. 937, 942) It stated that it could use one or more of the following metrics to compare the applications:

- Total charity care, Medicare, or Medicaid patients
- Charity care, Medicare or Medicaid patients as a percentage of total patients
- Charity care, Medicare or Medicaid patients per MRI procedure
- Total charity care, Medicare or Medicaid dollars

- Charity care, Medicare or Medicaid dollars as a percentage of total gross or net revenues
- Charity care, Medicare or Medicaid dollars per MRI procedure

(Jt. Ex. 1, p. 937).

356. The Agency determines which metrics to use based on whether or not the applications included in the review provide data that can be compared as presented above and whether or not such a comparison would be of value in evaluating the alternative factors. (Jt. Ex. 1, p. 938).

357. The agency has historically considered the applicant's total percentage of charity care, Medicare, and Medicaid in its comparative analysis. (Yakaboski, Vol. 4, pp. 732-33).

Projected Charity Care

358. The Agency compared charity care in the third fiscal year following project completion for all the applicants as a percentage of gross and net revenue, and per MRI scan, as shown below:

Applicant	Gross Revenue	Net Revenue	MRI Scans (Unweighted)	Charity Care	Charity Care as a % of Gross Revenue	Charity Care as a % of Net Revenue	Charity Care / MRI Scan
PHSNC	$8,624,545	$2,296,037	4,685	$86,245	1.00%	3.76%	$18.41
EmergeOrtho	$6,093,600	$2,729,933	5,078	$6,896	0.11%	0.25%	$1.36
Raleigh Radiology-Cary	$10,788,293	$2,935,153	6,946	$21,902	0.20%	0.75%	$3.15
Raleigh Radiology-Knightdale	$6,522,524	$1,737,496	4,269	$94,698	1.45%	5.45%	$22.18
DUHS	$6,874,811	$2,866,862	4,408	$86,525	1.26%	3.02%	$19.63
Wake Radiology	$11,113,991	$4,266,508	4,424	$0.00	0.00%	0.00%	$0.00

Source: Section Q Form C and Form F.2 of the respective applications

(Jt. Ex. 1, p. 938).

359. The Agency noted Raleigh Radiology-Knightdale proposed the highest percentage of charity care as a percent of net revenue and the highest dollar amount of charity care per MRI scan. (Jt. Ex. 1, p. 938). However, the Agency found that because the Raleigh Radiology-Knightdale Application did not comply with all applicable statutory and regulatory criteria, the Raleigh Radiology-Knightdale Application was not approvable. (Id.) The Agency found that PHSNC was the more effective alternative with regard to the highest percentage of charity care and that DUHS was the more effective alternative with regard to the dollar amount of charity care per MRI scan. (Id.)

360. According to the Agency's chart on page 121 of its findings, the Raleigh Radiology-Cary Application was a more effective alternative than the Wake Radiology

Application with respect to the highest percentage of charity care and the dollar amount of charity care per scan. (Jt. Ex. 1, p. 938).

Projected Medicare

361. The Agency compared projected access by Medicare patients in the third full fiscal year following project completion for all the applicants using gross Medicare dollars as a percentage of gross revenue and the total dollar amount as shown below:

Applicant	Gross Revenue	Medicare	Medicare as a % of Gross Revenue
PHSNC	$8,624,545	$1,990,520	23.08%
EmergeOrtho	$6,093,600	$1,043,524	17.13%
Raleigh Radiology-Cary	$10,788,293	$2,799,418	25.95%
Raleigh Radiology-Knightdale	$6,522,524	$2,047,980	31.40%
DUHS	$6,874,811	$2,598,303	37.80%
Wake Radiology	$11,113,991	$4,916,033	44.23%

Source: Section Q Form F.2 of the respective applications

(Jt. Ex. 1, p. 939).

362. The Agency noted that Wake Radiology proposed the highest dollar amount of Medicare and the highest percentage of Medicare as a percent of gross-revenue. (Jt. Ex. 1, p. 939). Raleigh Radiology-Cary proposed the second highest dollar amount of Medicare and Raleigh Radiology-Knightdale proposed the second highest percentage of Medicare as a percent of gross-revenue. (Id.) However, neither Raleigh Radiology-Knightdale nor Wake Radiology complied with all applicable statutory and regulatory criteria and thus neither application was approvable. (Id.)

363. The Agency thus found that the Raleigh Radiology-Cary Application was the more effective alternative with respect to the highest dollar amount of Medicare, and DUHS was the more effective alternative with respect to percentage of Medicare as a percent of gross revenue. (Jt. Ex. 1, p. 939).

A. Projected Medicaid

364. The Agency compared projected access by Medicaid patients in the third full fiscal year following project completion for all the applicants using gross Medicaid dollars as a percentage of gross revenue and highest dollar amount. (Jt. Ex. 1, pp. 939, 942).

365. The Agency noted that Raleigh Radiology-Knightdale proposed both the highest dollar amount of Medicaid and the highest Medicaid as a percentage of gross revenue. (Jt. Ex. 1, p. 939). However, the Agency found that because the Raleigh Radiology-Knightdale Application did not comply with all applicable statutory and regulatory criteria, the Raleigh Radiology-Knightdale Application was not approvable. (Id.) Thus, Raleigh Radiology-Cary proposed the second highest dollar amount of Medicaid and EmergeOrtho proposed the second highest Medicaid as a percent of Gross Revenue. (Id.)

366. The Agency determined that Raleigh Radiology-Cary was the more effective alternative with respect to proposing the highest dollar amount of Medcaid and EmergeOrtho was the more effective alternative with respect to proposing the highest Medicaid as a percent of gross revenue:

Applicant	Gross Revenue	Medicaid	Medicaid as a % of Gross Revenue
PHSNC	$8,624,545	$292,585	3.39%
EmergeOrtho	$6,093,600	$313,011	5.14%
Raleigh Radiology-Cary	$10,788,293	$363,279	3.37%
Raleigh Radiology-Knightdale	$6,522,524	$447,595	6.86%
DUHS	$6,874,811	$270,050	3.93%
Wake Radiology	$11,113,991	$129,138	1.16%

Source: Section Q Form F.2 of the respective applications

(Jt. Ex. 1, p. 939).

367. With respect to the highest Medicaid as a percent of gross revenue, the Raleigh Radiology-Cary Application was a more effective alternative than the Wake Radiology Application. (Jt. Ex. 1, p. 939).

Competition (Access to a New or Alternative Provider in the Service Area)

368. The Agency also compared the applications with respect to competition (patient access to a new or alternative provider). (Jt. Ex. 1, p. 940).

369. The Agency noted that all applicants and/or related entities already provide MRI services in the service area of Wake County. (Jt. Ex. 1, p. 940). However, because Raleigh Radiology-Knightdale and Wake Radiology failed to comply with all applicable statutory and regulatory criteria, the Raleigh Radiology-Knightdale Application and Wake Radiology Application were not approvable. (Id.) The Agency thus found that the applications submitted by PHSNC, EmergeOrtho, Raleigh Radiology-Cary and DUHS were equally effective alternatives and more effective than the applications submitted by Raleigh Radiology-Knightdale and Wake Radiology. (Id.)

Projected Average Net Revenue per MRI Procedure

370. The Agency compared the applications with respect to projected average net revenue per case. (Jt. Ex. 1, p. 940). The Agency Findings state, "[g]enerally regarding this factor, the application proposing the lowest average net revenue per MRI procedure is the more effective alternative since a lower average may indicate a lower cost to the patient or third-party payor." (Id.)

371. The Agency compared the projected average operating expense per unweighted MRI procedure in the third year of operation following project completion for all applicants, based on the information provided in the applicants' *pro forma* financial statements:

Applicant	Net Revenue	# of Unweighted MRI Procedures	Average Net Revenue per MRI Procedure
PHSNC	$2,296,037	4,685	$490
EmergeOrtho	$2,729,933	5,078	$538
Raleigh Radiology-Cary	$2,935,153	6,946	$423
Raleigh Radiology-Knightdale	$1,737,496	4,269	$407
DUHS	$2,866,862	4,408	$650
Wake Radiology	$4,266,508	4,424	$964

Source: Section Q Form C and Form F.2 of the respective applications

(Jt. Ex. 1, p. 940).

372. The Agency noted that Raleigh Radiology-Knightdale proposed the lowest average net revenue per MRI procedure in the third full fiscal year following project completion. (Jt. Ex. 1, p. 940). However, the Raleigh Radiology-Knightdale Application did not comply with all applicable statutory and regulatory criteria and thus the Application was not approvable. (Id.) The Agency thus determined that the proposal by Raleigh Radiology-Cary, which proposed the second lowest average net revenue per unweighted MRI procedure in the third full year following project completion, is the more effective alternative. (Id.)

373. The Agency did not include a comparative analysis based on information supplied by Raleigh Radiology-Cary its response to the comments. (See Jt. Ex. 1, p. 940). In its response to comments, Raleigh Radiology-Cary stated that it provided the wrong actual charge per MRI procedure and that rather than $1,553 per scan, it was $1,887 per scan. (Jt. Ex. 1, p. 433). Using the correct charge, there was an increase in revenue of $90 per scan by the third year of operation following project completion. (Id.)

374. The correct average net revenue per MRI procedure for Raleigh Radiology-Cary should be $513 ($423 + $90 = $513) Using the correct average net revenue per MRI procedure, the most effective alternative was PHSNC. (See Jt. Ex. 1, p. 940). However, Raleigh Radiology-Cary was still a more effective alternative than Wake Radiology – whose average net revenue per MRI procedure was $964. (See id.)

Projected Average Total Operating Expense per MRI procedure

375. The Agency compared the applications with respect to projected average total operating expense per MRI procedure. (Jt. Ex. 1, p. 940). The Agency Findings state, "[g]enerally, regarding this factor, the application proposing the lowest average operating expense per MRI procedure is the more effective alternative since a lower average may indicate a lower cost to the patient or third-party payor or a more cost-effective service." (Id.)

376. The Agency compared the projected operating expense per unweighted MRI procedure for the third year of operation following project completion for all the applicants, based on the information provided in the applicants' *pro forma* financial statements:

Applicant	Operating Expense	# of Unweighted MRI Procedures	Average Operating Expense per Procedure
PHSNC	$1,749,875	4,685	$374
EmergeOrtho	$1,305,239	5,078	$257
Raleigh Radiology-Cary	$2,021,044	6,946	$291
Raleigh Radiology-Knightdale	$1,482,189	4,269	$347
DUHS	$1,495,477	4,408	$339
Wake Radiology	$2,890,428	4,424	$653

Source: Section Q Form C, Form F.2, and Form F.3 of the respective applications

(Jt. Ex. 1, pp. 941).

377. The Agency found that EmergeOrtho proposed the lowest average operating expense per unweighted MRI procedure and was thus the more effective alternative. (Jt. Ex. p. 941). According to the Agency's analysis, the Raleigh Radiology-Cary Application was also a more effective alternative than the Wake Radiology Application. (See id.)

378. The Agency did not include a comparative analysis based on information supplied by Raleigh Radiology relating to the Raleigh Radiology-Cary Application in its response to the comments. (See Jt. Ex. 1, p. 941). In its response to comments, Raleigh Radiology-Cary stated that it provided the wrong actual charge. (Jt. Ex. 1, p. 433). The Agency thus did not consider what Raleigh Radiology-Cary's actual projected average total operating expense per MRI procedure.

379. Raleigh Radiology-Cary's error in misstating its charge would not have changed the comparative analysis between Wake Radiology and Raleigh Radiology-Cary. Raleigh Radiology-Cary's charge would have been less than Wake Radiology's. (Yakaboski, Vol. 4, p. 760).

380. Even though Raleigh Radiology-Cary used the wrong charge, the Raleigh Radiology Application and its responses to comments included sufficient information for the Agency to perform a comparative analysis with respect to the average operating expense per procedure. (See Yakaboski, Vol. 4, pp. 899-903).

381. Raleigh Radiology-Cary's expenses were tied to its revenue. (See Watson, Vol. 5, pp. 1172-74). The Agency had the total operating expense for the Raleigh Radiology-Cary Application - $2,021,044. (Jt. Ex. 1, p. 941). Had the Agency divided the total operating expense by the total net revenue ($2,935,153), it would have calculated that the operating expenses were approximately 68.86% of the total net revenue. (Yakaboski, Vol. 4, p. 901).

382. Accounting for correct charge of $1,887 and the additional revenue of $90 per scan, the Agency had enough information to determine the correct total net revenue. (Yakaboski, Vol. 4, pp. 901-02). First, the Agency would have needed to multiply $90 by the number of

unweighted scans that the proposed scanner was projected to perform in the third year of operation following project completion – 6,946 – resulting in an additional revenue of $625,140. (Id.; see also Jt. Ex. 1, p. 940). Adding this amount to the total revenue of $2,935,153, the new total revenue would have been $3,560,293 (Yakaboski, Vol. 4, pp. 901-02). Since costs approximately were 68.86% of revenue, multiplying the new total revenue by 68.86% would have resulted in the correct total operating expense: approximately $2,451,618. (Id., p. 902). Dividing the total operating expense by the number of unweighted scans that the proposed scanner was projected to perform in the third year of operation following project completion – 6,946 – results in the correct average operating expense per procedure – approximately $353. (Id.)

383. If the Agency had conducted the comparison analysis with the correct approximate average operating expense per procedure for Raleigh Radiology-Cary – $353, it would have still found that Raleigh Radiology-Cary's average operating expense was a more effective alternative than Wake Radiology's $653. (Yakaboski, Vol. 4, p. 902).

384. Based upon the entirety of the comparative analysis, the Agency in its discretion concluded that Raleigh Radiology-Cary was the most effective alternative, a finding which is supported by the evidence.

On the basis of these Findings of Fact, the Tribunal makes the following:

CONCLUSIONS OF LAW

1. The Office of Administrative Hearings has jurisdiction over all the parties and the subject matter of this action. All parties have been correctly designated and there is no question as to misjoinder or nonjoinder of parties. To the extent that certain portions of the foregoing Findings of Fact constitute mixed issues of law and fact, such Findings of Fact shall be deemed incorporated herein by reference as Conclusions of Law. Similarly, to the extent that any of the following Conclusions of Law is a Finding of Fact, it shall be so considered in spite of its designation as a Conclusion of Law.

2. The Tribunal need not make findings as to every fact which arises from the evidence and need only find those facts which are material to resolution of the dispute. Flanders v. Gabriel, 110 N.C. App. 438, 440, 429 S.E.2d 611, 612 (1993).

3. The subject matter of this contested case is the Agency's decision to deny the Wake Radiology Application and approve the Raleigh Radiology Application. Wake Radiology is entitled to bring this appeal, as the denial of the Wake Radiology Application makes Wake Radiology an "affected person" under N.C.G.S. 131E-188. Presbyterian Hosp. v. N.C. Dep't of Health and Human Servs., 177 N.C. App. 780, 784, 630 S.E.2d 213, 215 (2006).

4. In determining whether an Agency decision is "erroneous," under N.C.G.S. 150B-23(a)(2), the ALJ looks to see, among other things, whether the Agency properly reviewed an application and reached appropriate conclusions. An Agency decision is erroneous where the Agency fails to require the applicant to provide support for its assertions and assumptions, or where the Agency overlooks errors and omissions in an application. See Bio-Med'l

Applications of N.C., Inc. v. N.C. Dep't of Health & Human Serv., 2004 WL 2148389, Case No. 03 DHR 1553, Conclusions of Law ¶ 19 (N.C.O.A.H. June 2, 2004) (Chess, J.); Native Angels Home Care Agency, Inc. v. N.C. Dep't of Health & Human Serv., 2004 WL 1091431, Case No. 03 DHR 0903, Conclusions of Law ¶ 9 (N.C.O.A.H. Feb. 20, 2004) (Conner, J.).

5. In determining whether an Agency decision is arbitrary and capricious, the ALJ evaluates whether the Agency decision "indicate[s] a lack of fair and careful consideration" or "fail[s] to indicate any course of reasoning and the exercise of judgment." Lenoir Mem'l Hosp., Inc. v. N.C. Dept. of Human Ser., 98 N.C. App. 178, 181-82, 390 S.E.2d 448, 450 (1990).

6. As the Petitioner, Wake Radiology must establish that its rights were substantially prejudiced as a result of the CON Section's decisions, in addition to establishing that the Agency acted outside its authority, acted erroneously, acted arbitrarily and capriciously, used improper procedure, or failed to act as required by law or rule. Parkway Urology, P.A. v. N.C. Dep't of Health and Human Servs., 205 N.C. App. 529, 696 S.E.2d 187 (2010); see also N.C.G.S. §131E-188(a) and 150B-23(a).

7. A contested case challenging a CON decision is not a de novo proceeding. "[T]he purpose of the ALJ's determination in a CON case is to review the correctness of the Department's decision utilizing the standards enunciated in N.C. Gen. Stat. 150B-23(a) rather than to engage in a *de novo* review of the evidentiary record." E. Carolina Internal Med., P.A. v. N.C. Dep't of Health and Human Servs., 211 N.C. App. 397, 405 710 S.E.2d 245, 252 (2011); Britthaven, Inc. v. N.C. Dep't of Health and Human Servs., 118 N.C. App. 379, 382, 455 S.E.2d 455, 459, disc. review denied, 341 N.C. 418, 461 S.E.2d 754 (1995).

8. An administrative law judge does not conduct an independent review of the applications, nor does he substitute his judgment for that of the Agency. Raleigh Radiology LLC v. N.C. Dep't of Health & Hum. Servs., Div. of Health Serv. Regul., Health Care Plan. & Certificate of Need, 266 N.C. App. 504, 510, 833 S.E.2d 15, 21 (2019). Likewise, an administrative law judge may neither change the comparative factors used by the Agency in reviewing the application nor impose new ones. Id.

9. The administrative law judge may only set aside the initial agency decision if the petitioner proves, by the greater weight of the evidence, one of the stated grounds for overturning an agency decision in N.C.G.S. 150B-23. The administrative law judge may not overturn the initial agency decision because the judge might have made a different judgment if he or she had been the person making the initial agency decision. N.C.G.S. 150B-23(a); Gordon v. N.C. Dep't of Corr., 173 N.C. App. 22, 34, 618 S.E.2d 280, 289, (2005). The Tribunal is particularly attentive to the Court of Appeals' instruction on that point in this case, which features Agency error in addressing the accreditation and loss of image issue involving Raleigh Radiology.

10. When a party questions whether the Agency's decision was supported by the evidence or whether it was arbitrary or capricious, the appropriate standard is the whole record test. Under the whole record test, "a Tribunal must examine all of the record evidence - that which detracts from the agency's findings and conclusions as well as that which tends to support them - to determine whether there is substantial evidence to justify the agency's decision." Good Hope Health Sys. v. N.C. Dep't of Health and Human Servs., 189 N.C. App. 534, 543, 659

S.E.2d 456, 462 (2008) (quoting Watkins v N.C. State Bd. of Dental Exam'rs, 358 N.C. 190, 199, 593 S.E.2d, 764, 769 (2004)). Substantial evidence is "relevant evidence a reasonable mind might accept as adequate to support a conclusion." N.C.G.S. 150B-2(8c).

11. A review of the Agency's determination regarding the reasonableness of an applicant's projections is likewise subject to the whole record test. Craven Reg'l Med. Auth. v. N.C. Dep't of Health and Human Servs., 176 N.C. App. 46, 52-53, 625 S.E.2d 837, 841 (2006). "A reasonable projection of something that will occur in the future, by its very nature, cannot be established with absolute certainty." Id. at 176 N.C. App. at 53, 625 S.E.2d at 841.

12. The whole record test is not a "tool of judicial intrusion." Hosp. Grp. of W. N.C., Inc. v. N.C. Dept. of Human Res., 76 N.C. App. 265, 268, 332 S.E.2d 748, 751 (1985). However, a reviewing Tribunal (or Tribunal) must, in conducting the whole record test, consider evidence that both supports and detracts from the Agency decision, as the Court of Appeals of North Carolina has also very recently re-affirmed, albeit in an unpublished opinion. Belcher v. N. Carolina Dep't of Pub. Safety, State Highway Patrol, No. COA20-562, 2021 WL 2425899, at *3 (N.C. Ct. App. June 15, 2021) (citing Thompson v. Wake County Bd. of Educ., 292 N.C. 406, 410, 233 S.E. 2d 538, 541 (1977)).

13. In the CON context, under the whole record test, even an error in the Agency's analysis of an applicant may be harmless if it does not affect the outcome of the review. Britthaven, 118 N.C. App. at 386-89, 455 S.E.2d at 461-63. If a reviewing Tribunal finds that the Agency's analysis included an error that if correctly decided would have led to the same decision, the error is harmless under the whole record test. Id. That is of significant importance in this case; the Agency's error on the accreditation and loss of images issue ultimately did not affect the outcome of the review, as Wake Radiology's own application was un-approvable due to Wake Radiology's failure to meet the rules requiring minimum scanning frequency.

14. Agency Findings in prior cases are not persuasive or controlling in determining whether the Agency erred in a subsequent case. Charlotte-Mecklenburg Hosp. Auth. v. N.C. Dep't of Health and Human Servs., No. COA11-339, 2011 WL 6359618, at *10 (N.C. Ct. App. Dec. 20, 2011) (unpublished opinion). Nor is the Agency shackled in a subsequent case by choosing to use certain comparative factors as in a prior case.

15. Administrative agency decisions may be reversed as arbitrary and capricious only if they are "patently in bad faith" or "whimsical" in the sense that "they indicate a lack of fair and careful consideration" or "fail to indicate any course of reasoning in the exercise of judgment." ACT-UP Triangle v. Comm'n for Health Servs., 345 N.C. 699, 707, 483 S.E.2d 388, 393 (1997).

16. The Agency's interpretation and application of the statutes and rules it is empowered to enforce are entitled to deference as long as the agency's interpretation is reasonable and based on a permissible construction of the statute. Carpenter v. N.C. Dep't of Human Res., 107 N.C. App. 278, 279, 419 S.E.2d 582, 584 (1992), disc. rev. improvidently allowed, 333 N.C. 533, 427 S.E.2d 874 (1993); Total Renal Care of N. Carolina, LLC v. N. Carolina Dep't of Health & Hum. Servs., 242 N.C. App. 666, 674, 776 S.E.2d 322, 327 (2015) see also Mobile Imaging Partners of N. Carolina, LLC v. N. Carolina Dep't of Health & Hum.

Servs., No. COA20-605, 2021 WL 2793633, at *3 (N.C. Ct. App. July 6, 2021) (citing AH N.C. Owner LLC v. N.C. Dep't of Health & Human Servs., 240 N.C. App. 92, 102, 771 S.E.2d 537, 543 (2015)).

17. The Agency's decision to approve an applicant's certificate of need application is based upon the Agency's determination of whether the applicant has complied with the review criteria set forth in N.C.G.S. §131E-183(a) and any applicable regulatory criteria. The Agency is required to "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." N.C.G.S. §131E-183(a); see also Parkway Urology, P.A., v. N.C. Dep't of Health & Human Servs., 205 N.C. App. 529, 534, 696 S.E.2d 187, 191-92 (2010).

18. The Agency's review of a CON application can be described as a "two step test" or review: "A two stage process similar to that suggested by petitioner, and the ALJ in his Recommended Decision, is consistent with the language, purpose and overall scheme of the statute." Britthaven, Inc. v. N. Carolina Dep't of Hum. Res., Div. of Facility Servs., 118 N.C. App. 379, 385, 455 S.E.2d 455, 460 (1995). As described in Britthaven:

> **First**, after the Agency "batches" all applications for competing proposals, the Agency must review each application independently against the criteria (without considering the competing applications) and determine whether it "is either consistent with or not in conflict with these criteria." N.C.G.S. 131E–183(a). The use of singular nouns in the phrases beginning each listed criterion, such as "the applicant shall show" or "the proposed project shall show," support an initial independent evaluation of each application. Moreover, the plain language of Criterion 4 establishes that an applicant's burden is to show the least costly or most effective of the alternative methods, if any, within its own proposed project, not that its project is the least costly or most effective of all competing proposals. N.C.G.S. 131E–183(a)(4).
>
> **Second**, after each application is reviewed on its own merits, the Agency must decide which of the competing applications should be approved. This decision may include not only whether and to what extent the applications meet the statutory and regulatory criteria, but it may also include other "findings and conclusions upon which it based its decision." N.C.G.S. 131E– 186(b). Those additional findings and conclusions give the Agency the opportunity to explain why it finds one applicant preferable to another on a comparative basis. The CON law, therefore, does not contemplate that the Agency will review any criteria competitively, and subsequently find one applicant nonconforming to a criterion simply because another applicant is found conforming.

Britthaven at 379, 461 (emphasis supplied). "The Britthaven standard sets forth a two-pronged procedure for the Agency to review competing CON applications." Surgical Care Affiliates, LLC v. NC Dep't of Health & Hum. Servs., 237 N.C. App. 99, 766 S.E.2d 699 (2014).

19. Under Section 131E-186(b), within 5 days of issuance of its decision, the Agency findings must provide notice of "the findings and conclusions upon which it based its decision . . ." The Agency is not permitted to change its findings – in writing or by testimony.

20. Because "[t]he subject matter of a contested case hearing is [the] Agency decision," the ALJ's decision is to be based on "the evidence that is presented or available to the agency during the review period." Britthaven, 118 N.C. App. at 382, 455 S.E.2d at 459 (citing In re Application of Wake Kidney Clinic, 85 N.C. App. 639, 355 S.E.2d 788, disc. review denied, 320 N.C. 793, 361 S.E.2d 89 (1987)); Living Centers-Southeast, Inc. v. NC Dep't of Health & Hum. Servs., 138 N.C. App. 572, 581, 532 S.E.2d 192, 197 (2000).

21. Wake Radiology's impassable obstacle in this case is that the Wake Radiology Application "flunked" Step 1 by failing to conform to the statutory (and additionally here, regulatory) criteria in multiple respects. Though the Agency nonetheless (properly) still conducted a "Step 2" comparative review of the Wake Radiology Application with other, conforming applications, the Wake Radiology Application's failure to pass Step 1, stated simply, precluded its approval.

22. The Tribunal has thoroughly reviewed the evidence of the record and finds no error in the Agency's determination that the Wake Radiology Application failed to conform with all statutory (and, additionally, regulatory) criteria. The Agency's determination that the Wake Radiology Application failed to conform with all statutory criteria is supported by substantial evidence in the record in all respects. Moreover, the evidence shows that Yakaboski, in reviewing the application, attempted to find a way to approve the Wake Radiology Application, but was ultimately unable to do so.

23. Having discussed those criteria and how Wake Radiology failed to meet them in detail above, it is not necessary to restate them in detail here: the statutory criteria existed, and the Wake Radiology Application failed to meet them.

24. An application that fails to meet the statutory criteria cannot, in itself, be deemed comparatively superior to an application which does. To hold otherwise would be to effectively negate Step 1, to say nothing of abrogating statutory requirements enacted by the General Assembly. Such an action is untenable. "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." N.C.G.S. 131E-183(a); Parkway Urology, P.A., v. N.C. Dep't of Health & Human Servs., 205 N.C. App. 529, 534, 696 S.E.2d 187, 191-92 (2010), disc. review denied, 365 N.C. 78, 705 S.E.2d 753 (2011).

25. Though Wake Radiology has demonstrated material Agency error in this case on the accreditation and image loss issues, it is well established that demonstrating agency error, standing alone, is not enough to overturn the Agency in a CON case. CaroMont Health, Inc. v. N.C. Dep't of Health & Human Servs., 231 N.C. App. 1, 751 S.E.2d 244 (2013). Wake Radiology's claim fails because it cannot establish substantial prejudice due to its own application being un-approvable.

26. As set forth in N.C.G.S. 150B-23, Wake Radiology's failure to establish substantial prejudice, standing alone, prevents it from prevailing in this contested case. See Novant Health, Inc., Forsyth Memorial Hospital, Inc. d/b/a Forsyth Medical Center and Medical Park Hospital, Inc. v. N.C. Dep't of Health & Human Servs., 10 DHR 3788 2011 WL 2037599.

27. Substantial prejudice is a necessary element of a contested CON case. N.C.G.S. 150B-23(a); Surgical Care Affiliates, LLC v. N.C. Dep't of Health & Human Servs., 235 N.C. App. 620, 633, 762 S.E.2d 468, 476 (2014).

28. A party's status as a denied applicant – an "affected person" – does not, standing alone, establish substantial prejudice. Surgical Care Affiliates, LLC v. N.C. Dep't of Health & Human Servs., 237 N.C. App. 99, 766 S.E.2d 699 (2014). Nor, standing alone, does agency error establish substantial prejudice. CaroMont Health, Inc. v. N.C. Dep't of Health & Human Servs., 231 N.C. App. 1, 751 S.E.2d 244 (2013).

29. The Tribunal previously rejected claims that an applicant is unfairly prejudiced if it is a denied applicant and is prevented from carrying out its proposed project. Atrium Health Lake Norman v. N.C. Dep't of Health & Human Servs., 20 DHR 03986, 104-05 (N.C.O.A.H. 2021). The Court of Appeals recently reaffirmed this principle and rejected a similar argument made by a petitioner that was prevented from "conducting business as it chooses" in Bio-Med. Applications of N. Carolina, Inc. v. N.C. Dep't of Health & Human Servs., 2022-NCCOA-1999, ¶¶14, 16.

30. Where a petitioner cannot show any specific evidence of harm resulting from the Agency's decision apart from competitive harm and the denial of their application, the petitioner fails to establish substantial prejudice as a matter of law. Surgical Care Affiliates, LLC v. NC Dep't of Health & Hum. Servs., 237 N.C. App. 99, 766 S.E.2d 699 (2014); see also Parkway Urology, P.A. v. N.C. Dep't of Health & Human Servs., 205 N.C. App. 529, 539, 696 S.E.2d 187, 195 (2010) (rejecting an increase in competition resulting from the award of a CON as inherently and substantially prejudicial to any pre-existing competing health services provider in the same geographic area).

31. Accordingly, the Tribunal concludes that Wake Radiology failed to meet its burden of proof to demonstrate substantial prejudice, as a matter of law, as a result of the Agency's decision.

32. The Agency correctly and reasonably found the Raleigh Radiology Application to be conforming with Criterion 1.

33. The Agency correctly and reasonably found the Raleigh Radiology Application to be conforming with Criterion 3.

34. The Agency correctly and reasonably found the Raleigh Radiology Application to be conforming with Criterion 4.

35. The Agency correctly and reasonably found the Raleigh Radiology Application to be conforming with Criterion 5.

36. The Agency correctly and reasonably found the Raleigh Radiology Application to be conforming with Criterion 7.

37. The Agency correctly and reasonably found the Raleigh Radiology Application to be conforming with Criterion 13(c).

38. The Agency correctly and reasonably found the Raleigh Radiology Application to be conforming with Criterion 14.

39. The Agency correctly and reasonably found the Raleigh Radiology Application to be conforming with Criterion 18(a).

40. The Agency erred in its analysis and findings with respect to the Raleigh Radiology Application and Criterion 20. The Agency simply failed to do its duty of requiring Raleigh Radiology to demonstrate quality care during the lookback period. If its own criteria require a showing of quality care, as they unquestionably do, the Agency may not metaphorically shrug its shoulders and say, "that is someone else's problem," or "we rely on other people to make that call." If the criterion exists it should be enforced. If an applicant – as here - wholly omits from its application information that indisputably raises an issue of provision of quality care, the Agency should do its duty, ask the hard questions, and receive properly supported and provable assurances.

41. The Agency correctly and reasonably found the Raleigh Radiology Application to be conforming with 10A NCAC 14C .2103.

42. Finally, Wake Radiology failed to show that the Agency erred in failing to determine by an actual and appropriate comparative analysis that the Raleigh Radiology Application is the best and most effective alternative for the acquisition of an MRI scanner in Wake County pursuant to the 2019 SMFP Need Determination.

FINAL DECISION

The Agency's decision to conditionally approve the Raleigh Radiology Application and disapprove the Wake Radiology Application is **AFFIRMED**.

NOTICE OF APPEAL

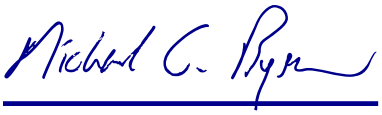
Under the provisions of N.C. Gen. Stat. 131E-188(b): "Any affected person who was a party in a contested case hearing shall be entitled to judicial review of all or any portion of any final decision in the following manner. The appeal shall be to the Court of Appeals as provided in G.S. 7A-29(a). The procedure for the appeal shall be as provided by the rules of appellate procedure. The appeal of the final decision shall be taken within 30 days of the receipt of the written notice of the Final Decision and notice of appeal shall be filed with the Office of Administrative Hearings and served on the Department [North Carolina Department of Health and Human Services] and all other affected persons who were parties to the contested hearing."

Under N.C. Gen. Stat. 131E-188(b1): "Before filing an appeal of a final decision granting a certificate of need, the affected person shall deposit a bond with the Clerk of the Court of Appeals. The bond requirements of this subsection shall not apply to any appeal filed by the Department."

In conformity with the Office of Administrative Hearings' Rule 26 NCAC 03.0102 and the Rules of Civil Procedure, N.C. Gen. Stat. 1A-1, Article 2, this Final Decision was served on the parties the date it was placed in the mail or served via electronic service as indicated on the Certificate of Service attached to this Final Decision.

SO ORDERED.

This the 8th day of August, 2022.



Michael C. Byrne
Administrative Law Judge

CERTIFICATE OF SERVICE

The undersigned certifies that, on the date shown below, the Office of Administrative Hearings sent the foregoing document to the persons named below at the addresses shown below, by electronic service as defined in 26 NCAC 03 .0501(4), or by placing a copy thereof, enclosed in a wrapper addressed to the person to be served, into the custody of the North Carolina Mail Service Center who subsequently will place the foregoing document into an official depository of the United States Postal Service.

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This the 8th day of August, 2022.

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