



North Carolina Department of Health and Human Services
Division of Health Service Regulation

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Division Director

July 31, 2015

Gary S. Qualls
K&L Gates
PO Box 14210
Research Triangle Park, NC 27709-4210

No Review

Record #: 1669
Facility Name: Carolinas HealthCare System NorthEast
FID #: 943049
Business Name: Charlotte-Mecklenburg Hospital Authority
Business #: 461
Project Description: Restart emergency and back-up care for dialysis patients that cannot be served by another local provider using the existing outpatient dialysis station authorized by Project ID #F-4704-92 (the services were suspended in 2008)
County: Cabarrus

Dear Mr. Qualls:

In response to your correspondence of July 28, 2015, the Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency) has determined that Carolinas HealthCare System NorthEast may restart emergency and back-up care for dialysis patients that cannot be served by another local provider using the existing outpatient dialysis station authorized by Project ID #F-4704-92 without having to obtain another certificate of need. This conclusion is based on the following:

1. The certificate of need issued for Project ID #F-4704-92 has not been surrendered or revoked.
2. Carolinas HealthCare System NorthEast is authorized for a total of 10 dialysis stations: 9 for inpatient dialysis services and 1 for emergency and back-up care for dialysis patients that cannot be served by another local provider.
3. Carolinas HealthCare System NorthEast reports the 10 dialysis stations on its License Renewal Application.
4. Carolinas HealthCare System NorthEast has provided inpatient dialysis services during the previous 12 months.

Healthcare Planning and Certificate of Need Section

www.ncdhhs.gov

Telephone: 919-855-3873 • Fax: 919-715-4413

Location: Edgerton Building • 809 Ruggles Drive • Raleigh, NC 27603

Mailing Address: 2704 Mail Service Center • Raleigh, NC 27699-2704

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Mr. Qualls
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However, you need to contact the Agency's Acute and Home Care Licensure and Certification Section to determine if they have any requirements for development of the proposed project.

It should be noted that this Agency's position is based solely on the facts represented by you and that any change in facts as represented would require further consideration by this office and a separate determination. If you have any questions concerning this matter, please feel free to contact this office.

Sincerely,

A handwritten signature in cursive script that reads "Martha J. Frisone".

Martha J. Frisone, Assistant Chief
Certificate of Need

cc: Acute and Home Care Licensure and Certification Section, DHSR
Assistant Chief, Healthcare Planning



July 28, 2015

Gary S. Qualls
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gary.qualls@klgates.com

Via Hand Delivery and E-Mail

Martha Frisone
Assistant Chief, Certificate of Need
Department of Health and Human Services
Division of Health Service Regulation
Health Planning and Certificate of Need Section
809 Ruggles Drive
Raleigh, North Carolina 27603

Re: Confirmation Letter Regarding One (1) outpatient dialysis station at Carolinas HealthCare System NorthEast (Project I.D. No. F-4704-92)

Dear Martha:

As we recently discussed by phone, my client Carolinas HealthCare System NorthEast ("CHS NorthEast") is planning to restart services on its one (1) outpatient dialysis station for limited purposes (the "OP Dialysis Station").

We wanted you to confirm our understanding that we may restart such services based on the authority conferred in the 1993 CON (Project I.D. No. F-4704-92), attached as Exhibit 1. The 1993 CON authorizes "one certified outpatient dialysis station for the provision of emergency and back-up care to patients who cannot be treated at another local dialysis facility." As explained below, the limited dialysis services CHS NorthEast wishes to restart are within that limited scope.

Limited Dialysis Services

The limited services CHS NorthEast wishes to restart are treating acute renal failure patients, after being discharged as hospital inpatients, but prior to the patient being eligible for ESRD services in a conventional outpatient dialysis station (such as a Fresenius or DaVita facility). This "Interim Treatment Period" described above can last up to 12 weeks.

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Prior Medicare Certification

Effective August 1, 2008, CHS NorthEast voluntarily terminated its Medicare Provider Agreement for the OP Dialysis Station. Since that time, the OP Dialysis Station has not been used, but CHS NorthEast never relinquished its CON and that CON was not revoked. Thus, CHS NorthEast still retains its CON rights to operate the OP Dialysis Station. If CHS NorthEast wanted to seek recertification from CMS for the OP Dialysis Station, it would need to undergo that recertification process. However, for the limited services authorized by the 1993 CON, CHS NorthEast may not bother with that recertification process because it is not essential in order to serve these Interim Treatment Period patients.

Prior Reporting

Incidentally, CHS NorthEast's OP Dialysis Station is not reported in the Semi-Annual Dialysis Report ("SDR"). That makes sense given that the 1993 CON conditioned the OP Dialysis Station to this limited use since inception. In other words, it is not a conventional ESRD station. CHS NorthEast has reported the OP Dialysis Station in its annual Licensure Renewal Applications ("LRAs"). Both before and after the 2008 decertification, CHS NorthEast's LRAs have reported 10 total dialysis stations, with nine being Inpatient Dialysis Stations and one being the OP Dialysis Station. Dialysis services have been performed each year at CHS NorthEast via the Inpatient Dialysis Stations, thus avoiding triggering N. C. Gen. Stat. § 131E-176(16)(d).

Conclusion

Since we will likely discuss this service with the Licensure and Certification Section, we wanted to obtain some written confirmation from you that you agree with our belief that reinitiating services on the OP Dialysis Station remains authorized by the 1993 CON.

Thank you in advance for your attention and let me know if you have any questions.

Sincerely,



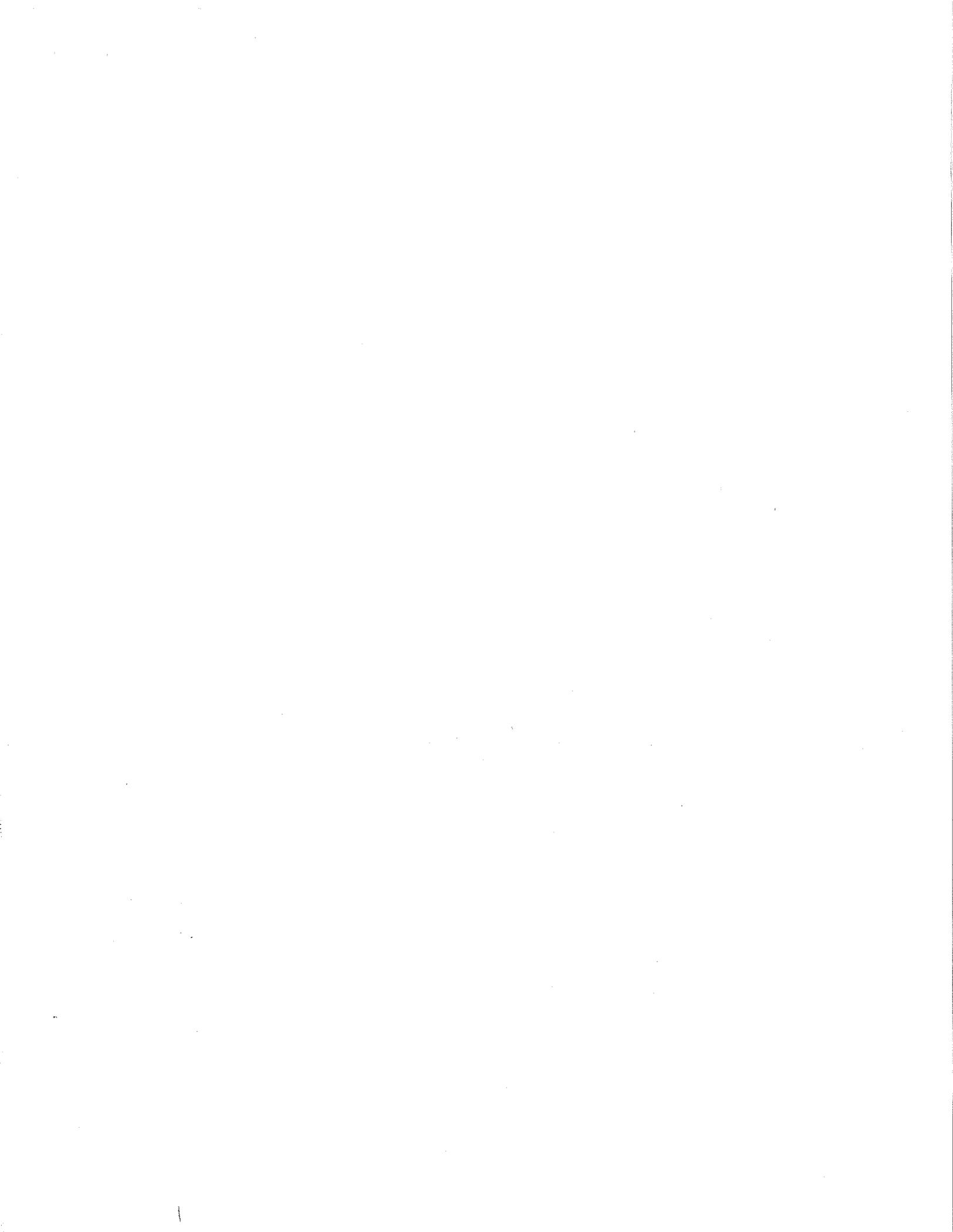
Gary S. Qualls

Enclosures

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Exhibits

1. 1993 CON for Project I.D. No. F-4704-92.



State Of North Carolina

Department Of Human Resources

Division Of Facility Services

Certificate Of Need

Project Identification Number E-6704-92 Effective Date August 24, 1993

Issued to: Cabarrus Memorial Hospital

920 Church Street, North
Concord, NC 28025

The North Carolina Department of Human Resources, pursuant to the North Carolina Health Planning and Resource Development Act of 1978, G.S. § 131-175, et seq., as amended and recodified, G.S. § 131E-175, et seq., hereby finds and certifies that the new institutional health service proposed by the person listed above is consistent with, or as conditioned is consistent with the plans, standards, and criteria prescribed by the Act and the rules and regulations promulgated thereunder. The findings of the Department are attached hereto and incorporated by reference.

This Certificate affords the person listed above the opportunity to proceed with development of the proposed new institutional health service in a manner consistent with the plans, standards, and criteria prescribed by the Act and the rules and regulations promulgated thereunder. This Certificate includes and is limited to:

SCOPE: Operate one certified outpatient dialysis station for the provision of emergency and back-up care to patients who cannot be treated at another local dialysis facility.

CONDITIONS: See Reverse Side

PHYSICAL LOCATION: 920 Church Street, North
Concord, NC 28025

MAXIMUM CAPITAL EXPENDITURE: \$15,000

TIMETABLE: See Reverse Side

FIRST PROGRESS REPORT DUE: September 16, 1993

This Certificate is limited to the person listed above and is not transferable or assignable. This Certificate may be withdrawn as provided in G.S. § 131E-169, and the rules and regulations promulgated thereunder.

Issuance of this Certificate does not supplant provisions or requirements embodied in codes, ordinances, statutes other than G.S. § 131E-175, et seq., rules regulations or guidelines administered or enforced by municipal, state or federal agencies or the agent thereof.

Lee P. Hoffman

Chief, Certificate of Need Section
Division of Facility Services

CONDITIONS:

1. The Hospital shall materially comply with all representations made in its CON application, with the exception of any changes necessary to comply with the conditions stated herein.

2. Within thirty (30) days of the date of the certification of the dialysis station, the Hospital shall provide to the CON Section a properly endorsed copy of its June 9, 1993 proposed agreement with Carolinas Medical Center for transplant services.

3. The Hospital shall be certified for and operate no more than one (1) certified outpatient dialysis station.

4. The Hospital shall not provide regularly scheduled maintenance dialysis treatments in its certified outpatient dialysis station; provided, however, the Hospital may provide emergency and back-up care to patients who cannot be treated at another local dialysis facility.

TIMETABLE:

Occupancy/Offering of Services-----September 1, 1993