

LIBERTY DIALYSIS

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November, 2010

Paula Quirin, Project Analyst
Certificate of Need Section
Division of Health Services Regulation
2704 Mail Service Center
Raleigh, NC 27699-2704

Re: Public Written Comments, CON Project ID F-008777-10
RE: Public Written Comments, CON Project ID F-008581-10
RE: Public Written Comments, CON Project ID F-008584-10

Dear Ms. Quirin:

Please consider these comments as part of the review process of the CON Projects listed above.

Regulatory Requirements

The 2010 State Medical Facilities Plan (SFMP) as prepared by the North Carolina Department of Health and Human Services under the direction of the North Carolina State Health and Coordinating Council has established 3 basic principles governing the development of this plan.

In the first, Safety and Quality Basic Principle, the State of North Carolina recognizes the right of its citizens in ensuring that health services be safe and efficacious as determined by scientific quantification of quality and safety data. These measures are to be "specific to the type of facility or service regulated" (2010 SFMP, Chapter 1, p.2), and "In all cases, metrics should be standardized and widely reported and **preference should be given to those metrics reported on a national basis**" (2010 SMFP, Chapter 1, p.2 emphasis added).

The second Basic Principle – Access Basic Principle – is defined as "Equitable access to timely, clinically appropriate **and high quality health care** for all the people of North Carolina is a foundation principle for the formation and application of the North Carolina State Medical Facilities Plan" (2010 SMFP, Chapter 1, p.2 emphasis added). In addition "A competitive marketplace **should favor providers that deliver the highest quality and best value care...**" (2010 SMFP, Chapter 1, p.3 emphasis added).

In Chapter 14 End-Stage Renal Disease Facilities, Basic Principle 8 - Quality of Care, states:

"An applicant already involved in the provision of end-stage renal disease services should provide **evidence that care of high quality has been provided in the past.**"(Emphasis added).

This chapter specifically indentifies a minimum of 7 indicators of quality of care including morbidity and mortality rates (8 b.).

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The Centers for Medicare and Medicaid Services (CMS) has established the Dialysis Facility Compare website to provide patients and families with a tool to compare services and quality measures of dialysis facilities. Patient Survival also known as morbidity lets a patient know if patients treated in a specific dialysis facility generally (i) live longer, (ii) as long, or (iii) not as long as expected. Patient survival data is collected over the most recent 3 year period (January 2005 to December 2008) and as such represents a historical trend of quality.

Discussion

Total Renal Care of North Carolina, LLC "TRC" (a subsidiary of DaVita, Inc.) is the sole provider of outpatient dialysis services in Rowan and Cabarrus counties. The dialysis facilities are under the medical direction of physicians from the same medical practice (Central Carolina Nephrology) in all instances. The 3 CON projects referenced above would expand the available services at the 2 existing Cabarrus County dialysis facilities and develop a 3rd dialysis facility in the same county under the medical direction of the same group of physicians.

Based on the Dialysis Facility Compare website, three of these facilities had worse than expected Patient Survival Rates during the relevant period:

Patient Survival for January 2005 to December 2008

	Better Than Expected**	As Expected	Worse Than Expected**
Survival Categories for the 4752 facilities with available data in US	482	3756	514
Survival Categories for the 150 facilities with available data in North Carolina	8	125	17
COPPERFIELD DIALYSIS			✓
DIALYSIS CARE OF ROWAN COUNTY INC			✓
DIALYSIS OF KANNAPOLIS			✓

The second dialysis unit operated in Cabarrus County by TRC – Harrisburg Dialysis Center - was opened in August of 2009. Thus no survival information is currently available for this facility.

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It should also be noted that one of the DaVita facilities under the medical direction of Central Carolina Nephrology received a CMS immediate jeopardy violation. Immediate jeopardy is defined by CMS as, "a situation in which the provider's non-compliance with one or more requirements of participation has caused, or is likely to cause, serious injury, harm, impairment, or death to a resident." It is the highest-level citation a facility can receive and reflects the facility's inability to provide safe effective dialysis care.

The quality results achieved by TRS, as publicly reported, do not meet the standards set forth in the Department's criteria for certification of need. These records of substandard quality are particularly disturbing in light of TRC's status as the monopoly provider in both Rowan and Cabarrus counties.

Currently, Total Renal Care via the dialysis facilities listed above are the only available options within the counties of Cabarrus and Rowan; therefore, the only available choice for residents to receive dialysis. Granting TRC the right to expand the facilities and build a new one under the medical direction of Central Carolina Nephrology will continue to deprive county residents of any choice in dialysis provider while perpetuating the legacy of substandard care. Further, in light of its monopoly status, TRC will have no incentive to enhance its quality. This outcome is counter to the goals of the regulations.

Conclusion

Total Renal Care of North Carolina, LLC does not meet the requirements of the CON by its failure to provide highest quality care as evidenced by consistently inferior outcomes as determined by national standards and compliance to Medicare guidelines as surveyed by the North Carolina Division of Health Service Regulation.

We strongly believe that based on the information provided above, that facilities owned by TRC do not meet the CON requirement for safety, quality, best valued care, or serve the need to provide residents of Cabarrus and Rowan County with the ability to have freedom in quality dialysis. We strongly urge the Certificate of Need Section to deny TRC's applications and instead provide the citizens of Cabarrus County access to options in providers with incentive to enhance quality.

Thank you in advance for your time and attention.

Sincerely,



Ronald F. Sawyer

Chief Operating Officer
Liberty Dialysis, LLC

