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STATE OF NORTH CAROLINA

GUILFORD COUNTY
JOHNSTON COUNTY

IN THE OFFICE OF
ADMINISTRATIVE HEARINGS

Bio-Medical Application of North Carolina Inc d/b/a BMA of South Greensboro Petitioner, v. NC Department of Health and Human Services, Division of Health Service Regulation, Health Care Planning & Certificate of Need Section Respondent. And Total Renal Care of North Carolina, LLC, D/B/A Central Greensboro Dialysis, Respondent-Intervenor	**20 DHR 2366**
Bio-Medical Applications of North Carolina Inc d/b/a Fresenius Kidney Care West Johnston, Petitioner, v. NC Department of Health and Human Services, Division of Health Service Regulation, Health Care Planning & Certificate of Need Section, Respondent. And Total Renal Care of North Carolina, LLC, D/B/A Clayton Dialysis, Respondent-Intervenor	**20 DHR 2367**

FINAL DECISION

THIS MATTER comes for consideration by Administrative Law Judge Stacey Bice Bawtinhimer on the cross-motions for summary judgment filed by Petitioner Bio-Medical Applications of North Carolina, Inc. d/b/a BMA of South Greensboro and d/b/a Fresenius Kidney Care West Johnston ("Petitioner" or "BMA") and filed jointly by Respondent North Carolina Department of Health and Human Services, Division of Health Service Regulation, Healthcare Planning and Certificate of Need Section ("Respondent", "Agency", or "CON Section") and Respondent-Intervenor Total Renal Care of North Carolina, LLC d/b/a Central Greensboro Dialysis and d/b/a Clayton Dialysis ("Respondent-Intervenor" or "TRC"). A hearing was held on October 6, 2020, in Raleigh, North Carolina. With the record now closed, this matter is ripe for adjudication.

Having considered Petitioner's Motion for Summary Judgment and memoranda in support thereof; Respondent and Respondent-Intervenor's Joint Motion for Summary Judgment and memorandum in support thereof; Petitioner's Response in Opposition to Respondent and Respondent-Intervenor's Joint Motion for Summary Judgment; Respondent and Respondent-Intervenor's Response in Opposition to Petitioner's Motion for Summary Judgment and corresponding Notice of Filing; the Joint Stipulated Facts, the Proposed Decisions of all Parties, and the relevant law and arguments of counsel; the Undersigned hereby incorporates the Parties' Joint Stipulations of Undisputed Facts, makes the following Conclusions of Law, and enters this Final Decision **GRANTING** Respondent and Respondent-Intervenor's Joint Motion for Summary Judgment and **DENYING** Petitioner's Motion for Summary Judgment.

APPEARANCES

For Petitioner BMA:	Marcus C. Hewitt Elizabeth Sims Hedrick Fox Rothschild LLP 434 Fayetteville Street, Suite 2800 Raleigh, NC 27601
For Respondent Agency:	Derek L. Hunter Kimberly M. Randolph North Carolina Department of Justice P.O. Box 629 Raleigh, NC 27602-0629
For Respondent-Intervenor TRC:	Lee M. Whitman Wyrick Robbins Yates & Ponton, LLP 4101 Lake Boone Trail, Suite 300 Raleigh, NC 27607

ISSUES

1. Whether BMA was substantially prejudiced by the Agency's decisions which conditionally approved BMA's applications for 10 of the 12 stations that BMA applied for in the Guilford County review and for 2 of the 4 stations that BMA applied for in the Johnston County review (the "Substantially Prejudiced Issue")?

2. Whether the Agency erred in its approval of both TRC's applications because of the Agency's review of Criterions 3 and 5 (the "Agency Error Issue")?

APPLICABLE LAW

The procedural statutory law applicable to this contested case is the North Carolina Administrative Procedure Act, N.C. Gen. Stat. § 150B-1, *et seq.*, N.C. Gen. Stat. § 1A-1 *et seq.*, N.C. Gen. Stat. § 131E-188 of the North Carolina Certificate of Need Law and the Rules of the Office of Administrative Hearings promulgated at 26 N.C.A.C. 3.0001 *et seq.*

The substantive statutory law applicable to this contested case is the North Carolina Certificate of Need Law promulgated at N.C. Gen. Stat. § 131E-175, *et seq.* (the "CON law"). The substantive administrative rules applicable to this contested case are the North Carolina Certificate of Need Program Administrative Regulations, promulgated at 10A N.C.A.C. 14C. 2200 *et seq.*

STANDARD OF REVIEW

Summary judgment is proper "if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show 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); *see also Moore v. Coachmen Indus.*, 129 N.C. App. 389, 393-94, 499 S.E.2d 772, 775 (1998).

An issue is material if the facts alleged are of such a nature as to affect the result of the action or if the resolution of the issue is so essential that the party against whom it is resolved may not prevail. *Kessing v. Nat'l Mtg. Corp.*, 278 N.C. 523, 534, 180 S.E.2d 823, 830 (1971).

The Parties submitted a Joint Stipulation of Undisputed Facts which is incorporated herein after the Procedural Review Section of this decision *infra.* on page 2.

The movant for summary judgment has the burden of establishing that there are no genuine issues of material fact and that it is entitled to judgment as a matter of law. *Hines v. Yates*, 171 N.C. App. 150, 157, 614 S.E.2d 385, 389 (2005).

Once the moving party meets this burden, the non-moving party must "come forward with specific facts, as opposed to mere allegations, revealing those genuine issues." *Lexington State Bank v. Miller*, 137 N.C. App. 748, 751, 529 S.E.2d 454, 456 (2000).

Within the summary judgment context, the burden is on the movants, Respondent and Respondent-Intervenor, to prove that, even in the light most favorable to Petitioner BMA, there are no genuine issues of material fact that Petitioner BMA was not substantially prejudiced as a result of the Agency's decisions ("Substantially Prejudiced Issue"). Once the Agency and TRC meet his burden, BMA must proffer evidence that there are genuine issues of material fact on the Substantially Prejudice Issue otherwise BMA cannot prevail in its case because this issue is an essential element of BMA's case. Although BMA attached numerous exhibits to its dispositive motion and response to the opposing joint motion, BMA filed a response but proffered no evidence in opposition to Respondent and Respondent-Intervenor's joint dispositive motion.

Petitioner BMA as the movant for summary judgment with respect to the Agency Error Issue must prove that, even in the light most favorable to Respondent and Respondent-Intervenor, there are no genuine issues of material fact that the Agency erred in its conditional approval of TRC's application because of the application's nonconformity to Criterions 3 and 5 ("Agency Error Issue"). Likewise, once the BMA has met its burden, the Agency and TRC must proffer evidence that there is a genuine issue of material fact on this issue. The Agency and TRC offered evidence directly responsive to BMA's dispositive motion.

To prevail in its claims, BMA must prove both the essential prongs of substantial prejudice and agency error. Failure to demonstrate one is grounds for dismissal. *Surgical Care Affiliates, LLC v. N.C. Dep't of Health & Human Servs.*, 235 N.C. App. at 629-630, 762 S.E.2d 468, 474-475 (2014).

PROCEDURAL HISTORY

1. On January 17, 2020, BMA filed a Petition for Contested Case Hearing in the Office of Administrative Hearings in Guilford County, Case No. 20-DHR-00274, and a Petition for Contested Case Hearing in the Office of Administrative Hearings in Johnston County, Case No. 20-DHR-00276 (collectively called the "Petitions"), each seeking to overturn the CON Section's respective decisions to conditionally approve TRC's applications in full and to conditionally approve BMA's applications in part.

2. On January 31, 2020, the Honorable J. Randall May, the Administrative Law Judge ("ALJ") formerly assigned to Case No. 20-DHR-00274, issued an Order allowing TRC to intervene in the contested case with all of the rights of a party thereto.

3. On February 3, 2020, the Honorable Stacey Bice Bawtinhimer, the Administrative Law Judge assigned to Case No. 20-DHR-00276, issued an Order allowing TRC to intervene in the contested case with all of the rights of a party thereto.

4. On March 2, 2020, the Parties filed a Consent Petition for Consolidation of Case Nos. 20-DHR-00274 and 20-DHR-00276.

5. On March 3, 2020, the Honorable Julian Mann, III, Chief Administrative Law Judge, ordered the consolidation of Case Nos. 20-DHR-00274 and 20-DHR-00276, and reassigned Case No. 20-DHR-00274 to Judge Bawtinhimer.

6. On June 10, 2020, the Parties entered into a Consent Order and Voluntary Dismissal Without Prejudice. According to the terms of the Consent Order, BMA was allowed to re-file its Petitions for contested case hearing ("Petitions") within 5 days after the entry of the Consent Order by the Undersigned. The Consent Order also identified TRC as a respondent-intervenor as previously allowed by the Tribunal and maintained the consolidation of cases without further order from the presiding administrative law judge. On June 12, 2020, BMA re-filed its Petitions contesting the Agency's decisions. The re-filed Petitions were designated as Case Nos. 20-DHR-2366 and 20-DHR-2367.

7. On September 14, 2020, Petitioner filed a Motion for Summary Judgment and memorandum in support thereof. On September 14, 2020, Respondent and Respondent-Intervenor filed a Joint Motion for Summary Judgment and memorandum in support thereof.

8. On September 24, 2020, Petitioner filed a Response in Opposition to Respondent and Respondent-Intervenor's Joint Motion for Summary Judgment. On September 24, 2020, Respondent and Respondent-Intervenor filed a Joint Response in Opposition to Petitioner's Motion for Summary Judgment and a corresponding Notice of Filing.

9. On October 6, 2020, the Undersigned held a hearing on the Parties' cross-motions for summary judgment.

10. With the record closed, the matter is now ripe for adjudication.

JOINT STIPULATIONS OF UNDISPUTED FACTS

Petitioner Bio-Medical Applications of North Carolina, Inc., Respondent North Carolina Department of Health and Human Services, Division of Health Service Regulation, Healthcare Planning and Certificate of Need Section, and Respondent-Intervenor Total Renal Care of North Carolina, LLC, at the request of the Undersigned, jointly submitted the following Joint Stipulations of Fact. Other than minor formatting changes to the headings, the Joint Stipulations are completely incorporated herein by reference as numbered 1 through 58 ("Jt. Stip."):

Parties:

1. Petitioner Bio-Medical Applications of North Carolina, Inc. ("BMA") is a Delaware corporation authorized to do business in North Carolina.

2. BMA operates dialysis treatment centers across North Carolina, including at the time of the relevant CON reviews, seven existing facilities in Guilford County, and three existing facilities in Johnston County. In total, BMA had been previously approved for seven facilities including 235 dialysis stations in Guilford County, and five facilities including 90 dialysis stations in Johnston County.

3. Respondent North Carolina Department of Health and Human Services, Division of Health Service Regulation, Healthcare Planning, and Certificate of Need Section ("Agency"), is the State agency that administers the Certificate of Need Act ("CON Act"), N.C. Gen. Stat. Chapter 131E, Article 9.

4. Respondent-Intervenor Total Renal Care of North Carolina, LLC ("TRC") is a Delaware LLC authorized to do business in North Carolina. TRC's parent company is DaVita, Inc.

5. TRC operates dialysis treatment centers across North Carolina. At the time of the relevant CON reviews, TRC did not operate any dialysis facilities in Guilford County or Johnston County.

End-Stage Renal Disease:

6. End-Stage Renal Disease ("ESRD") is a medical condition in which a person's kidneys stop functioning permanently, leading to the need for a regular course of long-term dialysis or a kidney transplant to maintain the person's life.

7. Dialysis is the artificially aided process of transferring body waste from a person's blood to a dialysis fluid to permit discharge of the waste from the body. Hemodialysis is one form of dialysis in which the blood is circulated outside the body through an apparatus which permits transfer of waste through synthetic membranes.

CON Regulation of ESRD Facility Proposals:

8. A Certificate of Need ("CON") is required before any person[1] may offer or develop any "new institutional health service." N.C. Gen. Stat. § 131E-178(a). "New institutional health service" includes many types of healthcare facilities, services, and other projects enumerated in N.C. Gen. Stat. § 131E-176(16), including the development of a health service facility. N.C. Gen. Stat. § 131E-176(16)a.

9. Dialysis facilities (end-stage renal disease facilities subject to 42 C.F.R. § 405) are "kidney disease treatment centers" under the CON Act and are one type of health service facility. N.C. Gen. Stat. § 131E-176(9b), (14e). Thus, a CON is required before any person may develop a new dialysis facility in the state. A CON is also required to relocate dialysis stations from one location to another. N.C. Gen. Stat. § 131E-176(5)a, (16) c.

10. To grant a CON, the Agency must determine that a CON application is consistent with or does not conflict with certain statutory review criteria. N.C. Gen. Stat. § 131E-183(a).

11. "An application for a certificate of need shall be made on forms provided by the Department. The application forms, which may vary according to the type of proposal, shall require such information as the Department, by its rules deems necessary to conduct the review. 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 implemented under

[1] Person is defined broadly under the CON Act as "[a]n individual; a trust or estate; a partnership; a corporation, including associations, joint stock companies, and insurance companies; the State; or a political subdivision or agency or instrumentality of the State." N.C. Gen. Stat. § 131E-176(19) (Footnote include in Joint Stipulations).

G.S. 131E-183 and with duly adopted standards, plans, and criteria." N.C. Gen. Stat. § 131E-182(b).

The Guilford County Review:

12. The July 2019 Semiannual Dialysis Report ("SDR") identified a deficit of 20 dialysis stations in Guilford County.

13. Pursuant to Policy ESRD-2 in the State Medical Facilities Plan ("Policy ESRD-2"), a dialysis provider can increase the number of stations within the county by relocating existing stations from a contiguous county if the applicant can show that the relocation will not result in a deficit in the county losing stations or a surplus in the county gaining the stations.

14. On July 15, 2019, BMA and TRC submitted competing applications to the CON Section for the Guilford County review beginning August 1, 2019.

15. Both BMA and TRC submitted their applications pursuant to Policy ESRD-2. Because the July 2019 Semiannual Dialysis report identified a deficit of 20 dialysis stations in the Guilford County service area, the Agency could approve no more than 20 additional stations in the Guilford review.

16. In BMA's application, identified as Project I.D. No. G-11737-19, BMA proposed to relocate 12 existing dialysis stations from BMA Burlington in Alamance County to BMA of South Greensboro, an existing BMA dialysis facility in Guilford County.

17. In TRC's application, identified as Project ID No. G-11744-19, TRC proposed to develop a new 10-station dialysis facility in Guilford County by relocating seven dialysis stations from Reidsville Dialysis in Rockingham County and three dialysis stations from Burlington Dialysis in Alamance County.

18. The applications were competitive pursuant to 10A NCAC 14C.0202(f) because they collectively proposed 22 additional stations, and therefore could not both be approved as proposed.

19. The Agency determined that both Guilford County applications were complete for review and began review of the applications on August 1, 2019.

20. BMA and TRC each submitted written comments in opposition to the other's application.

21. By a decision dated December 20, 2019, the CON Section found both Guilford County applications conforming to all applicable statutory and regulatory criteria. Following a comparative analysis, the CON Section conditionally approved the TRC application to develop the new dialysis treatment facility with 10 dialysis stations, and conditionally approved BMA to develop 10 of the 12 dialysis stations it proposed.

22. The CON Section issued its Required State Agency Findings on the competing Guilford County CON applications on December 30, 2019.

The Johnston County Review:

23. The July 2019 SDR identified a deficit of 12 dialysis stations in Johnston County.

24. On or about July 15, 2019, BMA and TRC submitted competing applications to the CON Section for the Johnston County review beginning August 1, 2019.

25. BMA and TRC both submitted their Johnston County applications pursuant to Policy ESRD-2. Because the July 2019 Semiannual Dialysis Report identified a deficit of 12 dialysis stations in the Johnston County service area, the Agency could approve no more than 12 additional stations in the Johnston Review.

26. In BMA's application, identified as Project I.D. No. J-11739-19, BMA proposed to relocate 4 existing stations from its Southwest Wake County Dialysis facility in Wake County to Fresenius Kidney Care West Johnston, an approved dialysis facility in Johnston County that is not yet operational.

27. The Fresenius Kidney Care West Johnston facility has a certificate of need with an effective date of May 8, 2017 and had an original proposed completion date of December 31, 2019. However, the facility has been delayed and currently has a proposed completion date of June 30, 2021.

28. In TRC's application, identified as Project ID No. J-11743-19, TRC proposed to develop a new 10-station dialysis facility in Johnson County by relocating 5 dialysis stations from Forest Hills Dialysis in Wilson County and 5 dialysis stations from Wilson Dialysis in Wilson County.

29. The applications were competitive pursuant to 10A NCAC 14C.0202(f) because they collectively proposed 14 additional stations, and therefore could not both be approved as proposed.

30. The Agency determined that both Johnston County applications were complete for review and began review of the applications on August 1, 2019.

31. BMA and TRC each submitted written comments in opposition to the other's application.

32. By a decision dated December 20, 2019, the CON Section found both Johnston County applications conforming to all applicable statutory and regulatory criteria. Following a comparative analysis, the CON Section conditionally approved the TRC application to develop the new dialysis treatment facility with 10 dialysis stations, and conditionally approved BMA to relocate 2 of the 4 requested dialysis stations.

33. The CON Section issued its Required State Agency Findings on the competing applications on December 30, 2019.

The ESRD Application Form:

34. Deposition Exhibit 118 is a true copy of the Agency's application form used for proposals for kidney disease treatment centers which was in effect at the time of the Guilford County Review and the Johnston County Review ("ESRD Application Form").

35. The ESRD Application Form took effect with CON reviews beginning June 1, 2019, or after and included changes from previous application forms.

36. The Agency denied BMA's application to relocate two additional stations to its facility in Guilford County by approving relocation of only 10 of the 12 stations BMA proposed and denied BMA's application to relocate two additional stations to its facility in Johnston County by approving relocation of only 2 of the 4 stations BMA proposed.

Criterion 3 - Access:

37. Section C of the ESRD Application Form relates to N.C. Gen. Stat. § 131E-183(a)(3) ("Criterion 3").

38. Section C, Question 7 included the following language: "provide the estimated percentage of total patients for each group during the second [operating year] following completion of the project." The enumerated groups include all the underserved groups identified in Criterion 3, including "handicapped persons."

39. Previous versions of the ESRD Application Form that were effective in reviews starting before June 1, 2019, did not request estimated percentages of patients for the underserved groups listed in Criterion 3.

40. The ESRD application form did not specify how an applicant should estimate percentages by underserved groups or specify the bases for an applicant's estimates.

41. TRC's applications included estimated percentages for all of the categories of underserved groups identified in the statutory language of Criterion 3 and in Section C, Question 7 of the application form except for "handicapped persons." On the line item labeled "handicapped persons" in each application, TRC's response stated: "(data not captured)."

42. The Agency determined that both TRC Applications conformed to Criterion 3, including the "access" component of that criterion.

43. TRC's applications stated the following in response to Section C, Question 7 of the application form: "By policy, the proposed services will be made available to all residents in its service area without qualification. The facility will serve patients without regard to race, sex age, or handicap. We will serve patients regardless of ethnic or socioeconomic situation. We will make

every reasonable effort to accommodate all patients, especially those with special needs such as the handicapped…."

44. "Payor mix" refers to a breakdown by percentage of an applicant's patients by source of reimbursement for healthcare services. Commercial insurance, Medicare, Medicaid, and self-pay are all "payor" categories.

Criterion 5 – Capital Expenditures

45. Section A of the ESRD Application Form relates to the identification of the Applicant(s) and allows for one or multiple applicants.

46. "Applicant" is defined in the ESRD Application Form as "each person, as that term is defined in G.S. 131E-176(19), who will:

(a) Incur an obligation for a capital expenditure to develop or offer the proposed dialysis services; or
(b) Offer or develop the proposed dialysis services."

47. Section A, Question 6 of the CON application form requires applicants (a) to identify what entity will operate the proposed facility; (b) to identify the owner of the building if the applicant is not the owner; and (c) to explain whether the owner of the building has or will have "any joint or common ownership with the applicant," and if so, to explain the relationship.

48. TRC is the sole applicant in both its Guilford County application and its Johnston County application.

49. In both applications, TRC identified its parent company as DaVita Inc.

50. In response to Section A, Question 6(a), TRC identified itself in both applications as the operator of the proposed dialysis facility.

51. In response to Section A, Question 6(b), TRC indicated in both applications that TRC would not own the building where the proposed facility would be located. The building owner was identified as: "[a] subsidiary of DaVita Inc. The specific subsidiary will be determined at a later date."

52. In response to Section A, Question 6(c), which asks: "Does the owner of the building or will the owner of the building have any joint or common ownership with the applicant?", TRC responded "No" in both applications.

53. The application form defines the term "Related Entities" as follows: "When used in this application form, the term "related entities" means persons that:

(a) Share the same parent corporation or holding company; or
(b) Are a subsidiary of the same parent corporation or holding company; or

(c) Are participants in a joint venture which provides dialysis services."

54. Section F of the ESRD Application Form relates to N.C. Gen. Stat. § 131E-183(a)(5) ("Criterion 5"). Section F, Question 1 and Form F.1a, require the applicant(s) to itemize the capital costs of the project.

55. Section F, Question 2 of the ESRD Application Form requires documentation that funds for the projected capital costs for the project are available for and committed to the project.

56. In response to Section F, Question 2, TRC provided a letter from the CFO of its parent entity, DaVita, Inc., to document that funds were available and committed for the capital costs identified in each of its applications. The amount of funds that were identified in both letters as available and committed for the capital costs of the projects were the same as the total capital costs of the project identified in TRC's applications.

57. The Agency found both of TRC's applications conforming to Criterion 5.

Exhibits, Transcripts and Documentary Evidence:

58. All exhibits, transcripts, and other documentary evidence submitted with the Parties' motions for summary judgment are authentic.

CONCLUSIONS OF LAW

Upon consideration of Petitioner's Motion for Summary Judgment[2], Respondent and Respondent-Intervenor's Joint Motion for Summary Judgment, the memoranda in support thereof filed by the respective Parties, Petitioner's Response in Opposition to Respondent and Respondent-Intervenor's Joint Motion for Summary Judgment, and Respondent and Respondent-Intervenor's Joint Response in Opposition to Petitioner's Motion for Summary Judgment, and the oral arguments of counsel at the October 6, 2020, hearing on the Parties' aforementioned cross-motions for summary judgment, and based upon the foregoing Joint Stipulations of Undisputed Facts, the Undersigned hereby enters the following Conclusions of Law:

1. To the extent that any portion of the foregoing Joint Stipulations of Undisputed Facts constitutes mixed issues of law and fact, such undisputed findings of fact shall be deemed incorporated herein by reference as Conclusions of Law. Similarly, to the extent that any of the following Conclusions of Law is a Finding of Fact, it shall be so considered in spite of its designation as a Conclusion of Law.

2. The Parties are properly before the Office of Administrative Hearings. The Office of Administrative Hearings has jurisdiction over the Parties and the subject matter of this action. The Parties received proper notice of the summary judgment hearing in this matter.

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[2] These documents are referenced herein as: "Pet'r Mot. Sum J."; "Pet'r Mem. Sum. J.", "Pet'r Not. of Filings"; "Pet's Ex."; "Resp't/Resp't Inter'r Jt. Mot. Sum. J.", "Pet'r Resp."; "Resp't/Resp't Inter'r Jt. Resp."; "Jt Not. of Filings", "Resp't/Resp't Inter'r Ex."; and "Jt. Stip."

I. SUBSTANTIALLY PREJUDICED ISSUE:

Whether BMA was substantially prejudiced by the Agency's decisions which conditionally approved BMA's applications for 10 of the 12 stations that BMA applied for in the Guilford County review, and for 2 of the 4 stations that BMA applied for in the Johnston County review?

3. The subject matter of the above-captioned consolidated contested cases are the CON Section's decisions to conditionally approve, in full, TRC's applications and to conditionally approve, in part, BMA's applications in the Guilford and Johnston County reviews. N.C. Gen. Stat. §§ 131E-188(a) (providing for administrative review of Agency decision to issue, deny or withdraw certificate of need) and 150B-23(a) (providing for a contested case petition challenging an administrative agency's action); *Presbyterian Hosp. v. N.C. Dep't of Health & Human Servs., 177* N.C. App. 780, 784, 630 S.E.2d 213, 215 (2006).

4. N.C. Gen. Stat. § 131E-188 allows "affected persons" who disagree with a decision of the Agency to approve, deny, or conditionally deny another party's CON application to petition for a contested case hearing to challenge the Agency's decision under Article 3 of Chapter 150B of the North Carolina General Statutes. *See* N.C. Gen. Stat. § 131E-188(a).

5. BMA is an "affected person" pursuant to N.C. Gen. Stat. § 131E-188 because it was an applicant in the Guilford and Johnston County reviews. N.C. Gen. Stat. § 131E-188(c).

6. A "person aggrieved" as defined by N.C. Gen. Stat. § 150B-2(6) "means an person or group of persons of common interest directly or indirectly *affected substantially* in his or its persons, property, or employment by an administrative decision." The term "person includes corporations such as BMA. N.C. Gen. Stat § 150B-2(7) (emphasis added).

A. The Burden of Proof:

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

8. Under the Administrative Procedure Act ("APA"), a petitioner must prove 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).

9. To prevail, BMA must establish that: (1) its rights were substantially prejudiced as a result of the CON Section's decisions; and (2) the CON Section "acted outside its authority, acted erroneously, acted arbitrarily and capriciously, used improper procedure, or failed to act as required by law or rule." N.C. Gen. Stat. § 150B-23; *Parkway Urology, P.A. v. N.C. Dep't of Health & Human Servs.,* 205 N.C. App. 529, 696 S.E.2d 187 (2010).

10. The burden of proving the facts required by N.C. Gen. Stat. § 150B-23(a) is by a preponderance of the evidence, the standard of proof established and required by N.C. Gen. Stat. § 150B-29(a). *Britthaven, Inc. v. N.C. Dep't of Health & Human Servs.,* 118 N.C. App. 379, 382, 455 S.E.2d 455, 459, *disc. review denied,* 341 N.C. 418, 461 S.E.2d 754 (1995).

11. However, at the summary judgment stage of this proceeding, BMA must only establish that there are questions of material fact about whether its rights were substantially prejudiced which as established below, BMA did not do.

Substantial Prejudice Is an Independent Element of BMA's Burden.

12. In order to be entitled to relief, BMA must demonstrate there are questions of material fact on how the Agency's decisions substantially prejudiced BMA's rights and that the Agency erred in one of the ways described in N.C. Gen. Stat. § 150B-23(a). N.C. Gen. Stat. § 150B-23; *Presbyterian Hosp.*, 177 N.C. App. 780, 630 S.E.2d 213.

13. Substantial prejudice and agency error are two separate and distinct prongs of Petitioner's burden. *Surgical Care Affiliates, LLC v. N.C. Dep't of Health & Human Servs.*, 235 N.C. App. at 629-630, 762 S.E.2d 468, 474-475 (2014). Each of these prongs is an essential element of BMA's case, and failure to demonstrate either one, standing alone, is grounds for dismissal. *Id.*

14. Essentially, failure to demonstrate substantial prejudice is fatal to a petitioner's case. *Parkway Urology*, 205 N.C. App. at 539, 696 S.E.2d at 195; *Surgical Care Affiliates,* 235 N.C. App. at 629-630, 762 S.E.2d at 475; *CaroMont Health, Inc. v. N.C. Dep't of Health & Human Servs.*, 231 N.C. App. 1, 751 S.E.2d 244 (2013); *Wake Radiology 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 (Sept. 6, 2011) (unpublished), *review denied*, 366 N.C. 229, 726 S.E.2d 838 (June 13, 2012); a*lso see Presbyterian Hosp.*, 177 N.C. App. 780, 630 S.E.2d 213 (upholding an administrative law judge's grant of summary judgment on the basis that petitioner failed to demonstrate substantial prejudice).

Status as an "Affected Person" Does Not Relieve Petitioner from Having to Show Substantial Prejudice.

15. Substantial prejudice requires more than a showing that a petitioner is an "affected person" as provided in N.C. Gen. Stat. § 131E-188(a). *Parkway Urology*, 205 N.C. App. at 535-536, 696 S.E.2d at 192-193.

16. While BMA has demonstrated that it is an "affected person" entitling BMA to commence a contested case with OAH to challenge the Agency's decisions, BMA's status as an "affected person" does not obviate the need for BMA to demonstrate it was substantially prejudiced as required by N.C. Gen. Stat. § 150B-23(a). *Id.* (holding that petitioner's contention that its status as an affected person entitled it to relief without any showing of substantial prejudice was contrary to North Carolina case law and without merit); *CaroMont Health,* 231 N.C. App. at 4-5, 751 S.E.2d at 248.

17. Although N.C. Gen. Stat. § 131E-188(a) provides the prerequisites to filing a petition for a contested case hearing, it "does not alter the statutory requirements that must be met in order for a petitioner to be entitled to relief" under N.C. Gen. Stat. §150B-23(a). *Parkway Urology*, 205 N.C. App. at 536, 696 S.E. 2d at 193; *see* N.C. Gen. Stat. § 131E-188(a) ("…any affected person…shall be entitled to a contested case hearing under Article 3 of Chapter 150B of the General Statutes…").

18. The mere taking of an action by the Agency does not absolve the petitioner of its obligation to demonstrate how that action caused it to suffer substantial prejudice. *Surgical Care Affiliates*, 235 N.C. App. at 630, 762 S.E.2d at 475.

19. N.C. Gen. Stat. §150B-23(a) thus requires that "the ALJ [ ] 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." *Parkway Urology*, 205 N.C. App. at 536, 696 S.E. 2d at 193 (emphasis in original); *see Eastern Carolina Internal Med., P.A. v. N.C. Dep't of Health & Human Servs.*, 211 N.C. App. 397, 405, 710 S.E.2d 245, 251-252 (2011); *see also Britthaven, Inc.*, 118 N.C. App. at 382, 455 S.E.2d at 459; Presbyterian Hosp., 177 N.C. App. at 784, 630 S.E.2d at 265.

20. Accordingly, a petitioner cannot establish substantial prejudice as a matter of law simply by virtue of its status as an "affected person".

21. Similar to the right of an "affected person" to bring a contested case under N.C. Gen. Stat. § 131E-188(a), a "person aggrieved" may commence a contested case under the Administrative Procedure Act where there is no ability for a person under a more specific statute (here N.C. Gen. Stat. § 131E-188 of the CON Law) to commence a contested case. N.C. Gen. Stat. § 150B-23(a).

22. As discussed previously, North Carolina case law is clear that "substantial prejudice" requires more than a showing that a petitioner is merely an "affected person". *Parkway Urology*, 205 N.C. App. at 535-536, 696 S.E.2d at 192-193.

23. Likewise, and analogously, substantial prejudice requires more than a mere showing that a petitioner is a "person aggrieved" as provided in N.C. Gen. Stat. § 150B-2(6), and a petitioner cannot establish substantial prejudice as a matter of law simply by virtue of alleging that it is a "person aggrieved".

B. BMA's Claims of Substantial Prejudice:

24. BMA argues that BMA has been substantially prejudiced, as a matter of law, on three (3) separate bases.

25. The first is that the Agency's decision to reduce the number of diagnosis stations awarded to BMA automatically substantially prejudiced its rights (the "Partial Award Claim").

26. Second, BMA claims that the Agency's decisions substantially prejudiced its ability to conduct a "lawful business" ("Conduct Lawful Business Claim").

27. Finally, BMA asserts that its liberty and property rights were substantially prejudiced because the Agency's decisions interfered with BMA's ability to conduct its own business "as it sees fit." This final basis appears to be a constitutional challenge that the CON law violated BMA's substantive due process rights ("Liberty and Property Rights Claims").

28. Of significance is that BMA attached numerous exhibits to its response to the opposing joint dispositive motion but with respect to proof of substantial prejudice, BMA has offered no fact witnesses, no expert witness, no Rule 30(b)(6) witness, no data, no reports, no analysis or other documentation produced in discovery, and no evidence quantifying any financial harm to BMA.

29. Basically, BMA has offered no evidence of any kind in opposition to the Agency and TRC's Motion for Summary Judgment on this issue.

30. Even when asked by the Undersigned at the hearing what data or evidence BMA had of any harm, BMA's counsel asserted that no evidence was produced because in prior cases such evidence has been considered as "too speculative".

31. According to BMA this issue is a matter of law, not fact. The Undersigned disagrees as shown below.

1. The Partial Award Claim:

BMA Failed to Proffer any Supporting Evidence That the Agency Substantially Prejudiced Its Rights Because of the Partial Award.

32. BMA's primary argument is that it has been substantially prejudiced because it was only awarded part of the dialysis facilities, i.e. the Partial Award Claim.

33. Paragraph 18 of BMA's Petitions and BMA's discovery responses allege that BMA was substantially prejudiced by the Agency's decisions to deny BMA two (2) stations in Guilford County and two (2) stations in Johnston County because TRC's proposed facilities and BMA's

facilities would be in "close proximity" to each other and TRC's operations would be "likely to have a negative impact on BMA's operations." (BMA's Petitions for Contested Case Hearing, ¶ 18; Jt. MSJ Ex. 6, pp. 10-13, 32; Jt. MSJ Ex. 7, pp. 11-13, 31).

34. In this argument, BMA essentially claims that the award of dialysis stations to TRC has increased the competition for patients.

35. However, to demonstrate substantial prejudice, a petitioner must show more than increased competition. *Parkway Urology*, 205 N.C. App. at 535-536, 539, 696 S.E.2d at 192-193, 195; *see also Cumberland County Hospital System, Inc. v. N.C. Dep't of Health and Human Servs.,* 237 N.C. App. 113, 123, 764 S.E.2d 491, 498 (2014); *CaroMont Health*, 231 N.C. App. at 8-10, 751 S.E.2d at 250-251; *Novant Health v. N.C. Dep't of Health & Human Servs.*, 223 N.C. App. 362 (2012).

36. A petitioner is "required to provide specific evidence of harm resulting from the award of the CON [] that went beyond any harm that necessarily resulted from additional [] competition." *Parkway Urology,* 205 N.C. App. at 539, 696 S.E.2d at 195.

37. "The harm required to establish substantial prejudice cannot be conjectural or hypothetical. It must be concrete, particularized, and 'actual' or imminent." *Surgical Care Affiliates*, 235 N.C. App. at 631, 762 S.E.2d at 476. A petitioner's claim of substantial prejudice thus must be based on more than conjecture or allegations. *CaroMont Health*, 231 N.C. App. at 6, 751 S.E.2d at 249; *Ridge Care, Inc. v. N.C. Dep't of Health & Human Servs.*, 214 N.C. App. 498, 506; 716 S.E.2d 390, 396 (2011).

38. In this case, BMA has presented no evidence of substantial prejudice beyond establishing that BMA was denied the opportunity to operate 2 additional stations in Guilford County (where BMA has been previously approved to operate 235 dialysis stations) and 2 additional stations in Johnston County (where BMA has been previously approved to operate 90 stations).

39. North Carolina courts have rejected claims of substantial prejudice that are based on speculation or unsupported testimony, or where "the party did not provide data, analysis, or support for its claim." *Ridge Care*, 214 N.C. App. at 506, 716 S.E.2d at 396; *see Wake Radiology*, 215 N.C. App. 393, 716 S.E.2d 87, 2011 WL 3891026, at *8, 10; *see CaroMont Health*, 231 N.C. App. at 6, 751 S.E.2d at 249.

40. Here, BMA failed to provide any data, analysis, or support for its claim of substantial prejudice either through testimony, affidavit or other documentary evidence, leaving BMA with only its bare and unsupported allegations. These allegations are insufficient to demonstrate substantial prejudice under circumstances where BMA was approved for 75% (12 of 16) of the stations that it applied for and the denial of 2 stations is less than 1% of BMA's current station count in Guilford County (2/235 = .0085) and the denial of 2 stations is less than 3% of BMA's current station count in Johnston County (2/90 = .022).

41. In a previous Nash County case involving the same parties, same counsel for BMA and TRC, same expert witness for BMA, and a competitive review regarding competing proposals from BMA and TRC to address a station deficit identified in the Semi-Annual Dialysis Report,

Administrative Law Judge Augustus Elkins ruled that "BMA cannot establish substantial prejudice by virtue of the fact that BMA is currently the only dialysis provider operating facilities in Nash County and that the approval of the TRC application will result in increased competition," and that "[t]he fact that BMA's request for 11 stations was denied, in and of itself, does not amount to substantial prejudice." *Bio-Medical Applications of N.C. v. N.C. Dep't of Health & Human Servs.,* 14 DHR 05495, 2015 WL 3813968, at ¶¶ 29 and 31 (N.C. OAH Mar. 26, 2015).

42. When BMA appealed that Nash County decision to the North Carolina Court of Appeals, BMA contended "that the denial of BMA's competitive application to develop four of the eleven dialysis stations for which it had demonstrated need constituted substantial prejudice." *Bio-Medical Applications of N.C., Inc. v. N.C. Dep't of Health & Human Servs.*, 247 N.C. App. 899, 788 S.E.2d 684 (Table), 2016 WL 3166601, at *1 (June 7, 2016) (unpublished). However, the North Carolina Court of Appeals rejected that argument under circumstances where BMA was approved for 7 of the 11 stations that it applied for and ruled that "BMA's inability to establish substantial prejudice as a result of the CON Section's decisions to use the erroneous AACR and the patient letters leaves us no other choice but to affirm the Final Decision." *Id*. at *3.

43. According to BMA, the Nash case is distinguishable from the current case. The Undersigned agrees with BMA, in part.

44. In the Nash County case, BMA argued that the Agency's reliance on an erroneous AACR substantially prejudiced it because this reliance deprived BMA of 7 of the 11 dialysis stations for which it had applied. *Id*. at *3. However, the Court noted that had the AACR been accurate, BMA and TRC both would have gotten zero (0) stations. *Id.* at *4.

45. The Court of Appeals decided that BMA was not substantially prejudiced because it got 7 stations when it would have gotten 0 if the AACR had been accurate. As a result, BMA "substantially benefited" from the erroneous AACR.

46. In the present case, there is no concern about the accuracy of the AACR and effect of that inaccuracy on the award of dialysis stations. But here, like that case, BMA again complains about receiving only a portion of the diagnosis stations. The harm from the partial award is at issue.

47. Regardless of whether the disparate treatment of BMA was due to the inaccuracy of the AACR or the reduction of the number of diagnosis stations awarded, for either event BMA must still prove by admissible evidence that it was substantially prejudiced by the Agency's action.

48. BMA cannot merely assert in its Petitions and pleadings that receipt of only a portion of the diagnosis stations substantially prejudiced its rights, as the opposing party to a summary judgment motion, BMA must at least attempt to show how the Agency's decision substantially prejudiced, its rights. N.C. Gen. Stat.§ 1A-1, Rule 56.

49. In BMA's Response to Respondent/Respondent-Intervenors' Motion for Summary Judgment, BMA has offered no testimony, affidavit, or other evidence from any fact witness, expert witness, or Rule 30(b)(6) designee regarding how or why the denial of only 2 stations in Guilford County (where BMA had already been previously approved for seven (7) dialysis facilities and 235 dialysis stations) and only 2 stations in Johnston County (where BMA had

already been previously approved for five (5) dialysis facilities and 90 dialysis stations) would "substantially" affect or prejudice BMA.

50. In BMA's own Motion for Summary Judgment has offered no testimony, affidavit, or other evidence from any fact witness, expert witness, or Rule 30(b)(6) designee regarding how or why the denial of only 2 stations in Guilford County (where BMA had already been previously approved for seven (7) dialysis facilities and 235 dialysis stations) and only 2 stations in Johnston County (where BMA had already been previously approved for five (5) dialysis facilities and 90 dialysis stations) would "substantially" affect or prejudice BMA.

51. Likewise, when asked by the Undersigned at the hearing BMA proffered no evidence regarding how or why the denial of only 2 stations in Guilford County (where BMA had already been previously approved for seven (7) dialysis facilities and 235 dialysis stations) and only 2 stations in Johnston County (where BMA had already been previously approved for five (5) dialysis facilities and 90 dialysis stations) would "substantially" affect or prejudice BMA.

2. Conduct Lawful Business Claim:

BMA Failed to Proffer any Supporting Evidence That the Agency Substantially Prejudiced Its Right to Engage in An Otherwise Lawful Business.

52. BMA alleges that the Agency's decisions "den[y] BMA of its right to engage in otherwise lawful business by precluding BMA from spending its own money to develop two dialysis stations needed for its business operations." (Jt. MSJ Ex. 6, pp. 9-10, 12, 31; Jt. MSJ Ex. 7, pp. 9-10, 12-13, 31).

53. "Everyone [has] the right to enjoy the fruits and advantages of his own enterprise, industry, skill, and credit. He has no right to be protected against competition." *Coleman v. Whisnant*, 225 N.C. 494, 506, 35 S.E.2d 647, 655 (1945).

54. BMA was not precluded from applying for the dialysis stations available in the Guilford and Johnston County reviews and did in fact apply for the number of stations it desired in both Guilford and Johnston Counties. Accordingly, BMA "is not being prevented from benefiting from 'the fruits and advantages of [its] own enterprise, industry, skill, and credit,' but is merely being required to compete for such benefit." *Bio-Medical Applications v. N.C. Dep't of Health and Human Servs*., 179 N.C. App. 483, 491-492, 634 S.E.2d 572, 578 (2006) (quoting *Coleman*, 255 N.C. at 506, 35 S.E.2d at 665).

55. Since BMA has no right to be protected from lawful competition, the Agency's decisions to deny BMA two (2) stations in Guilford County (where BMA had been previously approved for seven (7) dialysis facilities and 235 dialysis stations), and two (2) stations in Johnston County (where BMA had been previously approved for five (5) dialysis facilities and 90 dialysis stations and is the only provider of dialysis services) does not deprive BMA of the right to "conduct lawful business" in these counties. A certificate of need is a prerequisite for BMA, as a provider of dialysis facilities and services, to conduct a "lawful" business. The requirement of which BMA has not contested when BMA has been the recipient of numerous dialysis stations in past ESRD reviews.

56. To survive summary judgment, BMA has to proffer evidence that would permit the Tribunal to understand or conclude how and/or to what extent the denial of only 2 stations in Guilford County and only 2 stations in Johnston County under the particular facts and circumstances of this case would adversely affect BMA's business operations, if at all.

57. But BMA failed to produce any such evidence in discovery, during depositions, or in connection with the summary judgment motions and hearing that would permit the Undersigned to understand or conclude how and/or to what extent the denial of only 2 stations in Guilford County and only 2 stations in Johnston County under the particular facts and circumstances of this case would adversely affect BMA's business operations, if at all. This is particularly the case given that the Agency approved BMA for 12 of the 16 stations (75%) for which it applied and the denial of 2 stations is less than 1% of BMA's current station count in Guilford County (2/235 = .0085) and the denial of 2 stations is less than 3% of BMA's current station count in Johnston County (2/90 = .022).

3. Liberty and Property Rights Claim:

BMA Failed to Proffer any Supporting Evidence that the Agency Substantially Prejudiced Its Liberty Interest and Property Rights to Conduct Business as " It Sees Fit".

58. Similar to its argument that it was denied the right to conduct its lawful business, BMA asserts that:

> it is a person aggrieved simply by virtue of the undisputed facts that BMA applied to relocate 12 stations to its facility in Guilford County and 4 stations to its facility in Johnston County, but the Agency decision only allows it to move 10 and 2 stations, respectively. As explained in the memorandum in support of BMA's Motion, BMA has *both a liberty interest as well as a property right in conducting its business in the manner it sees fit*.
>
> Pet'r Resp. p. 6 (emphasis added).

59. The deprivation of a person's "property" by an agency decision is a separate basis for filing a petition under N.C. Gen. Stat. § 150B-23(a). According to BMA, the ability to "conduct business as it sees fit" is both a liberty interest and a property interest regardless of the amount of harm.

60. BMA asserts that the current CON law violates its substantive due process rights of liberty and property as set forth in Article I, Section 1 and Section 19 of the North Carolina Constitution and that <u>any</u> exercise by the State of its police power is a deprivation of liberty. Pet'r Memo. Sum. J. p. 24.

61. Article I, Section 1 establishes that all persons are afforded the "inalienable rights [of] ... life, liberty, the enjoyment of the fruits of their own labor, and the pursuit of happiness." N.C. Const. art. I, § 1. Article I, Section 19 provides, "[n]o person shall be ... deprived of his life,

liberty, or property, but by the law of the land." N.C. Const. art. I, § 19 *Hope--A Women's Cancer Ctr., P.A. v. State*, 693 S.E.2d 673, 680 (N.C. Ct. App. 2010).

62. As a successful applicant in many other similar reviews, BMA should understand that the fundamental purpose of the CON Act is to ***limit the construction of health care facilities*** to those that are needed by the public and that can be operated efficiently and economically for its benefit. *Living Centers-Southeast v. N.C. Dep't of Health & Human Servs.*, 138 N.C. App. 572, 574, 532 S.E.2d 192, 194 (2000) (emphasis added).

63. 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. *See* N.C. Gen. Stat. §§ 131E-175(7), 131E-183(a).

64. The CON laws were designed to prohibit a health care facility, like BMA or TRC, from "conduct[ing] its business as it sees fit" including building new health care facilities or providing new health care services anywhere "it sees fit" if these facilities are redundant or likely to increase health care expense.

65. In enacting the CON law, the General Assembly made certain findings of fact about the need for the law. Specifically, it seeks to prevent the development of services that are unnecessary or unlikely to be well utilized because such services tend to increase the expense of health care and unnecessarily burden the public. *See, e.g.*, N.C. Gen. Stat. § 131E-175(4), (6).

66. BMA argued that the "property rights" in the case of *In re Certificate of Need for Aston Park Hosp.* "are the same rights implicated by the Agency's decision here." (Pet. Mem. Sum. J. pp. 24-25). However, the *Aston Park* case did not involve a claim for substantial prejudice under N.C. Gen. Stat. § 150B-23, but instead involved a question of whether the predecessor version of the current CON law was constitutional. Furthermore, the holding in *Aston Park* has been superseded by statute. *See In re Certificate of Need for Aston Park Hosp.*, 282 N.C. 542, 550, 193 S.E.2d 729, 735 (1973), superseded by statute as stated in *Hope – A Women's Cancer Center, P.A. v. State of N.C.*, 203 N.C. App. 593, 693 S.E.2d 673 (2010) (holding "[t]he current CON law is distinguishable from the one invalidated in *Aston Park*", "the deficiencies identified by the Court in *Aston Park* are no longer present in the current CON law", and "the holding in *Aston Park* is moot").

67. Moreover, our Supreme Court recognized that a facial challenge to a law is "the most difficult challenge to mount successfully." *Affordable Care, Inc. v. N. Carolina State Bd. of Dental Examiners*, 571 S.E.2d 52, 61 (N.C. Ct. App. 2002) citing *State v. Thompson,* 349 N.C. 483, 491, 508 S.E.2d 277, 281 (1998) (quoting *United States v. Salerno,* 481 U.S. 739, 745, 107 S.Ct. 2095, 2100, 95 L.Ed.2d 697, 707 (1987)).

68. In a facial challenge, the presumption is that the law is constitutional, and a court may not strike it down if it may be upheld on any reasonable ground. *Id.* at 491, 508 S.E.2d at 281–82. "An individual challenging the facial constitutionality of a legislative act 'must establish that no set of circumstances exists under which the [a]ct would be valid.' " *Id.* at 491, 508 S.E.2d

at 282 (citation omitted). "The fact that a statute 'might operate unconstitutionally under some conceivable set of circumstances is insufficient to render it wholly invalid.' " *Id.* (citation omitted).

69. The ultimate purpose in enacting the CON law was to protect the health and welfare of North Carolina citizens by providing affordable access to necessary health care. N.C. Gen. Stat. § 131E–175(7) ("[T]he 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.").

70. The Court of Appeals determined that this purpose is a legitimate one. *Hope--A Women's Cancer Ctr., P.A. v. State*, 693 S.E.2d 673, 680 (N.C. Ct. App. 2010); s*ee also Affordable Care, Inc.,* 153 N.C.App. at 537, 571 S.E.2d at 60 (finding that the Rule's purpose … to protect the health and welfare with respect to the practice of dentistry" was a legitimate governmental purpose).

71. While "BMA,[or any health care facility in this State] has the right to operate upon its own property, with its own funds, an adequately equipped facility" (Pet'.r Mot. Sum J. p. 24), that right is subject to the CON laws of this State which is a legitimate governmental purpose. As such, the Agency acted reasonably in granting BMA a partial award of dialysis stations and did not substantially prejudice BMA's liberty or property rights.

4. Any Other Claims:

BMA Failed to Proffer any Supporting Evidence that There were Questions of Material Fact That BMA's Rights were Substantively Prejudiced on Any Other Claims.

72. In sum, while it is undisputed that BMA was not approved for a total of 4 stations in Guilford and Johnston Counties for which BMA applied, it is also undisputed that BMA provided no evidence during discovery or in connection with the summary judgment motions or hearing that would either demonstrate or permit a finding by the Tribunal that the harm, affect, and/or prejudice BMA suffered, if any, from the Agency's denial of these 4 stations was "substantial" as required by both N.C. Gen. Stat. § 150B-2(6) and § 150B-23(a).

73. Petitioner BMA failed to establish that the Agency substantially prejudiced its rights by conditionally approving TRC's applications in full and conditionally approving BMA's applications in part, which is an essential element of its claim under N.C. Gen. Stat. § 150B-23(a).

74. To survive summary judgment BMA had to demonstrate that genuine questions of fact existed that the Agency's decisions substantially prejudiced its rights in some way. In viewing this case in the light most favorable to the nonmovant, BMA failed to put forth any admissible evidence of substantial prejudice to support its claims, and therefore summary judgment must be granted to the Agency and TRC.

75. Because BMA has failed to establish an essential element of its case on any basis, the Undersigned hereby grants Respondent and Respondent-Intervenor's Joint Motion for Summary Judgment.

II. AGENCY ERROR ISSUE:

Whether the Agency erred in its approval of both TRC's applications because of the Agency's review of Criterions 3 and 5 (the "Agency Error Issue")?

76. Because BMA failed to raise questions of material fact about the Agency's decisions to deny BMA only two (2) stations in Guilford County (where BMA had been previously approved for seven (7) dialysis facilities and 235 dialysis stations), and only two (2) stations in Johnston County (where BMA had been previously approved for five (5) dialysis facilities and 90 dialysis stations and is the only provider of dialysis services) substantially prejudiced BMA's rights in any way, BMA failed to prove an essential element of its *prima facie* case. The relief requested by BMA must thus be denied and BMA's case is subject to dismissal without regard to whether or not it proved or could prove Agency error. *See* N.C. Gen. Stat. § 150B-23; *Parkway Urology, supra; Presbyterian Hosp., supra; Bio-Medical Applications, supra*.

77. Given the determination that BMA has failed to demonstrate substantial prejudice, it is unnecessary to reach or make any determinations regarding BMA's allegations of Agency error in the Agency's approvals of TRC's applications. *Surgical Care Affiliates*, 235 N.C. App. at 633, 762 S.E.2d at 476; *Wake Radiology*, 215 N.C. App. 393, 716 S.E.2d 87, 2011 WL 3891026, at *8, 10; *Bio-Medical Applications of N.C.*, 173 N.C. App. 641, 619 S.E.2d 593, 2005 WL 2429894, at *4 (Oct. 4, 2005) (unpublished).

78. However, as discussed below, the Undersigned concludes that based on both criteria decisions, the Agency and TRC have proffered sufficient evidence to raise questions of material fact as to the appropriateness of the Agency's approvals of TRC's applications.

A. In General:

Failure to Provide All Information Is Not Fatal to an Application's Conformity.

79. BMA asserts that TRC's failure to provide information that related to Criterions 3 and 5 should automatically render TRC's applications nonconforming and thus they should not have been approved. (Pet. Mot. Sum J. pp. 7, 10-14, 17, 21 & 23)).

80. According to the testimony of the CON Section's Chief Martha Frisone, failure to answer one or more questions in the application form is not fatal to an applicant's conformity. (*See* Jt . Mot. Notice of Filing: Ex. 9 (Frisone) pp. 94-100)). Chief Frisone explained that this is because the application is a "form" not a "rule" under the Administrative Procedure Act ("APA") and a

form does not "require" information to be provided in a response. (*See* Jt. Mot. Notice of Filing: Ex. 9 (Frisone) pp. 94-100) referring to N.C. Gen. Stat. § 150B-2(8a)(d)).

81. Even though the application form is not a "rule", under N.C. Gen. Stat. § 131E-182, the application form "shall require such information as the Department, by its rules deems necessary to conduct the review" and an applicant is only required to furnish such information. N.C. Gen. Stat. § 131E-182. The CON "review criteria" for these applications included Criterions 3 and 5.

82. The Agency contends that TRC's failure to answer one or more questions in the ESRD applications does not render them nonconforming with the statutory review criteria. Whether it does or not, raises a genuine issue of material fact.

B. Criterion 3 - Handicapped Persons' Access

Criterion 3 requests the "extent … handicapped persons, and other underserved groups *are likely to have access* to the service provided," not a percentage as requested in the Application.

83. BMA asserts that the Agency erred in reviewing TRC's application because TRC failed to list the anticipated percentage of handicapped persons to be served in the second operating year as requested by Criterion 3.

84. Criterion 3 states:

> the applicant shall identify the population to be served by the proposed project, and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and, in particular, low-income persons, racial and ethnic minorities, women, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.

N.C. Gen. Stat. § 131E-183(a)(3).

85. In the Applications, Section C, Question 7 asked the applicant to "provide the estimated percentage of total patients for each group during the second [operating year] following completion of the project." The enumerated groups include all the underserved groups identified in Criterion 3, including "handicapped persons." (Jt. Stip. 38). [3]

[3] The ESRD Application Form does not define the term "handicapped persons" nor is it defined in N.C. Gen.Stat. § 131E-176. None of the Parties referenced a definition in their motions and supporting documents and one did not appear readily in the record. But BMA did refer to the U.S. Census Bureau's definition of "disabled" in its Public Written Comments. Petitions Ex. B, pp. 7-8.

86. This question differs from the language in the statutory Criterion 3 which requires the applicant to identify "the extent … handicapped persons, and other underserved groups *are likely to have access* to the service provided." N.C. Gen. Stat § 131E-183(a)(3). Criterion 3 does not ask for a percentage over a period of time nor does it define "handicapped persons".

87. The term "handicapped persons" is also not defined anywhere in the record. However, the Parties did stipulate that "End-Stage Renal Disease ("ESRD") is a medical condition … which requires long-term dialysis or a kidney transplant to maintain the person's life" because of kidney failure. (Jt. Stip. 6). Basically, 100% of TRC and BMA's patients are in End-Stage Renal Failure and without dialysis, a life-saving procedure, these patients will die.

88. Most, if not all, of these patients would qualify as disabled under the Americans With Disabilities Act Amendment Act of 2009 ("ADAAA"), 42 U.S.C.A. § 12102(a) (2009). The ADAAA's definition of a "major life activity" includes a "major bodily function". In fact, Evelyn Vega testified in her deposition that "most are disabled." *See* Depo of Vega p. 12:5-18, Ex. K attached to Pet.'r Resp. to Jt. Mot. Sum. J.

89. BMA stipulated that TRC's response to Criterion 3 stated that "data not captured" about the estimated percentage of handicapped persons who would be served (Stip. 41). BMA also stipulated that later in TRC's Applications, TRC confirmed that "[t]he facility will serve patients without regard to race, sex[,] age, or handicap." (Stip. 43). As expected, 100% of all disabled/handicapped persons would be served at TRC's facilities which is the crux of the question.

90. Although TRC did not give a percentage, TRC answered, as required under N.C. Gen. Stat. § 131E-183(a)(3), the "extent" that "handicapped persons" were "likely to have access to the services provided" - which was "all".

91. BMA's "hyper-technical argument" is not only at odds with the deposition testimony from the Agency's witnesses but also with what the type of patients BMA and TRC anticipate to serve most of which, if not 100%, by the very nature of their medical condition would be categorized as handicapped (a.k.a. disabled).

C. Criterion 5 - Capital Expenditures and DaVita, Inc. As a "Related Entity"

Criterion 5 requires financial and operational projections of the project's availability of funds for capital and operating needs as well as immediate and long-term financial feasibility of the proposal.

92. According to BMA, TRC's applications were nonconforming to Criterion 5 because TRC failed to disclose its parent company, DaVita, Inc., as a "related entity" and DaVita's capital expenditures for the land and building as the landowner/developer.

93. Criterion 5 states:

> Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

N.C. Gen. Stat. § 131E-183(a)(5).

94. In opposition to BMA's summary judgment motion on this issue, the Agency proffered multiple deposition testimonies explaining how the ESRD application form defines "related entities". (*See* Jt. Notice of Filing Exhibits in Opposition to BMA Mot. Sum. J. (Jt. Notice"): Ex. 5 (Wilson), p. 212; Ex. 6 (Faenza), p. 227; Ex. 7. (Saporito), pp. 214-218; Exhibit 3, p. 0008, Exhibit 4, p. 0008). And the Agency's witnesses stated that the term "related entities" is not used in Section A, Question 6 of the ESRD application form. (Ex. 5 (Wilson), p. 212; Ex. 6 (Faenza), p. 227; Ex. 7 (Saporito), pp. 214-218; Ex. 9 (Frisone), pp. 139-.140; Ex. 3, p. 0015, Ex. 4, p. 0015).

95. The real question was not whether DeVita, Inc. was a related entity but whether the capital expenditures made by DaVita, Inc., as the landowner developer, should have been included in TRC's application. The Agency's witnesses explained the "relationship" between the "owner of the building" and the "operator of the facility" and when the landowner developer must be included in the capital costs of the proposed project. (Jt. Notice: Ex. 5 (Wilson), p. 65; Ex. 6 (Faenza), pp. 164, 190; Ex. 9 (Frisone), p. 156). Because the DaVita subsidiary was only the landowner developer and was neither offering the dialysis services nor incurring an obligation for a capital expenditure to develop or offer the dialysis services, the cost to buy the land or to build the building did not need to be included as part of the capital cost for the proposed project. (Jt. Notice: Ex. 6 (Faenza), pp. 163, 186-187).

96. The evidence demonstrates that the Agency analyzed TRC's applications, including the financials, the capital expenditure projections (which demonstrated TRC's costs for upfitting the building), and the operational expenses (which demonstrated TRC's lease costs). (Jt. Notice: Ex. 6 (Faenza), pp. 238- 239; Ex. 7 (Saporito), pp. 219; Ex. 5 (Wilson), pp. 215-217, 219-220; Ex. 3, pp. 0045-0047, 0087, 0089, 0281; Ex. 4, pp. 0045-0047, 0088, 0090, 0274; Ex. 1, pp. 0751-0754; Ex. 2, pp. 444-446). Based on this information, the Agency determined that TRC demonstrated the availability of funds for its capital costs, the financial feasibility of its project, and its conformity with Criterion 5.

97. The North Carolina Court of Appeals has upheld similar arrangements as being conforming with Criterion 5. *See Blue Ridge Healthcare Hosps., Inc. v. N.C. Dep't of Health and Human Servs.,* 255 N.C. App. 451, 453-454, 808 S.E.2d 271, 273(2017) (upholding the Agency's decision that a CON application to develop an ambulatory surgery center was conforming with Criterion 5 where the applicant, in its application, asserted and accounted for its costs to lease the

building, upfit and house the ambulatory surgery center, and did not include in its capital cost a course of funding for the developer's construction of the shell building); *see also Total Renal Care of N.C., LLC v. N.C. Dep't of Health and Human Servs.*, 171 N.C. App. 734, 615 S.E.2d 81 (2005) (reversing the ALJ and upholding the Agency's decision that BMA's application to develop a 10-station dialysis facility was conforming with Criterion 5 where BMA did not include the future lessor of the building as an applicant).

D. Questions of Fact About Agency Error:

The Agency Has Proffered Sufficient Evidence to Raise Questions of Material Fact as to Agency Error in Reviewing Criterions 3 and 5.

98. Based on the evidence presented by the nonmovants, the Agency and TRC, and seen in the light most favorable to them, they have sufficiently raised material questions of genuine fact to survive summary judgment about the appropriateness of the Agency's decisions with regard to Criterions 3 and 5. Therefore, BMA's motion for summary judgment as to Agency Error is denied.

ORDER AND FINAL DECISION

NOW based upon the foregoing, it is hereby decided that Petitioner BMA has failed to raise genuine issues of material fact as to whether BMA's rights were substantially prejudiced which is an essential element under N.C. Gen. Stat. § 150B-23(a), and therefore the Undersigned hereby **GRANTS** Respondent and Respondent-Intervenor's Joint Motion for Summary Judgment.

MOREOVER, the Respondent Agency and Respondent-Intervenor TRC have raised genuine issues of material fact as to the appropriateness of the Agency's decisions regarding Criterions 3 and 5 on TRC's application; therefore, Petitioner's Motion for Summary Judgment is **DENIED**.

THEREFORE, based on Petitioner BMA's failure to prove it was substantially prejudiced by the Agency's actions, an essential element of BMA's contested case, even though there are questions of material fact about Agency Error, BMA's Petitions must be **DISMISSED.**

IT IS HEREBY ORDERED as follows:

1. The decisions of the North Carolina Department of Health & Human Services, Division of Health Service Regulation, Certificate of Need Section in the Review are hereby **AFFIRMED;**

2. This ruling is a Final Decision on the merits of BMA's contested case and disposes of all issues in this contested case; and,

3. These consolidated contested cases are hereby **DISMISSED WITH PREJUDICE**.

NOTICE

This is a Final Decision issued under the authority of N.C. Gen. Stat. § 150B-34. Under the provisions of North Carolina General Statute § 131E-188(b), any party wishing to appeal the final decision of the Administrative Law Judge must appeal to the North Carolina Court of Appeals as provided in N.C. Gen. Stat. § 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 final decision and notice of appeal shall be filed with the Office of Administrative Hearings and served on the North Carolina Department of Health and Human Services and all other affected persons who were parties to the contested case.

Pursuant to N.C. Gen. Stat. § 131E-188(bl), 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.

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 as indicated by the date on the Certificate of Service attached to this Final Decision.

IT IS SO ORDERED.

This the 3rd day of November, 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:

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This the 3rd day of November, 2020.

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