Wake Forest University Health Sciences
Public Comments for: FMC Hickory Home Program
Project ID: E-8760-11

In accordance with N.C.G.S. Section 131E-185(a1)(1), Wake Forest University Health Sciences submits the following comments regarding the October 17, 2011, Certificate of Need Application submitted by Bio-Medical Applications of North Carolina, Inc. d/b/a FMC Hickory Home Program (hereinafter "BMA") for the November 1, 2011, review cycle to relocate peritoneal home dialysis training and support from BMA Hickory and develop a new freestanding Home Dialysis Program in Catawba County. For the following reasons, the FMC Hickory Application should be denied:

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

BMA states clearly on page 2 and throughout its application that it is applying to transfer peritoneal dialysis training and support services from BMA Hickory to FMC Hickory Home, a new free-standing home 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 training services outside of a certified dialysis facility. Home dialysis **training** services is not included in the ESRD services identified in § 405.2102. No need for this proposed service is identified in the SMFP. In fact, the SMFP specifically states that "need" in reference to dialysis is based solely on ICH patient populations and ICH dialysis station utilization. New dialysis facilities are required to have a minimum of 10 ICH dialysis stations, unless an adjusted need determination is in place. BMA fails to propose to offer ICH services, which are the only dialysis services applicable to 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 states on page 14 of its application that peritoneal patients from Alexander, Burke, Caldwell, and Lincoln Counties will utilize its proposed services in addition to Catawba County peritoneal patients. BMA states that Alexander County patients will not be included in its projections due to the assumption that they will utilize home dialysis training and support services in Alexander County upon opening of the BMA facility there in December 2011. However, BMA currently operates facilities in Burke and Caldwell Counties that also offer home dialysis services and unlike the FMC Hickory facility, have SDR reported utilization rates of 73% for 25 stations at BMA of Burke County and 64% for 34 stations at BMA of Lenoir in Caldwell County. BMA acknowledges on page 20 of its application the availability of home services at both locations. As the sole provider of dialysis services in Lincoln County, BMA could also request certification at its facility in Lincolnton to provide home dialysis training services to Lincoln County patients within their home county. FMC Lincolnton operates 25 ICH stations at a utilization rate of 74%.

It is BMA's contention that its proposal for a stand-alone home peritoneal training facility is necessary to alleviate "congestion during training days, and especially on home clinic days." Clearly the least costly and most efficient solution to alleviate "congestion" would be for BMA to allow patients to attend the under-utilized home training facilities in their home counties, freeing up space at FMC Hickory.

Correct data analysis fails to support BMA's findings, projections and assumptions. The data available at the SEKC website and in the SDR demonstrates that from 2006 through 2010, the NC AACR for home patients was 10.18%. Data specific to Catawba County yields similar analytic results with a change rate for home patients of 15.85% from 2006 through 2010. Home patients make up 9.81% of all patients statewide and 11.83% of patients in Catawba County. Of note is the fact that in September 2011, home hemodialysis patients comprised 15.84% of **total home patients** state wide and 10.71% of home patients in Catawba County. FMC Hickory states on page 42 of its application that it only serves half (14 of 28) of Catawba County's home dialysis patients. Finally, as noted previously, 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 its peritoneal home dialysis training and support program to a new site away from the existing BMA Hickory Dialysis Center and to leave home hemodialysis at the existing BMA Hickory to grow that program and in an effort to relieve patient congestion on training days and clinic days as stated on page 40 of its application.

The expanding ICH population at BMA Hickory is a main driving force in the "congestion" problem and a transfer of home peritoneal dialysis services to a new location will not decrease congestion in an un-expandable and heavily utilized facility. Since certified ICH stations are required to offer in-center home hemodialysis training, increasing home hemodialysis services will in turn lessen the number of certified ICH stations available. BMA has stated that its BMA Hickory location cannot be expanded and according to the July 2011 SDR that unit is at 85% utilization while BMA's other facility in Catawba County is at 60% utilization and is only 4.7 miles away.

A decrease in the number of ICH stations, which is required by CMS when a facility designates certified stations as a home hemodialysis training station, paired with **no** increase in ICH patients will result in increased utilization. Accordingly, BMA will still have the same number of ICH patients with less available stations to serve their needs.

It is unclear how transferring one service out of that location in order to grow another service will result in the desired effect of less congestion on clinic days at the existing facility. It is also unclear how the remaining BMA Hickory ICH patients will be better served.

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 40 of its application – to allow home hemodialysis training and support to "continue to expand." However, BMA goes on to state that "the BMA Hickory facility cannot be further expanded." These statements seemingly contradict one another and it is clear the most effective alternative has not been proposed by BMA due to the following factors:

1. A facility must have certified, dedicated ICH stations on which to perform home hemodialysis training.
2. In order to expand home hemodialysis training, the facility must dedicate additional ICH stations to home hemodialysis training.
3. The facility as it stands is at 85% utilization of its 33 ICH stations. A reduction in ICH stations to accommodate an expanding home hemodialysis training program will result in greater utilization.
4. Patient congestion will not be relieved as there will be more ICH patients using less ICH stations.
5. An increase in the number of home hemodialysis patients will add to the congestion problem.
6. BMA operates existing, certified home dialysis training programs in counties where it proposes some of its peritoneal patients will originate. The existing home training facilities in the patients' home counties are equally, if not more convenient to patients for the reasons of transportation and that patients will never have to travel more than 30 miles for their care.
7. BMA's other facility in Catawba County is only 4.7 miles from BMA Hickory, has 23 stations and a utilization rate of 60%, indicating a surplus of ICH stations that could be dedicated for home hemodialysis training services or the acceptance of ICH patients from BMA Hickory that would effectively relieve the congestion experienced at that unit at a minimal cost.

Further, there is no methodology to support a project of this scope.

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 22 and 23 of its application that it assumes its proposal can be approved within the definitions located at § 405.2102, and since "Liberty Dialysis has been operating five free standing home peritoneal dialysis facilities for several years. The development of an End Stage Renal Disease facility does not require dialysis stations when the facility is proposing to serve home peritoneal dialysis patients only." That statement is not entirely correct.

BMA includes an excerpt from §405 and places emphasis on "**(3) Home dialysis. Dialysis performed by an appropriately trained patient at home.**" However, within the definitions of

"**ESRD service,**" there is not one single definition that includes the term "**HOME DIALYSIS TRAINING.**" (Emphasis added by WFUHS.) Nor, is there an explanation of what home dialysis training entails. We are to assume that home dialysis training would be a service provided by a certified dialysis facility to educate a patient on the methods of performing home dialysis **at home**. However, the Section fails to provide information in regards to that specific process within its definitions of what qualifies as an "ESRD service." Because CMS requires a "Certified Dialysis Facility" to perform home dialysis training and home dialysis training on its own fails to fall under the categories of ESRD facilities nor ESRD services, BMA's proposal is fatally flawed. NC laws were revised after Liberty Dialysis began operations to more clearly match the Federal Regulations in regard to what qualifies as an ESRD Facility.

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 possible.

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 existing dialysis facilities in the home counties of BMA Hickory Home's proposed patients. BMA has indicated an exclusion of Alexander County peritoneal patients due to that facility's planned certification by 12/31/2011 and its ability to provide home hemodialysis and peritoneal training in county. BMA of Burke County provides both peritoneal and home hemodialysis training and support. It is certified for 25 stations and has a reported utilization rate of 73%. BMA of Lenoir, Inc., in Caldwell County also offers peritoneal and home hemodialysis training and support. That facility is equipped with 34 stations and has a reported utilization rate of 64%. BMA is the sole provider of dialysis services in Lincoln County. **However, BMA fails to offer in-county home training to Lincoln County patients.** Because three of the five counties from which BMA Hickory Home's projected patients reside offer in-county home dialysis training programs, projecting a need for services for those patients in Catawba County will result in an unnecessary duplication of existing or approved health service capabilities or facilities. All of the facilities in Alexander, Burke, and Caldwell Counties are located within 30 miles of all borders of each county, respectively.

The SMFP does not recognize a need for stand-alone home peritoneal dialysis training facilities. Approval of BMA's proposal would result in duplication of an existing service and not meet the SMFP "need" criterion, nor would such a proposal meet the guidelines identified in §405.

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 Catawba County with 38% commercial payors, 62% Medicare payors, no 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. By failing to meet CON Criterion, CON approval cannot be obtained, making Medicare certification impossible.

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 cannot establish utilization rates, as its proposal fails to meet "need" requirements in the SMFP, which are based on "utilization" of ICH stations.

2. **Isolation Station** – On page 84 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 training requiring no certified dialysis stations.