

NORTH CAROLINA DEPARTMENT OF HEALTH AND HUMAN SERVICES
DIVISION OF FACILITY SERVICES
RALEIGH, NORTH CAROLINA

IN RE: REQUEST FOR)
DECLARATORY RULING BY)
BIO-MEDICAL APPLICATIONS OF) DECLARATORY RULING
OF NORTH CAROLINA, INC.,)
d/b/a FMS DIALYSIS SERVICES OF APEX)
PROJECT I.D. # J-7107-04)

I hereby issue this declaratory ruling to Bio-Medical Applications of North Carolina, Inc. d/b/a FMS Dialysis Services of Apex (ABMA@), pursuant to N.C. Gen. Stat. ' 150B-4, 10A NCAC 14A .0103, and the authority granted to me by the Secretary of the Department of Health and Human Services. BMA is requesting a declaratory ruling to allow it to relocate ten dialysis stations from 1109 Markham Drive, Apex, North Carolina to 1002 American Way, Apex, North Carolina.

This ruling is binding on the Agency and the person requesting it if the material facts stated in the request are accurate and no material facts have been omitted from the request. This ruling applies only to this request. Except as provided by N.C. Gen. Stat. ' 150B-4, the Agency reserves the right to change the conclusions that are contained in this ruling. Jim Swann, Regional Director of Health Planning for Fresenius Medical Care, has requested this ruling on behalf of same and has provided the *material* facts set out below.

STATEMENT OF THE FACTS

On February 22, 2005, BMA was issued a certificate of need (ACON@) (Project ID No. J-7107-04) to develop a new ten station dialysis facility through the relocation of ten existing certified stations from BMA Cary Dialysis Clinic. The site proposed for the development of the new ten station dialysis facility was at 1109 Markham Drive, Apex, North Carolina (“the Approved Site”).

Since the filing and approval of its CON application, BMA has discovered that the Approved

Site was prone to flooding from a drainage ditch along the boundary of the site. Resolution of the flooding issue would require BMA to raise the level of the Approved Site by twelve feet, which would be cost prohibitive. In addition, a secondary cite identified in the application was determined to be of insufficient size, and therefore unsatisfactory. BMA has determined that a more effective alternative would be to develop the new ten station dialysis facility at 1002 American Way, Apex, North Carolina.

The site located at 1002 American Way, Apex, North Carolina (“the New Site) is approximately one mile from the Approved Site, and will not affect the access of BMA patients currently being served at the BMA Cary dialysis facility.

BMA further represents that changing sites will not affect its ability to develop this project in a manner consistent with the representations in the CON application.

ANALYSIS

The CON law would require a full review of BMA’s proposed change of site if that change were to represent a material change in the physical location of the project according to N.C. Gen. Stat. § 131E-181(a). The relocation of the site for the ten station dialysis facility from the Approved Site to the New Site does not constitute a material change in either the physical location or in the scope of the proposed project for the following reasons:

- (1) The New Site is located in close proximity to the Approved Site; and
- (2) The change in location is the only proposed change in the project, and therefore does not constitute a material change in either the scope of the project or in the person named in the application, which would result in a violation of N.C. Gen. Stat. § 131E-181(a).

N.C. Gen. Stat. § 131E-189(b) allows the Agency to withdraw BMA’s CON if BMA either

fails to develop the service in a manner consistent with the representations made in the application or with any conditions that were placed on the CON. The relocation of the dialysis facility would not violate this statute for the following reasons:

(1) BMA will not be developing its project in a manner that is materially different from the representations made in its application, nor will it be developing its project in a manner that is inconsistent with any of the conditions that were placed on its CON.

(2) The development of the project at the alternate site is in close proximity to the approved site and would not constitute a failure to satisfy a condition of the CON because none of the conditions on the CON refer to or relate to the project site.

CONCLUSION

For all of the foregoing reasons, assuming the statements of fact in the request to be true, I conclude that the change in the site for the development of the new ten station dialysis facility (Project ID No. J-7107-04) will not violate N.C. Gen. Stat. ' 131E-181, because it will not constitute a material change in the physical location of the proposed facility, and will not constitute a failure to satisfy a condition of the CON in violation of N.C. Gen. Stat. ' 131E-189(b).

This ruling is not intended, and should not be interpreted to authorize any increase in the approved capital expenditure for this project, a change in the approved timetable, a change in the conditions placed on the CON, or any other change in the approved project.

This the _____ day of January, 2006.

Robert J. Fitzgerald, Director
Division of Facility Services