

K-10126-13
May 1, 2013 Review

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Via Hand Delivery

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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

cc: June S. Ferrell, Esq. (via email and U.S. Mail)