ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS
C = Conforming
CA = Conditional
NC = Nonconforming
NA = Not Applicable

DECISION DATE: November 27, 2013
PROJECT ANALYST: Gloria C. Hale
TEAM LEADER: Craig R. Smith

PROJECT I.D. NUMBER: F-10196-13/ Carolinas Rehabilitation-NorthEast, LLC and The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas Rehabilitation/ Offer inpatient dialysis services which is a change in scope for Project I.D. #F-8161-08 (develop 40-bed inpatient rehabilitation hospital/ Cabarrus County

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

G.S.131E-183(a) The Department shall review all applications utilizing the criteria outlined in this subsection and shall determine that an application is either consistent with or not in conflict with these criteria before a certificate of need for the proposed project shall be issued.

(1) The proposed project shall be consistent with applicable policies and need determinations in the State Medical Facilities Plan, the need determination of which constitutes a determinative limitation on the provision of any health service, health service facility, health service facility beds, dialysis stations, operating rooms, or home health offices that may be approved.

NA

Carolinas Rehabilitation-NorthEast, LLC and The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas Rehabilitation propose to contract with either Total Renal Care of North Carolina, LLC, a subsidiary of DaVita Healthcare Partners, Inc. (DaVita), or Bio-Medical Applications of North Carolina, Inc., an affiliate of Fresenius Medical Care Holdings, Inc. (FMC) to provide hemodialysis to inpatients at Carolinas Rehabilitation-NorthEast (CR-NE). The applicants propose to up fit six inpatient rehabilitation rooms and two isolation rooms, for a total of eight rooms, for dialysis capability. The applicants will provide the water access boxes needed in each of these rooms and the water hook up. The contracted dialysis provider will provide the dialysis machines with portable reverse osmosis water systems that will connect to the water access boxes. The dialysis provider will provide a licensed and qualified registered nurse or other licensed and qualified health care professional to provide the dialysis services.

The applicants do not propose to increase the number of licensed beds in any category or acquire equipment for which there is a need determination in the 2013 State Medical

Facilities Plan (SMFP). There are no need determinations or policies in the 2013 SMFP that are applicable to the review of this project. Therefore, this criterion is not applicable to this review.

(2) Repealed effective July 1, 1987.

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

C

Carolinas Rehabilitation-NorthEast (CR-NE) is a private, non-profit acute care hospital serving the people of south central North Carolina and north east South Carolina. CR-NE proposes to enter into a contract with either DaVita or FMC to provide hemodialysis to inpatients in CR-NE. Either contractor will provide eight dialysis machines and appropriately trained staff to provide dialysis services as needed.

Population to be Served

The applicants state, in Section II.4, page 17, that the primary service area for the proposed inpatient dialysis services is the same as it is for CR-NE as a whole. CR-NE's projected inpatient patient origin for the entire facility for the first full year of operation is illustrated below:

CR-NE
Patient Origin by County
Project Year One, CY 2014*

County	CY 2014
Cabarrus	21.5%
Mecklenburg	36.4%
Stanly	13.7%
Rowan	5.9%
Union	3.3%
Anson	1.8%
Davidson	0.1%
Other/ In-migration	17.4%
Total	**100.0%**

*Percentages may not foot due to rounding.

The applicants adequately identify the population proposed to be served.

Demonstration of Need

In Section II.4, page 15, the applicants summarize the need for the proposed inpatient dialysis services as follows:

- *"inpatient rehabilitation patients have complex medical needs,*
- *access to in patient dialysis services for rehabilitation patients with ESRD is limited,*
- *transferring ESRD patients to a secondary location for dialysis is disruptive, not cost effective and can hinder the rehabilitation process,*
- *access to dialysis units in general acute care hospitals may be limited, and*
- *outpatient dialysis centers are not an appropriate treatment location for inpatient rehabilitation patients."*

The complex medical needs of inpatient rehabilitation patients are discussed in Section II.4, pages 15 – 20. The need for dialysis treatment is often the result of a serious underlying disease such as cardiovascular disease, including high blood pressure, elevated cholesterol, diabetes, and a family history of chronic kidney disease. High blood pressure and diabetes are the two diseases that have the highest risk for developing end stage renal disease (ESRD), also known as kidney failure. The applicants state that the age-adjusted diabetes incidence rate for Cabarrus County was 10.8 per 1,000 persons in 2009, and slightly higher than the statewide rate of 10.3 per 1,000, according to the Centers for Disease Control. The applicants illustrate the diabetes incidence rates for each county in its proposed service area in the following table:

Age-adjusted Diabetes Incidence Rate
2009

County	Incidence Rate
Cabarrus	10.8
Mecklenburg	9.1
Stanly	10.8
Rowan	12.3
Union	8.9
Anson	14.3
Davidson	9.8
Statewide	10.3

According to the table above, four of the seven counties in the applicants' proposed service area have higher diabetes incidence rates than the statewide rate.
Another medical condition that is a risk factor for developing ESRD is high blood pressure. According to a 2009 Community Health Status Report from the federal government, three of

the seven counties in the proposed project's service area have higher rates of high blood pressure than the national rate, as illustrated in the table below:

Percentage of Population with High Blood Pressure, 2009

County	%
Cabarrus	23.8%
Mecklenburg	24.0%
Stanly	21.3%
Rowan	36.6%
Union	24.7%
Anson	27.0%
Davidson	28.2%
Nationwide*	**26.0%**

*No statewide rate was available

In addition, patients with diabetes and/or high blood pressure who are on dialysis may suffer complications such as stroke, amputation, and heart attack, all of which require rehabilitation. The applicants state, on page 20, that *"stroke, neurologic and orthopaedic specialty areas are projected to account for approximately 59 percent of inpatient rehabilitation patients at CR-NE during the initial project years."*

In addition to complex medical conditions contributing to the need for dialysis services for inpatient rehabilitation patients, access to these services for these patients is limited. Although Carolinas Medical Center and Carolinas Medical Center-Mercy in adjacent Mecklenburg County offer inpatient dialysis services, inpatient rehabilitation patients at other Health Service Area III inpatient rehabilitation facilities, namely Carolinas Rehabilitation and Carolinas Rehabilitation-Mercy (CR-Mercy) in Charlotte, have limited access to these services since they must compete with acute care patients at Carolinas Medical Center and Carolinas Medical Center-Mercy who need these services. The applicants state, on page 21, that Carolinas Rehabilitation *"must limit the number of inpatient rehabilitation patients requiring dialysis to only eight at any given time, and CR-Mercy must limit the number* [sic] *patients requiring dialysis to only three (3) at any given time."* Carolinas Medical Center-NorthEast (CMC-NE) also has inpatient dialysis services, but the demand for these services is expected to increase *"over 17%"* in CY 2013 compared to CY 2012, as the applicants state on page 23. Moreover, the applicants state that CMC-NE will also limit the number of CR-NE patients it can provide dialysis for to only three at any given time.

Transferring CR-NE's inpatient rehabilitation patients in need of dialysis services to a general acute care hospital for inpatient dialysis services is problematic. Given that inpatient rehabilitation patients must tolerate a minimum of three hours of rehabilitation therapy, five

days a week, patients are often fatigued. Transporting them via ambulance to the hospital for dialysis three times a week for four hours of dialyzing per visit, plus prep time, would be burdensome and could hinder the recovery process. The applicants state, on page 22, *"it is very challenging to schedule and coordinate the patient's transfer amidst a rigorous daily therapy schedule."* In addition, transporting rehabilitation patients via ambulance to an acute care hospital for dialysis would raise the cost of rehabilitation services at CR-NE. A round trip ambulance transport to CMC-NE would cost approximately $1,000. Three round trips per week for dialysis treatment would equate to approximately $3,000.

Lastly, outpatient dialysis centers are not a feasible alternative for inpatient rehabilitation patients needing dialysis. In addition to the cost, time, and physical toll ambulance transport to and from these facilities would take on patients, rehabilitation patients would not be able to tolerate the *"physical prerequisites of outpatient dialysis centers."* As stated on page 23, *"Most outpatient dialysis centers will not accept patients if they cannot stand."* Due to fatigue from daily therapy and from recuperation from the medical condition that they were admitted for, they would not be able to tolerate this requirement. Additionally, recuperation often requires inpatient medical supervision which outpatient dialysis centers do not offer.

According to the North Carolina Semiannual Dialysis Report of July 2013, in calendar year 2012 there were 2,287 In-Center Dialysis patients in the seven counties that comprise 82.7 percent of CR-NE's projected service area. As a whole, the proposed service area had a projected surplus of seven stations.

In-Center Dialysis Patient Origin by County*
FFY 2010-FFY 2012

Cabarrus	**2008**	**2009**	**2010**	**2011**	**2012**
In-Center Patients	174	201	205	198	176
Annual Percent Growth		15.5%	2.0%	-3.4%	-11.1%
Average Annual Change Rate Past Five Years	0.7%				
Mecklenburg	**2008**	**2009**	**2010**	**2011**	**2012**
In-Center Patients	1,097	1,122	1,201	1,327	1,416
Annual Percent Growth		2.3%	7.0%	10.5%	6.7%
Average Annual Change Rate Past Five Years	6.6%				
Stanly	**2008**	**2009**	**2010**	**2011**	**2012**
In-Center Patients	74	67	70	65	69
Annual Percent Growth		-9.5%	4.5%	-7.1%	6.2%
Average Annual Change Rate Past Five Years	-1.5%				
Rowan	**2008**	**2009**	**2010**	**2011**	**2012**
In-Center Patients	149	150	145	140	177
Annual Percent Growth		0.7%	-3.3%	-3.5%	37.0%
Average Annual Change Rate Past Five Years	5.1%				
Union	**2008**	**2009**	**2010**	**2011**	**2012**
In-Center Patients	148	156	183	182	181
Annual Percent Growth		5.4%	17.3%	-0.6%	-0.6%
Average Annual Change Rate Past Five Years	5.4%				
Anson	**2008**	**2009**	**2010**	**2011**	**2012**
In-Center Patients	69	68	75	79	77
Annual Percent Growth		-1.5%	10.3%	5.3%	-2.5%
Average Annual Change Rate Past Five Years	2.9%				
Davidson	**2008**	**2009**	**2010**	**2011**	**2012**
In-Center Patients	172	181	180	195	191
Annual Percent Growth		5.2%	-0.6%	8.3%	-2.1%
Average Annual Change Rate Past Five Years	2.7%				
TOTAL # of Patients	1,883	1,945	2,059	2,186	2,287

*Data does not include dialysis patients in acute care hospitals since the number of dialysis patients is not reported on Hospital License Renewal Applications (LRAs)
Source: July 2013, North Carolina Semiannual Dialysis Report

The following table shows the number of existing dialysis units that are freestanding or based at a hospital in the primary service area of CR-NE. The 2013 Hospital License Renewal Applications for the hospitals listed in the following table show that six out of 15 hospitals

have inpatient dialysis services. Of the 28 free-standing dialysis centers in the CR-NE service area, 15 are operating at or above the minimum performance standard of 3.2 patients per station and 80% utilization, and one, Union County Dialysis is approaching the minimum operating standard at 2.93 patients per station. Two facilities are significantly below the minimum, under 2.0 patients per station.

Existing Hospital Inpatient and Freestanding Dialysis Stations
CR-NE Primary Service Area
12/31/2012

Anson	**Location Dialysis Stations**	**Certified Dialysis Stations**	**In-Center Dialysis Patients**	**Utilization Dialysis Stations**	**Patients Per Station**
Anson Community Hospital	N/A	0	N/A	N/A	N/A
Dialysis Care of Anson County	Wadesboro	15	37	61.67%	2.47
FMC of Anson County	Wadesboro	10	28	95.00%	2.80
Cabarrus	**Location Dialysis Stations**	**Certified Dialysis Stations**	**In-Center Dialysis Patients**	**Utilization Dialysis Stations**	**Patients Per Station**
Carolinas Medical Center-Northeast	Concord	10	N/A	N/A	N/A
Copperfield Dialysis	Concord	21	63	75.0%	3.00
Harrisburg Dialysis Center	Concord	19	54	71.1%	2.84
Davidson	**Location Dialysis Stations**	**Certified Dialysis Stations**	**In-Center Dialysis Patients**	**Utilization Dialysis Stations**	**Patients Per Station**
Lexington Medical Center	N/A	0	N/A	N/A	N/A
Thomasville Medical Center	N/A	0	N/A	N/A	N/A
Lexington Dialysis Center (WFU)	Lexington	36	97	67.36%	2.69
Thomasville Dialysis Center (WFU)	Thomasville	18	61	84.72%	3.39
Mecklenburg	**Location Dialysis Stations**	**Certified Dialysis Stations**	**In-Center Dialysis Patients**	**Utilization Dialysis Stations**	**Patients Per Station**
Carolinas Medical Center	Charlotte	9	N/A	N/A	N/A
Carolinas Medical Center Mercy-Pineville	Charlotte	6	N/A	N/A	N/A
Carolinas Medical Center-University	Charlotte	0	N/A	N/A	N/A

Carolinas Rehabilitation	Charlotte	0	N/A	N/A	N/A
Presbyterian Hospital	Charlotte	8	N/A	N/A	N/A
Presbyterian Hospital Huntersville	Huntersville	0	N/A	N/A	N/A
Presbyterian Hospital Matthews	Matthews	0	N/A	N/A	N/A
Presbyterian Orthopaedic Hospital	Charlotte	0	N/A	N/A	N/A
BMA Beatties Ford	Charlotte	32	116	90.63%	3.63
BMA of East Charlotte	Charlotte	24	85	88.54%	3.54
BMA of Nations Ford	Charlotte	24	97	101.04%	4.04
BMA of North Charlotte	Charlotte	27	100	92.59%	3.70
BMA West Charlotte	Charlotte	27	78	72.22	2.89
Carolina's Medical Center	Charlotte	9	11	30.56%	1.22
Charlotte Dialysis	Charlotte	34	120	88.24%	3.53
Charlotte East Dialysis Center	Charlotte	16	70	109.38%	4.38
DSI Charlotte Latrobe Dialysis	Charlotte	24	59	61.46%	2.46
DSI Glenwater Dialysis	Charlotte	34	114	83.82%	3.35
FMC Charlotte	Charlotte	40	129	80.63%	3.23
FMC Matthews	Matthews	21	76	90.48%	3.62
FMC of Southwest Charlotte	Charlotte	40	129	80.63%	3.23
Mint Hill Dialysis	Mint Hill	10	18	45.00%	1.80
North Charlotte Dialysis Center	Charlotte	20	64	80.00%	3.20
South Charlotte Dialysis	Charlotte	20	64	80.00%	3.20
Rowan	**Location Dialysis Stations**	**Certified Dialysis Stations**	**In-Center Dialysis Patients**	**Utilization Dialysis Stations**	**Patients Per Station**
Rowan Regional Medical Center	Salisbury	3	N/A	N/A	N/A
Dialysis Care Kannapolis	Kannapolis	25	64	64.00%	2.56
Dialysis Care Rowan County	Salisbury	29	93	80.17%	3.21
Stanly	**Location Dialysis Stations**	**Certified Dialysis Stations**	**In-Center Dialysis Patients**	**Utilization Dialysis Stations**	**Patients Per Station**
Stanly Regional Medical Center	Albemarle	2*	N/A	N/A	N/A
BMA Albemarle	Albemarle	22	74	84.09%	3.36
Union	**Location**	**Certified Dialysis**	**In-Center**	**Utilization**	**Patients**

	Dialysis Stations	Stations	Dialysis Patients	Dialysis Stations	Per Station
Carolinas Medical Center-Union	N/A	0	N/A	N/A	N/A
Marshville Dialysis Center	Marshville	10	28	70.00%	2.80
Metrolina Kidney Center	Monroe	21	56	66.67%	2.67
Union County Dialysis	Monroe	30	88	73.33%	2.93

Source: July 2013 North Carolina Semiannual Dialysis Report; Table A. [Data as of 12/31/2012] and 2013 Hospital License Renewal Applications.
*mobile dialysis stations

Utilization Projections

In Section II, pages 25-31, the applicants provide the methodology for projecting dialysis utilization at CR-NE, as described below:

> *"Step 1: Review Historical Dialysis Utilization at CR Facilities"*
> The applicants reviewed historical dialysis utilization for two inpatient rehabilitation facilities in its primary service area, Carolinas Rehabilitation (CR) in Charlotte and Carolinas Rehabilitation-Mercy (CR-M) in Charlotte, that do not offer inpatient dialysis services in-house, but must utilize dialysis services provided elsewhere. Historical utilization of dialysis services for patients at each of these inpatient rehabilitation facilities was reviewed, however the applicants determined that projected dialysis utilization for CR-NE would be more similar to CR-M's. CR-M's historical utilization is illustrated in the following table:

Carolinas Rehabilitation-Mercy (CR-M)
Inpatient Rehabilitation Patients & Dialysis Treatments
CY2010-CY2013*

	CY2010	CY2011	CY2012	CY2013*
Total Inpatients	780	814	834	773
Total Inpatient Rehab. Days	11,542	11,524	11,827	10,569
Ave. Length of Stay	14.8	14.2	14.2	13.7
Inpatients Who Received Inpatient Dialysis	40	38	59	33
Percent of Rehab. Patients Who Received Inpatient Dialysis	5.1%	4.7%	7.1%	4.2%
Total Dialysis Treatments	222	197	241	207
Ave. Treatments per Patient	5.6	5.2	4.1	6.4

*Year-to-date utilization.

The applicants explain, on page 27, the decrease in CY2013 year-to-date utilization for CR-M, as depicted in the above table, due to the transfer of 20 inpatient rehabilitation beds from CR-M to CR-NE.

"Step 2: Project Inpatient Dialysis Utilization for CR-NE"
The applicants determined that projected inpatient dialysis utilization for the proposed inpatient dialysis services at CR-NE would be most similar to CR-M's historical utilization rather than CR's since CR typically admits higher acuity patients and has a comparatively higher average length of stay. CR-NE's anticipated patient acuity and average length of stay is expected to be similar to CR-M's. Therefore, the applicants project CR-NE's inpatient dialysis utilization based on CR-M's utilization for CY2012. CY2013 utilization for CR-M was not used as a basis to project CR-NE's utilization due to the transfer of beds described above. The applicants state, on page 28,

> *"Therefore, CR-NE conservatively projects that during the initial three project years, approximately 7.1 percent of inpatient rehabilitation patients will receive inpatient dialysis services. Due to the fluctuation of the average number of dialysis treatments per patient during CY2010-CY2013, CR-NE projects average dialysis treatments per patient based on the weighted average number of treatments during CY2010-FY-2013 (5.1 treatments per patient), which is calculated in the following table."*

Carolinas Rehabilitation-Mercy

Inpatients Receiving Dialysis Treatments

	CY2010	CY2011	CY2012	CY2013*	CY2010-CY2013 Weighted Average
Inpatients Who Received Inpatient Dialysis	40	38	59	33	170
Total Dialysis Treatments	222	197	241	207	867
Ave. Treatments per Patient	5.6	5.2	4.1	6.4	5.1

**"Annualized based on Jan-July data.*
Source: Carolinas Rehabilitation"

The applicants state, on page 29, that CR-NE's first full project year will be CY2014, however services are not expected to become operational until July 1, 2014. Therefore, projected utilization is prorated for CY2014. The applicants provide a table, on page 30, which includes its projections from approved CON Project ID# F-8161-08 settlement documents for inpatient rehabilitation patient discharges, days of care, and average length of stay, and depicts projections of CR-NE's inpatient rehabilitation patients and dialysis treatments for CY2014, CY 2015, and CY2016. This is illustrated below:

Carolinas Rehabilitation-NorthEast
Inpatient Rehabilitation Patients and Dialysis Treatments

	Project Year 1 CY2014	Project Year 2 CY2015	Project Year 3 CY2016
CR-NE Patient Discharges	798	868	884
CR-NE Rehab Days of Care	10,863	11,810	12,023
Ave. Length of Stay	13.6	13.6	13.6
% of Patients to Receive Inpt. Dialysis	3.5%	7.1%	7.1%
# of Patients to Receive Dialysis	28	61	63
Total Dialysis Treatments	144	314	320
Ave. Dialysis Treatments per Patient	5.1	5.1	5.1

The applicants further state, on page 30, its projections are conservative and represent only a portion of the demand for dialysis services. Since inpatient dialysis services are currently not available at Carolinas Rehabilitation facilities, many patients

requiring dialysis are not admitted there. Therefore, *"CR-NE dialysis utilization is expected to exceed these very conservative projections."*

The applicants adequately demonstrate the need to provide inpatient dialysis services at CR-NE. Projected utilization is based on reasonable and supported assumptions.

In summary, the applicants adequately identified the population to be served and adequately demonstrated the need for the proposed inpatient dialysis services. Therefore, the application is conforming to this criterion.

(3a) In the case of a reduction or elimination of a service, including the relocation of a facility or a service, the applicant shall demonstrate that the needs of the population presently served will be met adequately by the proposed relocation or by alternative arrangements, and the effect of the reduction, elimination or relocation of the service on the ability of low income persons, racial and ethnic minorities, women, handicapped persons, and other underserved groups and the elderly to obtain needed health care.

NA

The applicants do not propose to reduce or eliminate any services nor relocate any service to another campus.

(4) Where alternative methods of meeting the needs for the proposed project exist, the applicant shall demonstrate that the least costly or most effective alternative has been proposed.

CA

In Sections II.4, pages 22 – 24, and II.5, pages 32 - 34, the applicants discuss the alternatives considered before pursuing the proposed project. The applicants considered the following alternatives:

1) Maintain the status quo,
2) Utilize Inpatient Dialysis Units at Service Area Hospitals with Inpatient Rehabilitation Beds, and
3) Utilize Outpatient Dialysis Centers

1) Maintain the Status Quo
The applicants determined that maintaining the status quo is not an effective alternative for several reasons. The applicants state that due to the unavailability of inpatient dialysis at CR-NE, many rehabilitation patients who need inpatient dialysis are not admitted there and must seek alternative settings such as remaining in a hospital for treatment or another setting. In Section II.4, pages 22 – 24, and Section II.5, page 32, the applicants state that transferring them to other locations to obtain dialysis services is *"disruptive, not cost*

effective and can hinder the rehabilitation process." On page 22, the applicants discuss how rehabilitation patients with ESRD must participate in three hours of rehabilitative therapy daily, and are therefore often fatigued, and that transferring them via ambulance is *"very burdensome and can hinder the recovery process"*. In addition, scheduling and preparing them for the transfer process can be very challenging to coordinate with their rigorous therapy schedule since it can add an additional one to two hours to a patients' schedules. On page 23, the applicants state that the additional cost incurred by CR-NE for these ambulance transfers is approximately $1,000 round trip, equating to at least $3,000 per week for an average of three dialysis sessions per week. This increases the cost of providing inpatient rehabilitation services for CR-NE.

In addition, inpatient rehabilitation patients at CR-NE with ESRD must compete with acute care hospital patients with ESRD for the use of a limited number of in-hospital dialysis stations. As an example, the applicants discuss that although CMC-NorthEast has 10 inpatient dialysis stations, they are already well utilized and that utilization is expected to increase by 17% from CY2012 to CY 2013. Further, the applicants state, on page 23, it must limit admissions of inpatient rehabilitation patients requiring dialysis to only three at any given time due to limited access to dialysis services at acute care facilities. Moreover, the applicants state, on page 32,

> *"This is not the most effective alternative for inpatient rehabilitation patients. Most acute care hospitals do not provide the level of rehabilitation services offered at CR-NorthEast delivered by a multidisciplinary team of physicians, therapists, nurses, social workers, case managers, administrators and other healthcare professionals working directly with patients and families to set and achieve individualized patient goals. Thus, CR-Northeast is the optimal location for rehabilitation patients with complex medical needs."*

2) Utilize Inpatient Dialysis Units at Service Area Hospitals with Inpatient Rehabilitation Beds

   The applicants state, on page 33, that utilizing inpatient dialysis units at hospitals in CR-NE's service area that have inpatient rehabilitation beds is also not an effective alternative. The only acute care hospital with inpatient rehabilitation beds that also has inpatient dialysis units in CR-NE's service area is Rowan Regional Medical Center. The applicants state that access to Rowan Regional Medical Center's three inpatient dialysis stations would be very limited since these would be used by acute care and rehabilitation inpatients in the 203-bed hospital. In addition, the cost and disruption caused by transferring CR-NE's rehabilitation inpatients to Rowan Regional Medical Center for dialysis services would still be problematic. Therefore, this is not an effective alternative.

3) Utilize Outpatient Dialysis Centers

   The applicants considered utilizing outpatient dialysis centers as an alternative to the proposed project, however it determined that these would not be appropriate settings for

the inpatient rehabilitation patients it serves. The applicants state, on page 33, that *"most outpatient dialysis centers will not accept patients if they cannot stand."* The applicants further state that CR-NE's patients are often unstable and fatigued from daily therapy and, as inpatients, they require a level of medical supervision that is not available in outpatient dialysis centers. Therefore, utilizing outpatient dialysis centers is not an effective alternative.

CR-NE determined that its proposal, to contract with either DaVita or FMC to provide hemodialysis to its inpatients would be the most effective alternative, summarized as follows:

- It would provide on site access to dialysis services for rehabilitation inpatients who have complex medical needs,
- It would address issues of limited access for dialysis services at both acute care facilities and other inpatient rehabilitation facilities, and
- It would negate the need for patient transfers to acute care facilities with dialysis services which would otherwise be disruptive and costly.

Furthermore, the application is conforming or conditionally conforming to all other statutory review criteria. Therefore, the application is approvable. An application that cannot be approved is not an effective alternative.

The applicants adequately demonstrate that its proposal is the least costly or most effective alternative to meet the need. Therefore, the application is conforming to this criterion and approved subject to the following conditions:

1. **Carolinas Rehabilitation-NorthEast, LLC and The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas Rehabilitation shall materially comply with all representations made in the certificate of need application and supplemental information provided. In those instances where representations conflict, Carolinas Rehabilitation-NorthEast, LLC and The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas Rehabilitation shall materially comply with the last made representation.**

2. **Carolinas Rehabilitation-NorthEast, LLC and The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas Rehabilitation shall not acquire, as part of this project, any equipment that is not included in the project's proposed capital expenditure in Section VI of the application and which would otherwise require a certificate of need.**

3. **Carolinas Rehabilitation-NorthEast, LLC and The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas Rehabilitation shall be certified for no more**

than 8 dialysis stations, 6 in inpatient rehabilitation rooms and 2 in isolation rooms.

4. Carolinas Rehabilitation-NorthEast, LLC and The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas Rehabilitation shall acknowledge acceptance of and agree to comply with all conditions stated in writing to the Certificate of Need Section.

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

C

In Section VI, page 51, the applicants project the capital cost for the proposal to be $62,629, as illustrated in the following table:

Projected Capital Cost

Description	Cost
Equipment and Furniture	17,629
Consultant/Administrative	45,000
Total	**$62,629**

In Section VI.6, page 54, the applicants state the project will be funded with accumulated reserves provided by Carolinas Healthcare System (CHS). In Exhibit 7, the applicants include a letter dated September 16, 2013 from the Executive Vice President and Chief Financial Officer, CHS, stating:

> *"The total capital expenditure for this abridged CON project is estimated to be $62,629.*
> …
>
> *CHS will fund the capital cost from existing accumulated cash reserves."*

Exhibit 8 includes audited financial statements for CHS for the years ended December 31, 2012 and 2011. As of December 31, 2012, the applicant had cash and cash equivalents of $85,603,000, total assets of $6,027,401,000 and $3,313,001,000 in net assets (total assets less total liabilities). The applicants adequately demonstrate the availability of sufficient funds for the capital needs of the project.

The applicants provide, in supplemental information, pro forma financial statements for the proposed services for the first three years of the project. The applicants project that

operating expenses will exceed revenues in each of the first three operating years of the project as illustrated in the table below:

CR-NE Inpatient Dialysis Services	**CY 2014* Project Year 1** 7/01/14 - 12/31/14	**CY 2016 Project Year 2** 1/01/15 - 12/31/15	**CY 2017 Project Year 3** 1/01/16 – 12/31/16
Projected # of Patients	144	314	320
Projected Average Charge (Gross Patient Revenue/Projected # of Patients)	$0	$0	$0
Gross Patient Revenue	$0	$0	$0
Deductions from Gross Patient Revenue	$0	$0	$0
Net Patient Revenue	$0	$0	$0
Total Expenses	$65,954	$133,099	$140,159
Net Income	- $65,954	- $133,099	- $140,159

*Note: CR-NE anticipates the proposed inpatient dialysis services to be operational July 1, 2014.

As stated by the applicants in Section VIII, page 62, competitive bids have been received by dialysis providers to provide inpatient acute dialysis services at CR-NE. In addition, in Section VIII, page 59, the applicants state, *"The incremental project capital costs …will not affect patient charges"*, and that the *average total charges per inpatient day are $1,730. This change in scope project has no impact on the projected daily patient charges."*

The applicants project a positive net income for the entire facility in each of the first three operating years of the project. Net income for the first three operating years of the project for the entire facility, CY 2014–2016, is projected to be $1,035,000, $1,603,000 and $1,710,000, for each of the operating years respectively. The assumptions used by the applicants in preparation of the pro forma financial statements are reasonable, including projected utilization, costs and charges. The pro formas and assumptions for the pro forma financial statements regarding costs and charges are provided in Section VIII, pages 59-64. See Criterion (3) for discussion regarding projected utilization which is incorporated hereby as if fully set forth herein.

The applicants adequately demonstrate that the financial feasibility of the proposal is based upon reasonable projections of costs and charges, and therefore, the application is conforming to this criterion.

(6) The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

The applicants adequately demonstrate that the proposal would not result in the unnecessary duplication of existing or approved health service capabilities or facilities. In Section II.4, page 21, the applicants state that inpatient dialysis services are limited at acute care facilities that have inpatient dialysis services in the primary service area as patients at inpatient rehabilitation facilities must compete with acute care facilities' patients needing dialysis. The applicants do not propose to increase the number of licensed beds or acquire any new equipment for which there is a need in the 2010 SMFP. See Criterion (3) for discussion of projected utilization which is incorporated hereby as if fully set forth herein. Therefore, the applicants adequately demonstrate that the proposal would not result in the unnecessary duplication of existing or approved health service capabilities or facilities. Consequently, the application is conforming to this criterion.

(7) The applicant shall show evidence of the availability of resources, including health manpower and management personnel, for the provision of the services proposed to be provided.

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The applicants state in Section V.1, page 44,

> *"The proposed addition of inpatient dialysis services will not result in incremental staffing at CR-NE. The existing clinical staff will continue to attend to all the inpatient rehabilitation patients, including ESRD patients. Specific to provision of inpatient dialysis services, CR-NE will contract with a dialysis provider to deliver the acute dialysis treatment to the inpatient rehabilitation patients.*
> …
>
> *To perform the acute dialysis treatments, the contractor will provide its own duly licensed and qualified nurses or qualified technicians trained in extracorporeal requirements. The provider will be prepared to offer acute dialysis treatment any time of day or night, 365 days each year."*

In Exhibit 11, the applicants include a table of the proposed staffing for CR-NE in the second year following completion of the project, CY2015. There are 102.3 FTEs proposed. In addition, Exhibit 9 contains proposals from two accredited dialysis providers. Both providers state they will provide licensed staff that are experienced and/or trained to provide the dialysis treatments.

In supplemental information, the applicants provide a letter of support signed by George Hart, MD, from Metrolina Nephrology Associates, PA that states, "*This letter also serves to document the intent of Metrolina Nephrology to serve as Medical Director for CR-NE's proposed inpatient dialysis services.*" A copy of Dr. Hart's resume is provided in supplemental information.

The applicants demonstrate the availability of adequate health manpower and management personnel for the provision of the proposed inpatient dialysis services. Therefore, the application is conforming to this criterion.

(8) The applicant shall demonstrate that the provider of the proposed services will make available, or otherwise make arrangements for, the provision of the necessary ancillary and support services. The applicant shall also demonstrate that the proposed service will be coordinated with the existing health care system.

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In supplemental information, the applicants provide a letter from a Carolinas HealthCare System Administrator which states, *"All ancillary and support services required for the proposed inpatient dialysis services are already in place at CR-NorthEast. These services include, but are not limited to: Clinical laboratory, Pharmacy, Dietary, Radiology services, Environmental services, Plant operations and maintenance, Clinical engineering, Infection control, Medical records, Quality management/performance improvement, and Clinical care management."*

The applicants provide letters of support from physicians and from local hospitals in Exhibit 10. The applicants adequately demonstrate that the necessary ancillary and support services will be available and that the proposed services will be coordinated with the existing health care system. Therefore, the application is conforming to this criterion.

(9) An applicant proposing to provide a substantial portion of the project's services to individuals not residing in the health service area in which the project is located, or in adjacent health service areas, shall document the special needs and circumstances that warrant service to these individuals.

NA

(10) When applicable, the applicant shall show that the special needs of health maintenance organizations will be fulfilled by the project. Specifically, the applicant shall show that the project accommodates:

(a) The needs of enrolled members and reasonably anticipated new members of the HMO for the health service to be provided by the organization; and

NA

(b) The availability of new health services from non-HMO providers or other HMOs in a reasonable and cost-effective manner which is consistent with the basic method of operation of the HMO. In assessing the availability of these health services from

these providers, the applicant shall consider only whether the services from these providers:

(i) would be available under a contract of at least 5 years duration;
(ii) would be available and conveniently accessible through physicians and other health professionals associated with the HMO;
(iii) would cost no more than if the services were provided by the HMO; and
(iv) would be available in a manner which is administratively feasible to the HMO.

NA

(11) Repealed effective July 1, 1987.

(12) Applications involving construction shall demonstrate that the cost, design, and means of construction proposed represent the most reasonable alternative, and that the construction project will not unduly increase the costs of providing health services by the person proposing the construction project or the costs and charges to the public of providing health services by other persons, and that applicable energy saving features have been incorporated into the construction plans.

NA

(13) The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and of members of medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and handicapped persons, which have traditionally experienced difficulties in obtaining equal access to the proposed services, particularly those needs identified in the 2012 State Health Plan as deserving of priority. For the purpose of determining the extent to which the proposed service will be accessible, the applicant shall show:

(a) The extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant service area which is medically underserved:

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Historical payer mix information was not available for inpatient dialysis services since CR-NE does not currently provide inpatient dialysis services. In addition, CR-NE only recently became operational. According to CR-NE's most recent progress report for Project ID# F-8161-08, the facility became operational on July 15, 2013. According to footnotes on page 11 of its application for the proposed inpatient dialysis services, 30 of

the 40 inpatient rehabilitation beds were licensed at the time of submission of this application. The applicants state, in Section IV.6, page 42, that its projected payer mix for the entire facility *"will be similar to the mix projected in the 2008 CR-NE application."* The applicants provide the projected payer mix for the entire facility for the second full fiscal year of the project, CY 2015, as illustrated below:

CR-NE
Inpatient Rehabilitation Services
Projected Payer Mix, CY 2015

Payer	Entire Facility*
Self Pay	0.9%
Medicare	56.9%
Medicaid	16.6%
Managed Care/ Commercial Insurance	22.6%
Workers Compensation	1.4%
Other	1.7%
Total	**100.0%**

*Percentages may not foot due to rounding.

In Section IV.2, page 39, the applicants state *"...CR-NE has a policy to provide services to all patients regardless of income, racial/ethnic origin, gender, physical or mental conditions, age, ability to pay, or any other factor that would classify a patient as underserved. With the addition of inpatient dialysis services, inpatient rehabilitation services at CR-NE will continue to be available to and accessible by any patient having a need for those services."* The applicants provide a copy of CR-NE's patient financial policies in Exhibit 4 and further states that patients admitted with no means of payment will receive follow up with financial counselors to determine whether they may qualify for financial assistance. On page 49, the applicants further state, *"Patients in need of services are not refused care based on their ability to pay."*

The Division of Medical Assistance (DMA) maintains a website which offers information regarding the number of persons eligible for Medicaid assistance and estimates of the percentage of uninsured for each county in North Carolina. The following table illustrates those percentages for Cabarrus, Mecklenburg, and Stanly counties, as well as statewide.

	Total # of Medicaid Eligibles as % of Total Population June 2010*	Total # of Medicaid Eligibles Age 21 and older as % of Total Population June 2010*	% Uninsured CY 2008-2009* (Estimate by Cecil G. Sheps Center)
Cabarrus County	14.3%	4.9%	18.5%
Mecklenburg County	14.7%	5.1%	20.1%
Stanly County	17.4%	7.6%	18.3%
Statewide	17.0%	6.7%	19.7%

*More current data, particularly with regard to the estimated uninsured percentages, was not available.

The majority of Medicaid eligibles are children under the age of 21. Moreover, the number of persons eligible for Medicaid assistance may be greater than the number of Medicaid eligibles who actually utilize health services. The DMA website includes information regarding dental services which illustrates this point. For dental services only, DMA provides a comparison of the number of persons eligible for dental services with the number actually receiving services. The statewide percentage of persons eligible to receive dental services who actually received dental services was 31.6 percent for persons aged 21 and older. Similar information is not provided on the website for other types of services covered by Medicaid. However, it is reasonable to assume that the percentage of those actually receiving other types of health services covered by Medicaid is less than the percentage eligible for those services.

The Office of State Budget & Management (OSBM) maintains a website which provides historical and projected population data for each county in North Carolina. In addition, data is available by age, race or gender. However, a direct comparison to the applicant's current payer mix would be of little value. The population data by age, race or gender does not include information on the number of elderly, minorities or women utilizing health services. Furthermore, OSBM's website does not include information on the number of handicapped persons.

The applicants demonstrate that medically underserved patients will have adequate access to the proposed services at CR-NE.

Therefore, the application is conforming to this criterion.

(b) Its past performance in meeting its obligation, if any, under any applicable regulations requiring provision of uncompensated care, community service, or access by minorities and handicapped persons to programs receiving federal assistance, including the existence of any civil rights access complaints against the applicant;

In supplemental information, the applicants state that CR-NE is not obligated to provide *"uncompensated care, community service, or access by minorities and handicapped persons."* In addition, the applicants state that CR-NE has a policy to provide services to all patients regardless of factors such as racial/ethnic origin, physical or mental conditions, ability to pay or any other factor that would classify a patient as underserved. Lastly, the applicants state, in supplemental information, that *"No civil rights access complaints have been filed against CR-NE since it began operation in July 2013."* Therefore, the application is conforming to this criterion.

(c) That the elderly and the medically underserved groups identified in this subdivision will be served by the applicant's proposed services and the extent to which each of these groups is expected to utilize the proposed services;

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The applicants provide projected payer mix for the entire facility and for the proposed inpatient dialysis services for the second full fiscal year of the project, CY2015, in Section IV.6, pages 42-43, illustrated as follows:

CR-NE
Projected Payer Mix, CY 2015

Payer	Entire Facility	Proposed Inpatient Dialysis Services
Self Pay	0.9%	2.5%
Medicare	56.9%	80.4%
Medicaid	16.6%	7.5%
Managed Care/ Commercial Insurance	22.6%	8.1%
Workers Compensation	1.4%	0%
Other	1.7%	1.4%
Total	**100.0%**	**100.0%**

*Percentages may not foot due to rounding.

The applicants state, in Section IV.5, page 41, that it admits patients in compliance with Federal law, including,

- *"Title VI of the Civil Rights Act of 1963.*
- *Section 504 of the Rehabilitation Act of 1973.*
- *The Age Discrimination Act of 1975.*

CR-NE will continue to provide services without regard to race, color, religion, sex, age, national origin, handicap, or ability to pay."

A copy of CR-NE's admission and financial policies is provided in Exhibit 4.

The applicants demonstrate that medically underserved populations will have adequate access to the proposed services. Therefore, the application is conforming to this criterion.

(d) That the applicant offers a range of means by which a person will have access to its services. Examples of a range of means are outpatient services, admission by house staff, and admission by personal physicians.

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In Section IV.5, page 41, the applicants state, *"Access to inpatient dialysis treatment will be by physician order."* Physicians refer patients for inpatient rehabilitation services and CR-NE Medical Staff member admits them. The applicants adequately demonstrate a range of means by which patients will have access to the proposed inpatient dialysis services that will be offered. Therefore, the application is conforming to this criterion.

(14) The applicant shall demonstrate that the proposed health services accommodate the clinical needs of health professional training programs in the area, as applicable.

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In Section V.3, pages 45-46, the applicants state that CR-NE already serves as a clinical training site for several programs, including, but not limited to, nursing programs at the The Cabarrus College of Health Sciences and therapy programs at Duke University, Central Piedmont Community College, and others listed on page 45. The applicants state, on page 46, that the various clinical training programs offered at The Cabarrus College of Health Sciences, Carolinas College of Health Sciences, The Center for Pre-Hospital Medicine, and the Charlotte Area Health Education Center *"will have access to clinical training opportunities at CR-NE, as is appropriate for the particular clinical service."*

The applicants adequately demonstrate that it will continue to accommodate the clinical needs of health professional training programs in the area. Therefore, the application is conforming to this criterion.

(15) Repealed effective July 1, 1987.
(16) Repealed effective July 1, 1987.
(17) Repealed effective July 1, 1987.
(18) Repealed effective July 1, 1987.
(18a) The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact upon the cost effectiveness, quality, and access to the services proposed; and in the case of applications for services where competition between providers will not have a

favorable impact on cost-effectiveness, quality, and access to the services proposed, the applicant shall demonstrate that its application is for a service on which competition will not have a favorable impact.

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In Section V.6, pages 47-49, the applicants discuss the impact of the proposed project on competition as it relates to promoting cost-effectiveness, quality and access, summarized as follows:

- Minimal cost is involved since only dialysis water boxes will be installed in eight patient rooms with no additional staff to be hired;
- Patient charges will not increase since the dialysis service provided on site will be contracted out;
- Access to inpatient rehabilitation services will be increased, thereby fostering competition, by providing dialysis services to inpatient rehabilitation patients with ESRD, eliminating the need to transfer them to acute care hospitals with limited capacity for inpatient dialysis services.
- Quality of inpatient rehabilitation care will be improved since patients will not have to physically endure the transfer process to obtain access to dialysis services, nor will rehabilitation therapy have to be interrupted.

See also Sections II, IV, and V. The information provided by the applicants in each of these sections is reasonable, credible, and adequately demonstrates that the expected effects of the proposal on competition include a positive impact on cost-effectiveness, quality, and access to CR-NE inpatient dialysis services in CR-NE's primary service area, including Cabarrus County.

This determination is based on a review of the information in the sections of the application referenced above and the following analysis:

- The applicants adequately demonstrate the need to offer inpatient dialysis services at CR-NE based on projected utilization at CR-NE and that it is a cost-effective alternative;
- The applicants have and will continue to provide quality services; and
- The applicants have and will continue to provide adequate access to medically underserved populations.

Therefore, the application is conforming to this criterion.

(19) Repealed effective July 1, 1987.

(20) An applicant already involved in the provision of health services shall provide evidence that quality care has been provided in the past.

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In Section II.8, pages 35-36, CR-NE indicates that it is a licensed inpatient rehabilitation hospital and is certified as a Medicare and Medicaid provider. According to the records in the Acute and Home Care Licensure and Certification Section, DHSR, no incidents have occurred at CR-NE from the date it became operational in June 2013 until the date of this decision for which any sanctions or penalties related to quality of care were imposed by the State. Therefore, the application is conforming to this criterion.

(21) Repealed effective July 1, 1987.

(b) The Department is authorized to adopt rules for the review of particular types of applications that will be used in addition to those criteria outlined in subsection (a) of this section and may vary according to the purpose for which a particular review is being conducted or the type of health service reviewed. No such rule adopted by the Department shall require an academic medical center teaching hospital, as defined by the State Medical Facilities Plan, to demonstrate that any facility or service at another hospital is being appropriately utilized in order for that academic medical center teaching hospital to be approved for the issuance of a certificate of need to develop any similar facility or service.

NA