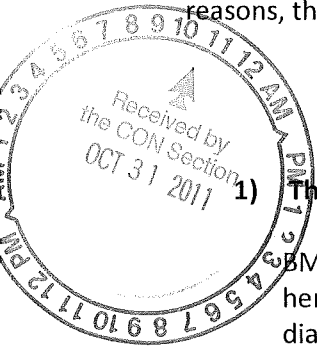


In accordance with N.C.G.S. Section 131E-185(a1)(1), Wake Forest University Health Sciences submits the following comments regarding the September 15, 2011 Certificate of Need Application submitted by Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Cabarrus County Home Dialysis Program (hereinafter "BMA") for the October 1, 2011 review cycle to relocate two dialysis stations from BMA Charlotte and develop a new freestanding Home Dialysis Program in Cabarrus County. For the following reasons, the BMA Application should be denied:



1) The proposed project is non-conforming with G.S. 131E-183(a).

BMA states clearly on page 2, 12, and 23 of its application that it is applying to transfer two ICH hemodialysis stations from Mecklenburg County to Cabarrus County to establish a new HOME dialysis training facility.

BMA's proposal does not meet the required need criteria identified in the SMFP. Their proposal is not authorized under CON guidelines, and cannot conform to G.S. 131E-183(a). Accordingly a CON may not be issued for their project.

2) The proposal is non-conforming with ESRD-2.

BMA's proposal violates ESRD-2 because it proposes a "need" for home dialysis stations in Cabarrus County. No need for this proposed service is identified in the SMFP. In fact, the SMFP specifically states that "need" for stations is based solely on ICH patient populations. BMA also fails to meet the requirement of establishing a minimum of 10 stations at a new facility with its proposal is solely to transfer either one or two stations to establish a new health service facility. BMA also fails to offer ICH services, which are the only dialysis services applicable to station need methodology.

3) The proposal is non-conforming with Criterion 3, which states that an applicant must identify the population to be served by the proposed project. .

BMA erroneously assumes on pages 12 through 15 a 78% annual change in home dialysis patient populations. On page 19 BMA assumes that 66% of home patients will continue to utilize peritoneal dialysis while 33% will use home hemodialysis.

Data available at the SEKC website and in the SDR demonstrates that from 2006 through 2010, the NC AACR for home patients is 10.18%. Data specific to Cabarrus County yields similar analytic results with a change rate for home patients of 11.54% from 2006 through 2010. Home patients make up 9.81% of all patients statewide and 12.56% of patients in Cabarrus County. In September 2011, home hemodialysis patients comprised 15.84% of total home patients state wide and 15.38% of home patients in Cabarrus County. Correct data analysis fails to support BMA's findings, projections and assumptions. In addition the SMFP fails to recognize a defined "need" for home dialysis services.

- 4) **The proposal is non-conforming with Criterion 3a, which states that an applicant must demonstrate that the needs of the population presently served will be met adequately by the proposed relocation or by alternative arrangements in the case of reduction or relocation of a service.**

BMA proposes to transfer one or two hemodialysis stations across county lines to serve home dialysis patients without first establishing a certified dialysis facility. Because the number of stations to be transferred is less than the 10 stations allowed under SMFP rules, BMA's proposal is non-conforming.

- 5) **The proposal is non-conforming with Criterion 4, which states that applicants must demonstrate that the proposed project is the least costly or most effective alternative.**

BMA states its reasoning behind its proposal on page 35 of its application. However, BMA fails to address the fact that home dialysis training is currently available in Cabarrus County at the existing certified dialysis facility at Harrisburg Dialysis Center, 3310 Perry Street, Concord, North Carolina, 28027. Pursuant to the CMS Facility Compare website, home patients are not a factor in determining station need. In addition, CKD patients are not a factor in determining patient growth as that is derived solely from ESRD patient population growth. The SMFP makes no provision for a project of the scope proposed by BMA.

- 6) **The proposal is non-conforming with Criterion 5, which states that 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.**

BMA states on page 20 of its application that it assumes compliance with ESRD 2 and therefore assumes it will be approved for the services proposed. CON approval provides the ability for Medicare certification and participation with commercial insurance carriers. Without CON approval it would be impossible for BMA to obtain Medicare Certification, which is a determining factor in its ability to meet its financial projections. Because BMA fails to conform to all other applicable CON criteria, CON approval is not likely.

- 7) **The proposal is non-conforming with Criterion 6, which states that the applicant will demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.**

Per the July 2011 SDR and the Medicare Facility Compare website, there are two existing dialysis facilities in Cabarrus County, Harrisburg Dialysis Center and Copperfield Dialysis Center. The Harrisburg Dialysis Center currently offers home dialysis training. The SMFP does not recognize a need for stand-alone home hemodialysis training facilities. Approval of BMA's proposal would result in duplication of an existing service and not meet the SMFP "need" criterion.

- 8) **The proposal is non-conforming with Criterion 7, which states that applicants will show evidence of the availability of resources, including health manpower and management personnel, for the provision of the services proposed to be provided.**

Because BMA is non-conforming with all other CON review criteria, it is by default non-conforming with these criteria.

- 9) The proposal is non-conforming with Criterion 8, which states that the applicant will provide the necessary ancillary and support services for the proposed project.**

Because BMA is non-conforming with all other CON review criteria, it is by default non-conforming with these criteria.

- 10) The proposal is non-conforming with Criterion 12, which states that applicants will demonstrate that the cost, design, and means of construction proposed represent the most reasonable alternative.**

BMA proposes to lease shelled-in space and upfit it for a project that fails to conform to “need” criteria as defined by the SMFP.

- 11) The proposal is non-conforming with Criterion 13, which states that applicants will demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and of members of medically underserved groups.**

BMA proposes on page 42 to serve the needs of minorities and underserved. However, on page 43, BMA identifies its expected payor mix to reflect a payor mix of its facility in Mecklenburg County with 31% commercial payors, 67.3% Medicare payors, 1.7% VA payors, and no Medicaid payors. These assumptions are confirmed on page 59 of the BMA application outlining revenue sources. Because BMA fails to propose to serve Medicaid patients, it is doubtful that it could adequately meet the needs of the underserved groups.

- 12) The proposal is non-conforming with Criterion 18a, which states that applicants will demonstrate the expected effects of the proposed services on competition in the proposed service area.**

BMA’s project fails to conform to established “need” criterion defined in the SMFP. Approval of BMA’s proposed project would result in an unfair competitive advantage over existing providers, which had to comply with SMFP rules and regulations in order to receive CON approval.

- 13) The proposal is non-conforming with NCAC 14C .2200, .2202, and .2203.**

- 1. Utilization Rates** – BMA’s utilization rates are based on HT utilization. The SMFP basis for measuring utilization is ICH utilization. Because BMA fails to propose to offer ICH, the utilization rates projected by BMA for the two (or one) dialysis station(s) it proposes to transfer to Cabarrus County fail to meet SMFP requirements for station utilization.
- 2. Isolation Station** – On page 69 of its application BMA fails to identify isolation capabilities for patients with infectious disease processes (hepatitis).

3. **Services provided in conformity with applicable laws and regulations** – BMA’s project fails to conform to acceptable SMFP criteria for “need,” it fails to propose service to ICH patients for which “need” determination is achievable, and it fails to propose a physical environment to accommodate the isolation needs of patients with infectious disease processes.
4. **Performance standards** – BMA proposes to only provide services to home patients. Without ICH patients, BMA cannot meet performance standards prescribed by the SMFP.
5. **Provide all assumptions including patient utilization** – BMA cannot comply with this criterion because SMFP utilization is based on ICH use and BMA’s proposal is strictly for home dialysis use of certified dialysis stations.