

STATE OF NORTH CAROLINA  
COUNTY OF WAKE

IN THE OFFICE OF  
ADMINISTRATIVE HEARINGS  
21 DHR 04543

<p>Pinnacle Health Services of North Carolina LLC d/b/a Cardinal Points Imaging of the Carolinas Wake Forest and Outpatient Imaging Affiliates LLC Petitioner,</p> <p>v.</p> <p>NC Department of Health and Human Services, Division of Health Service Regulation, Health Care Planning &amp; Certificate of Need Section Respondent,</p> <p>and</p> <p>Duke University Health System Inc., Respondent-Intervenor.</p>	<p><b>FINAL DECISION</b></p>
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THIS MATTER came for hearing before Administrative Law Judge Melissa Owens Lassiter on March 7-16, 2022, in Raleigh, North Carolina to hear Petitioner's contested case petition, filed pursuant to N.C. Gen. Stat. §§ 150B-23 and 131E-188, appealing Respondent's September 24, 2021 Agency decision and Required State Agency Findings, to approve, with conditions, a Certificate of Need application by Respondent-Intervenor to acquire one new fixed MRI scanner in a new diagnostic center in Raleigh, North Carolina, and to disapprove Petitioner's competing Certificate of Need application for one fixed MRI scanner at its existing facility in Wake Forest, North Carolina.

Thereafter, pursuant to the Tribunal's Order, the parties filed their respective proposed Final Decisions. Having heard and considered all of the testimony and evidence in this case and having considered the exhibits, arguments, and relevant law, the Undersigned makes the Findings of Fact by a preponderance of the evidence, enters her Conclusions of Law thereon, and makes the following Final Decision:

**APPEARANCES**

For Petitioners Pinnacle Health Services of North Carolina, LLC, d/b/a Cardinal Points Imaging of the Carolinas Wake Forest, and Outpatient Imaging Affiliates, LLC (collectively, “Pinnacle”):

Marcus C. Hewitt  
Elizabeth Sims Hedrick  
Fox Rothschild LLP  
434 Fayetteville Street, Suite 2800  
Raleigh, NC 27601

For Respondent N.C. Department of Health and Human Services, Division of Health Service Regulation, Healthcare Planning and Certificate of Need Section (the “CON Section” or “Agency”):

Kimberly Randolph  
Assistant Attorney General  
North Carolina Department of Justice, Health Services Section  
P.O. Box 629  
Raleigh, NC 27602

For Respondent-Intervenor Duke University Health System, Inc. (“Duke”):

Matthew A. Fischer  
Iain Stauffer  
Baker Donelson, Bearman, Caldwell & Berkowitz, PC  
2530 Meridian Parkway, Suite 300  
Durham, NC 27713

### **APPLICABLE LAW**

1. The procedural statutory law applicable to this contested case is the North Carolina Administrative Procedure Act, N.C. Gen. Stat. § 150B-2, *et seq.* and N.C. Gen. Stat. § 131E-188 of the North Carolina Certificate of Need Law.
2. The substantive statutory law applicable to this contested case is the North Carolina Certificate of Need Law, N.C. Gen. Stat. § 131E-175, *et seq.*
3. The administrative regulations applicable to this contested case are the North Carolina Certificate of Need Program Administrative Regulations, 10A N.C.A.C. 14C.0101, *et seq.* and 10A N.C.A.C. 14C.2700, *et seq.*

### **ISSUES**

1. Whether the Agency deprived Petitioner of property or substantially prejudiced Petitioner's rights as set forth in N.C. Gen. Stat. § 150B-23(a) by denying a certificate of need (CON) to Petitioner for a fixed magnetic resonance imaging (MRI) scanner in Wake County, North Carolina and instead awarding a CON for a fixed MRI scanner in Wake County, North Carolina to Respondent-Intervenor ?

2. Whether the Agency exceeded its authority or jurisdiction, acted erroneously, failed to use proper procedure, acted arbitrarily or capriciously, and/or failed to act as required by law or rule by issuing the Agency decision denying a CON to Petitioner for a fixed MRI scanner in Wake County and by awarding a CON for a fixed MRI scanner in Wake County, North Carolina to Respondent-Intervenor?

### **BURDEN OF PROOF**

1. The petitioner in a contested case hearing before the Office of Administrative Hearings ("OAH") must establish by a preponderance of the evidence that the state agency named as respondent has deprived the petitioner of property, has ordered the petitioner to pay a fine or civil penalty, or has otherwise substantially prejudiced the petitioner's rights and that the state agency named as respondent has:

- (1) Exceeded its authority or jurisdiction.
- (2) Acted erroneously.
- (3) Failed to use proper procedure.
- (4) Acted arbitrarily or capriciously; or
- (5) Failed to act as required by law or rule.

N.C. Gen. Stat. §§ 150B-23(a); 150B-29(a); 150B-34(a).

2. As Petitioner, Pinnacle bears the burden of proof in this contested case. N.C. Gen. Stat. § 150B-23(a); N.C. Gen. Stat. § 150B-29(a).

### **WITNESSES**

For Petitioner:

Amber George, Administrator, Pinnacle Health Services  
Greg Yakaboski, Project Analyst, CON Section  
Lisa Pittman, Assistant Chief for Certificate of Need, CON Section  
David Meyer, Keystone Planning Group

For Respondent-Intervenor

Catharine Cumber, Regulatory Counsel, Strategic Planning, Duke  
Karin L. Sandlin, Clarity Strategic Services

### **EXHIBITS ADMITTED INTO EVIDENCE**

#### Joint Exhibits

1. Agency File
2. Pinnacle Application and Exhibits (Project ID No. J-12063-21)
3. Duke Application and Exhibits (Project ID No. J-12073-21)
5. Agency Findings - 2021 Buncombe/Graham/Madison/Yancey fixed MRI Review
- 6a. Tables from Agency Findings p. CON 877 with Handwritten Corrections
7. Agency Findings - 2019 Forsyth Co. Fixed MRI Review
- 8a. Tables from Agency Findings pp. CON 881 and 882 with Handwritten Corrections
9. Excerpts from 2021 - N.C. State Medical Facilities Plan
10. Agency Template Findings - Competitive CON Review
20. David Meyer CV
21. Excerpt from Pinnacle 2019 Application - Section Q
26. Meyer Attachment 1 - Calculation of Financial Harm to Pinnacle
28. Meyer Attachment 3 - Proximity of Proposed Duke Scanner to Other Freestanding Fixed MRI Scanners
29. Meyer Attachment 4 - City Population Comparisons: Guilford, Wake, Forsyth Cos.
31. Meyer Attachment 6 - Agency Findings - 2016 Wake Co. Fixed MRI Review
32. Meyer Attachment 7 - Comparison of MRI Revenue per MRI Procedure Components

33. Meyer Attachment 8 - Comparison of MRI Operating Cost per MRI Components
34. Meyer Attachment 9 - Calculation of Improvement in Ratio of MRI Scanners/Population: Wake Forest, Garner and Raleigh
35. Excerpt from Agency Findings - 2021 Durham/Caswell Co. Operating Room Review: Geographic Accessibility
36. Excerpt from Agency Findings - 2020 Guilford Co. Fixed MRI Review: Geographic Accessibility
37. Excerpt from Agency Findings - 2020 Wake Co. Operating Room Review: Geographic Accessibility
38. Excerpt from Agency Findings - 2019 Forsyth Co. Fix MRI Review: Geographic Accessibility
39. Excerpt from Agency Findings - 2019 Mecklenburg Co. Acute Care Beds/ORs Review: Geographic Accessibility
42. Karin Sandlin CV
44. Agency Findings - 2019 Mecklenburg Fixed MRI Review
45. Duke Written Comments - 2016 Wake County Fixed MRI CON Review

For Petitioner:

101. Petition for Contested Case Hearing, *Duke Univ. Health Sys. v. N.C. Dep't of Health & Human Servs.* (Oct. 21, 2021)
102. Chart: Improvement in Ratio of Fixed MRI Scanners/Population
103. Tables: In-County City Population Comparisons
104. Tables and Charts: Comparison of MRI Net Revenue Components - WEIGHTED MRI Procedures and UNWEIGHTED MRI Procedures
105. Chart: Factor: Projected Average Net Revenue Per MRI Procedure Comparison of Professional/Technical Components
106. Tables and Charts: Comparison of MRI Total Operating Cost Components - WEIGHTED and UNWEIGHTED MRI Procedures
107. Chart: Factor: Projected Average Total Operating Expense Per MRI Procedure Comparison of Professional/Technical Costs

108. Tables: Comparison of Contracted Mobile and PHS Owned Mobile profit/loss
109. Table: Fixed MRI Scanners and Population if Duke Approved

For Respondent-Intervenor:

210. United States Census Bureau Data - Raleigh city, North Carolina
211. United States Census Bureau Data - Wake Forest town, North Carolina
214. Table: Pinnacle's MRI Professional Revenue ≠ MRI Professional Fees
215. Excerpts from Pinnacle's 2019 Wake County MRI CON and 2021 Wake County MRI CON ("Geographic Access")

### FINDINGS OF FACT

Upon 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 Undersigned makes the following Findings of Fact. In making the Findings of Fact, the Undersigned has weighed all the evidence and has assessed the credibility of each witness, including but not limited to, the demeanor of the witnesses; any interest, bias, or prejudice the witnesses 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 witnesses is reasonable; and whether the testimony is consistent with all other credible evidence in the case:

#### Parties

1. Petitioner Pinnacle is a limited liability company authorized to conduct business in North Carolina, with its principal place of business in Franklin, Tennessee and a registered agent in Wake County, North Carolina. Pinnacle operates an independent, unaffiliated outpatient medical imaging practice in the Wake County, North Carolina. (George, Tr. p. 43).

2. Petitioner Outpatient Imaging Affiliates, LLC, ("OIA") is a Tennessee limited liability company authorized to conduct business in North Carolina, with its principal place of business in Franklin, Tennessee and a registered agent in Wake County, North Carolina. OIA owns imaging centers across 13 states and owns Pinnacle. (George, Tr. p. 43).

3. Respondent CON Section is the administrative agency within the North Carolina Department of Health and Human Services responsible for the administration of North Carolina's Certificate of Need Law, Chapter 131E, Article 9 of the North Carolina General Statutes, including reviewing and approving the development of new institutional health services, codified at N.C. Gen. Stat. § 131E- 175 *et seq.*

4. Respondent-Intervenor Duke is a North Carolina corporation with its principal place of business in Durham County, North Carolina. Duke provides medical care, hospital care, medical education, and medical research. (Jt. Ex. 3, p. 17)

### Procedural and Factual Background

5. A Certificate of Need (“CON”) is required for certain “new institutional health services” as that term is defined by N.C. Gen. Stat. § 131E-176(16).

6. The acquisition of a magnetic resonance imaging (“MRI”) scanner is considered a new institutional health service that requires a CON. N.C. Gen. Stat. § 131E-176(16)f1.7.

7. The State Medical Facilities Plan (“SMFP”) is the official plan developed and published each year which inventories certain services, facilities, and equipment that are subject to CON regulation as well as the utilization of those services, facilities, and equipment. The SMFP includes “need determinations” which are determinations that certain additional services, facilities, and equipment are needed in certain service areas, including MRI scanners.

8. The SMFP is developed under the direction of the State Health Coordinating Council (“SHCC”), which is comprised of healthcare professionals and other citizens, each of whom is appointed by the Governor. N.C. Gen. Stat. §§ 131E-176(17), (25); 131E-177(4).

9. Under the CON rules, there are two types of MRI scanners: a mobile MRI scanner which is moved weekly to provide services at two or more host sites, and a fixed MRI scanner, which serves a single location. 10A NCAC 14C .2701(4), (7). Fixed scanners can either be hospital-based or freestanding. A hospital-based scanner operates under a hospital license, whereas a freestanding scanner is operated in an outpatient center that is neither part of a hospital nor operated under a hospital license. (Yakaboski, Tr. pp. 210-11).

10. The 2021 State Medical Facilities Plan (“2021 SMFP”) identified a need for one additional fixed MRI scanner in the Wake County MRI Service Area based upon the standard MRI need methodology. The 2021 SMFP set the schedule for review of any applications filed pursuant to this need determination to begin May 1, 2021. (Prehearing Order, Stip. 8.a).

11. The Agency’s review of CON applications is a two-step process. First, the Agency reviews each application to ensure compliance with the CON application criteria. Thereafter, the Agency must decide which of the competing applications should be approved. *Living Centers-Southeast, Inc. v. N.C. Dep’t of Health and Hum. Servs., Div. of Facility Servs., Certificate of Need Section*, 138 N.C. App. 572, 574, 532 S.E.2d 192, 194 (2000) (citation omitted).

12. On or about April 15, 2021, Pinnacle filed a CON application with the Agency proposing to acquire one fixed MRI scanner, pursuant to the need determination

in the 2021 SMFP, to be located at a new diagnostic center in Wake Forest, identified as Project I.D. No. J-12063-21 (the “Pinnacle Application”). (Prehearing Order, Stip. 8.b).

13. On or about April 15, 2021, Duke filed a CON application with the Agency proposing to acquire one fixed MRI scanner, pursuant to the need determination in the 2021 SMFP, to be located at a new diagnostic center in Raleigh, identified as Project I.D. No. J-12073-21 (the “Duke Application”). (Prehearing Order, Stip. 8.c).

14. On or about April 15, 2021, WR Imaging, LLC (“Wake Radiology”) filed a CON application with the Agency proposing to acquire one fixed MRI scanner, pursuant to the need determination in the 2021 SMFP, to be located at an existing diagnostic center in Garner (the “Wake Radiology Application”).

15. Wake Radiology is not a party to this contested case, the Wake Radiology Application is not at issue in this case, and the Agency properly determined that the Wake Radiology Application was non-conforming to certain statutory criteria and therefore could not be approved. (Prehearing Order, Stips. 8.d and 8.e).

16. The only applications at issue in this case are those submitted by Pinnacle and Duke.

17. Both the Pinnacle and the Duke applications were timely submitted, were complete for review, and properly reviewable by the Agency. (Prehearing Order, Stip. 8.f).

18. Pursuant to N.C. Gen. Stat. § 131E-183(a)(1) and the 2021 SMFP, the Agency determined that the approval of one of the applications would result in the denial of the others, and, therefore, a competitive review of the applications was required.

19. The Agency conducted a competitive review of the applications. (Prehearing Order, Stip. 8.g). The competitive review is designed to determine which application is comparatively more effective for the purposes of awarding the CON.

20. Greg Yakaboski was the Agency project analyst assigned to the CON review, and Lisa Pittman was his co-signer. (Yakaboski, Tr. pp. 151-52; Pittman, Tr. p. 483). As the project analyst, Mr. Yakaboski’s job was to review and analyze the CON applications and write the Required State Agency Findings. (Yakaboski, Tr. pp 130134). At the time of the review, Ms. Pittman was the Acting Chief of the Healthcare Planning and CON Section, and the ultimate decisionmaker within the Agency on CON reviews and applications. (Pittman, Tr. pp. 480-81).

21. On 24 September 2021, the Agency issued its Decision conditionally approving the Duke Application and disapproving both the Pinnacle and Wake Radiology Applications. (Prehearing Order, Stip. 8.h).

22. Thereafter, on 1 October 2021, the Agency issued its Required State Agency Findings setting forth the bases for its Findings and conclusions upon which the Agency based its conditional approval of the Duke Application and the disapproval of the



other competing applications. The Agency Decision and Findings at issue in this case were timely issued. (Prehearing Order, Stip. 8.i).

23. On 22 October 2021, Pinnacle timely filed a Petition for Contested Case Hearing (“Petition”) in the Office of Administrative Hearings (“OAH”), appealing the Agency’s disapproval of the Pinnacle Application and conditional approval of the Duke Application. (Prehearing Order, Stip. 8.j).

24. By Order issued by the Office of Administrative Hearings on 3 November 2021, Duke was, by consent of all parties, granted the right to intervene with all the rights of a party. (Prehearing Order, Stip. 8.k).

### **Expert Witnesses**

25. Mr. David Meyer is a Senior Partner for Keystone Planning Group in Durham, North Carolina who has worked in healthcare planning for approximately 25 years. Mr. Meyer was hired and prepared the Pinnacle CON application. At hearing, he was accepted as an expert witness for Pinnacle in the fields of healthcare planning, Certificate of Need preparation, and Certificate of Need analysis. (Meyer, Tr. pp. 660-670; Jt. Ex. 20)

26. Ms. Karin Lastowski Sandlin has been a partner at Clarity Strategic Services since 2019 and has worked in the files of CON and healthcare planning for approximately 19 years. Previously, Ms. Sandlin founded and worked at Keystone Planning Group with David Meyer. Ms. Sandlin assisted Duke, as a paid consultant, in preparing Duke’s comparative comments for this CON review. Ms. Sandlin was accepted as an expert witness for Duke in the fields of healthcare planning, Certificate of Need analysis and Certificate of Need preparation. (Sandlin, Tr. pp. 1200-1208; Jt. Ex. 42)

### **The CON Review Process**

27. The CON review criteria are both statutory and regulatory. The statutory review criteria are found in N.C. Gen. Stat. § 131E-183(a). There are 15 statutory review criteria (excluding the subparts of Criterion 13). N.C. Gen. Stat. § 131E-183(b) authorizes the Agency “to adopt rules for the review of particular types of applications that will be used in addition to those criteria outlined in subsection (a).” In the case of MRI scanners those rules are promulgated at 10A NCAC 14C .2700. The performance standard rules are consistent with the assumptions and methodology of the need methodology in the SMFP plan.

28. The CON Section relies on opinions from North Carolina Appellate Courts to guide the Agency’s evaluation of applications.

29. N.C. Gen. Stat. 131E-182 (b) states in part:

An applicant shall be required to furnish only that information necessary to determine whether the proposed new institutional health service is

consistent with the review criteria . . . and with duly adopted standards, plans and criteria.

30. N.C. Gen. Stat. § 131E-182(b) instructs the Agency to provide forms for the various types of CON proposals. The application form is not a rule but is a tool that the Agency has created for the purposes of guiding the applicants and getting the information the Agency needs to conduct its CON review of the proposed CON applications.

31. The Agency File is a compilation of everything, other than the applications themselves, produced by or considered by an analyst during the review of the applications. It includes correspondence, written comments, public hearing documents, working papers and the Agency Findings. (Yakaboski, Vol. 1, pp. 139-45) (Jt. Ex. 1).

32. N.C. Gen. Stat. § 131E-186(b) states:

Within five business days after it makes a decision on an application, the Department shall provide written notice of all the findings and conclusions upon which it based its decision, including the criteria used by the Department in making its decision, to the applicant.

That is, the Agency's Findings contain all the criteria upon which the Agency makes its decision during a CON review and provide an explanation how the Agency concludes whether an application was conforming or not conforming to each criterion, or if each criterion did not apply to an application. The Agency does not cite to every page of the application for every basis, but instead cites to the most pertinent information that shows the applicant satisfied its burden to demonstrate conformity. (Yakaboski, Vol. 1, pp. 240-251).

33. The Agency evaluates and makes CON decisions based upon the information that is contained in the narrative of submitted applications and the exhibits attached thereto on the date of filing of the applications. The Agency also considers written comments and responses to comments submitted by applicants and concerned members of the public. The burden is on the applicant to demonstrate to the Agency that its application is consistent with or not in conflict with all applicable statutory and regulatory review criteria. The applicant does this via their application and the exhibits attached to it. (Yakaboski, Vol. 1, pp. 132-34, 141-42, 196-98; Vol. 2, pp. 397-400) (Pittman, Vol. 3, pp. 565-66, 571-75, 578-80).

34. When reviewing an application to determine if something is reasonable and adequately supported, the analyst considers if the information the applicant is providing makes sense, if it is plausible. (Yakaboski, Vol. 2, pp. 334, 340).

35. Whether something is reasonable and whether the support provided by the applicant is adequate is a somewhat subjective determination based upon the specific facts provided in the application.

36. During a CON review, the Agency considers what the applicant provides in the application. The Agency accepts the representations in an application to be accurate unless they are given reasons to think they are not accurate.

### **Agency's Review at Issue**

37. After CON applications are submitted, the Agency assigns a project analyst and cosigner to each review, based on availability of Agency staff. The Agency does not know which analyst will conduct a given review until after applications are submitted, and applicants have no way of knowing in advance which analyst and cosigner will conduct the review. (Yakaboski, Tr. pp. 155-57, 456; Pittman, Tr. p. 581).

38. In competitive reviews, the Agency's project analyst conducts a standalone review of each application to assess its conformity with the applicable review criteria. (Yakaboski, Tr. pp. 137-38, 149-51). A comparative analysis is then conducted to determine which applicant, if any, will be approved. (*Id.*)

39. The Agency performs a comparative analysis so that in a competitive review, if there is more than one application that conforms to all the applicable review criteria, there is a basis to decide which application is comparatively more effective for the purposes of awarding the CON. (Yakaboski, Vol. 2, pp. 280-82).

40. Generally, the comparative factors are weighted equally, and the Agency approves the application that is found to be more effective under the most comparative factors. (Yakaboski, Tr. p. 174; Pittman, Tr. p. 486).

41. Although it is not strictly necessary to do a comparative review when there is only one conforming applicant, the Agency conducts one anyway, so that if it is determined late, that the Agency has erred in finding an applicant nonconforming, there will be a basis for the Court to determine who should have been approved. *Britthaven. v. N.C. Dep't of Human Res.*, 118 N.C. App. 379, 385, 455 S.E.2d 455, 460-61 (1995).

42. The Agency has broad discretion to choose comparative factors it uses in a CON review. (Yakaboski, Vol. 1, p. 163) (Pittman, Vol. 3, pp. 598) (Meyer, Vol. 4, pp. 748, 810-11) (Sandlin, Vol. 6, p. 1212; Vol. 7, p. 1489).

43. In a comparative analysis, the Agency generally selects certain criteria or factors upon which to compare the applications against each other. (Yakaboski, Tr. pp. 163-64; Pittman, Tr. p. 484). Comparative factors are chosen in part based on factors used in past competitive reviews, but also on specific issues that might be unique to a particular review. (Yakaboski, Tr. pp. 163-70).(Sandlin, Tr. pp. 1211).

44. However, there is no statute that mandates the specific review factors that the Agency uses. The only guidance comes from past practice and *Craven Regional Medical Authority v. N.C. DHHS*, 176 N.C. App. 46, 58, 625 S.E.2d 837, 844 (2006) (Yakaboski, Vol. 1, pp. 153-64, 201) (Sandlin, Vol. 6, pp. 1211).

### **Conformity with the Review Criteria**

45. During the subject review, the Agency concluded that both Pinnacle and Duke were fully conforming to the review criteria.

46. By further Joint Stipulation there are no issues before the Tribunal regarding the conformity of the Duke Application with the Statutory Review Criteria or Agency Rules.

47. By Joint Stipulation, the only criteria at issue with regard to conformity of the Pinnacle Application are Review Criteria 1, 3, 4, 5, 6, and (18a).

48. Duke's expert, Ms. Sandlin, offered opinion testimony that Pinnacle's application should have been found nonconforming to N.C. Gen. Stat. § 131E-183(a)(3) ("Criterion 3") and related criteria. (Sandlin, Tr. pp. 1386-87, 1538-41).

49. Criterion 3 requires an applicant to:

[I]dentify 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. Gen. Stat. § 131E-183(a)(3).

50. The version of 10A NCAC 14C .2703(b)(3) in effect at the time of the applications required each applicant to reasonably project that its proposed fixed MRI scanner and its existing fixed MRI scanners in the service area would perform at least 4,805 weighted MRI procedures in the third year of operation following completion of the project. The Agency's analysis of whether an applicant demonstrated need for its proposal includes a determination of whether the applicant's utilization projections are reasonable and adequately supported. (Joint Ex. 1, pp. CON-809-11).

51. Ms. Sandlin opined Pinnacle's projections were unreasonable because Pinnacle no longer contracted with Raleigh Radiology. Pinnacle previously contracted with Raleigh Radiology to interpret the MRI scans it administered. When Pinnacle's contract with Raleigh Radiology ended in October 2020, Pinnacle contracted with Greensboro Radiology for the same services. A few months earlier, Pinnacle changed its d/b/a to Cardinal Points Imaging. Pinnacle took steps to ensure that referring physicians were aware of the name change, and Pinnacle saw no significant impact on its business during that period as a result of the change. (George, Tr. pp. 54-57).

52. Although support letters are not required for MRI applications, Pinnacle's 2021 application contained more than 100 support letters from physicians and health care professionals in various specialties. (Sandlin, Tr. pp. 1556-57). While Pinnacle's 2021 application contained fewer support letters than its 2019 application, this does not support Ms. Sandlin's opinion that Pinnacle's utilization projections were not reasonable. (Sandlin, Tr. pp. 1393-95). In fact, Pinnacle had more support letters than any other applicant in the review. (Joint Ex. 1, pp. CON-138; Meyer, Tr. pp. 1638-39). Pinnacle's letters were

collected during the pandemic when it was harder to get in front of doctors to request a letter. (Meyer, Tr. p. 1663). In fact, 85 percent of Pinnacle's letters in both applications were from the same mix of specialists. (Meyer, Tr. pp. 1640-41).

53. Ms. Sandlin's opinions regarding Pinnacle's conformity to Criterion 3 were previously conveyed to the Agency in Duke's written comments submitted during the review. (Sandlin, Tr. pp. 1541-42, 1561).

54. Pinnacle's utilization projections were reasonable and supported, based upon Pinnacle's historical utilization and growth rates, its projections that some procedures would shift from one Pinnacle location to another, and the additional capacity that would result from the addition of full-time MRI service at Pinnacle's Wake Forest location. (Sandlin, Tr. pp. 1543-44, Ex. 1, pp. CON-810-11). At hearing, Duke did not question the Agency witnesses regarding their reasoning or otherwise provide evidence suggesting their conclusion was mistaken.

55. Ms. Sandlin also opined that Pinnacle's Application did not conform to several other review criteria (Criteria 1, 4, 5, 6, and 18a) based on the same facts and reasons upon which she contended Pinnacle was nonconforming to Criterion 3. (Sandlin, Tr. p. 1538-41). The same arguments were made to the Agency during the review in Duke's written comments, but the Agency found Pinnacle conforming with all applicable review criteria. (Sandlin, Tr. pp. 1541, 1561).

56. Duke did not appeal the conditional approval of its application or the Agency's decision to deny Pinnacle's application. Further, Duke did not appeal the Agency's Findings that Pinnacle's application conformed with the CON Criteria.

### **Comparative Analysis**

57. Because the Agency found both Duke and Pinnacle conforming with all applicable review criteria and were approvable standing alone, the Agency's project analyst conducted a comparative analysis to determine which applicant to approve. (Yakaboski, Tr. pp. 280-82).

58. In this case, Mr. Yakaboski used the comparative factors that had been used in prior sets of findings that he personally conducted or which he reviewed and included in the Agency File. (Yakaboski, Vol. 1, pp. 206, 250). Mr. Yakaboski reasoned that using the same or similar factors from review to review helps the Agency maintain consistency. The factors do change a bit over time, but by staying largely the same, it makes it easier for prospective applicants to have some idea of what the Agency would be looking at.

59. In this review, Mr. Yakaboski selected twelve comparative factors in which to compare the applicants. Of those twelve, Mr. Yakaboski concluded that only two factors differentiated between Duke and Pinnacle: Geographic Accessibility and Access by Service Area Residents. The Agency found Duke to be superior on both factors. (Joint Ex. 1, p. CON-883).

60. Of the remaining ten factors, Duke and Pinnacle were either equally effective (Conformity with Statutory and Regulatory Review Criteria, Competition, and Would Add to the Inventory) or the Agency believed no conclusion could be drawn (Historical Utilization, Access by Charity Care Patients, Access by Medicare Patients, Access by Medicaid Patients, Projected Average Net Revenue per MRI procedure, and Projected Average Operating Expense per MRI procedure). (Joint Ex. 1, pp. CON-883-84).

61. In this contested case, Pinnacle challenged the Agency's conclusions with respect to four comparative factors: Geographic Accessibility, Projected Average Net Revenue per MRI procedure, Projected Average Operating Expense per MRI procedure, and Historical Utilization.

#### 1. Geographic Accessibility

62. One of the purposes of the CON Act is to promote geographic access. (Pittman, Tr. p. 487). The statutory findings of fact in the CON Act explicitly find that, "if left to the marketplace to allocate health service facilities and health care services, geographical maldistribution of these facilities and services would occur[.]" N.C. Gen. Stat. § 131E-175(3).

63. The Agency uses "Geographic Accessibility" as a comparative factor in competitive reviews for all types of facilities and services. (Sandlin, Tr. pp. 1468-70; Ex. 10, p. 5).

64. Unlike some other comparative factors, the Agency's template for geographic accessibility does not include any suggested analysis or identify any determining principle. (Pittman, Tr. pp. 521-23; Joint Ex. 10, pp. 5-6, 8).

65. However, in analyzing geographic accessibility, the Agency has generally favored applications to place a new facility or service in a smaller town that lacked that type of facility over larger towns that already had that type of facility or service.

66. "Geographic maldistribution" is a concentration of facilities and services in larger population centers while rural and small communities go without those facilities and services. (Pittman, Tr. p. 488-89).

67. It is important that rural and smaller communities have access to healthcare services, and absent CON regulation, businesses would likely put services in the largest population centers where there is a higher revenue potential. (Pittman, Tr. pp. 489-90).

68. In this case, the Agency's analysis of geographic accessibility focused on the geographic location proposed by each applicant. (Joint Ex. 1, pp. CON-876-77).

69. All applicants in the review proposed to develop new freestanding fixed-site MRI scanners at outpatient diagnostic imaging locations. (Yakaboski, Tr. p. 211; Joint Ex. 1, p. CON-877).

- a. Pinnacle proposed to develop a new diagnostic center by acquiring one fixed MRI scanner which would be located at an existing facility that offered imaging mobile MRI but not fixed MRI services in the town of Wake Forest, in the northern part of Wake County. (George, Tr. pp. 41-42; Joint Ex. 1, pp. CON-808, 877).
- b. Duke proposed to place a freestanding fixed MRI scanner at an imaging center on the campus of Duke Raleigh Hospital in Raleigh, in the center of Wake County. Duke Raleigh campus already had other services in addition to inpatient services including a variety of specialty physician clinics, and the Duke Cancer Institute services, which include physician clinics and radiation oncology services.

70. Catharine Wildenthal Cummer has been Regulatory Counsel and Strategic Planning for Duke University Health System since 2011. Her responsibilities involve the oversight of state regulatory matters as they affect the Duke Health System facilities, including CON. (Cummer, Vol. 6, pp. 1073-75; 1083-84). Ms. Cummer opined that access to other services also benefits patients because it becomes easier for physicians to coordinate obtaining the MRI scans that they need for their diagnosis and treatment purposes. (Cummer, Tr. pp. 1104, 1108; Joint Ex. 1, pp. CON-818, 877).

71. At the time of this review, there were already thirteen (13) fixed MRI scanners in Raleigh, seven (7) of which were freestanding fixed MRI scanners, and no fixed MRI scanners, freestanding or otherwise, in Wake Forest. (Joint Ex. 1, pp. CON-876-877, Yakaboski, Tr. pp. 212-13).

72. The record in this case contains six examples of recent competitive reviews by various Agency analysts and cosigners in which the Agency compared proposals to put a new healthcare facility or service in a smaller town that lacked that type of facility/service against proposals to put another facility/service in a larger town that already one or more of that type of facility/service. (Meyer, Tr. pp. 726-44; Joint Exs. 31, 35-39).

- a. In each of these prior reviews, the Agency found the smaller town without such facilities or services the “more effective” location with respect to geographic access, without regard for whether the larger town would have a worse ratio of population per facility/service after approval. (Joint Exs. 31, 35, 36, 37, 38, 39)
- b. Half of those prior reviews were competitive reviews for fixed MRI scanners, the same service at issue here. (Joint Exs. 31, 36, 38).

73. In the two most recent fixed MRI CON reviews, the Agency calculated ratios of population per fixed MRI scanner and noted that the larger town had a much higher population than the smaller town and would have a higher population per scanner than the smaller town. (Joint Exs. 36, 38). Nevertheless, in each of those reviews, the Agency concluded that the smaller town was the “more effective” location specifically because it

lacked the type of fixed MRI scanner that was proposed. (Joint Ex. 36; Joint Ex. 38; *see also* Joint Ex. 29; Joint Ex. 103; Meyer, Tr. pp. 728-31, 733-36; Pittman, Tr. pp. 508-12).

74. However, in the 2021 Wake County fixed MRI review at issue here, the Agency reached the opposite conclusion. (Pittman, Tr. p. 507).

75. In its Findings in this review, the Agency analyzed the number of existing and approved fixed MRIs in the municipalities where each of the proposed MRIs would be located, as well as the population of each. Consistent with other recent MRI reviews, the Agency then calculated ratios of population per freestanding fixed MRI scanner in each town: (1) the *status quo* ratio, and (2) the resulting ratio in each town if an additional freestanding fixed MRI scanner were approved. (Joint Ex. 1, p. CON-877; Yakaboski, Tr. pp. 214-16; Pittman, Tr. pp. 492-94).

76. However, departing from all six prior reviews discussed above, the Agency concluded that the Duke application, which proposed an eighth freestanding fixed MRI scanner in Raleigh, was the more effective alternative even though Pinnacle's application proposed to put the scanner in Wake Forest which had no fixed MRI scanners. It summarized its analysis as follows: "If each application was approved, Raleigh would still have the lowest ratio of freestanding (fixed) MRI scanners per person, but the ratio would improve." (Joint Ex. 1, p. CON-877; Yakaboski, Tr. pp. 224-25; Pittman, Tr. p. 500).

77. It is apparent from the Agency's written Findings: (1) that the Agency used the ratio of MRI scanners per person as a measure of geographic accessibility of health services; and (2) that *improvement* in the scanners per population ratio is what this factor is intended to favor. (Joint Ex. 1, p. CON-877).

78. However, the Findings do not calculate or acknowledge any such improvement in Wake Forest's ratio if Pinnacle's application was approved. (Joint Ex. 1, p. CON-877).

79. Moreover, the Agency's analysis contained multiple mathematical errors (*see* Joint Ex. 6a), including the calculation of the *status quo* ratio of population per freestanding fixed MRI scanner in Wake Forest. (Joint Ex. 6a; Yakaboski, Tr. pp. 241-43; Pittman, Tr. p. 496).

80. The Agency erroneously calculated the ratio of population per freestanding fixed MRI scanner in Wake Forest as 37,469. That ratio would have been correct if Wake Forest already had one freestanding fixed MRI scanner. (Yakaboski, Tr. pp. 241-43; Pittman, Tr. pp. 496-97).

81. However, there are no fixed MRI scanners in Wake Forest, freestanding or otherwise. Thus, the ratio of population per freestanding fixed MRI scanner cannot be calculated because the population of 37,469 cannot be divided by zero MRI scanners, and it is impossible to have a ratio of people per scanner when there is no scanner. As such, the ratio in the *status quo* table regarding Wake Forest was erroneous. (Yakaboski, Tr. pp. 241-43; Pittman, Tr. pp. 496-97).



82. The miscalculation of Wake Forest's *status quo* ratio of population per freestanding fixed MRI scanner affected the analysis in two key ways.

- a. First, the Agency erroneously concluded that Raleigh currently has the worst ratio. In fact, *Wake Forest* has the worst ratio (0.0 freestanding fixed MRI scanners per population) because, unlike Raleigh and Garner, Wake Forest has no fixed MRIs at all. (Yakaboski, Tr. pp. 233-34; Pittman, Tr. pp. 500-03).
- b. Second, while Raleigh's ratio of freestanding fixed MRI scanners per person would indeed improve if Duke were approved, the Agency's analysis suggested that *Wake Forest's* ratio *would not* improve if Pinnacle's application were approved. (Yakaboski, Tr. pp. 229-31; Pittman, Tr. pp. 503-04). In fact, if Pinnacle were approved, Wake Forest's ratio of freestanding fixed MRI scanners per person would improve 12.5 times as much as the improvement in Raleigh's ratio if Duke were approved. (Joint Ex. 34; Pinnacle Ex. 102; Meyer, Tr. pp. 712-19). The Agency decision failed to calculate or acknowledge such improvement. (Joint Ex. 1, p. CON-877).

83. At deposition, Mr. Yakaboski stated that the written summary of his analysis regarding geographic accessibility in the Agency Findings was the reason that Duke was found comparatively superior on that factor. (Yakaboski, Tr. pp. 224-26). Mr. Yakaboski's analysis focused on where an additional fixed MRI scanner would help the most people and that Raleigh's population was much larger than Wake Forest's population. (Yakaboski, Tr. pp. 224, 240, 363-64, 413).

84. Mr. Yakaboski did not compare the *status quo* or quantify the *improvement* in access for either town; instead, he relied solely on his table comparing the hypothetical ratio of population to freestanding fixed MRI scanners in each town if all three projects were approved. (Yakaboski, Tr. pp. 363-71).

85. Mr. Yakaboski used the analogy of people in line for each MRI scanner to explain his rationale, suggesting that if all three applicants were approved, Raleigh would have a "longer line" (58,000 people per scanner) than Wake Forest (37,000 people per scanner). (Yakaboski, Tr. pp. 235-38, 363-71; Joint Ex. 1, p. CON-877).

86. He reasoned that, if there were 37,000 people "in line" for each freestanding fixed MRI scanner in Raleigh, then approximately 210,000 additional Residents of Raleigh would not have a scanner in Raleigh. (Yakaboski, Tr. pp. 235-236, 365). Mr. Yakaboski found Duke "more effective" based on this result, despite 37,000 residents of Wake Forest not having a scanner in Wake Forest. (Yakaboski, Tr. pp. 235-36, 250-51).

87. However, it is undisputed that there are already thirteen fixed MRI scanners in Raleigh, seven of which are freestanding fixed MRI scanners, and none in Wake Forest. There is no indication that there are 210,000 Raleigh residents who lack access to the existing MRI scanners in Raleigh. (Yakaboski, Tr. pp. 236-37, 457-58).

88. The “people in line” comparison adopted by the project analyst at trial disregards the *status quo* in both towns and prioritizes only the end result over the *improvement* in access in each town, which the Agency’s written Findings expressly relied upon. (Joint Ex. 1, p. CON-877, Yakaboski, Tr. p. 370). As such, the project analyst’s explanation at trial was different than the actual basis for the Agency’s decision.

89. Duke’s approval in this review would increase the concentration of fixed MRIs in Raleigh, resulting in a fourteenth fixed MRI scanner and an eighth freestanding fixed MRI scanner in Raleigh while Wake Forest would continue to go without fixed MRI. (Pittman, Tr. pp. 614-15).

90. Using the ratio-based logic described by the project analyst at trial, Raleigh would continue to be a more effective location than Wake Forest under the geographic accessibility comparative factor until Raleigh reaches 12-13 freestanding fixed MRI scanners (5-6 more than the seven it currently has). (Meyer, Tr. pp. 744-45; Pittman, Tr. pp. 505-06; Yakaboski, Tr. pp. 266-67). Under that analysis, it would take approximately eleven more years to reach that point, during which Wake Forest would continue to go without a fixed MRI scanner. (Meyer, Tr. pp. 745).

91. As a result, the Agency’s rationale of helping the most people or “people in line” under the Geographic Accessibility comparative factor favors the concentration of more facilities and services in larger cities that already have them, while smaller communities go without. (Pittman, Tr. pp. 506, 614-15).

92. Despite differing from the Agency’s general approach to Geographic Accessibility, the Agency could not explain any reason for the different approach here, and has no rule, policy, or procedure as to when the Agency should use one approach or another. (Pittman, Tr. p. 512-13).

93. The Agency’s Assistant Chief, Ms. Pittman, could not identify any principle followed by the Agency in comparing the geographic accessibility comparative factor other than the experience a given employee brings to the table. (Pittman, Tr. p. 515-17).

94. According to the Ms. Pittman, the Agency only has to do what the analyst and cosigner think is reasonable at the time. (Pittman, Tr. pp. 512-13). The Agency’s unwritten policy is that reasonableness, not consistency, is the standard by which decisions are made. (Pittman, Tr. p. 594).

95. Similarly, Duke’s expert witness could not identify any general principle that would explain why the Agency would analyze geographic accessibility one way in a prior review and the opposite way in the 2021 Wake County MRI review. (Sandlin, Tr. pp. 1478-80).

96. The most recent fixed MRI review before the review at issue was the 2020 Guilford County review, decided only two months before the beginning of the 2021 Wake County review. (Joint Ex. 1, pp. CON-527-589; Joint Ex. 36). In that review, despite a far lower population in Summerfield (the smaller town) than Greensboro, the Agency found

the applicant proposing a Summerfield location more effective as to geographic accessibility specifically “because it proposes to locate the proposed fixed MRI scanner in a town that does not currently have a fixed MRI scanner.” (Yakaboski, Tr. pp. 274-75; Joint Ex. 36, p. 57).

97. By statute, the Agency is required to provide notice of all Findings and Conclusions on which its decision is based. N.C. Gen. Stat. § 131E-186(b). In both the 2020 Guilford County MRI review and the 2021 Wake County MRI review at issue here, the Agency Findings noted the same general facts on which its geographic accessibility analysis relied, including the number of fixed MRI scanners in each town where a fixed MRI scanner was proposed, the populations of each, and the ratios of population per MRI scanner. (Pittman, Tr. pp. 514-15, 602-04).

98. The record contains only one prior Agency decision where the Geographic Accessibility comparative factor favored the larger town that already had similar facilities. (Joint Ex. 1, pp. CON-256-383). That review was done by Mr. Yakaboski, the same project analyst in the review at issue here. (Yakaboski, Tr. p. 456; Sandlin, Tr. pp. 1463-65).

99. None of the witnesses could identify any project analyst other than Mr. Yakaboski who has analyzed the geographic accessibility factor the way Mr. Yakaboski does (favoring the location with higher population). (Pittman, Tr. p. 517; Yakaboski, Tr. pp. 456-57; Sandlin, Tr. pp. 1463-65; Meyer, Tr. pp. 1625-26).

100. Mr. Yakaboski’s approach to geographic accessibility is his own. “He doesn’t talk to other project analysts and doesn’t look at other agency findings to tell whether any other analysts actually approach that particular factor the same way.” (Yakaboski, Tr. p. 456).

101. When questioned about findings by other project analysts in the most recent two fixed MRI reviews (the 2020 Guilford Co. review and the 2019 Forsyth Co. review) regarding the most effective location, Mr. Yakaboski disagreed with the analysts’ conclusions regarding Geographic Accessibility. (Yakaboski, Tr. pp. 278-79, 286-89).

## 2. Projected Average Net Revenue per Procedure

102. The comparative factor “Projected Average Net Revenue per MRI Procedure” (“Net Revenue”) relates to financial accessibility and minimizing healthcare costs. (Yakaboski, Tr. pp. 303, 411; Meyer, Tr. pp. 747-48). Applicants with a lower Net Revenue are considered more effective because lower net revenues correspond to a lower cost to the patient or payor. (Yakaboski, Tr. pp. 303, 411; Joint Ex. 1, p. CON-881).

103. Use of Net Revenue as a comparative factor is consistent with the purposes of CON regulation, one of which is to control the cost of healthcare services. (Pittman, Tr. p. 527).

104. In analyzing the Net Revenue comparative factor, the Agency calculated each applicant's projected average net revenue per MRI procedure based on the applicant's projected weighted procedure volume and total projected net revenue from Section Q of each application. (Yakaboski, Tr. pp. 303-07; Joint Ex. 1, p. CON-881).

105. Section Q of the applications included projections of both weighted and unweighted MRI procedures. (Yakaboski, Tr. p. 162). Weighted procedures are the actual number of procedures to be performed multiplied by a weighting factor. The weighting factor varies based on whether the procedure is inpatient or outpatient and whether it uses contrast. (Joint Ex. 1, p. CON-232; Yakaboski, Tr. p. 161).

106. A weighted MRI procedure means MRI procedures that are adjusted to account for length of time to complete the procedure based on several factors including inpatient or outpatient procedure and the use of contrast or sedation for the procedure. (Jt. Ex. 1, pp. 232).

107. There is no Agency rule, procedure, or policy requiring a project analyst to compare Net Revenues using weighted or unweighted procedures. (Yakaboski, Tr. pp. 318-19; Pittman, Tr. p. 531-32). Either weighted or unweighted procedures could have been used to compare Net Revenues. (Yakaboski, Tr. pp. 318-19; Pittman, Tr. p. 531).

108. In the previous 2019 Wake County fixed MRI CON review, the same project analyst and cosigner used unweighted MRI procedures to compare Net Revenue. (Yakaboski, Tr. pp. 313-14, 331-32).

109. Had the Analyst compared Net Revenues using unweighted procedures as it did in the 2019 review, Pinnacle would have projected the lowest average net revenue per unweighted MRI procedure. (Yakaboski, Tr. pp. 316-17; Pittman, Tr. pp. 530-31; Joint Ex. 1, p. CON-74).

110. However, using weighted procedures, the Agency determined that, of the three applicants, Duke projected the lowest average net revenue per weighted procedure at \$446 per procedure, which was \$16 less per procedure than Pinnacle at \$462 per procedure. (Joint Ex. 1, p. CON-881).

111. This remains true even though the project analyst miscalculated Duke's average net revenue per procedure. However, Duke's correct Net Revenue of \$455 per procedure was only \$7 less than Pinnacle's projection. (Yakaboski, Tr. pp. 305-06, 315-16, 319; Pittman, Tr. p. 532-33; Joint Ex. 8a).

112. Despite calculating the Net Revenue for each applicant, the Agency determined that the factor was inconclusive because Pinnacle and Wake Radiology bill "globally" while Duke does not bill for professional fees. (Joint Ex. 1, p. CON-881).

113. "Global billing" refers to a healthcare provider billing a patient or insurer for both the "professional fee" (cost for a physician to interpret a diagnostic image) and the

“technical fee” (cost for staff and imaging equipment to produce a diagnostic image). (Yakaboski, Tr. p. 320, George, Tr. p. 57).

114. Some providers such as Pinnacle bill globally, and others, such as Duke, bill only for the technical fee, in which case the patient or insurer will receive a separate bill for the professional fee from the radiologist or other physician who interprets the image. (George, Tr. pp. 59-60; Cummer, Tr. pp. 1133-35; Sandlin, Tr. pp. 1332, 1493). Consequently, a professional fee will still be part of the cost to Duke’s patients, but it will not be billed by Duke, and therefore the Agency does not know the extent to which Net Revenue would be affected if the professional fee revenue were included. (Pittman, Tr. p. 537; *see also* Joint Ex. 3, p. D-141).

115. Because Pinnacle’s projected revenues included revenue for professional fee services that Duke’s did not, the Agency did not consider a comparison of Pinnacle’s and Duke’s Net Revenues to be an “apples-to-apples” comparison and thus found the factor to be inconclusive. (Yakaboski, Tr. pp. 327, 424; Joint Ex. 1, p. 881).

116. The Agency could have excluded Pinnacle’s professional fees from total net revenue in the Net Revenue factorial analysis. Omitting Pinnacle’s professional fees results in a Net Revenue of \$361 per procedure, which was lower than Duke’s average Net Revenue of \$455 per procedure. (Meyer, Tr. pp. 748, 757-59; Joint Ex. 32; Pinnacle Exs. 105, 104).

117. However, Pinnacle’s professional fee expense is not necessarily equal to professional revenues. (Sandlin, Tr. pp. 1341-44, Meyer, Tr. pp. 906-07).

118. Because professional revenues are not projected in Pinnacle’s application, the project analyst could not determine Pinnacle’s professional revenue. (Sandlin, Tr. pp. 1333, 1340, 1346-47). Accordingly, the Agency’s determination that the Net Revenue factor was inconclusive was not erroneous.

### 3. Projected Average Operating Expense per Procedure

119. The comparative factor Projected Average Total Operating Cost per MRI Procedure (“Operating Cost” or “Operating Expense”) relates to financial access and the cost of healthcare. (Yakaboski, Tr. pp. 328, 411-12). Minimizing costs to the healthcare system is one purpose of CON regulation. (Pittman, Tr. pp. 539-40, Sandlin, Tr. p. 1510).

120. Therefore, applicants with a lower Operating Cost per procedure are more effective because they represent a more cost-effective service. (Yakaboski, Tr. pp. 328, 411-412; Joint Ex. 1, p. CON-882). Accordingly, the goal of the Operating Expense comparative factor is to identify the applicant with the lowest average operating expense per procedure. (Yakaboski, Tr. pp. 334-35).

121. The Agency analyzed the Operating Cost comparative factor similarly to the Net Revenue factor. The Agency calculated each applicant’s projected average Operating Cost per MRI procedure based on the applicant’s projected weighted

procedure volume and total projected operating costs in the third year of operation following project completion from Section Q of each application. (Yakaboski, Tr. p. 331; Joint Ex. 1, p. CON-882). Each applicant's total projected Operating Expenses were stated on Form F.2b and itemized on Form F.3b in its application. (Yakaboski, Tr. pp. 311-13; Sandlin, Tr. pp. 1511-13; Joint Ex. 2, pp. P-132, P-135; Joint Ex. 3, pp. D-116, D-118).

122. As with Net Revenue, the Agency compared Operating Costs using weighted procedures instead of unweighted procedures, unlike the previous 2019 Wake County fixed MRI review. (Pittman, Tr. p. 540; Yakaboski, pp. 331-32). However, this choice had no bearing on the Agency's analysis because Pinnacle projected the lowest Operating Cost per weighted procedure and per unweighted procedure. (Yakaboski, Tr. p. 333; Joint Ex. 1, p. CON-075)

123. The Agency determined that, of the three applicants, Pinnacle projected the lowest Operating Expense per weighted procedure at \$317 per procedure, which was \$9 less per procedure than Duke at \$326 per procedure. (Joint Ex. 1, p. CON-882). However, as with Net Revenue, the Agency miscalculated Duke's Operating Expense, which should have been \$332 per procedure, meaning Pinnacle's projected Operating Expense was actually *\$15 less* per procedure than Duke's projected Operating Expense. (See Yakaboski, Tr. p. 329; Pittman, Tr. pp. 541-542; Joint Ex. 8a).

124. Regardless, the Agency Findings accurately stated, "[Pinnacle] proposes a lower average operating expense per weighted MRI procedure. Therefore, regarding average operating expense per MRI procedure, the proposal by [Pinnacle] is the more effective alternative." (Joint Ex. 1, p. 882).

125. Even though Pinnacle projected the lowest operating expense per procedure, the Agency determined that the Operating Cost factor was inconclusive. Like the Net Revenue comparative factor, the Agency determined the factor was inconclusive because of the differences in billing proposed by the applicants (with Pinnacle and Wake Radiology billing for technical and professional services, and Duke only billing for technical services). (Yakaboski, Tr. pp. 333-34, 403; Joint Ex. 1, p. CON-882).

126. The Agency gave no other reason that the Operating Expense comparative factor was inconclusive. (Yakaboski, Tr. pp. 333-34, 337; Pittman, Tr. pp. 541-42; Sandlin, Tr. p. 1516; Joint Ex. 1, p. CON-882).

127. A professional fee will still be part of the cost to Duke's patients, but the professional fee will not be billed by Duke, and therefore the Agency does not know the amount of the professional fee. (Pittman, Tr. p. 537; Sandlin, Tr. pp. 1581-83).

128. While Pinnacle's Operating Expenses included professional fees and Duke's did not, the inclusion of professional fees in Pinnacle's application only serves to skew Pinnacle's Operating Expenses *higher* compared to Duke's Operating Expenses, because Pinnacle's Operating Expenses include additional costs (professional fees to Greensboro Radiology) that are not accounted for in Duke's expenses. (Yakaboski, Tr. pp. 440-41, 443; Joint Ex. 1, p. CON-882).

129. Nevertheless, Pinnacle's Operating Expense per procedure is still lower than Duke's. (Yakaboski, Tr. pp. 335-36, 444-45; Joint Ex. 33; Pinnacle Exs. 106, 107).

130. Consequently, it was and is unnecessary to compare Pinnacle's and Duke's Operating Expenses "apples to apples" by excluding professional fees. (Meyer, Tr. pp. 774-75, 930-31). Because Pinnacle's Operating Expense per procedure is lowest despite its inclusion of expenses not included by Duke, Pinnacle's application is more effective in the Operating Expense comparative factor. (Yakaboski, Tr. p. 337-38; Pittman, Tr. pp. 542-43; Meyer, Tr. p. 783; Joint Ex. 33; Pinnacle Exs. 106, 07).

131. Any adjustment to compare the applicants "apples to apples" would not change the outcome that Pinnacle's Operating Expenses were lowest. If any amount of professional fees were added for Duke, its Operating Expense per procedure would only increase, and "Pinnacle would still win." (Yakaboski, Tr. pp. 337-38). Similarly, if any amount of professional fees were excluded (subtracted) from Pinnacle's operating expenses, Pinnacle's Operating Expense per procedure would only decrease, and Pinnacle would still be lower than Duke. (Yakaboski, Tr. p. 338).

132. Even without excluding Pinnacle's professional fees, Pinnacle's Operating Expense per procedure is still the lowest of all three applicants. (Sandlin, Tr. p. 1517).

133. Based on the evidence presented, there is no set of circumstances in which Duke's average operating expense per procedure would be lower than Pinnacle's. (Yakaboski, Tr. pp. 451-52).

134. At trial, the project analyst and Duke's expert witness professed confusion about some of Pinnacle's individual operating expenses, and alleged conflicting information in Pinnacle's application. (Yakaboski, Tr. pp. 339-42; Sandlin, Tr. pp. 1367).

135. However, no such confusion or conflicting information was stated as a basis for the agency's conclusion that the Operating Expense comparative factor was inconclusive. (Joint Ex. 1, p. CON-882). To the contrary, the Agency specifically accepted all of Pinnacle's Operating expenses as "reasonable and adequately supported" elsewhere in its Findings (Joint Ex. 1, p. CON-828), and stated that "regarding average operating expense per MRI procedure, the proposal by [Pinnacle] is the more effective alternative." (Joint Ex. 1, p. CON-882). The *sole* reason that the Agency found the factor inconclusive was that some applicants billed globally but Duke did not. (Yakaboski, Tr. pp. 333-34, 337; Pittman, Tr. pp. 541-42; Sandlin, Tr. p. 1516; Joint Ex. 1, p. CON-882).

136. The Agency compared the applicants' operating expenses from the third year after project completion. Although this could be different calendar years for different applicants rather than comparing all applicants' expenses in calendar year 2024, this is consistent with the Agency's general practice. (Sandlin, Tr. pp. 1515-16, 1529-31, 1587).

137. There was no evidence the Agency has ever compared applicants' operating expenses based on the same fiscal year and no evidence that suggested the Agency's comparison by project year is unreasonable.

138. Included in Duke's written comments regarding the comparative analysis, which were submitted to the Agency during the review, was a comparison of the applicants' Operating Expenses. In Duke's analysis, Duke compared operating expenses using each applicant's third year after project completion and concluded that Pinnacle's projected Operating Expenses were lower than any other applicant. (Sandlin, Tr. p. 1529; Joint Ex. 1, p. CON-075).

#### 4. Historical Utilization

139. The Agency analyzed the Historical Utilization factor by comparing the average utilization (number of MRI procedures performed) per MRI scanner on the existing fixed MRI scanners in Wake County owned by each of the applicants and their related entities in fiscal year ("FY") 2019. (Joint Ex. 1, p. CON-875).

140. The Agency's analysis demonstrated that Pinnacle's existing fixed MRI in Wake County performed 7,532 weighted procedures per scanner in FY 2019, whereas Duke's two existing fixed MRI scanners in Wake County averaged 6,967.5 weighted procedures per scanner in FY 2019. (Joint Ex. 1, p. CON-875).

141. Nonetheless, the Agency's Findings stated that Pinnacle and Duke "ha[d] no historical utilization with a fixed MRI scanner" because they both proposed to provide MRI services at new facilities and "[t]hus, the result of this analysis is inconclusive." (Joint Ex. 1, p. CON-876).

142. Duke proposed to develop a new outpatient facility on the campus of the existing Duke Raleigh Hospital. (Joint Ex. 1, p. CON-806). Pinnacle proposed to put a new fixed MRI scanner at its existing Wake Forest imaging center. (Joint Ex. 1, p. CON-804; George, Tr. p. 41).

143. Pinnacle's Wake Forest facility does not have a fixed MRI scanner. It currently offers MRI services only certain days per week, using a mobile MRI owned by Pinnacle that serves that location and other Pinnacle sites. (George, Tr. p. 41).

144. Mr. Yakaboski found the analysis inconclusive because Duke and Pinnacle both proposed fixed MRI scanners at locations other than where they currently had a fixed scanner, but Wake Radiology proposed to put the new MRI at a facility where it already had a fixed MRI. However, neither the written Findings nor Mr. Yakaboski's testimony explained *why* the provision of services at a different location rendered the comparison inconclusive. (See Joint Ex. 1, p. CON-804).

145. The historical utilization factor relates to the basic principles of quality and value and that higher utilization indicates that a provider has been providing quality and cost-effective services. (Meyer, Tr. pp. 690-91).

146. Mr. Yakaboski did not know what the factor is intended to evaluate.

147. The Agency could have compared the applications using the historical utilization data Mr. Yakaboski compiled in the written Findings because the same provider



entities that currently operate the existing Pinnacle and Duke scanners would operate the new Pinnacle and Duke scanners. (Yakaboski, Tr. pp. 182-87).

148. The Agency has compared other applicants under similar circumstances in at least one prior review, a 2021 Buncombe County fixed MRI review. (Yakaboski, Tr. pp. 188-93; Joint Ex. 5). In that review, at least one competing applicant proposed to place a fixed MRI at a new location in the service area. (Yakaboski, Tr. p. 190-191). Instead of finding the historical utilization factor inconclusive, the Agency averaged the utilization of each applicant's fixed MRI scanners at all locations in the service area and found the applicant with the highest average utilization per fixed MRI most effective. (Yakaboski, Tr. p. 192; Joint Ex. 5, pp. 87-88). Mr. Yakaboski was not aware of this prior approach at the time he did the analysis in this review. (Yakaboski, Tr. pp. 193, 351-52).

149. There are no rules, policies, procedures governing how the Agency assess the comparative factors (Yakaboski, Tr. p. 195), and there is no training or manual how to analyze historical utilization. (Yakaboski, Tr. pp. 207-08). In analyzing the historical utilization, the same way, the Agency did in the 2021 Buncombe County MRI review, Pinnacle would have been the most effective because it had the highest average utilization. (Meyer, Tr. pp. 692-96).

#### **Substantial Prejudice to Pinnacle as a Result of the Denial**

150. Although Pinnacle currently offers MRI service in Wake Forest, it does so by using its mobile MRI scanner that rotates between Wake Forest, Clayton, and occasionally Pinnacle's Midtown and Brier Creek locations. (George, Tr. pp. 41, 45-46). Pinnacle's mobile MRI scanner is operating at capacity. (George, Tr. p. 60).

151. Under the Agency's rules, a mobile MRI must serve more than one location, and therefore, Pinnacle cannot use its mobile MRI in Wake Forest full time to provide as much service to Wake Forest patients as it could with the proposed fixed MRI scanner. (Yakaboski, Tr. pp. 177-78; George, Tr. pp. 64-65). Currently, the mobile MRI is only available at Wake Forest three days per week. (George, Tr. pp. 60-61).

152. In addition to Pinnacle's mobile MRI scanner, Pinnacle also contracts with Novant, another provider, for the use of Novant's mobile scanner several days per week to meet patient demand at Pinnacle's Midtown and Brier Creek locations, and its other sites as needed. (George, Tr. p. 41). Providing services with a contracted mobile MRI scanner is much more costly than using Pinnacle's own MRI scanner. (George, Tr. p. 61).

153. The fixed MRI scanner at Wake Forest proposed by Pinnacle would enable it to offer MRI services in Wake Forest seven days per week. In turn, that would free up capacity on Pinnacle's own mobile scanner to serve existing sites that are currently using the Novant-contracted MRI scanner, which would save Pinnacle significant expense. (George, Tr. pp. 61-62; Meyer, Tr. pp. 805-06). These savings were quantified at approximately \$400,000.00 per year. (George, Tr. pp. 67-71; Pinnacle Ex. 108).

154. If Pinnacle were awarded a CON to put a fixed MRI scanner at Wake Forest, Pinnacle would also realize significantly increased income at its Wake Forest facility alone. (Meyer, Tr. pp. 683-85). By replacing part-time mobile service with a fixed MRI scanner, Pinnacle's Wake Forest facility would earn approximately \$97,000 more in net income in a single year. (Meyer, Tr. p. 685; Joint Ex. 26). In terms of EBITDA, which excludes depreciation and other non-cash expenses, Pinnacle's increased income would rise to \$342,000.00 per year. (Meyer, Tr. pp. 685-88).

155. The denial of Pinnacle's application has a significant impact on Pinnacle's operations because such denial restricts Pinnacle's capacity to provide services and its ability to grow its business by preventing it from investing in capital and meeting patient demand in Wake Forest. (George, Tr. pp. 64-65)

### CONCLUSIONS OF LAW

1. The Office of Administrative Hearings has jurisdiction over the parties and the subject matter of this contested case pursuant to Chapters 131E and 150B of the North Carolina General Statutes. All parties have been correctly designated and there is no question as to misjoinder or nonjoinder and the notice of hearing was proper.

2. To the extent that the Findings of Fact contain Conclusions of Law, or that the Conclusions of Law are Findings of Fact, they should be so considered without regard to the given labels. *Charlotte v. Heath*, 226 N.C. 750, 755, 40 S.E.2d 600, 604 (1946); *Peters v. Pennington*, 210 N.C. App. 1, 15, 707 S.E.2d 724, 735 (2011).

3. A court "need not make findings as to every fact which arises from the evidence and need only find those facts which are material to the settlement of the dispute." *Brewington v. N.C. Dep't of Public Safety, State Bureau of Investigation*, 254 N.C. App. 1, 23, 802 S.E.2d 115, 131 (2017) (citation omitted).

4. Pinnacle timely filed its petition for contested case hearing pursuant to N.C. Gen. Stat. § 131E-188(a).

5. Upon the Agency's decision to issue, deny, or withdraw a certificate of need, any affected person is entitled to a contested case hearing. N.C. Gen. Stat. § 131E-188. Likewise, any affected person may intervene in a contested case hearing. *Id.*

6. Pinnacle is an "affected person" within the meaning of N.C. Gen. Stat. § 131E-188(c) because it was an applicant in the review and because it provides services similar to those proposed in the Duke application.

7. As Petitioner, Pinnacle bears the burden of proof on each element of its case. *Overcash v. N.C. Dep't of Env't & Natural Res.*, 179 N.C. App. 697, 704, 635 S.E.2d 442, 447-48 (2006).

8. Pursuant to N.C. Gen. Stat. § 150B-23(a), in a contested case hearing, "the ALJ is to determine whether the petitioner has met its burden in showing that the agency

substantially prejudiced petitioner's rights, and that the agency also acted outside its authority, acted erroneously, acted arbitrarily and capriciously, used improper procedure, or failed to act as required by law or rule." *Presbyterian Hosp. v. N.C. Dep't of Health & Hum. Servs.*, 177 N.C. App. 780, 784, 630 S.E.2d 213, 215 (2006) (citation omitted).

9. "The administrative law judge shall decide the case based upon the preponderance of the evidence, giving due regard to the demonstrated knowledge and expertise of the agency with respect to the facts and inferences within the specialized knowledge of the agency." N.C. Gen. Stat. § 150B-34(a). The burden of persuasion placed upon a petitioner is the "greater weight of the evidence." *Dillingham v. N.C. Dep't of Human Res.*, 132 N.C. App. 704, 712, 513 S.E.2d 823, 828 (1999).

10. The Agency must evaluate CON applications pursuant to North Carolina's CON statute. See N.C. Gen. Stat. §§ 131E-182, 131E-183; see also *Living Centers-Southeast*, 138 N.C. App. at 574, 532 S.E.2d at 194.

11. "The fundamental purpose of the [CON Act] is to limit the construction of health care facilities in North Carolina to those that are needed by the public and that can be operated efficiently and economically for its benefit." *Id.*; *In re Humana Hosp. Corp. v. N.C. Dep't of Hu. Res.*, 81 N.C. App. 628, 345 S.E.2d 235 (1986).

12. In enacting the CON law, the General Assembly made certain findings of fact about the need for the law. Relevant to this case, it seeks to encourage appropriate geographic distribution of services where needed to ensure equal access and seeks to control costs. N.C. Gen. Stat. § 131E-175(1)-(3a). The General Assembly adopted the statutory review criteria so that all proposals are evaluated for need, cost of service, accessibility to services, quality of care, and feasibility and to thereby ensure that only appropriate and needed health services are made available. N.C. Gen. Stat. §§ 131E-175(7), 131E-183(a).

13. In the initial review of the applications, the Agency must review each application individually to test it against the review criteria, without regard to any competing application. *Britthaven. v. N.C. Dep't of Human Res.*, 118 N.C. App. 379, 385, 455 S.E.2d 455, 460-61 (1995). Only after making these conformity determinations does the Agency conduct a comparative analysis to decide which of the competing applications should be approved, including any other findings and conclusions explaining why it finds one applicant preferable to another on a comparative basis. *Id.*

14. To obtain a CON for a proposed project, a CON application must satisfy all of the review criteria in N.C. Gen. Stat. § 131E-183(a). If an application fails to conform with any one of these criteria, then the applicant is not entitled to a CON for the proposed project. *Presbyterian-Orthopedic Hospital v. N.C. Dep't of Hum. Resources*, 122 N.C. App. 529, 534-35, 470 S.E.2d 831, 834 (1996).

15. N.C. Gen. Stat. § 131E-186(b) requires the Agency "provide written notice of all the findings and conclusions upon which it based its decision, including the criteria the used by the [Agency] in making its decision."

16. While there is a presumption that “an administrative agency has properly performed its official duties,” that presumption can be rebutted by showing the CON Section’s decision is subject to reversal under one or more of the standards enumerated in N.C. Gen. Stat. § 150B-23(a). *E. Carolina Internal Med. v. N.C. Dep’t of Health & Human Servs.*, 211 N.C. App. 397, 411, 710 S.E.2d 245, 255 (2011).

17. According to N.C. Gen. Stat. § 150B-23(a), an agency decision is subject to reversal if the agency substantially prejudiced Petitioner’s rights *and*:

- (1) Exceeded its authority or jurisdiction.
- (2) Acted erroneously.
- (3) Failed to use proper procedure.
- (4) Acted arbitrarily or capriciously; or
- (5) Failed to act as required by law or rule.

18. Arbitrary and capricious are largely synonymous terms. *In re Housing Auth. v. City of Salisbury*, 235 N.C. 463, 468, 70 S.E.2d 500, 503 (1952). “An administrative ruling is deemed arbitrary and capricious when it is ‘whimsical, willful, and an unreasonable action without consideration or in disregard of facts or law, without determining principle.’” *Donnelly v. Univ. of N.C.*, 236 N.C. App. 32, 37, 763 S.E.2d 154, 158 (2014) (citation omitted); *see also In re Housing Auth.*, 235 N.C. at 468, 70 S.E.2d at 503 (“An act is arbitrary when it is done without adequate determining principle” or “depending upon the will alone.”). When an agency is engaged in a discretionary act, the terms denote an abuse of discretion but do not signify or necessarily imply bad faith. *Id.*

19. Furthermore, an administrative “decision is arbitrary and capricious if it clearly evinces a lack of fair and careful consideration or want of impartial, reasoned decisionmaking.” *Joyce v. Winston-Salem State Univ.*, 91 N.C. App. 153, 156-57, 370 S.E.2d 866, 868-69 (1988) (reversing State Personnel Commission decision affirming university’s failure to promote the petitioner where evidence confirmed that neither the Commission nor the university considered the Commission’s promotion policy in their decision-making).

### **Pinnacle’s Conformity to the Statutory Review Criteria**

20. An application cannot be approved if it is not conforming to all review criteria. N.C. Gen. Stat. § 131E-183(a). (Yakaboski, Tr. p. 138).

21. Duke contends that the Agency erred in finding Pinnacle’s application conforming to all of the statutory review criteria. (*See Sandlin*, Tr. pp. 1218, 1406). However, Duke did not file a petition for contested case hearing challenging any part of the Agency’s decision.

22. Regardless, the issues raised by Duke regarding Pinnacle’s conformity are not sufficient to establish Agency error under N.C. Gen. Stat. § 150B-23(a).

23. There is no evidence that 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 concluding that Pinnacle had reasonably projected utilization.

24. Pinnacle's projections were reasonable and adequately supported and identified reasonable bases for its conclusions in its written Findings. (Ex. 1, pp. CON-810-11).

25. Therefore, the Agency did not exceed its authority or jurisdiction, act erroneously, fail to use proper procedure, act arbitrarily or capriciously, or fail to act as required by law or rule by concluding the Pinnacle application was fully conforming with the review criteria and approvable.

### The Comparative Analysis

26. Although the Agency has discretion to choose the comparative factors and how it analyzes them, that discretion is not unlimited. The CON law itself limits the Agency's authority to establish criteria, such as the comparative factors, to those that allow the Agency "to carry out the provisions and purposes of [the CON Act]." N.C. Gen. Stat. § 131E-177(1). The Agency must conduct the comparative analysis in a way that relates to the statutory criteria and purposes of the law. (Pittman, Tr. pp. 485-86).

27. The Agency has prepared a template for competitive reviews to guide project analysts when drafting their written Findings. (Pittman, Tr. pp. 517-18; Joint Ex. 10). This template offers suggested comparative factors for agency analysts, and it makes the determining principle for some, but not all, factors explicit. (*See* Pittman, Tr. pp. 518-19, 521-23; Joint Ex. 10, pp. 6, 8-9).

#### 1. Geographic Accessibility

28. The Agency's conclusion that Duke was the more effective application with respect to Geographic Accessibility is erroneous.

29. The errors in the Agency's Findings were material to the Agency's conclusion that Duke was the more effective application regarding Geographic Accessibility. On the face of the Agency's Findings, the Agency concluded (1) that Raleigh currently has the lowest (worst) ratio of existing MRI scanners per person and (2) that Raleigh's ratio would improve if Duke's application were approved. Implicit in the second conclusion is the assumption that Wake Forest's ratio would not improve if Pinnacle's application were approved. These conclusions were based upon the errors in the tables preceding them, where the Agency erroneously calculated Wake Forest's current ratio and showed no improvement in that ratio if Pinnacle's application were approved.

30. Had the Agency accurately accounted for the fact that Wake Forest has no existing scanner, it would have determined that (1) Wake Forest, not Raleigh, currently has the worst ratio of freestanding fixed MRI scanners per person, and (2) its ratio would

improve more from the addition of a freestanding fixed MRI scanner than Raleigh's. Using the analysis the Agency described in its written Findings, it necessarily follows that Pinnacle's proposed location in Wake Forest is the more effective location with respect to geographic accessibility. Consequently, the Agency's conclusion was erroneous because the clear errors in the Agency's analysis show a lack of fair and careful consideration. *See Joyce*, 91 N.C. App. at 156-57, 370 S.E.2d at 868-69.

31. At trial, Mr. Yakaboski rejected the comparison based on improvement that was described in the Findings and instead offered a "people in line" analogy that was not described in the Agency's Findings. This tribunal can only judge the Agency's decision upon the grounds "which the record discloses that its action was based." *See Sec. & Exch. Comm'n v. Chenery Corp.*, 318 U.S. 80, 87 (1943); *see also Godfrey v. Zoning Bd. Of Adjustment*, 317 N.C. 51, 63-64, 344 S.E.2d 272, 279-80 (1986) (a reviewing court is powerless to affirm an administrative action by substituting a more adequate or proper basis).

32. Regardless, this approach is inconsistent with the purposes of the CON law and the determining principles apparent from prior Agency Findings. The Agency's analysis and conclusion under the Geographic Accessibility comparative factor do not protect against geographic maldistribution of healthcare facilities, as the CON Act intended, but rather *encourages* geographic maldistribution by favoring the concentration of even more facilities in larger cities while smaller communities go without. (Pittman, Tr. pp. 506, 614-15; Meyer, Tr. pp. 699-700).

33. Further, there is no evidence that any project analyst other than Mr. Yakaboski applies Geographic Accessibility in such a manner.

34. As a result, the rationale relied on by the Agency to justify its analysis and conclusion regarding geographic accessibility in this review fails to follow any determining principle erroneous. It is solely the subjective belief of the project analyst who happened to be assigned to this review as to how geographic accessibility should be analyzed, uninformed by any general agency procedure or practice, or by the intent of the CON Act.

35. For the foregoing reasons, the Agency acted erroneously by concluding that Duke was superior on the Geographic Accessibility comparative factor. Pinnacle's Application was more effective on this factor, consistent with the purposes of CON regulation, and the principles of expanding geographic access and avoiding geographic maldistribution.

## 2. Average Net Revenue per Procedure

36. The evidence at hearing shows that if the Agency had analyzed Net Revenue on the basis of unweighted procedures, Pinnacle projected the lowest Net Revenue per unweighted procedure. However, Pinnacle has not met its burden of proving that the decision to use weighted procedures was error or was arbitrary and capricious. There is no rule or policy requiring use of one over the other, and the Agency provided a reasonable explanation of its decision to use weighted procedures.

37. Using weighted procedures, the Agency erred in calculating Duke's projected Net Revenue. However, this error is harmless because even when this error is corrected, Duke's projected Net Revenue remains the lowest of all the applicants.

38. Generally, a lower Net Revenue is considered more effective, but here Pinnacle's Net Revenue included revenue for professional services while Duke's did not because Duke's patient would be billed for professional services by a separate entity.

39. The Agency concluded that it could not draw any conclusion as to which applicant was the most effective. Pinnacle contends this was error because Duke's projected Net Revenue was only \$7 per procedure lower than Pinnacle's projected Net Revenue.

40. Based on the evidence in the record, it is likely that Pinnacle would be more effective in an apples-to-apples comparison given this relatively minor difference. However, based on the information available to the Agency at the time, which did not allow the Agency to quantify the amount of Pinnacle's revenue per procedure attributable to the professional services, the Undersigned cannot conclude that the Agency's conclusion that the analysis was inconclusive was arbitrary, capricious, or erroneous.

41. Consequently, the undersigned does not find that the Agency exceeded its authority or jurisdiction, acted erroneously, failed to use proper procedure, acted arbitrarily and capriciously, or failed to act as required by law or rule by finding the Net Revenue comparative factor inconclusive.

### 3. Average Operating Expense per Procedure

42. The Agency evaluated Operating Expense on the basis of weighted procedures. As with the Net Revenue factor, the Undersigned does not conclude that the Agency's decision to use weighted procedures for the Operating Expense factor was error or was arbitrary and capricious. Regardless, that decision was not material to the analysis of Operating Expense because, Pinnacle projected the lowest Operating Expense regardless of whether weighted or unweighted procedures were used for the comparison.

43. Despite the fact that Pinnacle projected the lowest Operating Cost of all applicants, the Agency concluded that the factor was inconclusive because Pinnacle included projected expenses for professional services and Duke did not. However, an apples-to-apples comparison that accounted for this difference was unnecessary and could only widen the difference between Pinnacle's projected expenses and Duke's projected expenses. Under no circumstances could Duke's projected expenses be lower than Pinnacle's in an apples-to-apples comparison, regardless of whether the Agency could calculate the exact apples-to-apples comparison.

44. Moreover, unlike with Net Revenue, the Agency had the information it needed to calculate an apples-to-apples comparison. The operating expenses attributable to professional services were segregated in the application on the line item where the Agency told the applicants to itemize those fees. (*See* Pittman, Tr. p. 625). If those fees were subtracted from Pinnacle's Operating Expense, it would have reduced

Pinnacle's Operating Expense per procedure to \$216 per procedure, \$116 less than Duke's projected expenses. (Meyer Tr. pp. 774-76; Pinnacle Ex. 107).

45. Pinnacle's Operating Expenses were the lowest of all three applicants, and therefore Pinnacle was more effective. By finding this factor inconclusive and failing to find Pinnacle more effective, the Agency acted erroneously by failing to give this factor fair and careful consideration and reaching an unreasonable conclusion in disregard of facts. *See, e.g., Joyce*, 91 N.C. App. at 156-57, 370 S.E.2d at 868-69 ; *Donnelly*, 236 N.C. App. at 37, 763 S.E.2d at 158.

46. The arguments advanced by the Agency and Duke regarding alleged confusion, conflicting information, or proposing a comparison using a different timeframe than the Agency used, do not undermine this conclusion. Instead, those arguments are merely post-hoc rationalizations of the conclusions that the Agency reached. As discussed above, this Tribunal can only judge the Agency's decision upon the grounds which the record discloses that the Agency's action was based. The Agency was required to disclose the facts upon which it relied for its decision. N.C. Gen. Stat. § 131E-186(b). In this review, the Agency found the Operating Expense comparative factor inconclusive for the sole reason that some applicants would bill globally, and Duke would not, which reason is clearly erroneous. A different basis cannot now be substituted to justify the Agency's decision. *See Godfrey*, 317 N.C. at 63-64, 344 S.E.2d at 279-80.

#### 4. Historical Utilization

47. The historical utilization comparative factor relates to the purposes of the CON Act to promote quality, cost-effective services. *See* N.C. Gen. Stat. § 131E-175. Higher utilization is indicative that the provider typically provides quality and cost-effective services.

48. The Agency's application of this factor in the 2021 Buncombe County MRI review (Joint Ex. 5) followed this principle. Despite one applicant's proposing a new location, the Agency compared the historical utilization of all the applicants' existing facilities in the service area and favored the applicant with the highest average utilization at its existing facilities.

49. The Agency did not follow this principle here. The Agency could have done the analysis the way it had been done in the 2021 Buncombe County MRI review but elected not to do so. The Agency did not offer an explanation as to why it elected not to consistently apply this analysis. (Yakaboski, Tr. pp. 193, 351-52).

50. This evidence shows by a preponderance that the Agency's analyst failed to follow any determining principle based on reason or adequate supporting theory.

51. The Agency's own calculations demonstrated that Pinnacle had the highest historical utilization per existing scanner and would be more effective with respect to this factor; and comparison of historical utilization by the same healthcare providers at other locations would indicate their provision of quality, cost-effective services, and therefore advance the purposes of the CON Act.



52. Here, the Agency's purported analysis was based on the "historical utilization of each applicant." Contradicting the data it collected and analyzed, the Agency erroneously concluded that Pinnacle and Duke "have no historical utilization with a fixed MRI scanner."

53. Pinnacle projected the highest historical utilization per scanner and should have been found "more effective" with respect to the historical utilization factor. The Agency's determination that this factor was inconclusive was erroneous because it failed to follow any course of reasoning, disregarded facts and/or law, and failed to follow any determining principle. *See Donnelly*, 236 N.C. App. at 37, 763 S.E.2d at 158.

### **Summary of Comparative Analysis**

54. The Agency determined that Duke was more effective as to two factors (Geographic Accessibility and Access to Service Area Residents). As discussed above, the evidence in this case demonstrates that the Agency acted erroneously in determining that the Duke Application was more effective with respect to Geographic Accessibility. Instead, Pinnacle's application should have been found more effective. Correcting this error alone, the comparative analysis is tied, with Duke and Pinnacle each being more effective as to one factor. (*See Meyer*, Tr. p. 1633).

55. As discussed above, the evidence in this case also demonstrates that the Agency erred by concluding that a comparison could not be drawn on the Projected Average Operating Expense per Procedure factor. Because there are no circumstances under which Duke's projected operating expense per procedure could be lower than Pinnacle's, the only rational conclusion is that the Pinnacle Application was more effective with respect to this factor. Correcting this error in addition to the error on geographic accessibility, the results of the comparative analysis are Pinnacle is more effective on two factors and Duke is more effective on one factor. (*See Meyer*, Tr. pp. 1633-34).

56. As the Agency witnesses testified, if Pinnacle is more effective on two factors and Duke is more effective on one factor, Pinnacle should be the approved applicant and is entitled to the CON. (*See Yakaboski*, Tr. p 175; *Pittman*, Tr. pp. 486-87).

57. This result is unchanged by the outcome of either the Historical Utilization or Average Net Revenue per Procedure factors, although correcting the Historical Utilization factor as discussed above would reinforce this result by adding a third factor on which Pinnacle was more effective.

### **Substantial Prejudice**

58. Pinnacle met its burden of demonstrating that the Agency substantially prejudiced its rights in denying Pinnacle's application for a CON and instead awarding a CON to Duke.

59. The Pinnacle Application was conforming to all applicable statutory criteria and rules, and it demonstrated a need for a fixed MRI scanner at its Wake Forest facility.

60. Nonetheless, the Agency denied the Pinnacle Application and conditionally approved the Duke Application. But for the Agency's decision to approve the Duke Application, the Pinnacle Application would have been approved.

61. The denial of its CON application infringes on Pinnacle's freedom to invest in additional equipment using its own funds, and the ability to compete with Duke on the same footing.

62. Pinnacle demonstrated it will suffer an injury in fact as a result of the Agency's decision. The denial of its application will have a significant impact on its operations, limiting its capacity and its ability to meet patients' needs, preventing it from realizing approximately \$400,000.00 annually in savings, and preventing it from earning approximately \$97,000 in additional net income annually.

63. Based on this evidence, Pinnacle has met its burden of demonstrating substantial prejudice to its rights.

64. Based on all of the foregoing, the Undersigned concludes that the Agency deprived Pinnacle of property substantially prejudiced Pinnacle's rights and acted erroneously in denying the Pinnacle Application and approving the Duke Application.

### **FINAL DECISION**

Based upon the foregoing Findings of Fact and Conclusions of Law, the preponderance of the evidence and having given due regard to the demonstrated knowledge and expertise of the Agency with respect to the facts and inferences within the specialized knowledge of the Agency, the Undersigned hereby **ORDERS**:

1. The decision of the North Carolina Department of Health & Human Services, Division of Health Service Regulation, Certificate of Need Section in the underlying review is hereby **REVERSED**.
2. The Duke Application is hereby denied.
3. The Pinnacle Application is hereby approved; and
4. The Agency is directed to issue a CON to Pinnacle for one fixed MRI scanner to be located at its facility in Wake Forest, Wake County.

### **NOTICE OF APPEAL**

**This is a Final Decision** issued under the authority of N.C. Gen. Stat. § 150B-34. Under the provisions of North Carolina General Statute § 150B-45, any party wishing to appeal the final decision of the Administrative Law Judge must file a Petition for Judicial Review in the Superior Court of the county where the person aggrieved by the administrative decision resides, or in the case of a person residing outside the State, the

county where the contested case which resulted in the final decision was filed. **The appealing party must file the petition within 30 days after being served with a written copy of the Administrative Law Judge's Final Decision.**

In conformity with the Office of Administrative Hearings' rule, 26 N.C. Admin. Code 03.0102, and the Rules of Civil Procedure, N.C. General Statute 1A-1, Article 2, **this Final Decision was served on the parties as indicated by the Certificate of Service attached to this Final Decision.** N.C. Gen. Stat. § 150B-46 describes the contents of the Petition and requires service of the Petition on all parties. Under N.C. Gen. Stat. § 150B-47, the Office of Administrative Hearings is required to file the official record in the contested case with the Clerk of Superior Court within 30 days of receipt of the Petition for Judicial Review. Consequently, a copy of the Petition for Judicial Review must be sent to the Office of Administrative Hearings at the time the appeal is initiated in order to ensure the timely filing of the record.

**IT IS SO ORDERED.**

This the 19th day of July, 2022.



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Melissa Owens Lassiter  
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 which subsequently will place the foregoing document into an official depository of the United States Postal Service.

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This the 19th day of July, 2022.



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