

**NORTH CAROLINA DEPARTMENT OF HEALTH AND HUMAN SERVICES
DIVISION OF HEALTH SERVICE REGULATION
RALEIGH, NORTH CAROLINA**

**IN RE: REQUEST FOR DECLARATORY)
RULING BY FRESENIUS MEDICAL CARE) DECLARATORY RULING
HOLDINGS, INC. d/b/a BIO-MEDICAL)
APPLICATIONS OF NORTH CAROLINA, INC.)**

I, Mark Payne, as Director of the Division of Health Service Regulation, North Carolina Department of Health and Human Services (the “Department” or “Agency”), do hereby issue this Declaratory Ruling pursuant to North Carolina General Statutes § 150B-4 and 10A N.C.A.C. 14A .0103, under the authority granted me by the Secretary of the Department of Health and Human Services.

On August 8, 2018, Fresenius Medical Care Holdings, Inc., d/b/a Bio-Medical Applications of North Carolina, Inc. (“BMA”), the owner and operator of end stage renal disease (“ESRD”) treatment facilities, requested a declaratory ruling as to the applicability of Chapter 131E, Article 9 (Certificate of Need Law) of the North Carolina General Statutes, and of the Department’s rules, to the facts described below. Specifically, BMA requests a determination that 10A NCAC 14C .2203 Performance Standards should not apply to proposals to develop dialysis stations dedicated exclusively to the provision of home hemodialysis training and support services. This ruling will be binding upon the Department and the entity requesting it as long as the material facts stated herein are accurate. This ruling pertains only to the matters referenced herein. Except as provided by North Carolina General Statutes § 150B-4, the Department expressly reserves the right to make a prospective change in the interpretation of the statutes and regulations at issue in this Declaratory Ruling. Jim Swann, Director of Operations, Certificate of Need, for Fresenius Medical Care Holdings, Inc., has requested this ruling on behalf of BMA and has provided the material facts upon which this ruling is based.

STATEMENT OF THE FACTS

There are three (3) methods or modalities for kidney dialysis: in-center, home hemodialysis, and home peritoneal dialysis. In-center patients report to the ESRD facility for dialysis while the other two modalities are performed in the patient's home. The home hemodialysis modality uses a machine or dialysis station similar to the ones used for in-center patients in the ESRD facility.

No person can develop a new dialysis station without first obtaining a certificate of need ("CON"). N.C. Gen. Stat. §§ 131E-178(a), -176(2), -(5), and -(16). In order to be approved for a CON, the applicant must demonstrate that its proposal is consistent with all applicable review criteria. N.C. Gen. Stat. § 131E-183(a). Pursuant to N.C. Gen. Stat. § 131E-183(b), the Department is authorized to adopt rules for review of particular types of applications that will be used in addition to the criteria contained in N.C. Gen. Stat. § 131E-183(a). In 1989, the Agency adopted rules for the review of dialysis applications. At present, there is only one such rule:

10A NCAC 14C .2203

PERFORMANCE STANDARDS

- (a) An applicant proposing to establish a new End Stage Renal Disease 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 State Medical Facilities Plan that is based on an adjusted need determination.
- (b) An applicant proposing to increase the number of dialysis stations in an existing End Stage Renal Disease facility or one that was not operational prior to the beginning of the review period but which had been issued a certificate of need shall document the need for the additional stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the additional stations.
- (c) An applicant shall provide all assumptions, including the methodology by which patient utilization is projected.

ANALYSIS

10A NCAC 14C .2203 has not been amended since 2010. According to the January 2010 Semiannual Dialysis Report (“SDR”), as of June 30, 2009, there were a total of 13,607 dialysis patients utilizing North Carolina facilities. Of these, 12,261 were being dialyzed in a facility (90%) and 1,346 were dialyzing at home (10%).¹ The percentage of home dialysis patients varied considerably from county to county. For example, 41% of patients living in Currituck County dialyzed at home. Even today, there is no dialysis facility located in Currituck County. According to the July 2018 SDR, as of December 31, 2017, there were a total of 18,038 dialysis patients utilizing North Carolina facilities. Of these, 15,804 were being dialyzed in a facility (87.6%) and 2,234 were dialyzing at home (12.4%).² Therefore, while the total number of dialysis patients has increased by 24% since 2010, the number of dialysis patients dialyzing at home has increased by 66%.

Since 2008, the Agency has received three (3) applications proposing to establish a new dialysis facility to exclusively serve home hemodialysis and home peritoneal patients by relocating existing dialysis stations. The language of 10A NCAC 14C .2203 does not expressly limit itself to dialysis stations used by in-center patients, so the rule was applied during the review of all three applications. All three applications were denied because the applicant could not adequately demonstrate that dialysis stations utilized exclusively by home hemodialysis patients would serve 3.2 patients per station per week as required by 10A NCAC 14C .2203.

The assumptions regarding the capacity of dialysis stations used by in-center dialysis patients are:

- The facility will be open six (6) days per week.
- The facility will staff two (2) shifts per day.

¹ The January 2010 SDR does not break down the home patients into peritoneal and home hemodialysis.

² The July 2018 SDR does break down the home patients into peritoneal and home hemodialysis.

- Each patient receives three (3) treatments per week.

Based on these assumptions, a single station can serve four (4) in-center dialysis patients per week at 100% of capacity. The performance standard requires 80% capacity, or 3.2 patients per station per week. While hemodialysis patients are trained in the facility and are monitored periodically in the facility, the patient completes dialysis at home. The number of home hemodialysis patients that can be served by a single station in a week differs from the number of in-center dialysis patients that can be served in a week. At this time, however, the Agency does not have a standard for home hemodialysis utilization.

As part of the periodic review of rules process, 10A NCAC 14C .2203 was determined by the Agency to be necessary with substantive public interest. This means that the rule will need to be re-promulgated. The reason the rule was designated by the Agency as necessary with substantive public interest is the need to reword the existing subparts (a) and (b) so that it is clear that they apply only to proposals involving in-center dialysis stations and to add a new performance standard specifically for home hemodialysis stations.

If 10A NCAC 14C .2203 did not apply to proposals to develop or expand a facility to exclusively serve home hemodialysis and home peritoneal patients, the applicant would still be required to demonstrate that the proposal is consistent with all applicable statutory review criteria, which includes demonstrating the need the patients to be served would have for the proposed services and that the proposal would not result in an unnecessary duplication of existing or approved dialysis stations in the service area.

CONCLUSION

For the foregoing reasons, assuming the statements of fact in the request to be true, I conclude that 10A NCAC 14C .2203 should not apply to proposals to develop or expand a facility to exclusively serve home hemodialysis and home peritoneal patients.

This the _____ day of October, 2018.

S. Mark Payne, Director
Division of Health Service Regulation
N.C. Department of Health and Human Services

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that I have this day served the foregoing Declaratory Ruling upon the PETITIONER by certified mail, return receipt requested, by causing a copy of same to be placed in the United States Mail, first-class, postage pre-paid envelope addressed as follows:

CERTIFIED MAIL

Jim Swann
FRESENIUS KIDNEY CARE
3390 Dunn Road
Eastover, North Carolina 28312

This the _____ day of October, 2018.

Patricia Bryant
Administrative Assistant
Division of Health Service Regulation