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STATE OF NORTH CAROLINA

COUNTY OF WAKE

IN THE OFFICE OF
ADMINISTRATIVE HEARINGS
20 DHR 00549

Wake Radiology Diagnostic Imaging LLC Petitioner, v. NC Department of Health and Human Services, Division of Health Service Regulation, Health Care Planning and Certificate of Need Respondent, and The Bone and Joint Surgery Clinic, LLP, Respondent-Intervenor.	**FINAL DECISION**

THIS MATTER came on before the Honorable Stacey Bice Bawtinhimer on the Motion for Summary Judgment filed by Petitioner Wake Radiology Diagnostic Imaging, LLC, on March 16, 2020. A Joint Response was filed on April 15, 2020, along with the Affidavit of Martha J. Frisone by the Respondent North Carolina Department of Health and Human Services, Division of Health Service Regulation, Health Care Planning and Certificate of Need Section and Respondent-Intervenor The Bone and Joint Surgery Clinic, LLP. A hearing on the motion was held on May 8, 2020.

After considering the hearing on the motion held on the above-mentioned date, arguments from counsel for both Parties, all documents in support of or in opposition to the Petitioner's motion, all documents in the record, including the Proposed and Amended Decisions, as well as all stipulations, affidavits, and exhibits, the Undersigned finds and concludes that Petitioner's Motion is **DENIED** but that summary judgment should be **GRANTED** against Petitioner and in favor of the Respondent and Respondent-Intervenor.

APPEARANCES

For Petitioner:
Frank S. Kirschbaum
fkirschbaum@wyrick.com
Charles George
cgeorge@wyrick.com
Wyrick Robbins Yates & Ponton LLP
4101 Lake Boone Trail
Suite 300
Raleigh, N.C. 27607

For Respondent: Bethany Burgon
bburgon@ncdoj.gov
North Carolina Department of Justice
P.O. Box 629
Raleigh, N.C. 27602-0629

For Respondent-Intervenor: Forrest W. Campbell, Jr.
fcampbell@brookspierce.com
James C. Adams II
jadams@brookspierce.com
Brooks, Pierce, McLendon
Humphrey & Leonard, L.L.P.
PO Box 26000
Greensboro, N.C. 27420

STANDARD OF REVIEW

An administrative law judges may rule on all prehearing motions authorized under the North Carolina Rules of Civil Procedure, including motions for summary judgment pursuant to Rule 56 of the North Carolina Rules of Civil Procedure. N.C. Gen. Stat. § 150B-33(b)(3a); 26 N.C.A.C. 03.0105(1). Summary judgment is appropriate when the record shows "that there is no genuine issue as to any material fact and that any party is entitled to judgment as a matter of law." N.C. Gen. Stat. § 1A-1, Rule 56(c). All evidence must be viewed in the light most favorable to the party against whom summary judgment is proposed and drawing all reasonable inferences in its favor. *Kennedy v. Guilford Tech. Community College*, 115 N.C. App. 581, 583, 448 S.E.2d 280, 281 (1994). The party seeking summary judgment bears the initial burden of demonstrating the absence of any genuine issue of material fact. *Celotex Corp. v. Catrett,* 477 U.S. 317, 323 (1986). "According to well-established North Carolina law, when a moving party has met his burden of showing that he is entitled to an award of summary judgment in his favor, the non-moving party cannot rely on the allegations or denials set forth in her pleading, *Ind–Com Elec. Co. v. First Union Nat. Bank,* 58 N.C. App. 215, 217, 293 S.E.2d 215, 216–17 (1982), and must, instead, forecast sufficient evidence to show the existence of a genuine issue of material fact in order to preclude an award of summary judgment." *Steele v. Bowden,* 238 N.C. App. 566, 768 S.E.2d 47, 57 (2014). An administrative law judge may grant summary judgment that disposes of all issues in the contested case." N.C. Gen. Stat. § 150B-34(e).

"A genuine issue of material fact is one that can be maintained by substantial evidence. Substantial evidence is such relevant evidence as a reasonable mind might accept as adequate to support a conclusion and means more than a scintilla or a permissible inference." *Ussery v. Branch Banking and Trust Co*., 368 N.C. 325, 335, 777 S.E.2d 272, 278-79 (2015) (citations omitted). "Factual disputes that are irrelevant or unnecessary will not be counted[.] … A fact is material only if it might affect the outcome of the suit under governing law." *Anderson v. Liberty Lobby*, 477 US 242, 247-48 (1986).

A non-movant may be entitled to summary judgment. "Rule 56 does not require that a party move for summary judgment in order to be entitled to it." *N.C. Coastal Motor Line, Inc. v. Everette Truck Line, Inc.,* 77 N.C.App. 149, 151, 334 S.E.2d 499, 501 (1985), *disc. review denied,* 315 N.C. 391, 338 S.E.2d 880 (1986). "Summary judgment, when appropriate, may be rendered against the moving party." *Erthal v. May*, 223 N.C. App. 373, 387, 736 S.E.2d 514, 523 (2012). Judgment "shall be rendered forthwith" if the pleadings and evidence of record show "that any party is entitled to judgment as a matter of law." N.C. Gen. Stat. § 1A-1, Rule 56(c). "Although a party does not have to move for summary judgment to be entitled to it, the nonmovant must be entitled to the judgment as a matter of law." *Carriker v. Carriker*, 350 N.C. 71, 74, 511 S.E.2d 2, 5 (1999).

The Parties agree, because they do not argue otherwise, that there are no genuine issues of material fact as it relates to the issues raised in the Petitioner's Motion. Both Parties assert that they are entitled to judgment as a matter of law.

ISSUES

The issues for review are:

1. Whether the doctrines of either *res judicata* and/or collateral estoppel: (a) preclude consideration of the issue of "substantial prejudice" and (b) compel the conclusion that the Agency erred in its 2019 certificate of need decision related to the expansion of the use of Bone & Joint's 3.0 Tesla magnetic resonance imaging scanner?

2. Whether the Agency had legal authority to issue the 2019 certificate of need, which allowed Bone & Joint to expand the health services provided by its 3.0 Tesla magnetic resonance imaging scanner from only allowing extremity scans to the inclusion of full-body scans?

FINDINGS OF UNDISPUTED FACTS

Although the summary judgment order is not normally required to having findings of facts and conclusions of law, both Parties have requested pursuant to N.C. Gen. Stat. § 1A-1, Rule 51(a)(2) that this decision includes findings of fact and conclusions of law. *See* N.C. Gen Stat. § 50B-34(e).

The following facts are undisputed:

A. The Parties and Contested 2019 CON Decision

1. Petitioner, Wake Radiology Diagnostic Imaging, LLC ("Petitioner" or "Wake Radiology"), currently operates diagnostic centers and provides diagnostic equipment in North Carolina, including Wake County. Wake Radiology's operations include the provision of MRI services, including full-body scans, at facilities in Wake County.

2. Respondent, North Carolina Department of Health and Human Services, Division of Health Service Regulation, Healthcare Planning and Certificate of Need Section ("Respondent", "CON Section", or the "Agency"), is the agency of the State of North Carolina authorized and required to review certificate of need ("CON") applications under the Article 9 of Chapter 131E of the North Carolina General Statutes (the "CON Law").

3. Respondent-Intervenor, The Bone & Joint Surgery Clinic, LLP ("Bone & Joint" or "Respondent-Intervenor"), operates and provides diagnostic magnetic resonance imaging ("MRI") scanning services in Wake County, however, Bone & Joint's MRI services had previously been limited to extremity imaging only based on a CON previously issued in 2007 (the "2007 CON"), the importance of which is discussed fully below.

4. Wake Radiology and Bone & Joint are competitors in the provisions of diagnostic MRI imaging. However, prior to the issuance of the 2019 certificate of need decision (the "2019 CON Decision"), this competition had been curbed by the limitation placed in Condition #2 on Bone & Joint's 3.0T MRI by the 2007 CON. Condition # 2 only allowed the MRI to be used for extremity imaging. If the 2019 CON Decision is upheld and Bone & Joint is allowed to expand the use of its 3.0T MRI to full body scans, Wake Radiology claims it will suffer future competitive harm. Wake Radiology provided no evidence of what that future potential harm would entail.

5. In 2019, Bone & Joint applied to the CON Section to "[e]xpand the type of procedures that may be performed on the existing MRI scanner acquired pursuant to the demonstration project need determination in the 2006 State Medical Facilities Plan, identified as Project ID # J-7605-06 (the "2007 CON").

6. On January 7, 2020, the CON Section issued its 2019 CON Decision with respect to Project ID# J-11757-19 to conditionally approve the CON application filed by Bone & Joint (the "2019 CON").

7. On February 5, 2020, Wake Radiology as an "affected person", timely filed a contested case petition with the Office of Administrative Hearings ("OAH") contesting the issuance of the 2019 CON.

8. The 3.0T MRI that is the subject of the 2019 CON Decision was also the subject of a prior contested case hearing involving the exact same parties and same MRI. This case was consolidated as OAH file numbers 18 DHR 01808 and 18 DHR 03281 (the "Prior Contested Case"). Pet. ¶ 12

B. The Prior Exemptions, CON, and Final Decision History

9. A Final Decision Summary Judgment ("Final Decision") was entered in the Prior Contested Case on February 22, 2019, by the Honorable J. Randolph Ward, Administrative Law Judge ("Judge Ward"), on cross-motions for summary judgment filed by Wake Radiology and jointly by Agency and Bone & Joint. Pet. ¶ ¶ 15-17

10. None of the Parties appealed Judge Ward's Final Decision; therefore, they are bound by his decision. Although invited to do so, the Undersigned declines to reconsider Judge Ward's decision that the 3.0T MRI constituted comparable medical equipment as a replacement MRI.

11. The facts of the Prior Contested Case are relevant in determining whether the doctrines of *res judicata* and collateral estoppel are applicable to this pending matter. For reasons explained below, the Undersigned finds that neither doctrine applies.

1. *The 2007 CON Decision*

12. In 2006, the State Medical Facilities Plan ("SMFP") included a "need determination" for a demonstration project for a fixed extremity MRI scanner in Wake County. Bone & Joint, along with five other applicants, submitted a CON application proposing to acquire a fixed extremity MRI scanner pursuant to that need determination.

13. On March 28, 2007, the Certificate of Need Section ("Agency") issued a CON to Bone & Joint (the "2007 CON") to conduct "a demonstration project for a fixed extremities MRI scanner" under CON Project J-7605-06. The 2007 CON authorized Bone & Joint to acquire an MRI scanner and to establish a diagnostic center. Bone & Joint acquired a .23T MRI, a fixed extremity MRI. The 2007 CON specified as Condition #2 that Bone & Joint "shall not perform whole-body scans on the [fixed] extremity MRI scanner."

a. *The 2016 Exemption Request for a Replacement .23T MRI (the ".23T MRI")*

14. In 2016, Bone & Joint requested an exemption under G.S. § 131E-184(a)(7) to replace its .23T MRI which had been irreparably damaged during its relocation (the "2016 Exemption Request"). The Agency issued a "no review" letter granting the exemption, and Bone & Joint acquired a replacement .23T MRI scanner.

15. Although an "affected person", Wake Radiology did not contest the 2016 Exemption Request.

b. *The 2018 Exemption Request for a Replacement 3.0T MRI (the "3.0T MRI")*

16. By letter to the Agency dated February 16, 2018, Bone & Joint requested another exemption under G.S. § 131E-184(a)(7) to replace the replacement fixed extremity .23T MRI scanner, which had been again irreparably damaged while being moved in January 2018 (the "2018 Exemption Request"). The 2018 Exemption Request differed from the earlier 2016 Exemption Request because Bone & Joint sought to acquire a 3.0 Tesla MRI ("3.0T MRI") whereas, in the first exemption request, Bone & Joint sought to replace the original .23T MRI with another .23T MRI.

17. Unlike the .23T MRI, the 3.0T MRI has enhanced features that would allow full-body scans. According to Wake Radiology these enhancements would controvert Condition #2 of the 2007 CON, which did not allow Bone & Joint to conduct full-body scans.

18. On February 20, 2018 (corrected April 30, 2018) the Agency issued a "no review" decision ("2018 Exemption Decision") granting Bone & Joint an exemption to acquire the 3.0T MRI as "replacement equipment" under G.S. § 131E-184(a)(7).

19. Unlike the CON Review Process, the exemption process in G.S. § 131E-184 does not include the opportunity for any person to file written comments and a public hearing after the conclusion of the written comment period prior to the issuance of the "no review" exemption decision. *Compare* N.C.G.S. § 131E-185 ("CON Review Process").

20. The 2018 Exemption Decision stated that the replacement 3.0T MRI was replacing the .23T MRI that Bone & Joint acquired pursuant to the certificate of need issued for the 2007 CON Project J-7605-06 and that Condition #2 in the 2007 CON remained in effect.

2. *The Prior Contested Case and Final Decision*

21. As an "affected person", Wake Radiology timely filed petitions contesting both the February 20, 2018 exemption decision (18 DHR 01808) and the April 30, 2018 corrected exemption decision (18 DHR 03281). These cases were consolidated, resulting in what is referred to as the "Prior Contested Case".

22. Wake Radiology's Petition in the Prior Contested Case challenged the correctness of the 2018 Exemption Decision and sought a complete reversal of the decision in order to prevent Bone & Joint from acquiring the 3.0T MRI.

23. Pending resolution of the Prior Contested Case, Wake Radiology did not seek a temporary restraining order or preliminary injunction to prevent Bone & Joint from acquiring the 3.0T MRI. Bone & Joint purchased the 3.0T MRI while the prior case was pending. *See* N.C. Gen. Stat. § 131E-190(h) (allowing an aggrieved person under G.S. § 150B-2(6) to seek injunctive relief).

24. The sole substantive issue raised in the Prior Contested Case was whether the 3.0T MRI scanner that Bone & Joint proposed to acquire (and did acquire) constituted "replacement equipment" under the CON regulations that defined "comparable medical equipment," 10A N.C.A.C. § 14C .0303.

25. By order dated February 22, 2019, Judge Ward granted the Agency's Motion for Summary Judgment and entered a Final Decision.

26. In his Final Decision, Judge Ward concluded that, even though the replacement 3.0T MRI possessed expanded capabilities, it constituted "replacement equipment" pursuant to 10A N.C.A.C. § 14C .0303, and he upheld the Agency's decision to issue the 2018 Exemption Decision. Final Dec. p. 9.

27. In his order Judge Ward restated Condition #2 of the 2007 CON: "[t]hat the Intervenor [Bone & Joint] shall use the replacement 3.0 Tesla MRI exclusively for studies that were previously performed with the extremity scanner it replaces." *Id.*

28. Judge Ward also concluded:

> As the Intervenor's operation of the replacement MRI is conditioned on conformance with the March 28, 2007 Certificate of Need, and the MRI must be used for the "same diagnostic or treatment purposes," the Intervenor is entitled to use the 3.0 Tesla to perform only the types of studies previously done with the extremity scanner it replaces, **unless and until the certificate of need is modified or replaced.**

Id. ¶ 18 (emphasis added)

29. As previously noted, neither Wake Radiology, Bone & Joint, nor the Agency appealed the Final Decision.

3. *Completion of the 2007 CON Demonstrative Project*

30. On April 17, 2019, the Technology and Equipment Committee of the State Health Coordinating Council ("SHCC") unanimously passed a motion to consider Bone & Joint's demonstration project to be complete. Frisone Aff. ¶ 6. Wake Radiology's owner, Lyndon Jordan, presided over the meeting. *Id.*

31. On May 29, 2019, the SHCC voted unanimously to adopt the Technology and Equipment Committee's recommendation that Bone & Joint's demonstration project was now complete and that the Bone & Joint's 3.0T MRI should be placed into the general inventory along with all the other MRI scanners in Wake County. *Id.* ¶ 6 & Ex. C

32. In the past and the 2019 State Medical Facilities Plans, Bone & Joint's MRI had been listed separately as a demonstration project. *Id.* ¶ 6 & Ex. E. As a result of the SHCC decision, the 2020 State Medical Facilities Plan included Bone & Joint's 3.0T MRI in the MRI regular inventory. *Id.* ¶ 6 & Ex. D.

33. Wake Radiology argues that the Agency erred by relying on the SHCC to end the 2007 CON demonstration project because SHCC does not issue certificate of need nor empowered to modify existing certificate of need. Moreover, Wake Radiology asserts that SHCC's decision to place the MRI on the roster of fixed MRIs is irrelevant to the issues in this case.

34. Wake Radiology, however, does not contest SHCC's authority to declare that the 2007 demonstration project ended in 2019.

35. The one year period is significant because a change, made in a project for which a CON had been issued, must be proposed within one year after the project was completed. N.C. Gen. Stat. § 131E-176(16)(e). A "change in a project" means more than a fifteen percent (15%)

increase in capital expenditure or, as in this case, the addition of a health service (full body scans) that is to be located in the facility that was developed in the project. *Id.*

36. Bone & Joint's application would constitute a "change" in the health services at the facility developed by the 2007 CON demonstration project.

C. 2019 Application for a CON to Expand Use of Bone & Joint's 3.0T MRI

37. In accordance with the directive in Judge Ward's Final Decision, on August 15, 2019, per G.S. § 131E-183(a) Bone & Joint submitted an application to the Agency for a CON seeking a new CON in order to offer new and expanded MRI procedures and services using its existing 3.0T MRI scanner.

38. On September 1, 2019, the Agency commenced its review. The Agency determined that the review was non-competitive because it only involved one application. Moreover, due to the 2007 CON Bone & Joint already owned the 3.0T MRI, so a need determination was unnecessary.

39. Other diagnostic centers like Wake Radiology, which had their own MRIs, already used them for full body imaging. In other words, they had no need for expanding the use of their existing MRIs. This was a unique situation that applied to only one possible applicant - Bone & Joint.

40. Because Bone & Joint had already acquired the 3.0T MRI and had an established facility with trained staff to perform the MRI scans, the proposed expansion would be of nominal cost, if any.

41. Not all institutional health services require an CON. Only a "new institutional health service" as defined by G.S. 131E-176 requires a CON. *See also* N.C. Gen. Stat. § 131E-178(a). There are even exceptions for some new institutional health services.

42. Expansions of an existing health service is such an exception to the CON Review Process if the cost of the expansion is less than two million dollars ($2 million). N.C. Gen. Stat. § 131E-176(16)(b).

43. Although the CON Review Process may not have been required in this case, because Bone & Joint's expansion request fell under G.S. § 131E-176(16)(b), in light of the unique circumstances in this situation, the Agency required Bone & Joint go through the review process anyway.

44. The Agency complied with the CON application review procedures. Public comments were solicited and received, and a public hearing was conducted as required by G.S. § 131E-185(a1). Pet. at ¶ 27. Unlike the 2018 Exemption Decision in the Prior Contested Case, Wake Radiology was afforded and did participate in all of the comment and hearing opportunities. *Id.*

45. The CON Review Process may not have been required but, in this unique situation, the Undersigned finds that the Agency's decision to require it was reasonable.

46. On January 7, 2020, the Agency timely issued the 2019 CON Decision and comprehensive findings as required by G.S. § 131E-186, approving Bone & Joint's application and awarding a new CON to Bone & Joint ("2019 CON"). The 2019 CON did not include the "whole body scan" Condition #2 that had been included in the 2007 CON. Instead, it stated that Bone & Joint would now be required to comply with its representations in the 2019 Application. Pet. Ex. 1

D. Appeal of 2019 CON Decision

47. On February 5, 2020 as an "affected person", Wake Radiology timely appealed the 2019 CON Decision, and subsequently, on February 17, 2020, Bone & Joint was permitted to intervene as a Respondent-Intervenor.

48. Wake Radiology argues that, through the 2019 CON process, Bone & Joint sought to by-pass Judge Ward's Final Decision, which limited the use of the replacement 3.0T MRI to extremity imaging only.

49. According to Wake Radiology, Bone & Joint is estopped from seeking the 2019 CON and the Agency from issuing it because the issues in this present case have already been decided in the Final Decision of the Prior Contested Case. The Undersigned disagrees.

50. Although the Prior Contested Case contained the same parties and subject matter (the 3.0T MRI machine), the issue in the prior case was not the same as in this one.

51. In the Prior Contested Case, Wake Radiology was contesting the Agency's 2018 Exemption Decision to allow an exemption for 3.0T MRI as replacement MRI equipment for the 2007 CON. This exemption was granted by a "no review" letter issued by the Agency.

52. In the current case, Wake Radiology is contesting the 2019 CON Decision and whether the Agency had the authority to expand the health services provided by the 3.0T MRI. This expansion was granted only after the completion of the CON Review Process.

53. In both their Joint Motion to Dismiss (which was denied) and Joint Response to Petitioner's Motion for Summary Judgment, Bone & Joint and the Agency contend that Wake Radiology is not prejudiced by virtue of the expanded use of the MRI at issue.

54. Wake Radiology relies on the doctrines of *res judicata* and collateral estoppel to prove it was substantially prejudiced by the Agency's subsequent approval of the 2019 CON and to compel the conclusion that the Agency erred in its 2019 CON Decision.

55. Outside of its *res judicata* and collateral estoppel argument, Wake Radiology made other claims of substantial prejudice. Wake Radiology suggested that there could be potential competitive harm, but proffered no evidence supporting this suggestion and potential competitive harm alone is not sufficient to prove substantial prejudice.

56. Wake Radiology, however, concedes that Bone & Joint's:

> failure to appeal the Final Decision did not necessarily preclude [Bone & Joint] from submitted its application to the Agency, through the competitive application process, to '[e]xpand the type of procedures that may be performed on the existing MRI scanner acquirement pursuant to the demonstration project need determination in the 2006 State Medical Facility Plan, identified as Project ID # J-7605-06.
>
> Pet'r Amend. Pro Dec. ¶ 16, p. 9

57. In order to do this, Wake Radiology claims that Bone & Joint's CON application must be made through the competitive process and that a need determination was a prerequisite. Wake Radiology concludes that because of this failure, the CON Section erred when it decided that Bone & Joint did "not propose to offer or develop a new institutional health services for which there is a need determination in the 2019 SMFP." Pet. ¶ 29, p. 6

58. To Wake Radiology, the ultimate result of the Agency's erroneous decision in this regard is that "Bone & Joint has *effectively acquired* a new MRI scanner with should have been made available to any successful applicant." Pet'r Resp. to Jt. Mot. to Dismiss, p. 11

59. This non-competitive application process purportedly unfairly prejudiced Wake Radiology because it was not permitted to "submit its own application for such a scanner and by allowing duplication of services in the relevant geographic area, including services provided in such area by Wake Radiology." Pet. ¶ 32, p. 7

60. The Undersigned finds that the expansion of the health services to be provided by the 3.0T MRI was not the same as the acquisition of a "new MRI scanner" and that the competitive process with a prerequisite need determination was not required in this situation.

61. With respect to Wake Radiology's *res judicata* and collateral estoppel arguments regarding substantial prejudice and Agency error, the Undersigned finds that these doctrines do not preclude consideration of the issue of substantial prejudice or compel the conclusion that the Agency erred in its 2019 CON Decision.

62. Alternatively, Wake Radiology challenges the Agency's legal authority to even issue the 2019 CON.

63. In support of its legal authority, the Agency proffers two theories. First, that this is an "expansion" of an existing health services permitted by G.S. § 131E-176(16)(b), which does not require the CON Review Process. Secondly, that this is a "change in project" within one year of the completion of the demonstration project pursuant to G.S. § 131E-176(16)(e) which did

require the CON Review Process. Regardless of whether the CON Review Process was required, the Agency, in its discretion did require Bone & Joint to complete the CON Review Process.

64. The Undersigned finds that the Agency had legal authority to allow expansion of the 3.0T MRI's use and that the Agency's requirement that Bone & Joint to complete the CON Process was reasonable.

65. After careful review of the records in this contested case and applicable law, the Undersigned finds that there are no genuine issues of material fact that Wake Radiology failed to prove substantial prejudice and that the Agency had legal authority to issue the 2019 CON to Bone & Joint.

BASED UPON the foregoing findings of fact, exhibits, stipulations, sworn affidavit, relevant laws, legal precedent, and upon the preponderance or greater weight of the evidence in the whole record, the Undersigned makes the following Conclusions of Law.

CONCLUSIONS OF LAW

1. OAH has jurisdiction over the Parties and subject matter of this contested case pursuant to G.S. § 150B-23 *et seq*. and G.S. § 131E-188, and there is no question as to misjoinder or nonjoinder. The Parties received proper notice of all proceedings in this matter.

2. Pursuant to G.S. § 150B-33(b)(3a); 26 N.C.A.C. § 03.0105(1), administrative law judges may rule on all prehearing motions authorized under the North Carolina Rules of Civil Procedure, including motions to dismiss pursuant to Rule 56 of the North Carolina Rules of Civil Procedure.

3. To the extent that the foregoing Findings of Fact contain conclusions of law, or that these Conclusions of Law are findings of fact, they are intended to be considered without regard to their 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). *Warren v. Dep't of Crime Control*, 221 N.C.App. 376, 377, 726 S.E.2d 920, 923, disc. rev. den., 366 N.C. 408, 735 S.E.2d 175 (2012); *Watlington v Rockingham Co. Department of Social Services*, COA17-1176 (October 2, 2018); *Bonnie Ann F. v. Callahen Indep. Sch. Bd*., 835 F. Supp. 340 (1993).

CON Law Overview

4. With respect to institutional health services, the General Assembly of North Carolina has found:

(1) That the financing of health care, particularly the reimbursement of health services rendered by health service facilities, limits the effect of free-market competition, and government regulation is, therefore, necessary to control costs, utilization, and distribution of new health service facilities and the bed complements of these health service facilities.

(2) That the increasing cost of health care services offered through health service facilities threatens the health and welfare of the citizens of this State in that citizens need assurance of economic and readily available health care.

(3) That, if left to the market place to allocate health service facilities and health care services, geographical maldistribution of these facilities and services would occur and, further, less than equal access to all population groups, especially those that have traditionally been medically underserved, would result.

…

(7) That the general welfare and protection of lives, health, and property of the people of this State require that new institutional health services to be offered within this State be subject to review and evaluation as to need, cost of service, accessibility to services, quality of care, feasibility, and other criteria as determined by provisions of this Article or by the North Carolina Department of Health and Human Services pursuant to provisions of this Article prior to such services being offered or developed in order that only appropriate and needed institutional health services are made available in the area to be served.

…

N.C. Gen. Stat. § 131E-175(1-3)&(7).

5. One of the underlying policies of the CON Law is to guard against "underuse of facilities, with the availability of excess capacity leading to unnecessary use of expensive resources and overutilization of health care services" and the resulting "enormous economic burden on the public who pay for " the services as a result of that "excess capacity." N.C. Gen. Stat. § 131E-175(4) & (6).

6. To address underutilization, the CON Law specifically contemplates expanding an existing health service such as a MRI service and does not require a CON for expansions under certain circumstances. For example, per N.C. Gen. Stat. § 131E-176(16)(b) a provider is required to obtain a CON if it seeks to expand an existing health service, and the expansion involves an expenditure of more than two million dollars ($2 million). The necessary implication is that an expansion of a health service that does not involve an expenditure exceeding $2 million does not meet the definition of a new institutional health service and so it can be accomplished without a certificate of need.

7. Pursuant to G.S. § 131E-178, the North Carolina certificate of need law ("CON Law") requires certificates of need for new institutional health services with some limited exemptions. *See* N.C. Gen. Stat. 131E-184.

8. The CON Section is tasked with carrying out the purposes and provisions of the CON Law, N.C. Gen. Stat. § 131E-177, including the application, review process, and enforcement. N.C. Gen. Stat. §§131E-182, 131E-183, 131E-185 through 187, and 131E-190. The CON Section is also responsible for determining when the expansion of an institutional health service requires a CON. *See* N.C. Gen. Stat. § 131E-176(16)(b).

ISSUE 1: Whether the doctrines of either *res judicata* and/or collateral estoppel (a) preclude consideration of the issue of "substantial prejudice;" and, (b) compel the conclusion that the Agency erred in its 2019 decision to grant a certificate of need to Bone & Joint related to its 3.0 Tesla magnetic resonance imaging scanner?

A. Wake Radiology Is Not Entitled to Summary Judgment on the Issue of Substantial Prejudice Based on the Doctrine of Collateral Estoppel.

9. After a decision of the CON Section to issue, deny or withdraw a CON or exemption or to issue a CON pursuant to a settlement agreement, any "affected person" can file a contested case hearing challenging the action. N.C. Gen. Stat. § 131E-188(a).

10. In this case, both Wake Radiology and Bone & Joint (as intervenor) were "affected persons" under the statute. N.C. Gen. Stat. § 131E-188(c).

11. However, Wake Radiology's "affected person" status does not automatically mean that Wake Radiology was "substantially prejudiced" by the issuance of the 2019 CON.

12. In order to prevail in a contested case, a petitioner must satisfy the requirements of G.S. § 150B-23(a).

> A petition shall be signed by a party, an attorney representing a party, or other representative of the party as may specifically be authorized by law, and, if filed by a party other than an agency, shall state facts tending to establish that the agency named as the 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 agency:
>
> (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) (emphasis added)

13. Substantial prejudice is an element of Wake Radiology's claim separate and apart from whether the Agency made an error in its evaluation of Bone & Joint's 2019 CON application.

14. Under N.C. Gen. Stat. § 150B–23(a), the administrative law judge is to "determine whether the petitioner has met its burden in showing that [1] the agency substantially prejudiced [the] petitioner's rights, and that [2] 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. *Surgical Care Affiliates, LLC v. N.C. Dep't of Health & Human Servs., Div. of Health Serv. Regulation, Certificate of Need Section*, 235 N.C. App. 620, 628, 762 S.E.2d 468, 473–74 (2014) (quoting *Britthaven, Inc. v. N.C. Dep't of Human Res.*, 118 N.C.App. 379, 382, 455 S.E.2d 455, 459 (1995)) (emphasis in original).

15. When a petitioner alleges that the Agency did not properly apply its own rules or properly examine an application, "the petitioner *must also* prove, and the ALJ must separately decide the issue of, substantial prejudice, i.e., that the Agency's failure to follow its rules *actually* caused sufficient harm to the petitioner." *Surgical Care Affiliates*, 235 N.C. App. at 628, 762 S.E.2d at 473–74; *Blue Ridge Healthcare Hosps. Inc. v. N. Carolina Dep't of Health & Human Servs., Div. of Health Serv. Regulation, Healthcare Planning & Certificate of Need Section*, 255 N.C. App. 451, 464, 808 S.E.2d 271, 279 (2017) (emphasis in original).

16. Even if the Agency erred based on one of the bases in G.S. § 150B-23(a), a petitioner still has the ***additional*** burden of showing "it was substantially prejudiced by the [Agency]'s decision to grant [] a CON." *CaroMont Health, Inc. v. N. Carolina Dep't of Health & Human Servs. Div. of Health Serv. Regulation, Certificate of Need Section*, 231 N.C. App. 1, 5, 751 S.E.2d 244, 248 (2013) (citing *Wake Radiology Servs. LLC v. N.C. Dep't of Health & Human Servs*., 215 N.C.App. 393, 716 S.E.2d 87, 2011 WL 3891026, at *5, 2011 N.C.App. LEXIS 1924, at *14 (2011))

17. The North Carolina Court of Appeals has held on multiple occasions that the existence of error by the CON Section does not, by itself, create substantial prejudice. *See, e.g., Blue Ridge Healthcare*, 255 N.C. App. at 464-65, 808 S.E.2d at 279-80; *Surgical Care Affiliates*, 235 N.C. App. at 628, 762 S.E.2d at 473-74; *CaroMont Health*, 231 N.C. App. at 4-5, 751 S.E.2d at 248. Any allegation that the CON Section failed to follow its rules or procedures cannot, as a matter of law, constitute substantial prejudice.

18. A petitioner may not rely on the Agency's alleged failures in its analysis to show substantial prejudice but must show that the decision itself caused some harm that legally constitutes "substantial prejudice." *Blue Ridge Healthcare Hosps.*, 255 N.C. App. at 464, 808 S.E.2d at 279; *Surgical Care Affiliates*, 235 N.C. App. at 628, 762 S.E.2d at 473–74; *CaroMont Health*, 231 N.C. App. at 5, 751 S.E.2d at 248.

19. Wake Radiology claims that the issue of substantial prejudice was decided in the Prior Contested Case and that, as a result, this Tribunal is bound under the doctrine of collateral estoppel to find that the substantial prejudice element has been satisfied as a matter of law. The Undersigned disagrees.

20. The only reference made about "substantial prejudice" in the Final Decision concerned the denial of the Respondent/Respondent-Intervenor's motion to dismiss in which Judge Ward stated:

> Our Court of Appeals has held that "the issuance of a 'No Review' letter, which results in the establishment of 'a new institutional health service' without a prior

> determination of need, substantially prejudices a licensed, pre-existing competing health service provider as a matter of law." *Hospice at Greensboro, Inc. v. N.C. Dep't of Health & Human Servs., Div. of Facility Servs.*, 185 N.C. App. 1, 16–18, 647 S.E.2d 651, 661–62 (2007), *writ denied, review denied,* 361 N.C. 692, 654 S.E.2d 477 (2007).
>
> Final Dec. p. 2.

21. There, Judge Ward was referring to substantial prejudice due to the issuance of a "no review" letter, not due to the issuance of a CON through the CON Review Process.

22. The doctrine of collateral estoppel precludes re-litigation of specific issues that were actually litigated and determined in a prior suit. *Hillsboro Partners, LLC v. City of Fayetteville*, 226 N.C.App. 30, 35, 738 S.E.2d 819, 824 (2013); *Strates Shows, Inc. v. Amusements of Am., Inc*., 184 N.C. App. 455, 461, 646 S.E.2d 418, 423 (2007). The elements of collateral estoppel are: "(1) a prior suit resulting in a final judgment on the merits; (2) identical issues involved; (3) the issue was actually litigated in the prior suit and necessary to the judgment; and (4) the issue was actually determined." *Royster v. McNamara*, 218 N.C.App. 520, 526, 723 S.E.2d 122, 126 (2012) (quoting *McDonald v. Skeen*, 152 N.C.App. 228, 230, 567 S.E.2d 209, 211 (2002)).

23. Although Wake Radiology contends that the issue of whether it suffered substantial prejudice from the 2019 CON Decision was actually litigated and decided by the Final Decision, the elements of collateral estoppel have not been satisfied with respect to substantial prejudice. While the same parties and MRI were involved in the Prior Contested Case, and it was actually litigated to final judgment on the merits, this case and the Prior Contested Case do not involve the identical substantial prejudice issue; therefore, collateral estoppel is not applicable. *Royster*, 218 N.C. App. at 526, 723 S.E.2d at 126.

24. The scope of the 3.0T MRI use was not the "subject matter" in the Prior Contested Case nor in this case. The "subject matter of a contested case hearing by the ALJ is an agency decision." *Britthaven, Inc. v. N. Carolina Dep't of Human Res., Div. of Facility Servs*., 118 N.C. App. 379, 382, 455 S.E.2d 455, 459 (1995). *See Presbyterian Hosp. v. N.C. Dep't of Health & Human Servs.*, 177 N.C. App. 780, 784, 630 S.E.2d 213, 215 (2006); *Living Centers-Se., Inc. v. N.C. Dep't of Health & Human Servs., Div. of Facility Servs., Certificate of Need Section*, 138 N.C. App. 572, 581, 532 S.E.2d 192, 198 (2000). "[T]he purpose of the ALJ's determination in a CON case is to review the correctness of the Department's decision utilizing the standards enunciated in N.C. Gen. Stat. § 150B–23(a) …." *E. Carolina Internal Med., P.A. v. N. Carolina Dep't of Health & Human Servs., Div. of Health Serv. Regulation, Certificate of Need Section*, 211 N.C.App. 397, 405, 710 S.E.2d 245, 252 (2011). The ALJ is required to evaluate the actual Agency decision at issue and determine whether the agency made any errors in making that decision under G.S. § 150B-23(a).

25. In the Prior Contested Case, the issue before Judge Ward was the correctness of the 2018 Exemption Decision, which was issued through a "no review" letter. The issue in this case is the correctness of the 2019 CON Decision, which included the CON Review process.

26. The "substantial prejudice" issue before the Undersigned here is whether the Agency, in issuing the 2019 CON Decision, "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 whether it committed one of the enumerated errors in issuing the decision. The Final Decision in the Prior Contested Case decided only issues related to the 2018 Exemption Decision; it could not decide any issues about whether Wake Radiology would be substantially prejudiced by a future Agency decision.

27. The Final Decision in the Prior Contested Case – issued on February 22, 2019 – never considered or decided whether Petitioner was substantially prejudiced by the 2019 CON Decision as that decision had not yet been made. The issue of substantial prejudice from the 2019 CON Decision was not decided in the Prior Case, and therefore collateral estoppel does not apply.

28. Finally, Wake Radiology has also failed to come forward with any other proof of substantial prejudice except its allegations of potential future competitive harm.

29. While the expansion of Bone & Joint's MRI services could cause competitive harm to Wake Radiology, competitive harm is not a legal injury that the contested case process is designed to protect. *Parkway Urology, P.A. v. N. Carolina Dep't of Health & Human Servs., Div. of Health Serv. Regulation, Certificate of Need Section*, 205 N.C. App. 529, 539, 696 S.E.2d 187, 195 (2010). *See Blue Ridge Healthcare Hosps. Inc. v. N. Carolina Dep't of Health & Human Servs., Div. of Health Serv. Regulation, Healthcare Planning & Certificate of Need Section*, 255 N.C. App. 451, 464– 65, 808 S.E.2d 271, 279 (2017); *Surgical Care Affiliates, LLC v. N.C. Dep't of Health & Human Servs., Div. of Health Serv. Regulation, Certificate of Need Section,* 235 N.C. App. 620, 631, 762 S.E.2d 468, 476 (2014); *CaroMont Health, Inc. v. N.C. Dep't of Health & Human Servs.*, 231 N.C.App. 1, 8, 751 S.E.2d 244, 249 (2013); *Wake Radiology Servs. LLC v. N. Carolina Dep't of Health & Human Servs., Div. of Health Servs. Regulation, Certificate of Need Section*, 215 N.C. App. 393, 716 S.E.2d 87 (2011) (dismissing case because "Wake Radiology's primary concern is the effect of competition")

30. Wake Radiology's allegations are insufficient as a matter of law to establish substantial prejudice at summary judgment. *Parkway Urology, P.A. v. N. Carolina Dep't of Health & Human Servs., Div. of Health Serv. Regulation, Certificate of Need Section*, 205 N.C. App. 529, 539, 696 S.E.2d 187, 195 (2010); *Blue Ridge Healthcare*, 255 N.C. App. at 464–65, 808 S.E.2d at 279; *Surgical Care Affiliates,* 235 N.C. App. at 631, 762 S.E.2d at 476; *CaroMont Health*, 231 N.C. App. at 8, 751 S.E.2d at 249.

31. Wake Radiology's alternative substantial prejudice arguments are also rejected as follows:

a. Under the decisions in *Blue Ridge Healthcare Hosps.* and *Surgical Care Affiliates*, Wake Radiology is not substantially prejudiced as a result of the Agency's failure to follow its rules or conduct its statutory analysis; substantial prejudice must be shown in addition to any Agency error.

b. Equally unavailing is Wake Radiology's argument that it was substantially prejudiced by being required to go through a competitive review process to acquire an MRI while Bone & Joint was not. Nothing in the 2019 CON Decision precludes Wake Radiology from filing any application with respect to its own MRI equipment or with respect to any new need determination contained in the SMFP to acquire a new MRI machine. Bone & Joint acquired its MRI scanner through a competitive process in 2006 based upon a need determination in the 2006 SMFP for a demonstration project. Thereafter, Bone & Joint merely submitted exemption requests to replace the previously acquired MRI scanner. At no time, including 2019, has Bone & Joint proposed to acquire a new MRI scanner.

c. Wake Radiology contends it is substantially prejudiced because the 3.0T MRI is not replacement equipment. The 2019 CON Decision made no finding or decision that the 3.0T MRI was "replacement equipment." That decision was made in the 2018 Exemption Decision which Wake Radiology appealed and was decided against it in the Final Decision of Judge Ward. Wake Radiology is estopped from complaining about the Final Decision under the doctrine of collateral estoppel. Moreover, Wake Radiology cannot establish substantial prejudice in this case based on an unfavorable decision in a prior contested case.

32. Wake Radiology has failed to come forward with **any** proof of substantial prejudice in support of its motion for summary judgment.

33. Wake Radiology's Motion for Summary Judgment on the issue of substantial prejudice is denied. Because there are no genuine issues of material fact regarding whether Wake Radiology has established substantial prejudice, the Undersigned grants summary judgment against Wake Radiology and in favor of the Agency and Bone & Joint pursuant to Rule 56(c) of the North Carolina Rules of Civil Procedure.

34. Because Wake Radiology has failed to meet its burden on the essential issue of substantial prejudice, the additional issues need not be decided. However, for the purposes of review, the remaining issues are addressed below.

B. Wake Radiology Is Not Entitled to Summary Judgment on the Issue of an Agency Error Regarding the 2019 CON Decision Based on Either Doctrine of *Res Judicata* or Collateral Estoppel.

35. Wake Radiology next contends it is entitled to summary judgment on the merits arguing that the doctrines of *res judicata* and collateral estoppel dictate the result in this case and, separately, arguing that the Agency lacked the authority to issue the 2019 CON Decision.

36. Wake Radiology's *res judicata* and collateral estoppel are rejected for reasons similar to those set forth above with regard to the substantial prejudice issue.

37. *Res judicata* bars all causes of action which were or could have been presented in a previous suit based on the same cause of action between the same parties or their privies."

Williams v. Peabody, 217 N.C.App. 1, 7, 719 S.E.2d 88, 93 (2011); *Goins v. Cone Mills Corp*., 90 N.C.App. 90, 93, 367 S.E.2d 335, 336–37, (1988). "A final judgment 'operates as an estoppel not only as to all matters actually determined or litigated in the prior proceeding, but also as to all relevant and material matters within the scope of the proceeding which the parties, in the exercise of reasonable diligence, could and should have brought forward for determination.'" *Williams*, 217 N.C.App. at 7, 719 S.E.2d at 93-94 (quoting *Rodgers Builders, Inc. v. McQueen*, 76 N.C.App. 16, 22, 331 S.E.2d 726, 730 (1985)). The elements required to establish *res judicata* are: "(1) a final judgment on the merits in an earlier suit, (2) an identity of the causes of action in both the earlier and the later suit, and (3) an identity of the parties or their privies in the two suits." *Herring v. Winston–Salem/Forsyth Cnty. Bd. of Educ*., 188 N.C.App. 441, 444, 656 S.E.2d 307, 310 (2008). *See R.C. Koonts & Sons Masonry, Inc. v. First Nat'l Bank*, 830 S.E.2d 690, 694 (N.C. App. 2019).

38. While the parties and the MRI machine were the same in both cases and a final judgment on the merits in the Prior Contested Case, all three elements are required for the application of *res judicata.*

39. As discussed above, the subject matter of a contested case is an "agency decision". In the Prior Contested Case, the subject of the case was the Agency's 2018 Exemption Decision to issue an exemption to Bone & Joint for acquisition of the 3.0T MRI as "replacement equipment." In that case the legal question was whether the 3.0T MRI constituted "replacement equipment" under G.S. § 131E-184 and "comparable medical equipment" under 10A N.C.A.C. § 14C .0303.

40. The issues to be decided in this case are separate and distinct. This case involves whether the 2019 CON Decision correctly evaluated the Bone & Joint's 2019 application with regard to the review criteria in G.S. § 131E-183 and any applicable performance standards for MRI contained in 10A N.C.A.C. 14C .2703, as well as whether the Agency erred in finding the application should be approved.

41. Wake Radiology contends that the subject of the Prior Contested Case was the scope of the uses of the 3.0T MRI. Pet'r Sum. J. Mot. pp. 3 & 9. Even if the Petition in that case had sought to raise as an issue the scope of procedures Bone & Joint could perform with the 3.0T MRI, that issue would have been decided only in the context of the 2018 Exemption Decision, not the 2019 CON Decision.

42. Judge Ward's comments in the Final Decision regarding the scope of use were not a new finding, decision, or restriction. The limitations on the use of the 3.0T MRI were contained in the 2007 CON and were imposed by the Agency under the authority of G.S. § 131E-186, and the Final Decision in that case recognized that fact. *See* Final Dec. ¶ 18, p. 9.

43. The Final Decision further noted that those restrictions were subject to being changed through a modified 2007 CON or a new CON. To the extent the Final Decision purported to decide whether there were restrictions on scope of use of the 3.0T MRI, that was *obiter dicta* because that was not an issue before this Tribunal. It was therefore unnecessary to the ultimate holding that the Agency's 2018 Exemption Decision was proper. *Freedman v. Payne*, 253 N.C. App. 282, 287, 800 S.E.2d 686, 690 (2017) (citing *Hayes v. Wilmington*, 243 N.C. 525, 536, 91 S.E.2d 673, 681-82 (1956)).

44. To the extent, Wake Radiology claims that *res judicata* applies because both cases involve the same 3.0T MRI scanner, that argument is also rejected. An identity of subject matter does not also mean that two separate cases shared an identity of claims as required for application of *res judicata*. *Intersal, Inc. v. Hamilton*, 373 N.C. 89, 109, 834 S.E.2d 404, 418 (2019) (holding that *res judicata* did not apply to breach of contract claim because prior action involving same contract did not involve a breach of contract claim).

45. The two cases involve completely distinct causes of action, based on separate and distinct requests by Bone & Joint, and separate and distinct statutory and regulatory standards. At the time, the petition in the Prior Contested Case was filed, and at the time, the Final Decision was issued, and the Prior Contested Case was concluded, Bone & Joint had not filed its application, and the 2019 CON Decision had not been issued. The Prior Contested Case did not involve the same cause of action as this contested case. Because Wake Radiology has failed to prove all three elements, *res judicata*.

46. Wake Radiology's collateral estoppel contention on the merits suffers from the same defects as on the substantial prejudice issue. The Final Decision in the Prior Contested Case did not decide whether the Agency made any substantive or procedural errors in issuing the 2019 CON Decision as that decision had not been issued. It also did not decide what if any limitations were on the 3.0T MRI as that issue was not before it. The only issue decided in the Final Decision was whether the Agency's 2018 Exemption Decision was correct under G.S. § 150B-23(a). Any restrictions on the scope of use of the 3.0T MRI were contained in the 2007 CON itself which was not altered or at issue.

47. *Res judicata* and collateral estoppel are inapplicable to this case and do not dictate its substantive results about the appropriateness of the Agency's actions in the issuance of the 2019 CON Decision.

48. Wake Radiology's Motion for Summary Judgment on the issue of Agency error, based on the doctrines of *res judicata* or collateral estoppel, is denied. Because there are no genuine issues of material fact regarding whether Wake Radiology has established Agency error on either of these bases, the Undersigned grants summary judgment against Wake Radiology and in favor of the Agency and Bone & Joint pursuant to Rule 56(c) of the North Carolina Rules of Civil Procedure.

ISSUE 2. Whether the Agency had legal authority to issue the 2019 CON Decision which expanded the use of the 3.0T MRI to include full body scans?

49. Separately from its *res judicata* and collateral estoppel bases, Wake Radiology argues that the Agency lacked the authority to issue the 2019 CON Decision approving Bone & Joint's application. Based on the unique facts, in this case, the Undersigned rejects this argument and concludes that the Agency had the legal authority to make the 2019 CON Decision and to issue the 2019 CON as explained below.

A. The Agency Has Authority Over Implementation of the CON Laws

50. According to G.S. § 131E-177(1) & (6), the Agency is granted plenary power over the certificate of need laws of this State and it states that:

> The Department of Health and Human Services is designated as the State Health Planning and Development Agency for the State of North Carolina, and is empowered to exercise the following powers and duties:
>
> (1) To establish standards and criteria or plans required to carry out the provisions and purposes of this Article and to adopt rules pursuant to Chapter 150B of the General Statutes, to carry out the purposes and provisions of this Article;
>
> …
>
> (6) Have the power to grant, deny, or withdraw a certificate of need and to impose such sanctions as are provided for by this Article;

N.C. Gen. Stat. § 131E-177(1) & (6); s*ee also, AH N. Carolina Owner LLC v. N.C. Dep't of Health & Human Servs*., 240 N.C. App. 92, 100, 771 S.E.2d 537, 542 (2015) (explaining that Agency has authority to establish its standards regarding CON criteria).

51. Pursuant to its statutory authority, the Agency has issued regulations which further reflect that it has the authority to decide what requires a CON. 10A N.C.A.C. § 14C .0202(a) states that "the agency shall determine whether the proposed project requires a certificate of need."

52. Subpart (c) states:

> If the agency determines that the project requires a certificate of need, the agency shall determine the appropriate review category or categories for the proposed project, the type or types of application forms to be submitted, the number of separate applications to be submitted, the applicable review period for each application, and the deadline date for submitting each application, as contained in this Subchapter.

10A N.C.A.C. § 14C .0202(c); s*ee also, Hospice & Palliative Care Charlotte Region d/b/a Hospice at Charlotte v. North Carolina Department of Health and Human Services, Division of Facility Services, Certificate of Need Section*, 05 DHR 1211 2006 WL 2035400 (March 21, 2006) (Elkins, ALJ) (Agency decides whether a planned activity requires a certificate of need).

B. The "Expansion of the Use" of the 3.0T MRI Is Authorized by CON Law

53. According to Wake Radiology, the Agency did not have the authority to expand the type of procedures that may be performed using the 3.0T MRI scanner, and the statutes and administrative code provisions relied upon by the Agency and Bone & Joint do not support the contention that such authority exists. The Undersigned disagrees.

54. The Agency's authority to issue the 2019 CON is vested in two provisions of the CON Law: N.C. Gen. Stat. §§ 131E-176(16)(b) and 131E-176(16)(e).

55. Under N.C. Gen. Stat. § 131E-176(16)(b), the Agency can grant the "expansion" of an existing health service subject to certain conditions. N.C. Gen. Stat. § 131E-176(16)(e) allows the Agency to grant a "change in a project" for which a CON has already been issued.

56. Wake Radiology is correct that the acquisition of a MRI, other than as replacement equipment, requires a CON review. N.C. Gen. Stat. § 131E-176(16)(f1)(7). However in this case, Bone & Joint is applying to expand the use of its MRI existing health service, not to acquire another one.

57. Some new institutional health services do not require a certificate of need. North Carolina's certificate of need law specifically contemplates expanding an existing health service with a CON. *See* N.C.G.S. § 131E-176(16)(b).

58. One such exception to the certificate of need requirement is an expansion of a health service which costs less than two million dollars ($2 million). N.C.G.S. § 131E-176(16) states:

> Except as otherwise provided in G.S. 131E-184(e), the obligation by any person of a capital expenditure exceeding two million dollars ($2,000,000) to develop or *expand a health service* or a health service facility, or *which relates to the provision of a health service.* The cost of any studies, surveys, designs, plans, working drawings, specifications, and other activities, including staff effort and consulting and other services, essential to the acquisition, improvement, expansion, or replacement of any plant or equipment with respect to which an expenditure is made shall be included in determining if the expenditure exceeds two million dollars ($2,000,000).
>
> N.C. Gen. Stat. § 131E-176(16)(b) (emphasis added).

59. Because Bone & Joint did not propose to spend more than $2 million, a new CON arguably was not required, and the Agency could have permitted the expansion through a "no review" letter. *See Cape Fear Mem'l Hosp. v. N. Carolina Dep't of Human Res.*, 121 N.C. App. 492, 494, 466 S.E.2d 299, 301 (1996) ("the legislature clearly did not intend to impose unreasonable limitations on … expanding … presently offered health services.").

60. The Agency required Bone & Joint to complete the full certificate of need application process, which included a comment period and public hearing. The Agency's CON decision allowed Wake Radiology to take advantage of the opportunity to air their grievances about the application in a public forum. *See* Pet. Ex. 2 The Agency did not err in this regard.

61. Wake Radiology's argument that the 2019 CON Decision was error because there was no "need determination" in the SMFP also is rejected. The SMFP is clear that a need determination is required before a healthcare provider can make an "acquisition" of a new MRI scanner. Frisone Aff. ¶ 8. "An 'acquisition' is defined by Black's Law Dictionary as '[t]he gaining of possession or control over something.'" *Hope-A Women's Cancer Ctr., P.A. v. N. Carolina Dep't of Health & Human Servs., Div. of Health Serv. Regulation*, 203 N.C. App. 276, 284, 691 S.E.2d 421, 426 (2010) (quoting Black's Law Dictionary 24 (7th ed. 1999)). Bone & Joint did not propose the acquisition of a new MRI scanner because it already owns the 3.0T MRI at issue, having acquired it in 2019 based on the Final Decision's holding that it was "replacement equipment". The absence of a "need determination" for an MRI in the SMFP is irrelevant.

62. Bone & Joint's request to provide new and expanded MRI services and procedures with its 3.0T MRI met the requirements of G.S. § 131E-176(16)(b) and did not necessarily require a certificate of need. However, in this case, the Agency's determination that the CON Review Process was necessary was appropriate because, without a new certificate of need, Bone & Joint's MRI was subject to the limitations of its 2007 Application and the limitations in the 2007 CON. *See* G.S. § 131E-181 & 186. Bone & Joint filed an application on the form required by the Agency by the deadline set by the Agency. The Agency reviewed the application as required by G.S. § 131E-185, received comments, conducted the public hearing, and timely issued the decision and findings required by law and concluded that the CON should be issued. Frisone Aff. ¶ 10-11.

63. The Agency's decision and interpretation of its basic authority are subject to deference because the Agency itself is the agency that is charged with administering the certificate of need law. An agency's interpretation of a statute that it is tasked with administering should be accorded some deference by the reviewing tribunal. North Carolina law gives great deference to an agency's interpretation of a law it administers. *Frye Reg'l Med. Ctr. v. Hunt*, 350 N.C. 39, 45, 510 S.E.2d 159, 163 (1999).

64. The Agency's interpretation and application of the statutes it is empowered to enforce are entitled to deference as long as the Agency's interpretation is reasonable and based on a permissible construction of the statute. *Good Hope Health Sys. v. N.C. Dep't of Health & Human Servs.*, 189 N.C. App. 534, 544, 659 S.E.2d 456, 463 (2008), *aff'd*, 632 N.C. 504, 666 S.E.2d 749 (2008); *see also Carpenter v. N.C. Dep't of Human Res.*, 107 N.C. App. 278, 279, 419 S.E.2d 582, 584 (1992), *disc. rev. improvidently allowed*, 333 N.C. 533, 427 S.E.2d 874 (1993). *See Blue Ridge Healthcare Hosps. Inc. v. N. Carolina Dep't of Health & Human Servs., Div. of Health Serv. Regulation, Healthcare Planning & Certificate of Need Section*, 255 N.C. App. 451, 459–60, 808 S.E.2d 271, 276–77 (2017); *AH N. Carolina Owner*, 240 N.C. App. at 110, 771 S.E.2d at 547; *Craven Reg'l Med. Auth. v. N.C. Dep't of Health & Human Servs*., 176 N.C. App. 46, 58, 625 S.E.2d 837, 844 (2006).

65. Moreover, Wake Radiology cites no authority for the proposition that the Agency lacks authority to decide what projects require a certificate of need or that the Agency lacks power to exercise its fundamental authority to regulate and administer the certificate of need laws.

66. The Undersigned concludes that in light of the unique facts in this case, *e.g.* an existing MRI machine which had additional capabilities that could not be utilized without a new CON, that the Agency acted reasonably within its authority.

C. The "Change in Project" Provision is Authorized by CON Law

67. In the alternative, the Agency determined that Bone & Joint's desire to expand its capabilities and offer new MRI services implicated the "change in a project" provision found in the definition of "new institutional health service" in G.S. § 131E-176(16)(e). Frisone Aff. ¶ 10-18. That section states in relevant part:

> A change in a project that was subject to certificate of need review and for which a certificate of need was issued, if the change is proposed during the development of the project or within one year after the project was completed.

N.C. Gen. Stat. § 131E-176(16)(e).

68. The 2007 CON was issued as a demonstration project for development of a diagnostic center with an extremity MRI scanner. Demonstration projects are created by the SHCC in order to determine whether certain technologies, techniques or health service projects might have wider use. The SHCC governs demonstration projects and their scope and duration. On May 29, 2019, the SHCC approved a recommendation from its Technology and Equipment Committee (chaired by one of Petitioner's owners) to declare the 2007 demonstration project was complete. Pet., Ex. 1 (Findings) at 2; Frisone Aff. ¶ 6, Ex. C. Wake Radiology does not challenge the SHCC's authority to determine when a demonstration project is completed. The CON Law does not address the completion of a demonstration project.

69. Within one year of the SHCC determining that Bone & Joint's demonstration project was complete, Bone & Joint filed its 2019 Application requesting to modify the scope of the project to add new health services in the form of unrestricted MRI capabilities. The Agency determined that the application was proper and therefore proceeded to review and approve the application and award the 2019 CON to Bone & Joint. Frisone Aff. ¶ 10-11, 18-20. That decision is entitled to deference.

70. Wake Radiology argues that this action was simply the modification of the 2007 CON and that there is no authority in the certificate of need law for such a modification.

71. Although the certificate of need law does not specifically include a provision permitting the Agency to "modify" a certificate of need, the law grants the Agency authority to issue new or additional certificates of need which have the same effect. For example, in *Surgical Care Affiliates, LLC v. N.C. Dep't of Health & Human Servs., Div. of Health Serv. Regulation, Certificate of Need Section*, 235 N.C. App. 620, 628, 762 S.E.2d 468, 473–74 (2014), Southern Eye Surgery Center had earlier obtained a certificate of need for the development of operating

rooms. After WakeMed acquired Southern Eye (and therefore the CON for the operating rooms) WakeMed sought to relocate the operating rooms to its Raleigh campus and to change them from dedicated outpatient only to shared inpatient and outpatient. Because the original CON conditioned the use of the operating rooms for the location stated in the original application, a new CON was required to change the location. In 2012, WakeMed applied for a new certificate of need to permit it to move the operating rooms to a new location and make them shared operating rooms. The application was not competitive because it involved existing operating rooms of Southern Eye/WakeMed. The Agency granted the new CON to permit WakeMed to move the operating rooms and make them shared operating rooms, which would have otherwise been contrary to the original CON.

72. Similarly, the SHCC has in the past, created demonstration projects for single-specialty ambulatory surgery centers ("ASC"), orthopedics for example. Tr. p. 44. Following a review, the Agency issued a CON for that single-specialty ASC and the ASC was constructed by the prevailing applicant. The CON would include limitations on the procedures that could be performed in the surgery center. After the conclusion of the demonstration project, if the healthcare provider saw that it had capacity in the ASC to perform types of procedures in addition to the single specialty, it would apply for a new CON to modify the types of procedures available at the ASC. In that instance, the first CON authorized the development of the ASC and the second CON authorized the increased utilization, furthering the goals of the CON law to have full utilization of the healthcare facilities and equipment. *See* Tr. pp. 44, 85-86, 88-89 (Mr. Adam and Ms. Burgon explaining demonstration projects).

72. The same is true here. The 2007 CON permitted Bone & Joint to acquire an MRI scanner, and Bone & Joint was permitted to operate it subject to the scope limitations in the 2007 CON. Bone & Joint's 2019 CON Application was filed to permit it to modify and expand the uses of its 3.0T MRI scanner. The Agency had legal authority to permit that change just as it had permitted WakeMed to change its scope of use for its operating rooms and permitted the ASC provider to increase the uses in the ASC.

73. The Undersigned concludes that the Agency had the power and authority to make the 2019 CON Decision and to issue the 2019 CON. Wake Radiology's Motion for Summary Judgment on that issue is denied. The Undersigned grants summary judgment against Wake Radiology on the issue of the Agency's authority to issue the 2019 CON Decision pursuant to Rule 56(c) of the North Carolina Rules of Civil Procedure.

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FINAL DECISION

BASED ON THE FOREGOING, the Undersigned hereby finds proper authoritative support of the conclusions of law noted above, and it is hereby ordered, adjudged, and decreed that:

Wake Radiology's Motion for Summary Judgment on the issues of substantial prejudice and Agency error, based on the doctrines of *res judicata* and collateral estoppel, is **DENIED**. The Undersigned **GRANTS** summary judgment against Wake Radiology and for the Agency and Bone & Joint on these issues.

Moreover, Wake Radiology has failed to prove substantial prejudice on any alternative grounds. Therefore, summary judgment that Wake Radiology was not substantially prejudiced by the Agency's 2019 CON Decision is **GRANTED** to the Agency and Bone & Joint.

Wake Radiology's Motion for Summary Judgment on the issue of the Agency's power and authority to issue the 2019 CON Decision is **DENIED.** The Undersigned **GRANTS** summary judgment against Wake Radiology and for the Agency and Bone & Joint on the issue of the Agency's power and authority to issue the 2019 CON Decision.

A Final Decision is hereby entered for Agency and Bone & Joint, and this case is **DISMISSED WITH PREJUDICE.**

NOTICE OF APPEAL RIGHTS

This is a Final Decision issued under the authority of N.C. Gen. Stat. § 131E-188.

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

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

In conformity with the Office of Administrative Hearings' Rule 26 N.C.A.C. 03 .0102 and the Rules of Civil Procedure, N.C. Gen. Stat. § 1A-1, Article 2, this Final Decision was served on the parties the date it was placed in the mail or served via electronic service as indicated on the Certificate of Service attached to this Final Decision.

IT IS SO ORDERED.

This the 12th day of June, 2020.

Stacey Bice Bawtinhimer
Administrative Law Judge

CERTIFICATE OF SERVICE

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

Frank Kirschbaum
Wyrick Robbins Yates & Ponton LLP
fkirschbaum@wyrick.com
Charles George
cgeorge@wyrick.com
Attorneys for Petitioner

Bethany A. Burgon
NC DOJ
bburgon@ncdoj.gov
Attorney for Respondent

James C. Adams, II
Brooks Pierce
jadams@brookspierce.com
Forrest W Campbell
fcampbell@brookspierce.com
Attorneys for Respondent-Intervenor

This the 12th day of June, 2020.

Anita M Wright
Paralegal
N. C. Office of Administrative Hearings
1711 New Hope Church Road
Raleigh, NC 27609-6285
Phone: 919-431-3000