STATE OF NORTH CAROLINA	IN THE OFFICE OF ADMINISTRATIVE HEARINGS
COUNTY OF NASH	14 DHR 05495

BIO-MEDICAL APPLICATIONS OF NORTH CAROLINA, INC. d/b/a BMA ROCKY MOUNT, Petitioner, v. NORTH CAROLINA DEPARTMENT OF HEALTH AND HUMAN SERVICES, DIVISION OF HEALTH SERVICE REGULATION, CERTIFICATE OF NEED SECTION, Respondent, And TOTAL RENAL CARE, INC. d/b/a NASH COUNTY DIALYSIS, Respondent-Intervenor.	**FINAL DECISION**

THIS MATTER came for hearing before the undersigned Augustus B. Elkins II, Administrative Law Judge ("ALJ"), on October 8-10 and October 13-17, 2014, in Raleigh, North Carolina. Having heard all of the evidence in this case and having considered the exhibits, arguments, and relevant law, the Undersigned makes the Findings of Fact by a preponderance of the evidence, enters Conclusions of Law thereon, and makes the following Final Decision.

APPEARANCES

For Petitioner Bio-Medical Applications of North Carolina, Inc. d/b/a BMA Rocky Mount ("BMA"):

Marcus C. Hewitt
Elizabeth Sims Hedrick
Smith Moore Leatherwood LLP
434 Fayetteville Street, Suite 2800
Raleigh, NC 27601

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

Bethany A. Burgon
North Carolina Department of Justice
P.O. Box 629
Raleigh, NC 27602-0629

For Respondent-Intervenors Total Renal Care, Inc. d/b/a Nash County Dialysis ("TRC"):

Lee M. Whitman
Elizabeth Frock Runyon
Wyrick Robbins Yates & Ponton LLP
4101 Lake Boone Trail, Suite 300
Raleigh, NC 27607

APPLICABLE LAW

N.C. Gen. Stat. § 150B-1 *et seq.*
N.C. Gen. Stat. § 131E-175 *et seq.*

BURDEN OF PROOF

BMA has the burden of proof by a preponderance of the evidence regarding the issues presented in this contested case. N.C. Gen. Stat. § 150B-34(a).

PRELIMINARY MATTERS

1. These cases arise from the Agency's decisions: (1) to approve an application submitted by TRC ("the TRC Application") to develop a new 12-station dialysis facility in Rocky Mount, Nash County; and (2) to approve, with conditions, an application submitted by BMA ("the BMA Rocky Mount Application") to add 7 stations to an existing dialysis facility in Rocky Mount.

2. On February 27, 2014, the Agency issued its decision approving the TRC Application and conditionally approving the BMA Application. BMA filed a petition for contested case hearing (14 DHR 02398) to appeal the Agency decision to approve the TRC Application and to conditionally approve the BMA Application for 7 stations instead of the 11 for which BMA applied. TRC intervened in this contested case with all rights of a party to support the Agency's decision to approve the TRC Application. On July 22, 2014, this case was dismissed without prejudice pursuant to a Consent Order, and a petition for contested case hearing on the same subject matter was subsequently re-filed by BMA on July 23, 2014 (14 DHR 05495). In accordance with the terms of the Consent Order, TRC was automatically made an intervenor in case 14 DHR 05495.

3. On September 22, 2014, TRC and the Agency filed a Motion to Dismiss and Motion for Summary Judgment, seeking dismissal of the case or entry of summary judgment against BMA. TRC and the Agency asserted that BMA had failed to exhaust its administrative remedies because it failed to seek amendment of the July 2013 Semi-Annual Dialysis Report ("SDR") or the 2013 State Medical Facilities Plan ("SMFP"), and sought to use the contested case hearing to challenge the published average annual change rate ("average annual change rate" or "AACR") contained in those final published documents. On Oct. 2, 2014, BMA filed a Brief in Opposition to the Motion to Dismiss and Motion for Summary Judgment. A hearing on the Motion was held by the undersigned ALJ on October 3, 2014.

In response to the Motion, BMA presented evidence that reporting errors by two BMA facilities inflated the patient population reported for Nash County in the July 2013 SDR which in turn inflated the average annual change rate ("AACR") reported for Nash County in the July 2013 SDR. BMA asserted that both TRC and the Agency knew that the published AACR was inflated and that TRC's application would not have been conforming to certain rules and statutory criteria had TRC projected growth and utilization using the actual AACR. TRC and the Agency contended that as a matter of law, the Agency is required to apply the standards contained in the SDR, which are binding on the Agency and all CON applicants and that these standards include the AACR.

The Undersigned found that dismissal was not warranted in this case. Further, the Undersigned found that summary judgment may not be used where conflicting evidence is involved, *See Smith v. Currie*, 40 N.C. App. 739, 253 S.E.2d 645, *cert. denied*, 297 N.C. 612, 257 S.E.2d 219 (1979); and if there is a question which can be resolved only by the weight of the evidence, summary judgment must be denied. *See City of Thomasville v. Lease-Afex, Inc.*, 300 N.C. 651, 268 S.E.2d 190 (1980). The Undersigned found that multiple material facts and issues in this matter were in dispute. Respondent-Intervenor's and Respondent's Joint Motion was denied.

ISSUES

BMA's Contested Issues

1. Whether the CON Section substantially prejudiced BMA's rights when it approved the TRC Application to develop a 12-station dialysis facility in Nash County.

2. Whether the CON Section substantially prejudiced BMA's rights when it conditioned approval of the BMA Application upon BMA developing only 7 of the stations for which it applied.

3. Whether the CON Section exceeded its authority or jurisdiction, acted erroneously, failed to use proper procedure, acted arbitrarily or capriciously, or failed to act as required by law or rule when it approved the TRC Application to develop a 12-station facility in Nash County.

4. Whether the CON Section exceeded its authority or jurisdiction, acted erroneously, failed to use proper procedure, acted arbitrarily or capriciously, or failed to act as required by law or rule in determining that the TRC Application was conforming with N.C. Gen. Stat. § 131E-183(a) subsections (3), (4), (5), (6), and (18a).

5. Whether the CON Section exceeded its authority or jurisdiction, acted erroneously, failed to use proper procedure, acted arbitrarily or capriciously, or failed to act as required by law or rule in determining that the TRC Application was conforming with 10A N.C.A.C. 14C .2203(a).

6. Whether the CON Section exceeded its authority or jurisdiction, acted erroneously, failed to use proper procedure, acted arbitrarily or capriciously, or failed to act as required by law or rule in conditioning approval of the BMA Application upon BMA developing only 7 of the stations for which it applied.

The CON Section's Contested Issues

1. Whether the Respondent substantially prejudiced Petitioner BMA; exceeded its authority or jurisdiction; acted erroneously; failed to use proper procedure; acted arbitrarily or capriciously; or failed to act as required by law or rule, when it conditionally approved its CON application upon BMA developing only 7 of the stations for which it applied and in approving the application of TRC to develop a 12-station dialysis facility in Nash County.

2. Whether BMA failed to exhaust its administrative remedies for challenging the 2013 SDR by failing to petition the Governor for amendment of the SDR.

TRC'S Contested Issues

1. Whether BMA failed to exhaust its administrative remedy for challenging the July 2013 SDR when it failed to petition the Governor for amendment of the SDR?

2. Whether BMA is prevented from challenging: (a) TRC's use of the 9.6% average annual change rate published in the July 2013 SDR; and/or (b) the Agency's acceptance of that growth rate as reasonable, credible, and supported.

3. Whether the published July 2013 SDR was in effect at the time the review of the TRC application commenced?

4. Whether the Agency was correct in applying the published July 2013 SDR to the TRC application?

5. Whether TRC's use of the 9.6% average annual change rate was reasonable based on the published July 2013 SDR and the use of this 9.6% growth rate by the Planning Section to calculate a need determination of 19 dialysis stations for Nash County?

6. Whether the Agency was correct to accept TRC's use of the 9.6% average annual change rate which was published in the July 2013 SDR, as reasonable, credible and supported?

7. Whether the Agency was correct in determining that TRC conformed with all applicable statutory and regulatory review criteria?

8. Whether the Agency was correct in finding TRC's application comparatively superior to BMA's application in the comparative review?

9. Whether the Agency was correct in approving TRC for a new dialysis facility in Nash County with 12 dialysis stations?

WITNESSES

For Petitioner

Elizabeth Brown, Planner, Medical Facilities Planning Branch
Anita Harris, Director of Operations, Fresenius Medical Care
Mary Bone, Clinical Manager, Fresenius Medical Care
Cynthia Preston, Secretary, Receptionist and Ward Clerk, Fresenius Medical Care
Julie Halatek, Project Analyst, CON Section
Jim Swann, Director of Operations for Certificate of Need, Fresenius Medical Care
Martha Frisone, Interim Chief, CON Section
Dodie Robinson, Regional Operations Director, DaVita, Inc.
David French, President, Strategic Healthcare Consultants

For Respondent

Drexdal Pratt, Director, Division of Health Service Regulation

For Respondent-Intervenor

Bill Hyland, Director of Healthcare Planning, DaVita, Inc.

EXHIBITS

Joint

1	2013 Nash County Dialysis Review Agency File
2	BMA Nash County Application, Project ID No. L-10182-13
3	TRC Nash County Application, Project ID No. L-10211-13
5	10A NCAC 14C .2201 - Criteria and Standards for End Stage Renal Disease Services, Definitions
6	January 2014 Semiannual Dialysis Report
7	Required State Agency Findings, Project ID Nos. J-7438-05 and J-7451-05, 5/5/06

8	TRC's Responses to BMA's First Set of Interrogatories and Requests for Production of Documents
9	State Health Coordinating Council Meeting Minutes, 10/2/13
11	10A NCAC 14C .0207 – Agency Decision
12	Second Amended Notice of Rule 30(b)(6) Deposition of DHSR, 7/28/14
13	Data Collection Form ESRD Facilities, December 2012
14	State Health Coordinating Council meeting minutes, 5/29/13
15	e-mail, Bone to DHSR re ESRD Collection Forms, 5/22/13
16	e-mail, Hyland to Brown re DSHR Reports - DaVita Region 4, 6/4/13
17	e-mail, Brown to multiple recipients re Request Assistance in Reviewing a Draft of Table A for 2013 July SDR, 6/25/13
18	e-mail, Brown to Swann re Request Assistance in Reviewing a Draft of Table A for 2013 July SDR, 6/25/13
19	e-mail, Swann to Brown, Ayden Census, 6/25/13
20	e-mail, Swann to Brown re 3427 to decert 1, 6/25/13
21	e-mail, Pfeiffer to multiple recipients re 2013 July SDR - Final Drafts of Table A and B, 6/28/13
22	e-mail, Frisone to multiple recipients re July 2013 SDR, 7/1/13
23	e-mail, Frisone to multiple recipients re Another Incorrect FID #, 7/1/13
24	e-mail, Glendening to Brown re Narrative, Tables, and Other Documents for the July 2013 SDR, 7/1/13
25	e-mail, Glendening to multiple recipients re On Test Site, 7/1/13
26	e-mail, Brown to Swann re July 2013 SDR, 7/2/13
27	e-mail, Brown to multiple recipients re 2013 July SDR, 7/2/13
28	e-mail, Hyland to Brown re 2013 July SDR, 7/2/13
29	e-mail, Swann to Brown re ESRD Info Submission, 7/3/13
30	e-mail, Swann to Brown re ESRD Data Collection Patient Population Tab - Corrected, 7/3/13
31	e-mail, Swann to Brown re ESRD Data Collection Form BMA East Rocky Mount - Corrected, 7/3/13
32	e-mail, Glendening to Brown re Request ESRD Database, 7/2/13
33	e-mail, Pfeiffer to Brown re Revised July 2013 SDR, 7/8/13
34	e-mail, Hyland to Brown re July 2013 SDR, 7/8/13
35	e-mail, Pfeiffer to Swann re Agency Report for Data Reporting Errors Petition to SHCC, 9/10/13
36	Long-Term and Behavioral Health Committee minutes, 9/11/13
37	Long Term and Behavioral Health Committee Recommendations to the NC State Health Coordinating Council, 10/2/13
38	DHSR's Responses to BMA's First Set of Interrogatories and Request for Production of Documents
39	January 2013 Semiannual Dialysis Report (Reissued January 18, 2013)
40	January 2013 SDR, 1/2/13
41	DHSR's Supplemental Responses to BMA's First Set of Interrogatories and Request for Production of Documents
42	résumé of Jim Swann
43	e-mail, Swann to multiple recipients re Brief Question, 7/30/13 **(Confidential)**

44	e-mail, Swann to Harris re ESRD Data Collection Patient Population Tab - Corrected, 7/3/13 **(Confidential)**
45	e-mail, Swann to Pfeiffer re July 2013 SDR, 7/10/13
47	excerpts from FMC South Rocky Mount application, 8/15/13
48	e-mail, Swann to Harvey re Rocky Mount CON Application, 9/3/13 **(Confidential)**
50	e-mail, Swann to Harris re FMC South Rocky Mount has been conditionally approved, 10/18/13 **(Confidential)**
57	e-mail, Brown to Hyland re July 2013 SDR, 7/8/13
58	e-mail, Hines to Hyland re July 2013 Semiannual Dialysis Report, 7/8/13
60	e-mail, Nichols to Hyland re Rocky Mount DN-TGC on the 30th, 8/23/13
61	e-mail to Hyland attaching Index of Patient Support Letters for Nash County Facility, 9/13/13
62	e-mail, Hyland to Lewis re Nash County Dialysis Patient Letters, 8/20/13
63	e-mail, Hyland to Robinson re Nash County Dialysis CON Application Documents, 8/8/13
64	excerpts from TRC's Scotland County Dialysis Application, 9/16/13
66	e-mail, Hyland to Hines re July 2013 SDR, 7/8/13
67	e-mail, Hyland to multiple recipients re TOPCATS CON Opportunities, 7/9/13
68	e-mail, Robinson to multiple recipients re Can you help on a few TC models, 7/26/13
73	David French résumé
75	e-mail, Hyland to multiple recipients re Nash County Dialysis CON Application Documents, 8/8/13
76	e-mail, Lewis to Hyland re CON, 9/4/13

Petitioner

101	Required State Agency Findings, Project ID No. G-7681-06, 12/11/06
104	Required State Agency Findings, Project ID No. F-7912-07, 1/7/08
105	Required State Agency Findings, Project ID No. F-8073-08, 9/5/08
109	Required State Agency Findings, Project ID Nos. F-8577-10, F-8581-10, F-8584-10, F-8590-10, 3/4/11
110	Required State Agency Findings, Project ID No. N-8801-12, 7/27/12
111	Required State Agency Findings, Project ID No. F-10056-12, 2/4/13
114	Required State Agency Findings, Project ID Nos. G-10127-13, G-10133-13, 10/28/13
115	Required State Agency Findings, Project ID No. O-10042-12, 2/27/12
117	Required State Agency Findings, Project ID No. N-10200-13, 12/20/13
118	Required State Agency Findings, Project ID No. J-10025-12, 2/4/13
119	Excerpts of Required State Agency Findings, Project ID Nos. J-8169-08, J-8170-08, J-8177-08, J-8179-08, J-8180-08, J-8181-08, J-8182-08, J-8190-08, 1/30/09
121	Draft Revised July 2013 SDR
122	June 2014 ESRD Collection Form

124	excerpts from Transcript of Deposition of Clarkston Hines, 8/25/14
125	Excerpts from Transcript of Rule 30(b)(6) deposition of NCDHHS/DHSR
127	e-mail, Harris to Weaver, 5/22/13
128	e-mail, Harris to Bone, with attachments, 7/3/13
133	Tables - Comparison of data reporting errors
134	Tables - Analysis of TRC utilization projections
135	Maps of facility locations
136	Graph - TRC projected utilization growth
137	Graphs - Reported and corrected patient populations
138	Graph - AACR as reported in SDR and as corrected
140	excerpted pages from deposition of Martha Frisone, 7/9/14
141	excerpted pages from deposition of Bill Hyland, 8/22/14

Respondent

200	4/23/13 e-mail from Elizabeth Brown with 5/3/13 meeting invitation
201	5/3/13 ESRD Data Source Meeting Agenda

Respondent-Intervenor

300	Bio-Medical Applications of North Carolina, Inc. d/b/a BMA Rocky Mount's Objections and Responses to First Interrogatories and First Request for Production of Documents from Total Renal Care, Inc., d/b/a Nash County Dialysis, 5/9/14
301	Bio-Medical Applications of North Carolina, Inc. d/b/a BMA Rocky Mount's First Supplement to Its Objections and Responses to First Interrogatories and First Request for Production of Documents from Total Renal Care, Inc., d/b/a Nash County Dialysis, 9/22/14
302	Demonstration of Compliance with Performance Standards Pursuant to Joint Exhibit 61

EXHIBITS SUBMITTED AS OFFERS OF PROOF

BMA Offers of Proof

52. Jim Swann – Summary of Expert Opinions
139. Required State Agency Findings, Project ID Nos. G-10254-06 and G-10262-14

TRC Offer of Proof

51. Email from Aaron Carrow to Mike Nelms re Project Proposal “Rocky Mount Kidney Ctr” is Ready for Your Review and Approval (January 13, 2014) (**Confidential**)

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

FINDINGS OF FACT

1. Petitioner BMA is a Delaware corporation authorized to conduct business in North Carolina, with its principal place of business in Waltham, Massachusetts, and its registered agent in Wake County, North Carolina.

2. Respondent CON Section is the Agency within the North Carolina Department of Health and Human Services that carries out the Department's administration of the CON Law, codified at N.C. Gen. Stat. § 131E-175, et. seq., including the review of applications for new institutional health services that are defined in N.C. Gen. Stat. § 131E-176 (16).

3. Respondent-Intervenor TRC is a Delaware Limited Liability Company authorized to do business in North Carolina, and is in the business of providing dialysis services.

4. Jim Swann was accepted as an expert witness for BMA in renal dialysis services and CON planning and preparation. For the last ten years, Mr. Swann has served as the Director of Operations for Certificate of Need for Fresenius Medical Care, the parent company of BMA. In that role, Swann has prepared approximately 300 Certificate of Need applications in North Carolina, West Virginia, and Washington, D.C., with a 91% approval rate.

5. David French was accepted as an expert witness for BMA in the preparation of a CON application and the applicant's filing of a CON application as it regards a need determination/competitive bid. Mr. French is a healthcare consultant and the president of Strategic Healthcare Consultants. He has 23 years' experience in Certificate of Need and has prepared about 120 CON applications for various services. French also has experience in long-range planning activities for healthcare providers.

6. Bill Hyland was accepted as an expert witness for TRC in ESRD health planning as it relates to CON planning and his role in the CON preparation and analysis. Mr. Hyland is the Director of Health Care Planning for DaVita Incorporated. Hyland has been employed by DaVita since May 4, 1999. As the Director of Health Care Planning, he is in charge of the development, relocation, and expansion of dialysis facilities operated by DaVita within North Carolina. Hyland

prepared the TRC Application. He has prepared close to 300 certificate of need applications in his fifteen years at DaVita, all of which involve end stage renal disease.

7. Julie Halatek has been a project analyst for the Agency for approximately two years. She was assigned to review the TRC and BMA Applications and was primarily responsible for preparing the Required State Agency Findings.

8. Martha Frisone has served as the Interim Chief of the Certificate of Need Section of the Division of Health Service Regulation since January 1, 2013. She also held the position of Assistant Chief of the CON Section for almost four years, and she oversaw Ms. Halatek's work on the review of the BMA and TRC applications. Frisone, having been employed by the CON Section for over twenty years, has had experience with reviewing and analyzing dialysis applications as a project analyst, a team leader, assistant chief of the CON Section, and interim chief of the CON Section. Approximately one-third of the applications reviewed by the CON Section are dialysis applications.

9. Drexdal Pratt is the Director of the Division of Health Service Regulation, Department of Health and Human Services.

10. Elizabeth Brown has worked for the Medical Facilities Planning Branch of the Division of Health Service Regulation ("Planning Branch or Planning Section") since 2006 and has been a planner for more than three years. The Planning Section is responsible for preparing the State Medical Facilities Plan ("SMFP") and the Semi-Annual Dialysis Report ("SDR").

11. Dodie Robinson is a Regional Operations Director for DaVita, which is the parent company of Total Renal Care. Ms. Robinson has been in this position for over six years. In this role, Robinson has oversight for the clinical and financial performances of the eleven facilities within her region that covers the eastern part of North Carolina. She was familiar with the TRC application to develop a 12 station facility in Rocky Mount to the extent that Nash County was in her region and she collected certain documentation and patient letters of support for the TRC Application.

12. Anita Harris is a Director of Operations for Fresenius Medical Care. She is responsible for budgetary matters and regulatory compliance for seven facilities, including the BMA Rocky Mount facility in Nash County and the BMA East Rocky Mount facility in Edgecombe County.

13. Mary Bone is Clinical Manager at the BMA Rocky Mount facility. Cynthia Preston is Secretary at the BMA East Rocky Mount facility.

14. Dialysis facilities are among the types of health care organizations listed in the definition of "health service facility" in the CON Law. The construction of a dialysis facility is *per se* reviewable under the CON law and is subject to the methodologies and need determinations contained in the applicable State Medical Facilities Plan ("SMFP") and Semi-Annual Dialysis Report ("SDR").

15. The SMFP is the official plan developed and published each year which inventories certain services, facilities, and equipment that are subject to CON regulation as well as the utilization of those services, facilities, and equipment. The SMFP also projects future needs for additional services, facilities, and equipment in each service area. The SMFP is developed under the direction of the State Health Coordinating Council ("SHCC"), which is comprised of healthcare professionals and other citizens, each of whom is appointed by the Governor.

16. As part of its planning responsibilities under the CON Law, the N.C. Department of Health and Human Services issues an SDR twice each year; and currently, the SDRs are published each January and July. SDRs contain detailed information about the number of patients in each county who are receiving any of the different dialysis services and identify the dialysis facilities that are in operation in each county, or which have received certificate of need approval to begin operations. In addition, the SDRs present information about the capacity of dialysis facilities which is expressed in terms of the number of dialysis "stations" that they are permitted to operate.

17. The SDRs contain data used to project the need for additional dialysis stations in each county in the future, based on the size and capacity of the existing dialysis facilities, and the projected dialysis patient population in the future. Based on this data, the SDR contains "need determinations" which are determinations that additional dialysis stations are needed in a given county. A county need determination is realized upon the occurrence of both a projected station deficit of 10 or more stations and a utilization rate of at least 80 percent at each existing dialysis facility in the county. Under a Facility Need methodology, a facility may apply to expand by up to ten stations if its utilization is 80% or greater.

18. The Planning Section, not the CON Section, handles the creation and publication of the SDR. The CON Section uses the published SDR to fulfill its duties in reviewing CON applications pursuant to county need determinations.

19. Historically, the data upon which need determinations were made was reported by the Southeastern Kidney Council. Beginning with the July 2013 SDR, the Planning Branch began collecting data directly from existing ESRD providers.

20. Prior to the July 2013 SDR, the Southeastern Kidney Council and the Mid-Atlantic Renal Coalition collected data from providers, which it provided to the Planning Section. Upon being informed that the data from the Southeastern Kidney Council and Mid-Atlantic Renal Coalition would no longer be available in the form that the Planning Section needed, the Planning Section implemented a new system in which dialysis providers in North Carolina would self-report data to the Planning Section. The self-reported data would then be used by the Planning Section to prepare the SDR.

21. The Planning Branch had a short lead time in which to implement the new system for collecting provider-reported data. The Planning Branch developed a form (the data collection form) which it first presented to providers at a meeting in May 2013. The data collection form was a new form that dialysis providers in North Carolina had not previously used.

22. A meeting was held on May 3, 2013, in which the Planning Section met with all of the dialysis providers in the State to discuss the new procedure and explain the obligations of the providers in self-reporting. The Planning Section showed attendees a copy of the data collection form that was to be used going forward for the July 2013 SDR. Mr. Swann and Mr. Hyland both attended the May 2013 meeting. No directors of operations or facility managers/administrators for BMA attended the informational May 3 meeting with Swann.

23. During the May 2013 meeting, the Planning Section explained that all data would need to be reported no later than June 6, 2013, and that for any facility not reporting its information by that deadline, the SDR would reflect their utilization data as zero.

24. Based on Mr. Swann's familiarity with the SDRs and from his attendance at the May 3 Meeting, Swann knew that the Planning Section was going to use the data regarding patients' county of residence for the purpose of preparing the July 2013 SDR. Swann understood that the information regarding where patients reside flowed directly into Table B of the July 2013 SDR.

25. After Mr. Swann left the May 3 Meeting, he informed the four regional vice presidents within BMA that this new process was coming and asked to be included in any conference calls that the regional vice presidents may have about this new process. Although Swann remembers reaching out to all four regional vice presidents, he did not recall at either his deposition or the contested case hearing how many conference calls he was on which discussed the processes or procedures for returning the data collection forms. Swann did not have any in-person meetings with directors of operations to go over best practices for the data collection form before they were submitted to the state.

26. Following the State's dissemination of the data collection forms to the facilities, Mr. Swann did nothing to collect the data and/or otherwise review it for accuracy. He never saw the information from the BMA facilities before it was submitted to the Planning Section. Swann did not recall looking at any of the data collection forms until sometime after July 1, 2013 when the SDR was published.

27. Following the May 3 Meeting, Mr. Hyland briefed TRC's Regional Vice President, Clarkston Hines, TRC's six Regional Operations Directors, TRC's Regional Operations Coordinators, and directly emailed the facility administrators who would be populating the forms with a copy to the Regional Operations Coordinators and the Regional Operations Directors.

28. Once the facility administrators populated the data collection forms, Mr. Hyland asked that those forms be sent to the Regional Operations Coordinator for that particular region who would put them in zip drive and send to Hyland for review. After receiving the zip files from the six regions, Hyland reviewed each tab of each of the data collection reports for each of the 65 DaVita facilities. He personally submitted to the State on or before June 6, 2013 the data collection forms for the 65 DaVita facilities after they had been certified by the facility administrators.

29. The Planning Section collected data from all dialysis providers by the June 6 deadline and Ms. Brown prepared a draft Table A for the July 2013 SDR based on this self-reported data.

30. On June 25, 2013, Ms. Brown circulated a draft of Table A to Mr. Hyland and Mr. Swann for any comments or corrections, and stated in her cover email that it was extremely important for the information to be accurate.

31. Mr. Hyland performed an analysis of the proposed Table A and compared it to what he had reviewed on the previously submitted data collection forms. Hyland did not notice any errors in Table A.

32. In reviewing the draft of Table A, Mr. Swann was able to determine what counties had facilities that were 80% utilized. The draft Table A circulated by Ms. Brown to Swann and Mr. Hyland reflected that the facilities in Nash County and Scotland County were all over 80% utilized. Swann responded to Ms. Brown with some corrections regarding draft Table A, but no changes were identified for BMA's data relating to Nash or Scotland County.

33. Several facilities of both BMA (BMA Rocky Mount in Nash County, BMA East Rocky Mount in Edgecombe County, and BMA Laurinburg in Scotland County) and TRC (Dialysis Care of Rockingham County and Dialysis Care of Richmond County) misreported data to the Planning Branch for purposes of the July 2013 SDR.

34. Each of the misreporting BMA facilities reported that every patient receiving treatment at the facility was a resident of the county in which the facility was located. In fact, all three facilities served residents of multiple counties. One of the misreporting TRC facilities, Dialysis Care of Richmond County, made the same error. The second of the misreporting TRC facilities made a reporting error, mistakenly reporting that 47 Rockingham County in-center patients were residents of Caswell County.

35. The Planning Branch incorporated these errors (except for the Richmond County error which was discovered by TRC after the data had been submitted but before the SDR was published) into the July 2013 SDR into (1) the totals of dialysis patients living in each of the affected counties and (2) the resultant AACR for each of the affected counties that was used to calculate the deficit of stations and the need for additional dialysis stations. Accordingly, the reporting errors by the misreporting BMA facilities and misreporting TRC facilities overstated the number of dialysis patients living in Nash County, Scotland County, and Caswell County.

36. As a result, the July 2013 SDR identified deficits of stations in Nash, Caswell, and Scotland Counties that were significantly larger than would have been recognized had the information been correctly reported. The errors also resulted in need determinations for both Nash and Scotland Counties that would not have been recognized had the information been correctly reported. In the case of Caswell County, a need determination was not triggered because the existing facility in Caswell County was not at 80% utilization.

37. The July 2013 SDR reflected a county need determination in Nash County and in Scotland County. For Nash County, the published AACR contained in the official SDR was 9.6%. The 9.6% AACR published in the July 2013 SDR was used by the Planning Section to calculate the 19-station deficit in Nash County, which led to the 19-station need determination in Nash County.

38. Pursuant to the county need determinations reflected in the July 2013 SDR, both Nash and Scotland counties were open for competitive applications. As of July 2013, BMA was the only in-center dialysis provider of dialysis services in both Nash and Scotland counties.

39. Once the July 2013 SDR was published, and since the July 2013 SDR was not changed or republished, the CON Section had to proceed with accepting CON application pursuant to the county need determinations in the SDR. If providers wanted to file an application pursuant to the county need determinations for Nash or Scotland counties, providers were required to file their respective competitive applications with the CON Section.

40. Mr. Hyland noticed when reviewing the July 2013 SDR that TRC had reported to the Planning Section erroneous data caused by a facility administrator who mistakenly inverted the numbers of in-center patients by placing the Rockingham County patients on the Caswell County line. Hyland contacted Elizabeth Brown the morning after the SDR was published to inform her of the TRC error and request that she correct the TRC error in the SDR. On July 8, 2013, Hyland followed-up with Ms. Brown to inquire whether the July 2013 SDR would be amended or whether the SDR would stand as published. Brown responded to Hyland that the SDR was final and would stand as it had been published on July 1, 2013.

41. Mr. Hyland did not try to petition the Governor to amend the July 2013 SDR as a result of TRC's error. He also did not apply for a *de novo* facility in Caswell County because he believed it would not be the right thing to do since TRC made the error that would have permitted a *de novo* application which otherwise would not have existed but for TRC's error.

42. Mr. Hyland determined from his review of the SDR that TRC should file competitive applications in Scotland and Nash Counties along with 12 other CON applications on September 16, 2013.

43. BMA suspected there had been reporting errors when its Director of Operations for Certificate of Need, Jim Swann, reviewed the published July 2013 SDR on July 1, 2013. Upon reviewing Table B in the SDR, which reflects the need determinations by planning area and includes the data on which the station deficits or surplus are determined, Mr. Swann noticed that Caswell, Nash, and Scotland Counties had abnormally high deficits and immediately contacted Ms. Brown at the Planning Branch. Although the Planning Branch had provided Swann with a draft copy of Table A from the SDR prior to its publication, Table A primarily inventories the stations for each facility and thus the errors were not apparent from Table A but were apparent from Table B. Table B was not made available to any providers prior to publication of the SDR because it was not completed in time.

44. Mr. Swann promptly brought the issue to the attention of the Planning Branch, investigated the information reported by the Misreporting BMA Facilities, and provided the corrected data from those facilities within two days of the publication of the July 2013 SDR.

45. The errors that BMA discovered occurred in the data collection forms submitted by BMA. Mr. Swann agreed that Ms. Brown properly took the 259 total patients from Nash County shown in the patient origin report and accurately placed it into Table B of the July 2013 SDR. Brown then calculated the AACR to be 9.6% based on the 259 patients shown in Table B for Nash County. Swann agreed that the AACR calculates to 9.6% and agreed with Brown's math. Swann also agreed that the State does not arrive at a 19-station deficit in Nash County without using the 9.6% AACR.

46. In the week after the SDR was published, Mr. Swann emailed Ms. Brown in the Planning Section to ask whether the Agency was going to amend the SDR pursuant to the corrected forms Swann had submitted.

47. Both BMA and TRC requested that the Planning Branch correct the reporting errors. Ms. Brown emailed Mr. Swann and Mr. Hyland and notified them that the SDR would not be amended. Specifically, Brown informed Swann and Hyland that: "Legal counsel has advised the Division of Health Service Regulation that we do not have the legal authority to make changes to a Semiannual Dialysis Report once it has been released to the public. Therefore, the July 2013 Semiannual Dialysis Report released on July 1, 2013 will stand as published." (Jt. Ex. 45).

48. The CON Section proceeded to accept applications for the need determinations recognized in the July 2013 SDR, with the applications being due on September 16, 2013 for the review beginning October 1, 2013.

49. After Ms. Brown informed Mr. Swann via email communication that the Planning Section legally cannot amend the SDR, Swann requested that Brown set up a meeting between Swann and Drexdal Pratt. The meeting between Swann and Director Pratt occurred on July 15, 2013. In addition to Swann and Pratt, Elizabeth Brown and Nadine Pfeiffer were also present. Erin Glendenning may also have been in attendance.

50. During the meeting with Director Pratt, Mr. Swann requested that an amended SDR be published to correct the erroneous data that BMA had reported. Pratt testified that Swann explained the errors to him during the meeting and requested that the numbers in the published July 2013 SDR be changed to eliminate the county need determinations from Nash and Scotland Counties. Director Pratt told Swann that the Agency could not amend the SDR and that the Division would not request an amendment from the Governor since the Agency had no role in the error. Pratt informed Swann that if he wanted to have the SDR changed, he should and could petition the Governor to change it.

51. Mr. Swann testified that Mr. Pratt told him that the BMA reporting error would be sorted out in the CON process. Director Pratt testified that he never suggested to Swann at the July 15 meeting that the errors Swann raised during the meeting could be sorted out during the CON process.

52. Director Pratt does not recall any discussion about the CON Section in the July 15 meeting nor does he recall there being a reason to discuss CON. Director Pratt testified that had there been any reason to discuss the CON Section or had a CON issue arisen during the course of the meeting, consistent with his typical practice, Pratt would have invited the CON Section to be present, or since the CON Section is upstairs from Pratt's conference room, he would have called to ask that the CON Section chief, assistant chief, or a manager come downstairs to join the meeting.

53. At no point after the July 15, 2013 meeting did Director Pratt have any conversation with Craig Smith, the Chief of the CON Section at the time, or Martha Frisone, the Assistant Chief of the CON Section at the time, since this was a Planning Section issue and not a CON Section issue.

54. Mr. Swann's statement that Director Pratt would sort it out during the CON process was not made in his July 31 letter, was not made in BMA's August 15, 2013 South Rocky Mount Application, was not made in BMA's September 16, 2013 Rocky Mount Application, and was not made in BMA's public written comments dated October 31, 2013. The first time that Swann made the comment that Pratt had indicated that this would be sorted out in the CON process was four months after his meeting with Pratt in BMA's public hearing comments on November 18, 2013.

55. BMA submitted a letter dated July 31, 2013 to the Planning Branch and the CON Section, which the Planning Branch subsequently treated as a petition to the State Health Coordinating Council (SHCC). BMA also sent the letter, including the corrected data, to other dialysis providers in the state to avoid "confusion or inaccurate assumptions or projections in the upcoming CON review." (Jt. Ex. 1, p. 206; Swann, T. Vol. 3, pp. 643-47). The letter stated the errors skewed the AACR and included revised calculations for Table B showing that rather than 9.6%, the actual historical AACR for Nash County was only 2.1%. It also included copies of the corrected data for the misreporting BMA facilities and requested that the Planning Branch correct the total patient population figures for the counties affected by BMA's reporting errors in future SDRs which would use the same data to calculate the AACR.

56. Mr. Swann did not send his July 31 letter to the Governor's office to explain BMA's errors or otherwise request an amendment to the July 2013 SDR. Swann never asked Director Pratt or anyone else at the Agency, DHSR, the CON Section, or the State if they would be willing to support a petition from BMA to the Governor to amend the July 2013 SDR. Swann and BMA made the decision not to petition the Governor.

57. Ms. Frisone testified that in her opinion, the Court of Appeals case, *Bio-Medical Applications of North Carolina, Inc. v. N.C. Dep't of Health and Human Servs.*, 179 N.C. App. 483, 634 S.E.2d 572 (2006) ("2006 BMA Case") stands for the proposition that the Governor has the final authority to approve or amend the SMFP, which becomes the binding criteria for the review of CON applications and that only the Governor can amend the SDR. Frisone included the 2006 BMA Case in the Agency File to document that only the Governor has the authority to amend the SDR.

58. The Planning Branch and the CON Section, reviewed BMA's letter and materials and prepared an Agency Report for the Long-Term and Behavioral Health Committee of the SHCC in which DHSR concluded that the data reported in the July 2013 SDR for the misreporting BMA facilities was erroneous and recommended that the SHCC correct the errors in future SDRs. The Committee adopted the recommendation of the Agency Report on September 11, 2013.

59. The SHCC adopted the recommendation of the Agency Report at its October 2, 2013 meeting, and accordingly, in the January 2014 SDR, the Planning Branch corrected the December 31, 2012 patient census totals and the resulting AACR for the years ending December 31, 2008 through December 31, 2012 for the affected counties.

60. At the time of that meeting, the TRC Application and the BMA Application were already under review by the CON Section and the CON Section had made the determination that the published July 2013 SDR was the plan in effect at the time review of the TRC Application and the BMA Application commenced.

61. The January 2014 SDR was not published as of September 16, 2013 nor had the January 2014 SDR been published on October 1, 2013 when the Nash County Review began.

62. The January 2014 SDR was not published until January 2, 2014 and was in effect for reviews that began on April 1, 2014. The January 2014 SDR is a different document published for a different review cycle than the July 2013 SDR.

63. Since the July 2013 SDR was not amended, changed or republished, the CON Section proceeded with accepting CON applications pursuant to the county need determinations in the July 2013 SDR, which was in effect for the Nash and Scotland county reviews.

64. On September 16, 2013, both BMA and TRC submitted applications for the 2013 Nash County ESRD Review. BMA proposed to add 11 new stations to its existing BMA Rocky Mount facility in Nash County. TRC proposed to develop a new 12-station dialysis facility in Rocky Mount, Nash County.

65. The BMA Application and the TRC Application were filed in the same review period. Because together the BMA Application and the TRC Application proposed to develop a total of 23 new dialysis stations, exceeding the 19 station need determination, the Agency could not approve both of the applications in their entirety. Accordingly, the Agency batched the two applications for a competitive review.

66. BMA filed its application in complement to a previously filed application to develop a new facility in southern Rocky Mount (the "South Rocky Mount Application") by relocating 12 stations from the BMA Rocky Mount facility. BMA filed the South Rocky Mount Application to allow BMA to serve existing patients living in southern Rocky Mount at a more convenient location, while freeing up space at BMA Rocky Mount for additional stations to address a growing number of patients seeking treatment at BMA's facility both from within and outside of Nash County.

67. At the time the BMA South Rocky Mount Application was filed, BMA was the sole provider of dialysis services in Nash County. BMA was the only provider that could have filed such an application for a *de novo* facility in Nash County because there were no other providers in the county at that time. Because BMA proposed to use its existing stations for the South Rocky Mount facility, this application was non-competitive.

68. BMA decided not to seek a *de novo* facility in South Rocky Mount in a single step process in a competitive review, but rather to seek a *de novo* facility in Rocky Mount through a multi-step process: (1) filing a noncompetitive application on August 15, 2013 to remove 12 stations from its Rocky Mount facility and transfer those 12 stations to a new *de novo* facility in South Rocky Mount; and (2) filing a competitive application on September 16, 2013 pursuant to the Nash County need determination to backfill 11 of the 12 the stations that were transferred out of BMA's Rocky Mount facility.

69. BMA included all of its capital costs in the non-competitive South Rocky Mount Application. In the competitive BMA Rocky Mount Application that BMA filed on September 16, Mr. Swann represented to the CON Section that BMA would have no capital costs because it was backfilling stations. With the exception of BMA, all other competitive applications filed on September 16, 2013 had capital costs associated with those applicants' proposed projects.

70. The South Rocky Mount Application was approved during the Agency's review of the BMA Application and the TRC Application. TRC did not appeal the Agency's approval of the South Rocky Mount Application, and the Agency's approval of the South Rocky Mount Application is not an issue in this contested case.

71. BMA and TRC each filed applications during the competitive review in Scotland County on September 16, 2013. Due to the number of stations being sought in BMA's two competitive applications in the Scotland County Review, if either BMA application was approved by the Agency and BMA's application was deemed to be comparatively superior to TRC, TRC's application would have been denied because less than ten stations would have remained available.

72. BMA and TRC's applications in the Scotland County Review were found by the Agency to be conforming with all of the applicable statutory review criteria and performance standards. BMA's application was approved and was deemed comparatively superior to TRC's application. Because BMA's Scotland County application was approved, there were not enough stations for the CON Section to grant TRC's application for a *de novo* facility in Scotland County.

73. Once CON applications in this present Nash County ESRD Review matter were filed, the Agency assigned a project analyst. Julie Halatek was the project analyst assigned to the 2013 Nash County ESRD Review. The Interim Chief of the CON Section, Martha Frisone, was the co-signer for this Review. BMA and TRC each submitted written comments and public hearing comments regarding the other's application. Halatek and Frisone read and considered the comments made by the applicants, and Halatek investigated comments she thought were relevant to the statutory review criteria.

74. The Agency determined that both the BMA Application and the TRC Application were fully conforming with all applicable statutory review criteria and rules. In the comparative analysis, the Agency determined that TRC was comparatively superior with regard to more of the factors it chose in this Review and therefore decided to approve the TRC Application for all 12 stations for which it applied.

75. Because the approval of the TRC Application left seven stations which could be approved consistent with the need determination, the Agency approved the BMA Application on the condition that it develop only 7 of the 11 stations it had proposed. The Agency issued its decision in this Review on February 27, 2014, and issued the required state agency findings for the Review on March 6, 2014.

76. In the September 16, 2013 TRC application, Mr. Hyland relied on the July 2013 SDR as published by the State for TRC's applications. Hyland testified that he typically uses the AACR as published in the SDR when determining the rate at which to grow a patient population. Hyland relied on the information in the July 2013 SDR, including the AACR, and the need determination for 19 stations, to guide his preparation of the TRC Application in Nash County.

77. At the hearing in this contested case, BMA challenged the Agency's decision with respect to the statutory review criteria found at N.C. Gen. Stat. § 131E-183(a)(3), (4), (5), (6), and (18a) ("Criterion 3," "Criterion 4," "Criterion 5," "Criterion 6," and "Criterion 18a").

78. Criterion 3 in the CON Law, which pertains to demonstrating need for a proposed project, states that an 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 like to have access to the services proposed." N.C. Gen. Stat. § 131E-183(a) (3).

79. The TRC Application provided assumptions made by Mr. Hyland in order to support the application's projection utilizations to satisfy Criterion 3.

80. One of TRC's assumptions was that "TRC assumes that a significant number of Nash County in-center ESRD dialysis patients are leaving Nash County three times a week to receive their dialysis treatments at facilities outside [of] Nash County." (Hyland, Tr. Vol. 8, p. 1715; Frisone, Tr. Vol. 6, p. 1423; Jt. Ex. 3, p. 30). TRC's assumption was based on Patient Origin Data that TRC had that TRC was treating 15 Nash County in-center patients as of December 31, 2012 who were receiving services in four of DaVita dialysis facilities outside of Nash County.

81. TRC provided support for this assumption in the chart on page 31 of the TRC Application wherein TRC showed that it had 15 patients that would grow to 25 patients by September 1, 2013 that resided in Nash County but were seeking treatments in DaVita facilities outside of Nash County as of September 1, 2013. Mr. Hyland grew those 15 Nash County patients being served by the four DaVita facilities outside of Nash County to 25 patients by September 1, 2013 based on numbers he received from one of DaVita's insurance specialist, Marilyn Stauter. Stauter is responsible for and has access to all of the patient data for every DaVita facility in North

Carolina, and can pull that data for Hyland by facility for him for his use in preparing CON applications.

82. Criterion 3 requires each applicant to identify the patient population to be served and to demonstrate the need that this population has for the proposed services. To identify a patient population who might use its proposed facility when it opened, TRC presented letters from existing patients at TRC facilities who were receiving in-center hemodialysis treatment, or who had received training on home dialysis, and were interested in receiving services through the new facility. TRC's identification of a starting population of patients who were projected to receive in-center or home dialysis services from its proposed Nash County facility when it opened was based upon expressions of interest from specific dialysis patients.

83. Mr. Hyland received a total of 32 patient letters to include in TRC's Application. The 32 letters from patients were presented in Exhibit 12 to the TRC Application, and the text of each letter was very similar, indicating the patient's interest in receiving treatment at the proposed facility and explaining that doing so would be more convenient and less expensive for them. Only one of the 32 letters specified the patient's county of residence.

84. BMA contends that TRC's utilization projections were not reasonable, credible, or supported because they were based on the assumption that 26 Nash County residents and six Wilson County residents had signed letters of support for the project.

85. BMA pointed out TRC's lack of documentation for its patient origin assumptions to the Agency in its written comments on the TRC Application. Ms. Halatek testified that she raised concerns during the Review over the lack of documentation to support TRC's statements regarding the patients' county of origin.

86. In a TRC application for a new facility in Scotland County filed the same day as the Nash County application and which also relied on patient letters to support the utilization projections, every support letter stated the patient's county of residence.

87. Ms. Frisone was aware at the time of the Nash County Review that only one of the 32 letters that TRC submitted in its application stated the county in which the patient lived, but this did not require the CON Section to find TRC's Application non-conforming. The CON Section did not agree with BMA's written comments that TRC's letters of support were non-specific and unreliable. Each of TRC's patients stated "I could travel between my home and a location in Rocky Mount more easily and quickly, which would save me time and money." (Hyland, Tr. Vol. 8, p. 1731). In addition, each letter stated: "But I definitely would consider transferring because it would mean a shorter trip to dialysis [and] would make getting my treatments easier." (Hyland, Tr. Vol. 8, p. 1731).

88. Ms. Frisone, Mr. Swann, Mr. French, and Mr. Hyland each agree that if an applicant is going to provide a letter of support, there is no statute, law or rule within CON that requires or dictates the content of the patient letters of support. The content placed in that letter of support is up to the provider.

89. In a prior Franklin Review in which BMA filed a CON Application to relocate stations from Wake County to Franklin County, BMA argued to the Agency that when a patient says they believe the proposed facility is closer to their home and more convenient, the Agency should give deference to that statement and place greater weight on the patients' preference for the proposed location as they expressed in the support letters. As a result of the Franklin review, the Agency has since recognized when they see a patient letter of support similar to the ones in the TRC Application that the concept of patient choice is more important than focusing on a zip code.

90. The Agency accepted TRC's representations regarding patient origin at face value. Ms. Frisone maintained that the absence of the county of residence in the support letters did not undermine the reasonableness, credibility and support for the utilization projections because there is no rule or statute that requires the letters of support to state information regarding the patient's residence. Frisone testified that, although the letters may not have documented the county of residence, they nonetheless documented intent to transfer. Although 31 of the TRC patient support letters do not indicate the county in which the patients live, there is information in the letters that supports the utilization projections used in TRC's Application.

91. The evidence presented by TRC in this contested case establishes that TRC incorrectly represented the county of residence of the patients who signed support letters. In fact, there were letters from 21 Nash County patients, 9 Wilson County patients, 1 Edgecombe County patient, and 1 patient whose county of residence is unknown.

92. At some point in time after he had already prepared the chart on page 31 of the TRC Application based upon data provided by Ms. Stauter, Mr. Hyland received 32 patient letters back from Ms. Robinson and Ms. Lewis. Hyland made copies of those letters and attached them as an exhibit to the TRC Application.

93. In the course of discovery during this litigation, Mr. Hyland located a document which tallies the number of patient letters from Nash, Wilson, and Edgecombe counties. According to Joint Exhibit 61, TRC had obtained 21 patient letters from Nash County residents; 9 patient letters from Wilson County residents; 1 letter from an Edgecombe County resident; and 1 patient letter of unknown residence due to the illegible handwriting. Hyland recalls seeing this document for the first time in August 2014 the night before his deposition in this contested case, in connection with preparing for his deposition.

94. Although Mr. Hyland does not contest that Joint Exhibit 61 is dated September 13, 2013 and contains his handwriting, he had no specific recollection of completing this document on or about September 13, 2013. According to Joint Exhibit 61, on September 13, 2013, three days before Hyland filed 14 applications on the September 16, 2013 CON review deadline, he scanned and emailed to himself a document entitled "Index of Patient Support Letters for [the] Nash County facility." Hyland wrote on this document the county of residence for each of the 32 patients shown on that document by denoting the county with an "E," and "N", or a "W" for Edgecombe, Nash or Wilson, respectively. Hyland indicated on this document that the 32 patient letters for TRC's Nash application include 21 Nash County residents, 9 Wilson county residents, 1 Edgecombe County resident, and 1 unknown county resident whose name was illegible.

95. Mr. Hyland testified that although he had done the analysis in Joint Exhibit 61 three days before he submitted the TRC Application, he does not recall preparing this document. If he had realized that this document showed numbers that were different than what he had previously written in the TRC Application, he would have revised the TRC Application to recalculate the number of patients TRC would be serving based on assumptions that TRC would start with 21 Nash County patients and 9 Wilson County patients.

96. The information in the TRC application regarding patients' county of residence was correct based on the information that Ms. Stauter provided. Hyland made the erroneous assumption that the patient letters of support he would receive from patients through Ms. Robinson would match the information that had been provided to him by Stauter in the course of his preparation of the TRC Application. The TRC Application erroneously represents that TRC had letters of support from 26 Nash County residents. Hyland admitted his mistake of failing to realize that the numbers contained on Joint Exhibit 61 were different than what he previously wrote into the TRC Application and testified that he was in no way trying to deceive or mislead the CON Section.

97. In analyzing an applicant's demonstration of need under Criterion 3, the Agency evaluates an applicant's utilization projections to see both whether the projected utilization is expected to meet the applicable performance standard and also whether these utilization projections are reasonable, credible, and supported.

98. The Agency has adopted rules setting forth performance standards applicable to dialysis reviews, requiring an applicant to document need by demonstrating that its stations will be utilized at the rate of 3.2 patients per station per week (or 80% utilization) by the end of the first operating year. When an applicant projects to meet the performance standard based on reasonable, credible, and supported assumptions, the Agency generally finds the application to be conforming to Criterion 3. However, if an applicant projects to meet the performance standard based on assumptions that are not reasonable, credible, and supported, the Agency finds the application nonconforming to Criterion 3.

99. Because TRC proposed a 12-station facility, it had to project that there would be at least 39 in-center patients at the end of its first year of operations in order to meet the performance standard.

100. Mr. Hyland took 25 Nash County patients treating in facilities outside of Nash County as of September 1, 2013, notated in the TRC Application that those in-center patients were based on support letters, and then added one letter from a non-DaVita patient being followed by Dr. Bynum who indicated that the patient lived in Nash County and would be referred to DaVita. As a result, Hyland based his assumption that he had 26 patients living in Nash County.

101. Mr. Hyland believed there were 6 patients from Wilson so he added the 26 patients living in Nash County and the 6 patients living in Wilson for a total of 32 patients as the starting point for TRC's utilization projections. TRC's starting census of 32 patients matched the number of support letters signed by actual patients which were attached to TRC's Application.

102. Ms. Frisone testified that without regard to whether Mr. Hyland ultimately made an error with regard to whether it was 26 Nash County patients and 6 Wilson patients or 21 Nash County patients, 9 Wilson patients, 1 from Edgecombe, and 1 unknown, there were a total of 32 patients who made direct, unambiguous statements that treating at the TRC facility in Rocky Mount would be more convenient for them. TRC's submission of support letters from 32 actual patients was a factor that Frisone took into consideration in determining that the need projections in the TRC Application were reasonable.

103. There is no error in the number of patient letters that Mr. Hyland provided with the TRC Application; there are 32 letters and 100% of those 32 patients indicated it would be more convenient and less costly to them to receive dialysis at a proposed TRC facility in Rocky Mount.

104. In addition to the 32 patient letters of support attached to the TRC Application, the following also supported TRC's patient projections in TRC's Application: (1) the December 31, 2012 Patient Origin Report, which was accurate and available to both the CON Section and Mr. Swann; (2) letters to the CON Section in support of TRC's growth projections that there was physician support for TRC's proposed project; and (3) two physician letters included with TRC's Application that evidenced the physicians' intent to refer ESRD patients to TRC's proposed facility.

105. To grow the patient population going forward, Mr. Hyland grew the 26 Nash County patients using the 9.6% AACR published in the July 2013 SDR and then added the 6 Wilson County patients. By applying the five-year AACR to TRC's assumption that it was starting with 26 Nash County in-center patients and then adding the Wilson patients, TRC projected that the Nash County facility would serve 39.8 patients by the end of Operating Year one, which would be 3.2 patients per station per week as required by 10A NCAC 14C .2203(a).

106. Mr. Hyland testified that no growth rate was applied to the Wilson County patients because the projections for the new facility already met the performance standards, and therefore he saw no need to grow the Wilson County population.

107. Mr. Hyland re-calculated in TRC Exhibit 302 projections using the numbers that were in Exhibit 61 of 21, 9, 1, and 1. When Hyland carried the same calculations through on these numbers, he concluded that at the end of Operating Year 1, TRC would have a total of 39 in-center patients with 27 Nash County patients, 10 Wilson County patients, plus two other patients. Accordingly, even using the numbers shown in Joint Exhibit 61, TRC would have projected a total of 39 in-center patients.

108. In TRC's Application, Mr. Hyland grew the 26 Nash County patients forward at 9.6% and did not add any growth rate for the six Wilson County patients. Although Hyland could have grown the Wilson County patients, he chose not do so to be conservative and because simply growing forward the total of the 26 Nash County patients (the 25 patients Mr. Stauter indicated TRC was actually treating as of September 1, 2013 and the one patient from Dr. Bynum) allowed TRC to meet the performance standard in .2203. In contrast, in Hyland's re-calculation using the numbers shown in Joint Exhibit 61, Mr. Hyland grew the Wilson County patients by the 4.7% AACR for Wilson County in order to satisfy the performance standard of .2203.

109. BMA contends that TRC's assumption that the Nash County patient population it identified would grow at 9.6% per year was not reasonable, credible, or supported. Criterion 3 requires the applicant to reasonably demonstrate the need that its identified population has for the services proposed.

110. Before it applied, TRC and BMA knew that the published AACR was based on data erroneously reported by BMA. Mr. Swann testified that the reporting errors were obvious, noting that the population spike for Nash County residents reported in the July 2013 SDR was inconsistent with historical trends. The Agency had publicly recognized the AACR was erroneous and had endorsed the corrected data. The Agency acknowledged that 2.1% was the historical growth rate.

111. BMA's expert witness, David French testified that need determinations are hypothetical determinations that set the maximum number of dialysis stations that can be approved, but the CON review process checks the applications against real world circumstances. Mr. French testified that the fact that a statistic is published does not, in his opinion, give it more credibility than data from another source. French agreed that it is within the discretion of the Agency to determine what circumstances are reasonable or not.

112. Ms. Frisone testified that the Agency may look beyond the published growth rate and determine whether it presents a reasonable assumption noting that the Agency looks to the totality of the circumstances when evaluating conformity.

113. The 9.6% AACR was in a published SDR, which is a part of the SMFP, and was in effect at the time that the Nash County Review began. In Ms. Frisone's experience, the CON Section has historically deemed the AACR in the published SDR to be reasonable, supported, and credible. Further, the CON Section determined that TRC's use of the published AACR was reasonable, credible, and supported since the Planning Section had used that 9.6% average annual change rate to calculate the 19-station deficit.

114. Mr. Hyland routinely uses the published AACR in CON applications that he has filed over the years and has never had his practice of using the published AACR determined by the Agency to be unreasonable. Hyland testified it was reasonable for TRC to use the published 9.6% AACR in its Application to develop a 12-station *de novo* facility in Nash County for the following reasons: (1) the 9.6% AACR was the driving force to the need determination of a 19-station deficit of stations for a county need determination in Nash County; (2) one hundred percent of the CON applications Hyland submitted for *de novo* facilities and county need determination have been submitted using the published AACR; and (3) neither DaVita nor TRC has historical data on which to depend since they have never operated a facility in Nash County.

115. Ms. Frisone determined that it was reasonable for TRC to use the 9.6% AACR in its Application in the Nash County Review because it was the AACR contained in a published SDR that was in effect on the date that the Nash County Review began and was the applicable SDR for the Nash County Review. As of the time of the Nash County Review, the CON Section had found that an applicant's use of a published average annual change rate was reasonable. Frisone's analysis of the TRC Application in the Nash County Review was consistent with that

historical practice. Ms. Halatek consulted with Frisone regarding the issue of whether it was reasonable to use the 9.6% AACR. Frisone advised Halatek that it was reasonable and supported for TRC to rely on the published AACR of 9.6%.

116. TRC relied on the published AACR as one of its assumptions for its need methodology of its application and had the reasonable expectation that it could rely on the published SDR that was in effect on the date that the Nash County Review began.

117. The 9.6% growth rate is what led to the need determination and is the growth rate on which the 19 stations depend. Of great importance in this case, without the 9.6% growth rate, there would not have been a 19-station deficit in Nash County nor would there have been a need determination in Nash County. If the July 2013 SDR had been changed by the Governor, then neither BMA's nor TRC's applications would have been before the CON Section.

118. The Agency has the discretion to take into account all circumstances of any given application in order to determine whether the applicant's use of the published SDR growth rate is reasonable, credible, and supported. Under the facts and circumstances of the Nash County Review, it was reasonable for TRC to use the published 9.6% growth rate.

119. Criterion 4 requires an applicant to demonstrate that the least costly or most effective alternative has been proposed where there are alternative methods of meeting the need for the proposed project. N.C. Gen. Stat. § 131E-183(a)(4).

120. The CON Section made a reasonable determination that the TRC Application was conforming with Criterion 4 because the TRC Application was conforming with all other applicable statutory and regulatory review criteria and TRC adequately demonstrated that its proposed project was the least costly or most effective alternative to meet the need.

121. Criterion 5 requires that "[f]inancial 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 and charges for providing health services." N.C. Gen. Stat. § 131E-183(a)(5).

122. The CON Section made a reasonable determination that the TRC Application was conforming with Criterion 5 because TRC adequately demonstrated that the financial feasibility of the proposed project was based on reasonable projections of revenues and operating costs.

123. Criterion 6 requires that an applicant demonstrate that its proposed project will not result in unnecessary duplication of existing or approved health service capabilities. N.C. Gen. Stat. § 131E-183(a)(6).

124. The CON Section made a reasonable determination that the TRC Application was conforming with Criterion 6 because TRC adequately demonstrated the need to develop a new 12-station dialysis facility in Nash County. As a result, the Agency found that TRC's proposed project would not result in the unnecessary duplication of existing or approved health service capabilities or facilities.

125. Criterion 18a requires that an applicant demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition would have a positive impact upon cost effectiveness, quality, and access to the proposed services. N.C. Gen. Stat. § 131E-183(a)(18a).

126. The CON Section made a reasonable finding that the TRC Application conformed with Criterion 18a because TRC provided information in Sections II, III, V, VI, and VII of its Application which was reasonable and credible, and that adequately demonstrated that any enhanced competition in the service area would have a positive impact on the cost-effectiveness, quality and access to the proposed services.

127. The Agency found that the TRC Application was conforming with the performance standards at 10A NCAC 14C .2203(a), because it proposed to serve 3.2 patients per station by the end of operating year one.

128. The TRC and BMA applications were reviewed competitively by the Agency. Both applications could not be approved as proposed, because they collectively proposed 23 dialysis stations, but the need determination for Nash County was only for 19 dialysis stations.

129. The Agency found that the TRC Application conformed with all statutory and regulatory review criteria in N.C. Gen. Stat. § 131E-183(a). BMA was also found conforming with all applicable review criteria in the Nash County Review. The Agency's comparative analysis utilized twelve comparative factors on which the two applications were compared. These factors are consistent with the factors that the Agency has historically reviewed and used in other ESRD applications to compare those applications and determine whose application is comparatively superior.

130. The CON Section reviewed and used the following factors in the comparative analysis in the Nash County Review: Home Training, Hours of Availability, Services in Rural, Remote Areas, Facility Location, Access to Ancillary and Support Services, Service to Nash County Residents, Availability of Staff and Medical Director, Access by Underserved Groups, Average Net Revenue per Treatment, Average Operating Cost per Treatment, and Direct Care Staff Salaries. TRC was the more effective alternative on all factors where it was not an equally effective alternative to the BMA Application.

131. The Agency determined that the TRC and BMA applications were comparatively equal with respect to the following seven factors: home training; hours of availability; services in rural, remote areas; facility location; access to ancillary and support services; service to Nash County residents; and availability of staff and medical director. The Agency determined that TRC was the comparatively superior applicant with respect to the following five factors: access by underserved groups, access to alternative providers, average net revenue per treatment, average operating cost per treatment, and direct care staff salaries.

132. Because the CON Section determined that TRC was the comparatively superior applicant, the CON Section awarded TRC the 12 stations sought by the TRC Application. On February 27, 2014 and by Required State Agency Findings issued on March 6, 2014, the Agency

issued its decision approving the TRC Application for a new twelve-station facility in Nash County and conditionally approving the BMA Application for seven of the eleven stations for which BMA applied.

133. Pursuant to North Carolina General Statute 131E-186, the Agency has the authority to conditionally approve an applicant for a *de novo* dialysis facility that contains fewer stations than for which the applicant applied if the Agency determines that the applicant demonstrated a need for a fewer amount of stations than for which it applied.

134. The fact that TRC's Application was comparatively superior to BMA's Application was material to Ms. Frisone's testimony that had TRC demonstrated the need for a 12, 11, or 10 station facility, Frisone would have conditionally approved TRC for a downsized facility had she felt the need to do so, which she did not.

135. Ms. Frisone reviewed and understood the chart contained in Mr. Swann's written comments wherein he took exactly what was in TRC's Application and applied a 2.1% AACR. Specifically, he used the same numbers in TRC's Application, 26 patients from Nash and 6 from Wilson, duplicated TRC's methodology, and changed the AACR to 2.1%. From this chart, prepared by Swann, Frisone surmised that if the CON Section were to accept BMA's argument that the highest possible growth rate that could be used was 2.1%, the CON Section would still consider conditioning TRC to develop a 10-station facility instead of denying TRC's Application because by Swann's calculations using a 2.1% AACR, TRC would have satisfied the performance criteria for at least a 10-station *de novo* facility.

136. Ms. Frisone agreed that Mr. Swann conducted another analysis wherein Swann changed the AACR from 9.6% to 2.1%, the 26 Nash County patients to 21, the 6 Wilson County patients to 9, and included both the Edgecombe and unknown patients. Even under this scenario, TRC would have satisfied the performance standard and demonstrated the need for a 10-station *de novo* facility in Nash County.

137. Had Ms. Frisone determined that TRC demonstrated the need for a 10 station *de novo* facility, she would have approved TRC for the 10 station *de novo* facility and conditionally approved BMA for 9 of its requested 11 stations.

138. In BMA Exhibit 134, Mr. Swann took the same analysis that TRC used in their application except that he broke down the patient support letters as 21 Nash County patients, 9 Wilson County patients, 1 Edgecombe County patient, and 1 patient from an unknown county for a total of 32 support letters. Swann then took 21 patients for Nash County and projected those patients at the 9.6% AACR that was published in the July 2013 SDR. Swann admitted that using 21 patients for Nash County at a 9.6% AACR would satisfy the performance standard for an 11 station *de novo* facility. Had the information in TRC's Application shown 21 Nash County patients rather than 26, and 9 Wilson County patients instead of 6, Ms. Frisone would have conditioned TRC for an 11 station *de novo* facility, and conditionally approved BMA for 8 stations.

139. Ms. Frisone and Ms. Halatek both acknowledged that the Agency did not perform any analysis during the Review to determine the impact of a lower growth rate on TRC's

conformity or give any consideration to the impact of the inaccurate patient support letter assumptions.

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

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

3. The subject matter of the above-captioned contested cases are the CON Section's decisions to approve the TRC Application and to conditionally approve the BMA Application. 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). *See also Presbyterian Hosp. v. N.C. Dep't of Health and Human Servs.*, 177 N.C. App. 780, 784, 630 S.E.2d 213, 215 (2006).

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

5. As the Petitioner, it is BMA's burden to prove the facts required by G.S. 150B-23(a) by a preponderance of the evidence. N.C. Gen. Stat. § 150B-29(a).

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

455, 459, *disc. review denied*, 341 N.C. 418, 461 S.E.2d 754 (1995) (rejecting petitioner's contention that initiation of a contested case commenced a *de novo* proceeding by the ALJ).

7. When a party questions whether the Agency's decision was supported by the evidence or whether it was arbitrary or capricious, the appropriate standard is the whole record test. *Britthaven*, 118 N.C. App. at 386, 455 S.E.2d at 461.

8. Under the whole record test, "a court must examine all of the record evidence – that which detracts from the agency's findings and conclusions as well as that which tends to support them – to determine whether there is substantial evidence to justify the agency's decision." *Good Hope Health Sys. v. N.C. Dep't of Health and Human Servs.*, 189 N.C. App. 534, 543, 659 S.E.2d 456, 462 (2008) (quoting *Watkins v N.C. State Bd. of Dental Exam'rs*, 358 N.C. 190, 199, 593 S.E.2d, 764, 769 (2004)). Substantial evidence is "relevant evidence a reasonable mind might accept as adequate to support a conclusion." N.C. Gen. Stat § 150B-2(8c).

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

10. When employing the whole record test, a reviewing court may not substitute its opinion for that of the Agency even if it would reach a different conclusion given its consideration of the whole record. *Gordon v. N.C. Dep't of Corr.*, 173 N.C. App. 22, 34, 618 S.E.2d 280, 289, (2005); *Watkins*, 358 N.C. at 199, 593 S.E.2d at 769. The whole record test cannot be used as a "tool of judicial intrusion." *E. Carolina Internal Med*, 211 N.C. App. at 407, 710 S.E.2d at 253 (quoting *Hosp. Grp. of W. N.C., Inc. v. N.C. Dept. of Human Res.*, 76 N.C. App. 265, 268, 332, S.E.2d 748, 751 (1985)).

11. Under the whole record test, even an error in the Agency's analysis of an applicant may be harmless if it does not affect the outcome in the review. *Britthaven*, 118 N.C. App. at 386-89, 455 S.E.2d at 461-463. If a reviewing court finds that the Agency's analysis included an error that if correctly decided would have led to the same decision, the error is harmless under the whole record test. *Id* at 386-89, 455 S.E.2d at 461-63.

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

13. The Agency's interpretation and application of the statutes and rules it is empowered to enforce are entitled to deference as long as the agency's interpretation is reasonable and based on a permissible construction of the statute. *Carpenter v. N.C. Dep't of Human Res.*, 107 N.C. App. 278, 279, 419 S.E.2d 582, 584 (1992), *disc. rev. improvidently allowed*, 333 N.C. 533, 427 S.E.2d 874 (1993).

14. North Carolina law presumes that the Agency has properly performed its duties. *See, e.g.*, *In re Broad & Gales Creek Cmty. Assoc.*, 300 N.C. 267, 280, 266 S.E.2d 645, 654 (1980); *Adams v. N.C. State Bd. of Registration for Prof'l Eng'rs & Land Surveyors*, 129 N.C. App. 292, 297, 501 S.E.2d 660, 663 (1998); *In re Land & Mineral Co.*, 49 N.C. App. 529, 531, 272 S.E.2d 6, 7, *disc rev. denied*, 302 N.C. 397, 297 S.E.2d 351 (1981) (holding that "[t]he official acts of a public agency . . . are presumed to be made in good faith and in accordance with law").

15. The development and establishment of a new dialysis facility like those proposed by BMA and TRC in their respective applications requires a certificate of need. N.C. Gen. Stat. §§ 131E-178(a) and 131E-176(16).

16. In implementing the State's CON program, the CON Section has a statutory duty to review and decide applications submitted for certificates of need in accordance with the laws adopted by the General Assembly. N.C. Gen. Stat. § 131E-177(6). In doing so, the Agency must evaluate CON applications pursuant to North Carolina's CON statute. *See* N.C. Gen. Stat. §§ 131E-182 and 131E-183; *see also Living Centers-Southeast, Inc. v. N.C. Dep't of Health and Human Servs.*, 138 N.C. App. 572, 574-75, 532 S.E.2d 192, 194 (2000).

17. "N.C. Gen. Stat. § 131E-183(a) charges the Agency with reviewing all CON applications utilizing a series of criteria set forth in the statute. The application must either be consistent with or not in conflict with these criteria before a certificate of need for the proposed project shall be issued." *Parkway Urology*, 205 N.C. App. at 534, 696 S.E.2d at 191-92.

18. In the review of applications, the Agency must review each application individually to test it against the statutory and applicable regulatory review criteria. *Britthaven*, 118 N.C. App. at 384-85, 455 S.E.2d at 460.

19. BMA's reliance on other sets of Agency Findings is not persuasive or controlling in determining whether the Agency erred in this case. *Charlotte-Mecklenburg Hosp. Auth. v. N.C. Dep't of Health and Human Servs.*, No. COA11-339, 2011 WL 6359618, at *10 (N.C. Ct. App. Dec. 20, 2011) (unpublished opinion) (cited for the proposition that prior Agency findings are irrelevant unless those findings address sufficiently similar issues to those presented in the above-captioned contested case).

20. The TRC Application presented reasonable, credible, and supported projections of patient origin for the services to be provided by the proposed Nash County facility, including both in-center and home dialysis services, and adequately provided the methodology and assumptions by which it projected patient origin, in conformity with 10A N.C.A.C. 14C.2203.

21. Pursuant to 10A N.C.A.C. 14C.0402, "The correctness, adequacy, or appropriateness of criteria, plans, and standards shall not be an issue in a contested case hearing."

22. Based on 10A N.C.A.C. 14C.0207(a), the Agency could not use the January 2014 SDR to evaluate the conformity of the TRC or BMA applications. Although the Agency is permitted to utilize information available to it during the review, the Agency is required to apply

the plan in effect at the time the review commences. The July 2013 SDR was in effect at the time the review commenced, and the Agency was correct in its decision not to use the January 2014 to evaluate the TRC or BMA application.

23. The TRC Application presented reasonable, credible and supported projections for utilization of the proposed Nash County facility, and adequately provided the methodology and assumptions by which it projected utilization, in conformity with 10A N.C.A.C. 14C.2203.

24. Pursuant to 10A N.C.A.C. 14C.2203(a), "An applicant proposing to establish a new [ESRD] facility shall document the need for at least 10 stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the facility, with the exception that the performance standard shall be waived for a need in the [SMFP] that is based on an adjusted need determination."

25. Using the fact that TRC had 32 patient letters of support, TRC's Application demonstrates compliance with Performance Rule .2203 requiring at least a 10-station *de novo* facility. This conclusion is true whether TRC used a 2.1% AACR, or the 9.6% AACR published in the July 2013 SDR.

26. The CON Section correctly and reasonably determined the TRC Application conformed with all statutory and regulatory review criteria applicable to applications proposing dialysis facilities, including the performance standards set forth in and 10A N.C.A.C. 14C.2203.

27. Considering all matters as found in the findings of fact, the CON Section did not exceed its authority or jurisdiction, act erroneously, fail to use proper procedure, act arbitrarily or capriciously, or fail to act as required by law or rule in issuing its decision to approve the TRC Application for 12 dialysis stations in Nash County.

28. A petitioner must "establish that the agency named as the respondent has . . . substantially prejudiced the petitioner's rights." N.C. Gen. Stat. § 150B-23(a); s*ee also Britthaven*, 118 N.C. App. at 382, 455 S.E.2d at 459 (noting "the ALJ is to determine whether the petitioner has met its burden in showing that *the agency* substantially prejudiced petitioner's rights") (emphasis in original).

29. 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 approval of the TRC Application will result in increased competition. *See CaroMont Health, Inc. v. N.C. Dep't of Health and Human Servs.*, 751 S.E.2d 244, 250-51 (2013) (holding that a provider challenging an agency decision to grant a CON must show specific evidence of harm beyond any harm resulting from additional competition arising from the approval).

30. The North Carolina Court of Appeals has held that a denied competitive CON applicant "must present other evidence at a contested case hearing to demonstrate substantial prejudice – its mere status as a denied competitive CON applicant alone is insufficient as a matter of law." *Surgical Care Affiliates, LLC v. N.C. Dep't of Health and Human Servs.*, No. 12 DHR 12086, 2014 WL 5770252, at *3 (N.C. Ct. App. Oct. 21, 2014) (unpublished opinion) (citing

CaroMont Health, 751 S.E.2d at 247, and *Parkway Urology*, 205 N.C. App. at 536-37, 696 S.E.2d at 193).

31. The fact that BMA's request for 11 stations was denied, in and of itself, does not amount to substantial prejudice. *See id.* The CON Section conditionally awarded BMA 7 of the 11 stations it requested.

32. It was BMA's reporting error to the Planning Section that resulted in the erroneous 19 station need determination in Nash County in the July 2013 SDR, not any action of the CON Section. But for BMA's reporting error, there would have been no county need determination in the July 2013 SDR for which TRC could have applied to establish a *de novo* facility in Nash County. Despite BMA being told by Director Pratt that the Agency could not amend the SDR and that BMA would need to petition the Governor to do so, BMA decided not to petition the Governor to amend the July 2013 SDR in order to have the need determination removed.

33. As set forth by the United State Supreme Court, "we have held that "the burden of proof" is a "'substantive' aspect of a claim." *Medtronic, Inc. v. Mirowski Family Ventures, LLC*, 134 S. Ct. 843, 849, 187 L. Ed. 2d 703 (2014) (quoting *Raleigh v. Illinois Dept. of Revenue,* 530 U.S. 15, 20–21, 120 S.Ct. 1951, 147 L.Ed.2d 13 (2000)); *see also Director, Office of Workers' Compensation Programs v. Greenwich Collieries,* 512 U.S. 267, 271, 114 S.Ct. 2251, 129 L.Ed.2d 221 (1994) ("[T]he assignment of the burden of proof is a rule of substantive law ..."); *Garrett v. Moore–McCormack Co.,* 317 U.S. 239, 249, 63 S.Ct. 246, 87 L.Ed. 239 (1942) ("[T]he burden of proof ... [is] part of the very substance of [the plaintiff's] claim and cannot be considered a mere incident of a form of procedure")."

34. Our own North Carolina courts have emphasized in multiple cases that "[t]he rule as to the burden of proof is important and indispensable in the administration of justice. It constitutes a substantial right of the party upon whose adversary the burden rests, and therefore it should be carefully guarded and rigidly enforced by the courts." *Tippite v. Atl. Coast Line R. Co.*, 234 N.C. 641, 644, 68 S.E.2d 285, 288 (1951).

35. Petitioner has failed to carry its burden of proof that the Agency's decisions to approve the application submitted by TRC to develop a new 12-station dialysis facility in Rocky Mount, Nash County; and to approve, with conditions, an application submitted by BMA to add 7 stations to an existing dialysis facility in Rocky Mount were in error.

BASED UPON the foregoing Findings of Fact and Conclusions of Law the Undersigned makes the following Final Decision.

FINAL DECISION

The Undersigned finds and holds that there is sufficient evidence in the record to properly and lawfully support the Conclusions of Law cited above. The Undersigned enters the following

Final Decision based upon the preponderance of the evidence, having given due regard to the demonstrated knowledge and expertise of the Agency with respect to facts and inferences within the specialized knowledge of the Agency.

Based upon the foregoing Findings of Fact and Conclusions of Law, the Undersigned holds that Petitioner failed to carry its burden of proof by a greater weight of the evidence regarding the issues presented in this contested case. The finder of fact cannot properly act upon the weight of evidence, in favor of the one having the *onus*, unless it overbears, in some degree, the weight upon the other side. The weight of Petitioner's evidence does not overbear the weight of evidence of Respondent to the ultimate issues, and as such Respondent's decisions to approve the TRC Application and conditionally approve the BMA Application is **AFFIRMED.**

NOTICE

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

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 26th day of March, 2015.

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Augustus B. Elkins II
Administrative Law Judge