TOPCATS Division 2321 West Morehead Street Charlotte, NC 28208 (P) 704-577-2853 (F) 866-480-7831

William L. Hyland Director of Healthcare Planning

## DaVita "he/she that gives life"

July 31, 2013

Mr. Craig R. Smith, Chief Certificate of Need Section Division of Health Service Regulation 809 Ruggles Drive Raleigh, North Carolina 27603



RE: Project #N-10153-13/Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Bladen Home Dialysis/Bladen County

Dear Mr. Smith:

BMA offers a Certificate of Need application that proposes to develop a new free standing home peritoneal dialysis program in Elizabethtown in Bladen County, North Carolina. DaVita Healthcare Partners Inc., operating as Southeastern Dialysis Center – Elizabethtown currently operates a twenty-four station End Stage Renal Disease facility that includes in-center dialysis and a peritoneal dialysis training program. There is no need to duplicate the peritoneal dialysis program in Bladen County. The facility operates a very successful peritoneal dialysis facility under the leadership of Rebecca Pait, RN, Facility Administrator and Billie Dove, RN, Peritoneal Dialysis Program Director.

As of July 30, 2013 Southeastern Dialysis Center - Elizabethtown was serving fifteen peritoneal dialysis patients. Twelve of the patients or 80% were referred by Nephrologists associated with Southeastern Nephrology Associates. Three of the patients or 20% were referred by Carolina Kidney Care.

As of July 30, 2013 Southeastern Dialysis Center – Elizabethtown was serving a total of eighty-four dialysis patients. Sixty-eight of the patients were receiving in-center dialysis, fifteen were receiving training and/or follow-up for peritoneal dialysis and one patient was a home hemodialysis patient.

As of July 30, 2013 Southeastern Nephrology Associates had referred a total of forty-nine of the eighty-four SEDC – Elizabethtown patients. Thirty-six were in-center patients, twelve peritoneal dialysis patients and one home hemodialysis patient. The twelve peritoneal dialysis patients represent 24.5% of the patients referred by Southeastern Nephrology Associates.

As of July 30, 2013 Carolina Kidney Care had referred thirty-five of the eighty-four SEDC – Elizabethtown patients. Thirty-two were in-center patients and three were peritoneal dialysis patients. The three peritoneal dialysis patients represent 8.6% of the patients referred by Carolina Kidney Care.

Carolina Kidney Care has had a presence in Southeastern Dialysis Center — Elizabethtown prior to the certification of the peritoneal dialysis program. The Nephrologists associated with Carolina Kidney Care have had the same opportunity to refer End Stage Renal Disease patients to the peritoneal dialysis program as the Nephrologists associated with Southeastern Nephrology Associates. However, there is a wide disparity in the number of patients referred by each practice.

The applicant proposing to develop the proposed FMC Bladen Home Dialysis in Elizabethtown wants you to believe that magically the percentage of patients living in Bladen County will increase to 20%. Dr. Ezra Lee McConnell, III, M.D. with Carolina Kidney Care in Fayetteville in Cumberland County indicates in his letter dated 04/03/2013, "My associates and I have been providing nephrology services for patients residing in Bladen and surrounding counties for many years." Yet, Dr. McConnell and his practice have only 20% of the peritoneal patients population in Bladen County, which represents only 8.6% of the patient population that they have referred to the SEDC – Elizabethtown facility.

Let's take a look at the Carolina Kidney Care growth of the PD patient population in Cumberland County, the county where they operate their practice office. The Nephrologists associated with Carolina Kidney Care serve as the Medical Directors for all of the facilities in Cumberland County. Therefore, it can be assumed that most of the End Stage Renal Disease patients who reside in Cumberland County are patients of Nephrologists associated with Carolina Kidney Care.

As of December 31, 2011 there were 533 End Stage Renal Disease patients living in Cumberland County. Of those patients, there were 475 in-center patients and 58 hometrained (peritoneal and home hemodialysis patients) patients. 10.8% of the Cumberland County patients were home-trained.

As of December 31, 2012 there were 579 End Stage Renal Disease patients living in Cumberland County. Of those patients, there were 518 in-center patients and 61 hometrained (peritoneal and home hemodialysis patients) patients. 10.5% of the Cumberland County patients were home-trained, a reduction of .3%. Cumberland County ESRD patient census increased by 43 total patients. 93% of the patient increase were in-center patients and only 7% of the patients were home-trained patients, which includes peritoneal dialysis and home hemodialysis patients.

Further I have attached a document that lists the counties where Fresenius or Fresenius affiliates are the only provider in the county. In 2011 only two of thirty-two counties had a home-training patient population of over 20%. The average home-training patient population for the thirty-two counties was 10.9%, 9.1% less than the 20% indicated in the

FMC Bladen CON application. In 2012 only one of the thirty-two counties had a home-training patient population of over 20%. The average home-training patient population for the thirty-two counties was 11%, 9% less than the 20% indicated in the FMC Bladen CON application.

I have also listed the counties where Fresenius or Fresenius affiliates and one or more other providers operate ESRD facilities. In 2011 one of the fourteen counties had a home-training patient population of over 20%. The average home-training patient population for the fourteen counties was 11.2%, 8.8% less than the 20% indicated in the FMC Bladen CON application. In 2012 two of the fourteen counties had a home-training patient population of over 20%. The average home-training patient population for the fourteen counties was 11.2%, 8.8% less than the 20% indicated in the FMC Bladen CON application. The additional county with more than a 20% home-training patient population was Brunswick County, where Fresenius operates a 10-station in-center facility with a total of 5 in-center and zero home-trained patients as of 12/31/13. The majority, if not all, of the home-trained patients in Brunswick County are being trained and followed by DaVita affiliated facilities.

The Certificate of Need application that was submitted by Fresenius for the proposed development of a stand-alone peritoneal dialysis facility in Elizabethtown in Bladen County should be denied. The applicant failed to identify a population to be served and proposes to duplicate a very successful peritoneal dialysis program that is supported by two large Nephrology groups.

DaVita Healthcare Partners Inc. reserves the right to make additional comments at the public hearing on this Certificate of Need application.

Sincerely,

William L. Hyland Director of Healthcare Planning DaVita Healthcare Partners Inc.

Attachment c: Martha Frisone Tanya Rupp

County	IC Patients	Home Patients	% Home Patients	<b>Total Patients</b>
Alexander	26	9	25.7	35
Beaufort	87	16	15.5	103
Bertie	58	7	10.8	65
Burke	72	15	17.2	87
Caldwell	90	12	11.8	102
Carteret	63	11	14.9	74
Caswell	30	2	6.3	32
Catawba	157	32	16.9	189
Chatham	76	5	6.2	81
Craven	154	15	8.9	169
Cumberland	475	58	10.8	533
Dare	26	1	3.7	27
Gaston	243	27	10	270
Granville	116	12	9.4	128
Halifax	199	34	14.6	233
Harnett	192	18	8.6	210
Johnston	210	20	8.7	230
Jones	30	. 3	9.1	33
Lee	100	8	7.4	108
Lenoir	159	11	6.5	170
Lincoln	63	18	22.2	81
Nash	171	22	11.4	193
Northampton	68	8	10.5	76
Orange	115	11	8.7	126
Pitt	284	33	10.4	317
Randolph	135	16	10.6	151
Sampson	150	14	8.5	164
Scotland	112	9	7.4	121
Stanley	60	5	7.7	65
Warren	58	2	3.3	60
Washington	35	1	2.8	36
Wautauga	18	12	40	30
Totals	3832	467	10.9	4299

## Counties Where At Least One Other Provider and Fresenius or Fresenius Affiliates Operate as of 12/31/11 13.8 Alamance 7.6 Anson Brunswick Duplin 7.4 Durham 11.5 Edgecombe 12.4 Franklin 7.4 Guilford 20.1 Iredell

Mecklenburg	1188	139	10.5	1327
Robeson	315	22	6.5	337
Union	155	27	14.8	182
Wake	883	133	13.1	1016
Wayne	209	41	16.4	250
Totals	4962	623	11.2	5585

Counties Where Only Provider is Fresenius or Fresenius Affiliates as of 12/31/12

County	IC Patients	<b>Home Patients</b>	% Home Patients	Total Patients
Alexander	38	4	9.5	42
Beaufort	79	18	18.6	97
Bertie	55	6	9.8	61
Burke	84	17	16.8	101
Caldwell	96	11	10.3	107
Carteret	66	12	15.4	78
Caswell	76	1	1.3	77
Catawba	158	24	13.2	182
Chatham	86	5.	5.5	91
Craven	148	16	9.8	164
Cumberland	518	61	10.5	579
Dare	29	2	6.5	31
Gaston	247	23	8.5	270
Granville	119	12	9.2	131
Halifax	160	26	14	186
Harnett	128	11	7.9	139
Johnston	208	24	10.3	232
Jones	20	. 1	4.8	21
Lee	127	10	7.3	137
Lenoir	169	19	10.1	188
Lincoln	78	21	21.2	99
Nash	216	43	16.6	259
Northampton	73	8	9.9	81
Orange	109	11	10.8	120
Pitt	278	48	14.7	326
Randolph	157	17	9.8	174
Sampson	147	13	8.1	160
Scotland	140	8	8.9	148
Stanley	64	5	7.2	69
Warren	66	8	10.8	74
Washington	34	2	5.6	36
Wautauga	17	8	32	25
Totals	3990	495	11	4485

Counties Where At Least One Other Provider and Fresenius or Fresenius Affiliates Operate as of 12/31/12				
Alamance	250	40	13.8	290
Anson	73	4	5.2	77
Brunswick	102	32	23.9	134
Duplin	132	6	4.3	138
Durham	473	45	8.7	518
Edgecombe	198	8	3.9	206
Franklin	104	10	8.8	114
Guilford	764	66	8	830
Iredell	172	47	21.5	219
Mecklenburg	1236	180	12.7	1416
Robeson	310	20	6.1	330
Union	163	18	9.9	181
Wake	914	132	12.6	1046
Wayne	216	39	15.3	255
Totals	5107	647	11.2	5754

## Frisone, Martha

From:

Bill Hyland [Bill.Hyland@davita.com]

Sent:

Wednesday, July 31, 2013 2:48 PM

To:

Smith, Craig

Cc:

Frisone, Martha; Rupp, Tanya; Bill Hyland

Subject:

Public Written Comment for Certificate of Need Application N-10153-13

Importance: High

Attachments: FMC Bladen Home Dialysis PWC.doc; Percentage of Home Patients in FMC Counties.xls

## Craig:

See the attached public written comment and attached chart in response to the Certificate of Need application submitted by Fresenius Medical Care. Please send a return email indicating that you have received this email.

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

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-DaVita, Inc.-