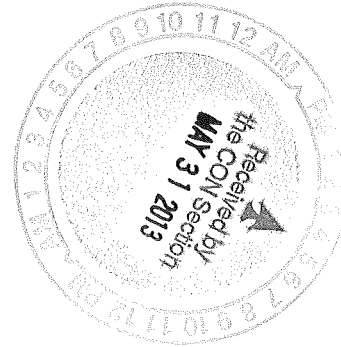


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May 31 2013



VIA HAND DELIVERY

Craig R. Smith
Chief
Certificate of Need Section
N.C. Division of Health Service Regulation
809 Ruggles Drive
Raleigh, NC 27603

Martha Frisone
Assistant Chief
Certificate of Need Section
N.C. Division of Health Service Regulation
809 Ruggles Drive
Raleigh, NC 27603

Re: Certificate of Need Application for Youngsville Dialysis Facility
Project ID No. K-10126-13
Our File No. 052389.0008

Dear Mr. Smith and Ms. Frisone:

We are writing on behalf of our client Bio-Medical Applications of North Carolina, Inc. ("BMA"), in response to the letter dated 13 May 2013 to the CON Section from Bill Shenton, counsel for Total Renal Care of North Carolina, LLC ("TRC"). A copy of Mr. Shenton's letter is attached hereto for your reference as **Exhibit A**.

As you know, BMA applied for a CON to develop a 10-station dialysis facility in Franklin Co. (PID # K-10099-13) ("BMA Application") on 15 March 2013 for the Review Category D review period beginning 1 April 2013; and TRC subsequently applied for a CON to develop a 10-station dialysis facility in Franklin Co. (PID #K-10126-13) ("TRC Application") on 15 April 2013 for the Review Category I review period beginning 1 May 2013. TRC's letter argues that the TRC and BMA Applications should be batched for a competitive review.

BMA respectfully disagrees with TRC's request. As discussed herein, the TRC Application falls into Review Category D, not Review Category I, and therefore the TRC application was not timely filed and cannot be reviewed competitively with the BMA Application. Also, even if TRC's application were properly filed in Review Category I, it would be contrary to the CON Section's rules, inconsistent with Agency precedent, and highly inequitable for the two applications to be reviewed competitively.

A Professional Corporation

I. The BMA and TRC Applications should have been filed in the same review.

a. BMA's and TRC's proposals both fell into Review Category D.

TRC asserts that its application to develop a 10-station dialysis facility in Youngsville is a Category I application, and filed its application on 15 April 2013 for the review period commencing 1 May 2013. (Ex A, p. 1; CON Section Application Log, April 2013). However, TRC proposes to develop this facility via relocation of eight beds from its existing Franklin County facility and two beds from Wake County, which is contiguous to Franklin Co. (Ex. A, p. 1). The 2013 SMFP designated all proposals for "relocation of existing certified dialysis stations to another county pursuant to Policy ESRD-2" as Category D. (2013 SMFP, Chapter 3). TRC's letter acknowledges that "TRC filed its application pursuant to Policy ESRD-2..." (Ex. A p. 1). Therefore, the project proposed in the TRC Application falls into Category D, not Category I as claimed by TRC.

TRC's letter to the CON Section states: "[s]ince the TRC application proposed the establishment of [its proposed facility] predominantly through the relocation of stations within Franklin County, it was timely filed as a Category I application and began review on May 1, 2013." (Ex. A p. 1). TRC also asserts that "TRC's proposal to develop Youngsville Dialysis primarily through the relocation of existing stations within the same county fits under Category I." (Ex. A p. 2). But Policy ESRD-2 is not limited to proposals made up "predominantly" or "primarily" of dialysis stations from the same county. To the contrary, the plain language of the SMFP refers simply to proposals for "relocation of existing certified dialysis stations to another county pursuant to Policy ESRD-2"; and the TRC Application unquestionably proposes to relocate two existing certified dialysis stations from Wake County to another county pursuant to Policy ESRD-2. (See Ex. A p. 1).

TRC cites no statute, rule or Agency policy to support its contention that its application fell into Review Category I. (Ex. A). Therefore, the inclusion of additional dialysis stations from within Franklin County does not remove TRC's Application from the scope of Policy ESRD-2 or place it in any other review category.

b. TRC failed to timely file its application.

Franklin County is in Health Service Area IV (See 2013 SMFP, Appendix A), and the 2013 SMFP established two review periods for Review Category D Applications in Health Service Area IV. The review periods began on 1 April 2013 and 1 October 2013, respectively. (2013 SMFP, Chapter 3).

CON Applications must be filed "no later than 5:30 p.m. on the 15th day of the month preceding the scheduled review period." 10A NCAC 14C.0203(b). "An application shall not be included in a scheduled review if it is not received by the agency by this deadline." *Id.* Since

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TRC's Application was not filed until 15 April 2013 (See CON Section Application Log, April 2013), it was not timely filed for the Category D review period that began 1 April.

c. TRC Application cannot be reviewed in same review period as BMA application.

The BMA Application was timely filed by 15 March 2013 and was deemed to be complete by the CON Section via letter dated 21 March, a copy of which is attached hereto as **Exhibit B**. Accordingly, the review of the BMA Application began in the scheduled review period for Category D applications on 1 April 2013. (See **Ex. B**, attached). However, because the TRC Application was *not* timely filed by 15 March and deemed complete by 1 April 2013, it *cannot* be reviewed in review period beginning 1 April. See 10A NCAC 14C.0203(b) ("An application shall not be included in a scheduled review if it is not received by the agency by this deadline").

10A NCAC 14C.0203(e) provides that "[t]he review of an application shall commence in the next applicable review period that commences after the application has been determined to be complete. Therefore, assuming the TRC application was determined complete for review, it can only be reviewed in the *next* scheduled review for Category D Applications, which begins 1 October 2013. (2013 SMFP, Chapter 3).

II. Even if the TRC Application were in Review Category I, it cannot be reviewed competitively with the BMA Application.

a. The BMA and TRC Applications are not competitive under Agency rules.

Pursuant to 10A NCAC 14C.0202(f), "[a]pplications are competitive if they, in whole or in part, are for the same or similar services and the agency determines that the approval of one or more of the applications may result in the denial of another application reviewed in the same review period." In this case, regardless of whether the BMA and TRC applications proposed the same or similar services, they are not competitive because they are not being reviewed in the same review period.

The BMA application is under review in the review period commencing 1 April 2013. But the TRC application was submitted on 15 April for the review period commencing on 1 May 2013. As set forth above, BMA believes that the TRC Application cannot be reviewed in that review period, but may only be reviewed in the next scheduled Category D review period, starting 1 October 2013. However, neither the 1 May review period nor the 1 October review period are the same review period in which the BMA application is being reviewed. Therefore the TRC and BMA applications are, by definition, not competitive. 10A NCAC 14C.0202(f).

TRC's letter nevertheless contends that the two applications are competitive because: "[t]he TRC and BMA applications, filed within just one month of each other, will both be under review at the same time during the period from May 1 forward." TRC contends that the use of

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the term “review period” instead of “review category” in 10A NCAC 14C.0202(f) implies that “...the competitive review provision is not limited to applications that are in the same review category.” (Ex. A p. 2). TRC cites no Agency policy to support its position, nor any prior instance in which applications filed for reviews beginning at different times were deemed competitive and batched for review.

BMA believes that TRC’s position is incorrect. Despite the partial overlap of the 1 April and 1 May review periods, they are separate “review periods” within the meaning of 10A NCAC 14C.0202(f).

Pursuant to subsection .0202(c), the “appropriate review category” into which a project falls and the “applicable “review period” for such applications shall be determined by the Agency. 10A NCAC 14C.0103(a)(5) and .0202(e) provide that the scheduled review period shall be set, by review category, in the State Medical Facilities Plan. As required by GS 131E-185(a1) and (c), every application must be reviewed within 150 days. Consequently, the “review period” for any given application is the specific period, not to exceed 150 days, designated in the SMFP for applications of that review category.

In this case, the “review period” for the BMA application (Category D) began 1 April 2013, and the review period for Category I applications began 1 May 2013. Accordingly, they are separate and distinct review periods, and applications filed in either review period cannot be competitive with those filed in the other. 10A NCAC 14C.0202(f).

b. The CON Section has previously declined to batch applications for competitive review under similar circumstances.

In July 2006, Presbyterian Hospital Mint Hill, LLC (“Presbyterian”) filed a CON application for a new hospital in Mint Hill (Project ID #F-7648-06). Two months later, The Charlotte Mecklenburg Hospital Authority (“CMHA”) filed two applications, one of which also proposed a new hospital in Mint Hill (project ID #F-7707-06). Prior to the filing of the CMHA Applications, counsel for CMHA requested that the CON Section consider the CMHA and Presbyterian applications competitive and batch them for a competitive review.

However the CON Section declined to do so, and instead reviewed the two hospital proposals in stand-alone reviews according to the review schedule set forth in the SMFP. By a decision and findings dated 22 December 2006, the CON Section conditionally approved the Presbyterian application. By a separate decision and findings, dated 25 February 2007, the CON Section denied the later-filed CMHA application, excerpts of which are attached hereto as Exhibit C. Notably, the CMHA application was denied in part because it failed to demonstrate need for the project in light of the Agency’s approval of the earlier-filed Presbyterian application. (See Ex. C pp. 42-44).

Thus, in the past when the Agency was asked to competitively review applications for similar projects in the same service area, but which were filed in separate review periods, the

Agency properly declined. It would therefore be inconsistent with prior Agency decisions to do otherwise with respect to the BMA and TRC applications.

c. Reviewing the TRC and BMA Applications competitively would give TRC an unfair advantage.

Further, it would be highly inequitable if the CON Section accepted TRC's argument and batched the applications for review. Since BMA's application was filed a full month before the TRC application, TRC could have easily obtained and reviewed the BMA application prior to filing its own (and almost certainly did), allowing it to adjust its own proposal and projections to ensure it would be found comparatively superior in a comparative analysis. The CON Section has never and should not now condone such gamesmanship.

III. N.C. Gen. Stat. § 131E-182(a) does not support TRC's argument.

In arguing for the two applications to be reviewed competitively, TRC relies partly on N.C. Gen. Stat. § 131E-182(a), which reads "The Department in its rules shall establish schedules for submission and review of completed applications. The schedules shall provide that applications for similar proposals in the same service area will be reviewed together." However, this statute does not support TRC's proposition.

First, as set forth above, TRC's proposal included stations from outside the county, and therefore should have been filed in the same review category as and review period as BMA's. It was only TRC's failure to file timely for the correct review category and review period that prevented the TRC and BMA applications from being reviewed competitively.

Second, even if TRC were correct that its proposal fell into Category I, the Agency would have no obligation to review the applications competitively. Specifically, the first sentence of Section 131E-182(a) gives the agency the authority to group similar applications, *by rule*, for competitive review. The CON Rules expressly provide that the Agency will establish review categories and review periods in the SMFP (*see* 10A NCAC 14C.0103(a)(5) and .0202(e)), and indeed, the SMFP is incorporated as an Agency rule (*see* 10A NCAC 14C.0103(b)). As set forth above, The 2013 SMFP designated all proposals for "relocation of existing certified dialysis stations to another county pursuant to Policy ESRD-2" as Category D, and separately included Category I as a catch-all for projects not falling into another category. (2013 SMFP, Chapter 3).

Therefore, by its rules grouping proposals into review categories and corresponding review periods, the Agency determined which proposals are similar, and which must therefore be reviewed competitively. The Agency has exercised its statutory discretion to determine (a) that applications filed under Category D are similar and should be reviewed together; but (b) Category I proposals and Category D proposals are *not* similar and *need not* be reviewed competitively.

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IV. The court decisions cited by TRC do not support its argument.

TRC cites the *Ashbacker* US Supreme Court case and four court decisions under Florida and New Hampshire law in support of its argument that the TRC and BMA applications should be reviewed competitively.¹ However, none of the cited cases is analogous to the facts of this case.

As set forth above, BMA believes that the TRC Application should properly have been submitted in Review Category D, and therefore that TRC failed to timely file its application in the scheduled review period that began 1 April. None of the cases cited by TRC concerned the batching of two applications for similar proposals, one of which was not timely filed.

Also, as set forth above, if TRC's application correctly belonged in Review Category I, the Agency has exercised its statutory discretion and determined, by rule, that Category D and Category I proposals are not sufficiently similar to be reviewed in competition with each other. None of the cases cited by TRC concerned a challenge to Agency rules categorizing projects for purposes of competitive review.

Consequently, neither the facts nor the statutes or state agency rules at issue in the cases cited by TRC are similar to the facts of this situation. The out-of-state court decisions cited by TRC therefore impose not requirement for the BMA and TRC applications to be reviewed competitively.

Very truly yours,

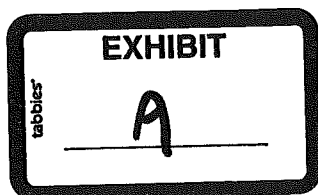


Marcus C. Hewitt

Enclosures

cc: Bill Shenton (via e-mail)
Jim Swann (via e-mail)

¹ *Ashbacker Radio Corporation v. F.C.C.*, 326 U.S. 327, 90 L.Ed. 108 (1945); *Methodist Regional Hospital System, Inc. v. Dept. of Health & Rehabilitative Services*, 497 So.2d 272, 1986 Fla. App. LEXIS 9824 (Fla. 1st DCA 1986); *Appeal of Behavior Science Institute*, 121 N.H. 928, 436 A.2d 1329 (1981); *Bio-Medical Applications of Clearwater, Inc. v. Dept. of Health & Rehabilitative Services*, 370 So.2d 19, 1979 Fla. App. LEXIS 14186 (Fla. 2d DCA 1979); *Gulf Court Nursing Center v. Department of Health and Rehabilitative Services*, 483 So.2d 700, 1985 Fla. App. LEXIS 15543 (Fla. App. 1985).



Poyner Spruill^{LLP}

May 13, 2013

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RE: Certificate of Need Application for Youngsville Dialysis Facility submitted April 15, 2013
(Project I.D. No. K-10126-13) – Competitive Review with BMA Application

Dear Mr. Smith and Ms. Frisone:

We are writing, on behalf of our firm's client, Total Renal Care of North Carolina, LLC (TRC), to present the basis for a determination that TRC's recent application proposing to develop the Youngsville Dialysis Facility in Franklin County should be reviewed competitively with a similar application for a Franklin County dialysis facility filed by Bio-Medical Applications of North Carolina, Inc. (BMA).

On April 15, 2013, TRC filed its Youngsville Dialysis application proposing to develop a new facility by relocating eight dialysis stations from Dialysis Care of Franklin County, within the same county, and two dialysis stations from Wake Forest Dialysis Center, in Wake County. TRC filed its application pursuant to Policy ESRD-2 in the 2013 State Medical Facilities Plan (SMFP), which permits establishment of a new facility through relocation of existing, certified stations within the same county, as well as transfers of existing, certified dialysis stations across county lines. Policy ESRD-2 allows the transfer of stations to a contiguous county so long as the sending county has a surplus of stations, and the relocation of the stations to a site in the receiving county will not create a surplus of stations in that county. Since the TRC Application proposed the establishment of Youngsville Dialysis predominantly through the relocation of stations within Franklin County, it was timely filed as a Category I application and began review on May 1, 2013.

On March 15, 2013, BMA filed a certificate of need application to develop a new facility (Tar River Dialysis) in Franklin County (Project I.D. No. K-10099-13) by transferring stations from its existing BMA Zebulon and FMC Eastern Wake facilities in Wake County. The BMA Application also was filed under Policy ESRD-2. Since the BMA Application proposed the establishment of its facility exclusively via the transfer of stations from outside Franklin County, it was a Category D application, and it began review on April 1, 2013.

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The TRC and BMA Applications, filed within just one month of each other, will both be under review at the same time during the period from May 1 forward. The CON Section's rules generally require the Agency to complete its review of an application within 90 days from the beginning review date. 10A NCAC 14C .0205(a). During the review period for the BMA Application, which began on April 1, and continues on the date of this letter, the TRC Application also will be reviewed. Note that the provision in the CON Rules on competitive applications that is quoted above does not use the term "review category." It refers to a "review period." Other parts of the same rule do use the "review category" concept, and since subsection (f) uses the term "review period" instead, the clear implication is that the effect of the competitive review provision is not limited to applications that are in the same review category. The only chronological requirement is that the applications be "reviewed in the same review period." 10A NCAC 14C .0202(f) (emphasis added).

Although the TRC and BMA Applications both proposed to establish a new dialysis facility in Franklin County, they fell within different review categories because they hinged upon different prongs of Policy ESRD-2. BMA's proposal to establish Tar River Dialysis through the relocation of existing stations to another county fits under Category D. TRC's proposal to develop Youngsville Dialysis primarily through the relocation of existing stations within the same county fits under Category I. Category I is the only catchall grouping of types of projects which do not fall squarely within another review category, and specifically includes proposals to relocate existing stations within the same county. Notwithstanding the fact that these two applications happen to fall within different review categories with slightly different filing deadlines under the schedule in the 2013 SMFP, they will be under review contemporaneously and should be reviewed competitively, in keeping with the statutory requirement that similar services in the same service area be reviewed together. The fact that the CON application schedule published in the SMFP prompted the filing of these similar proposals within slightly different timeframes does not relieve the CON Section of its duty to review these similar proposals for a new dialysis facility in Franklin County together.

Competitive Reviews Under the CON Law

North Carolina's CON Law provides applicants the right to a fair review of an application in accordance with applicable CON statutes and rules and the applicable SMFP. N.C. Gen. Stat. §§ 131E-183(a) and -185. The law mandates, "The schedules [for submission and review of completed applications] shall provide that applications for similar proposals in the same service area will be reviewed together." N.C. Gen. Stat. 131E-182(a). The CON Section's rule on competitive reviews further provides:

Applications are competitive if they, in whole or in part, are for the same or similar services and the agency determines that the approval of one or more of the applications may result in the denial of another application reviewed in the same review period.

10A NCAC 14C .0202(f). Based on the rule, applications must be deemed competitive whenever 1) the applications are for the same or similar services and 2) the approval of one application may result in the denial of another. In other words, mutually exclusive applications for the same or similar services in the same service area which cannot both be approved are deemed competitive. These two applications to establish new dialysis facilities in Franklin County clearly meet each of the two criteria in the Rule.

The TRC and BMA Applications Propose Similar Services.

The BMA and TRC Applications propose to transfer certified dialysis stations from existing facilities located in contiguous counties or within Franklin County to develop a new 10-station facility in Franklin County. The applications seek to provide similar services – outpatient dialysis services in Franklin County. Each application proposes to offer in-center dialysis and includes an isolation area. BMA and TRC each propose that their new Franklin County facility would primarily serve patients who reside in Franklin County.

Approval of Either Application May Result in the Denial of the Other.

Policy ESRD-2 is a controlling, determinative criterion for both applications. If either proposal created a surplus in Franklin County, then that application would contravene Policy ESRD-2, and as a result, it would be determined to be non-conforming with Review Criterion 1, N.C. Gen. Stat. § 131E-183(a)(1), and unapprovable.

Table B of the January 2013 Semi-Annual Dialysis Report shows a deficit of 10 stations in Franklin County, and a surplus of stations in Wake County. The BMA Application acknowledges that if approved, its application would “reduce that [Franklin County] deficit to zero.” BMA Application, p. 2. The TRC and BMA Applications each propose to develop a new 10-station facility through relocation of existing stations. Each of these applications is based upon the same Franklin County deficit of 10 stations that is identified in the January 2013 SDR. Approving both applications would add a total of 12 stations to the Franklin County inventory, creating a two-station surplus there in contradiction of Policy ESRD-2. Thus, it appears that given the requirements of Policy ESRD-2, only one of these applicants could be approved and awarded a CON for its proposed dialysis facility.

TRC explained in its Application how Youngsville Dialysis would not result in a surplus in Franklin County due to the 10-station deficit for Franklin County indicated in the January 2013 SDR. TRC Application, p. 17. The approval of the BMA Application might result in the denial of the TRC Application because if there is no station deficit in Franklin County, the two stations TRC proposes transferring from Wake County would create a surplus of stations in the county.

Under the well-established ESRD methodology in the SMFP, a new dialysis facility must have at least 10 stations in order to be approved. The only exceptions to this are situations where a special need allocation for fewer than 10 stations in a county has been recognized in the applicable SMFP. Therefore, TRC’s Youngsville Dialysis Facility will need to operate with all 10 of its proposed stations, in order to be approvable.

Basic Administrative Law Principles Dictate a Competitive Review

The status of these two applications as competitive is clearly demonstrated by simply applying the two criteria in the Rule. However, there is also a well-established body of administrative law which supports that conclusion and outcome.

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It has long been established that mutually exclusive applications for similar services in the same area should be considered competitively to avoid substantial prejudice to either applicant's rights. This principle, commonly known as the *Ashbacker* Doctrine, stems from the threshold case of *Ashbacker Radio Corporation v. F.C.C.*, 326 U.S. 327, 90 L. Ed. 108 (1945), which involved the FCC's consideration of two rival applications for a radio license. The FCC granted a license to one applicant without a hearing and on the same day set another application for hearing; but because each applicant had a statutory right to a hearing before its application was denied, the U.S. Supreme Court held that if the approval of one applicant effectively precluded the approval of the other, the right to a hearing provided by Congress was "an empty thing." The Court held that "where two *bona fide* applications are mutually exclusive the grant of one without a hearing to both deprives the loser of the opportunity, which Congress chose to give him." *Id.* at 333, 90 L. Ed. at 133. The *Ashbacker* Doctrine simply recognizes that when agency action on one application might affect its decision on another, within the relevant time frame, the two applications must be reviewed together.

North Carolina's Court of Appeals has acknowledged the applicability of the *Ashbacker* doctrine in certificate of need cases. In *Britthaven v. N.C. Dep't of Human Resources*, it noted, "The CON statute calls for competing applications to be reviewed together, or 'batched,' in compliance with *Ashbacker*" 118 N.C. App. 379, 384, 455 S.E.2d 455, 460 (1995) (emphasis added). See also *Living Centers-Southeast, Inc. v. N.C. DHHS*, 138 N.C. App. 572, 580, 532 S.E.2d 192, 197 (2000) (relying upon *Ashbacker* in requiring an adjudicatory hearing in CON contested case involving two or more applicants).

Although North Carolina courts have not addressed this specific question, other jurisdictions have found that a comparative review was required for CON applications submitted sequentially, but timely, for a fixed need pool. See, e.g., *Methodist Regional Hospital System, Inc. v. Dept. of Health & Rehabilitative Services*, 497 So. 2d 272, 1986 Fla. App. LEXIS 9824 (Fla. 1st DCA 1986) (holding nursing home applicant was entitled to comparative hearing with batch of applications for nursing home beds filed six months earlier); *Appeal of Behavior Science Institute*, 121 N.H. 928, 935, 436 A.2d 1329, 1333 (1981) (holding mutually exclusive CON applications must be considered together to ensure fair treatment of each); *Bio-Medical Applications of Clearwater, Inc. v. Dept. of Health & Rehabilitative Services*, 370 So. 2d 19, 1979 Fla. App. LEXIS 14186 (Fla. 2d DCA 1979) (holding comparative review required where two applicants applied for new dialysis facilities in same planning area, and agency erred in hearing and approving one application prior to the hearing scheduled on the second).

In *Bio-Medical*, the Florida Court of Appeal recognized the inherent right to comparative review of mutually exclusive CON applications, based on its application of the *Ashbacker* guiding principle:

[A]n administrative agency is not to grant one application for a license without some appropriate consideration of another bona fide and timely filed application to render the same service; the principle, therefore, constitutes a fundamental doctrine of fair play which administrative agencies must diligently respect and courts must be ever alert to enforce.

Id. at 23, 1979 Fla. App. LEXIS 14186, **11-12. The Court went on to address why the *Ashbacker* principle requires that competitive applications be reviewed simultaneously:

Only in that way can each party be given a fair opportunity to persuade the agency that its proposal would serve the public interest better than that of its competitor. Such an opportunity is not afforded by merely allowing an applicant to intervene in the proceedings pertaining to a competing application since the merits of the intervenor's

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proposal are not thereby presented for comparative consideration. (internal citations omitted)

Id. (emphasis added). In another Florida case, the Court found error in the denial of a comparative review where the applications were submitted sequentially, but timely, and each applicant's proposal was based upon a fixed pool of nursing beds. *Court Nursing Center v. Department of Health and Rehabilitative Services*, 483 So. 2d 700, 705, 1985 Fla. App. LEXIS 15543, **14 (Fla. App. 1985).

Conclusion

TRC and BMA Applications meet all of the requirements for a competitive review under North Carolina CON law and under the basic principles of equity in administrative proceedings that have been applied in other states. Each of the two applications seek approval to establish a new dialysis facility in Franklin County to address the same 10-station deficit in Franklin County. The approval of one of the applications may result in the denial of the other application, because if both are approved that would create a surplus of stations in Franklin County, in violation of Policy ESRD-2. Therefore, the applications are mutually exclusive, and should be reviewed competitively.

We appreciate your consideration of this issue and we are ready to respond to any questions that the CON Section or its counsel may have.

With best regards, we are

Sincerely,



William R. Shenton



Pamela A. Scott



North Carolina Department of Health and Human Services
Division of Health Service Regulation

Pat McCrory
Governor

Aldona Z. Wos, M.D.
Ambassador (Ret.)
Secretary DHHS

Drexdal Pratt
Division Director

March 21, 2013

Jim Swann
3717 National Drive, Suite 206
Raleigh, NC 27612

Non-Competitive

Project I.D. Number:	K-10099-13
Facility:	FMC Tar River
Date of Receipt:	March 15, 2013
Date of Completeness:	March 20, 2013
Scheduled Review Period Begins:	April 1, 2013
Written Comment End Date	May 1, 2013
Review End Date:	June 29, 2013
Project Description:	Develop a new 10 station dialysis facility in Franklin County
County:	Franklin
FID #:	130122

Dear Mr. Swann:

On the "Date of Receipt" indicated above we received your certificate of need application for the project specified. This is to notify you that the application has been determined complete for review. It will be included in the next scheduled review which begins on the "Scheduled Review Period Begins" date noted above.

The review period is 90 days beginning with the "Scheduled Review Period Begins" date noted above. However, under specific conditions the review may be extended an additional 60 days for a total of 150 days.

Any person may file written comments and exhibits concerning a proposal under review with the Department no later than 30 days after the date on which the application review begins. To be considered by this office, your comments must be received by the CON Section no later than 5:30 pm on the "Written Comment End Date" noted above. The comments and exhibits will be available on the Agency's website on or about the **second business day** following the deadline for submission of comments (<http://www.ncdhhs.gov/dhsr/coneed/comments/index.html>).

If a public hearing is scheduled for this project, you will be notified in writing. By law the public hearing will be held no more than 20 days from the conclusion of the written comment period.

Please contact me if you have any questions regarding the review process. Please refer to the Project I.D. # and Facility I.D. # (FID) in all correspondence.

Sincerely,

Michael J. McKillip, Project Analyst
Certificate of Need Section

Certificate of Need Section

www.ncdhhs.gov

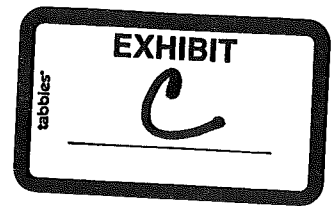
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Mailing Address: 2704 Mail Service Center • Raleigh, NC 27699-2704

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ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

DECISION DATE: February 5, 2007
PROJECT ANALYST: Martha J. Frisone
CHIEF: Lee B. Hoffman

PROJECT I.D. NUMBERS: **F-7707-06/** The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas Medical Center–Mint Hill, Mercy Hospital, Inc. and CS Center, LLC/ Relocate 50 existing acute care beds and one existing gastrointestinal endoscopy procedure room from Carolinas Medical Center–Mercy/Pineville and four existing dedicated outpatient operating rooms from Carolinas Surgery Center–Randolph to establish a new hospital in Mint Hill/ Mecklenburg County

F-7709-06/ The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas Medical Center–University/ Develop a healthplex (i.e., freestanding emergency room with outpatient imaging and diagnostic services) in Mint Hill which will be licensed as part of Carolinas Medical Center–University/ Mecklenburg County

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

G.S. 131E-183(a) The Department shall review all applications utilizing the criteria outlined in this subsection and shall determine that an application is either consistent with or not in conflict with these criteria before a certificate of need for the proposed project shall be issued.

- (1) The proposed project shall be consistent with applicable policies and need determinations in the State Medical Facilities Plan, the need determination of which constitutes a determinative limitation on the provision of any health service, health service facility, health service facility beds, dialysis stations, operating rooms, or home health offices that may be approved.

NC – Project I.D. #F-7707-06

NA – Project I.D. #F-7709-06

On September 15, 2006, The Charlotte-Mecklenburg Hospital Authority, which does business as Carolinas HealthCare System (CHS) submitted the following applications:

Project I.D. #F-7707-06 – In Section I.1, pages 1-2, the applicants are identified as The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas Medical Center–Mint Hill, Mercy Hospital, Inc. and CS Center, LLC.¹ The applicants propose to relocate 50 existing acute care beds and one existing gastrointestinal endoscopy procedure room (GI endoscopy room) from Carolinas Medical Center–Mercy/Pineville (CMC-Mercy/Pineville) and four existing dedicated outpatient operating rooms (ORs) from Carolinas Surgery Center–Randolph (CSC-Randolph) in Charlotte to establish a new hospital at 10545 Blair Road in Mint Hill. The new hospital will also include a 24 hour emergency room (ER), a laboratory (lab), a pharmacy, and offer the following diagnostic imaging services: x-ray, CT scanner, ultrasound (US) and nuclear medicine. These applicants and application will hereinafter be referred to as **CMC-Mint Hill Hospital**.²

Project I.D. #F-7709-06 – In Section I.1, page 1, the applicant is identified as The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas Medical Center – University (CMC-University). The applicant proposes to develop a freestanding ER with outpatient imaging and diagnostic services at 10545 Blair Road in Mint Hill, which will be licensed as part of CMC-University. The applicant calls the proposed facility a “healthplex,” which will also include a lab and offer the following diagnostic imaging services: x-ray, CT scanner and US. This applicant and application will hereinafter be referred to as **CMC-Mint Hill Healthplex**.³

Neither proposal results in an increase in the total number of licensed beds, ORs or GI endoscopy rooms located in Mecklenburg County. Further, the applicants do not propose in either application to acquire any medical equipment or develop any health service facility beds or services for which there is a need determination in the 2006 State Medical Facilities Plan (2006

¹ Mercy Hospital, Inc. and CS Center, LLC are wholly owned subsidiaries of The Charlotte-Mecklenburg Hospital Authority. Mercy Hospital, Inc. operates Carolinas Medical Center–Mercy/Pineville and CS Center, LLC operates Carolinas Surgery Center–Randolph in Charlotte.

² See Criterion (3) for a more detailed description of the proposal.

³ See Criterion (3) for a more detailed description of the proposal.

procedures that are over the defined capacity of the three fixed units.”

According to the above statements, the following table illustrates projected utilization for only the three units of fixed x-ray equipment at CMC-Mint Hill Hospital during the first three operating years, as reported by the applicants in Section IV.1, page 249.

	# OF X-RAY PROCEDURES
Year One (9/1/09 – 8/31/10)	13,011
Year Two (9/1/10 – 8/31/11)	18,216
Year Three (9/1/11 – 8/31/12)	23,570

Source: Section IV.1, page 249.

As shown in the above table, using “Methodology 2” described above, the applicants project that the fixed x-ray equipment at CMC-Mint Hill Hospital will perform a total of 23,570 procedures during Year Three. However, this projection exceeds the applicants’ stated capacity of 22,464 procedures for the fixed equipment by about 5% [$23,570 / 22,464 = 1.049$], and therefore is not reasonable.

Duplication of Previously Approved Hospital

Section III.7 of the application requests that the applicant “*Explain and provide specific documentation of the inadequacy or inability of existing providers to meet the identified need.*” In response, on pages 227-228, the applicants state

“[T]here are no providers of the proposed services in the four zip code service area; thus, no providers can meet the identified need within the service area. Moreover, there are no hospitals in the service area, and, as demonstrated in Section III.1, CHS believes there is a need for a hospital in Mint Hill. No existing providers can meet the need for the proposed services at a location in the four zip code service area. In fact, the proposed project is designed specifically to address and meet the need represented by the lack of providers in the service area.”

Although there is no existing hospital in the proposed service area, in a previous review, the Certificate of Need Section approved the development of a new 50-bed hospital in the proposed service area, Presbyterian Hospital Mint Hill (see Project I.D. #F-7648-06). The new hospital will be located approximately three miles from the proposed CMC-Mint Hill Hospital. Presbyterian Hospital Mint

Hill will offer the same services proposed by CMC-Mint Hill Hospital, as illustrated in the following table.

SERVICES TO BE PROVIDED	PRESBYTERIAN HOSPITAL MINT HILL	CMC-MINT HILL HOSPITAL
# of General med/surg beds	38	38
# of ICU beds	4	4
# of LDRPs	8	8
Level I Nursery (unlicensed bassinets)	yes	yes
# of Unlicensed Observation Beds	10	10
# of Shared ORs	4	4
# of Dedicated C-section ORs	1	0
# of GI endoscopy Rooms	1	1
ER	yes	yes
Lab	yes	yes
Pharmacy	yes	yes
Cardiopulmonary	yes	yes
Respiratory Therapy	yes	yes
PT/ST/OT	yes	yes
CT scanner	yes	yes
Nuclear Medicine	yes	yes
US	yes	yes
X-ray	yes	yes
Mammography	yes	no

Further, the population proposed to be served by Presbyterian Hospital Mint Hill and CMC-Mint Hill Hospital is similar, as illustrated in the following table.

CMC-MINT HILL HOSPITAL		PRESBYTERIAN HOSPITAL MINT HILL	
Primary Service Area (80%)		Primary Service Area (90%)	
Zip Code	County	Zip Code	County
28215	Mecklenburg	28215	Mecklenburg
28227	Mecklenburg	28227	Mecklenburg
28107	Cabarrus	28107	Cabarrus
28075	Cabarrus	28075	Cabarrus
		28213	Mecklenburg
Secondary Service Area (20%)		Secondary Service Area (10%) ⁽¹⁾	
Zip Code	County	Zip Code	County
28213	Mecklenburg		
28212	Mecklenburg		
28105	Mecklenburg		
28211	Mecklenburg		
28205	Mecklenburg		
28079	Union		
28270	Mecklenburg		
28104	Mecklenburg and Union		
28262	Mecklenburg		
28097	Stanly		
28163	Stanly		

⁽¹⁾ Presbyterian Hospital Mint Hill defines its secondary service area as "volume from outside the proposed zip code service area, surrounding zip codes in surrounding counties."

CHS does not adequately demonstrate that the population it proposes to serve needs a second hospital that would provide the same services that will be provided by the previously approved Presbyterian Hospital Mint Hill. Therefore, the applicants did not adequately demonstrate the need for their proposal and the application is nonconforming with this criterion.

CMC-Mint Hill Healthplex, a wholly owned subsidiary of CHS, proposes to develop a freestanding ER with outpatient imaging and diagnostic services at 10545 Blair Road in Mint Hill, which will be licensed as part of CMC-University. The applicant calls the proposed facility a "healthplex." Based on the representations in Section II.1, pages 41-49, Section IV.2(c), pages 140-143, the design schematic provided in Exhibit 29, and the list of equipment to be acquired provided in Exhibit 32, the applicant proposes to offer the following services at the healthplex:

- a new 24 hour freestanding ER with 10 exam rooms
- 3 unlicensed observation beds
- lab
- pharmacy (through a Pyxis MedStation unit) ⁸
- 2 new x-ray machines
- 1 new portable x-ray machine
- 1 new mini C-arm
- 1 new portable fluoroscopy unit
- 1 new CT scanner
- 1 new portable US unit

POPULATION TO BE SERVED

In Section III.5(a), pages 131-132, the applicants state

"[T]he proposed primary service area includes four zip codes in the Mint Hill area, including 28215 and 28227 (Mecklenburg County) and 28075 and 28107 (Cabarrus County). The secondary service area, also described in Section III.1(b), is assumed to be the zip codes in the counties contiguous to the proposed primary service area, for which

⁸ According to information obtained from the WEB, the Pyxis MedStation functions "like an ATM with PIN-controlled access, the system delivers precise amounts of prescribed drugs for administration by caregivers to patients."