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August 12, 2016

Via Email to DHSR.SMFP.Petitions-Comments@dhhs.nc.gov and Paige.Bennett@dhhs.nc.gov

North Carolina Division of Health Service Regulations
Attention: Paige Bennett, Assistant Chief
Healthcare Planning and Certificate of Need Section
Edgerton Building
809 Ruggles Drive
Raleigh, NC 27603

Re: Comments regarding Petition to the State Health Coordinating Council by Triangle Lithotripsy Corporation

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Dear Ms. Bennett:

Attached are Comments submitted on behalf of our firm's clients Carolina Lithotripsy, a Limited Partnership, Fayetteville Lithotripters Limited Partnership – South Carolina II, and Fayetteville Lithotripters Limited Partnership – Virginia I concerning the above-referenced Petition.

If there are any questions, please let me know.

Sincerely yours,

Anthony H. Brett

AHB/sln

Enclosures

cc: Debbie Scott

COMMENTS REGARDING
Petition to the State Health Coordinating Council by
Triangle Lithotripsy Corporation

Commenters: Carolina Lithotripsy, a Limited Partnership ("Carolina Lithotripsy")
Fayetteville Lithotripters Limited Partnership – South Carolina II ("South Carolina II")
Fayetteville Lithotripters Limited Partnership – Virginia I ("Virginia I")

Through their general partners, ESL, Inc. and Lithotripters, Inc.

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On behalf of the three above-named Commenters, ESL, Inc. as general partner of Carolina Lithotripsy and Lithotripers, Inc. as general partner of South Carolina II and Virginia I, provide the following comments concerning the above-referenced Petition. In short, Commenters oppose the Petition submitted by Triangle Lithotripsy Corporation ("Triangle") because the Petition is based upon two arguments, both of which are false: (1) the SMFP methodology does not underestimate need and (2) the statewide distribution of lithotripsy services is not uneven.

Triangle's Petition proposes that there be a need determination for one addition mobile lithotripter in the 2017 State Medical Facilities Plan ("SMFP") on a statewide basis that "may only serve North Carolina sites." (Petition, page 1). The arguments which Triangle advances for this proposal are ones that have been addressed in comments to the petition filed by Hampton Roads Lithotripsy, LLC ("Hampton Roads") in the spring of 2016 and in comments concerning the CON Application filed by Eastern Carolina Lithotripsy, Inc. ("Eastern Carolina") in the summer of 2016.

1. The SMFP Methodology Does Not Underestimate Need.

Triangle's Petition begins as follows: ". . . TLC [Triangle] discovered that the Proposed 2017 State Medical Facilities Plan (SMFP) overlooks critical factors that limit access to North Carolina's inventory of lithotripter units. Several North Carolina mobile lithotripsy units serve sites out-of-state." (Petition, page 2) Commenters find this "discovery" at this late date to be surprising given that this has been the case since lithotripsy first became subject to CON review in 1993.

In light of this new discovery, Triangle noted that the lithotripsy need methodology (contained in Exhibit A) "does not include an adjustment for lithotripter units that owners put in service outside North Carolina." (Petition, page 2) In order to address this alleged deficiency in

the methodology, Triangle adjusts the methodology in its proposal to remove procedures performed at host sites outside of North Carolina with the result that Triangle suggests that "[t]he resulting need for additional lithotripters [in 2017] is 1.67" in addition to the 14 currently existing lithotripters and the one additional lithotripter to be awarded pursuant to the 2016 SMFP. (Petition, page 4)

Commenters agree with Triangle that the methodology is no longer sound. In fact, it is apparent that the methodology overestimates need. As Table 3 (Petition, page 4) of Triangle's Petition shows, the methodology estimates that 14,777 procedures would be expected to be performed in North Carolina in 2017. However, Triangle notes in its Table 1 that in 2015 only 8,823 procedures were performed at North Carolina sites. (Petition, page 3) Triangle argues that procedures being performed by current lithotripsy operators outside of North Carolina overstates the capacity of 15 North Carolina lithotripters to meet North Carolina's 2017 needs. However, Triangle does not explain why the methodology projects a need in North Carolina of almost 6,000 more procedures in 2017 (67% more procedures) than were actually performed in 2015. Triangle's Petition notes in its Table 1 on page 3 that only 1,196 procedures were performed by current lithotripsy operators outside of North Carolina in 2015, so out-of-state procedures performed do not account for so many fewer procedures being performed in North Carolina than the methodology predicts to be needed in North Carolina.

Triangle incorrectly states that 1,000 procedures per year is the practical capacity of a lithotripter. (Petition, page 3) However, as noted in Exhibit A, "[t]he annual treatment capacity of a lithotripter has been estimated to be 1,000 to 1,500 cases." The methodology in Step 3 uses 1,000, "which is the low range of the annual treatment capacity of a lithotripter" for purposes of the determination of need as shown in Exhibit A.

Only 7 of the 14 current lithotripters in operation in North Carolina operate at this minimum capacity[1] as shown in Exhibit A. Exhibit A shows that the four lithotripters operated by Commenters, two lithotripters operated by Catawba Valley Medical Center ("Catawba Valley") and the (fixed-based) lithotripter operated by Mission Hospital, Inc. function at volume levels that are substantially below that minimum capacity. Assuming that the providers using the seven lithotripters which operate substantially below 1,000 procedures per year are rational and would increase their volume of procedures if they could to meet any unmet needs and to benefit financially by doing so, then it is apparent that the error in the methodology is not the one suggested by Triangle. Instead, something else is seriously wrong with the methodology that substantially overestimates the need for lithotripters in North Carolina.

As these Commenters stated in their comments filed in response to the Hampton Roads' Petition, the flaw in the methodology is its assumption in Step 2 that 90% of patients with urinary stone disease "have the potential to be treated by lithotripsy in one year." (Exhibit A) The technology used to treat kidney stones has changed over time since the time that the methodology was adopted. It is no longer the case that 90% of urinary stones are treated by lithotripsy as the treatment of choice. Over time, the use of ureteroscopic procedures have displaced the use of lithotripsy for many patients as the preferred treatment for ureteral stones,

[1] The four machines operated by Piedmont Stone Center, PLLC, two machines operated by Stone Institute of the Carolinas, LLC and one machine operated by Triangle.

and this trend of the increasing ureteroscopic procedures (with a corresponding decline in the use of lithotripsy) may continue as is reflected in the five articles that are attached in Exhibit B.

Triangle recognized that the methodology was flawed in its comments (attached as Exhibit C) in response to the Hampton Roads' Petition. On page 3 of Triangle's comments, Triangle stated that the proposal contained in the Hampton Roads' Petition would result in a duplication of services. For this reason, Triangle then suggested that a work group be convened to study the methodology and to report to the Technology and Equipment Committee in the spring of 2017 concerning whether the methodology should be changed. (Triangle's Comments, page 3) In the meantime, Triangle proposed the following: "The Hampton Roads Lithotripsy petition should be tabled until the conclusion of the 2016 Lithotripsy CON review cycle . . . . This allows the work group to account for the 2016 application decision and yield the best recommendations." This conclusion by Triangle took into account its earlier statements on page 3 of its Hampton Roads' comments that the 2016 SMFP would provide for one additional lithotripter, applications are due midyear [2016] and the review may not finish before the end of the year. "Consideration of the policy now, before filing the batch applications, would put the state in an untenable position. Certificate of Need staff would be constrained in their comments because of a review in progress." (Triangle's Comments, page 3) What has changed in so little time?

One thing that has not changed is low utilization of these Commenters' four lithotripters. Attached Exhibit D reflects Commenters' volumes for the first half of calendar year 2016. On an annualized basis, these volumes suggest that Carolina Lithotripsy would perform 630 procedures per machine, South Carolina II would perform 570 procedures per machine, and Virginia I would perform 292 procedures per machine for this entire calendar year. Commenters would love to have the opportunity to increase their volume by providing service at additional host sites and serve additional patients at existing sites in North Carolina or elsewhere. However, despite the argument by Triangle that there are insufficient lithotripters to serve North Carolina, the additional patients needing lithotripsy service in North Carolina do not exist.

While Commenters cannot speak for another party, the volume statistics for Catawba Valley listed in Exhibit A suggest that it would probably agree. Between Commenters and Catawba Valley, there are six mobile lithotripters that can provide service at host sites throughout North Carolina that have the clear capacity to do so. In addition, there will be one more mobile lithotripter added to that capacity following the award of a CON pursuant to the 2016 SMFP. These facts clearly show that the first argument made in Triangle's Petition is a false one.

2. The Statewide Distribution Of Lithotripsy Is Not Uneven.

Triangle's Second Argument is also one considered with respect to the Hampton Roads Petition earlier this year. Hampton Roads argued that eastern North Carolina rural areas were underserved by lithotripters, whereas Triangle now has expanded that argument to rural areas throughout North Carolina. ". . . 45 counties have no lithotripsy services within the county. Although it is not possible for every small county to support a lithotripter, it is not reasonable that almost half of North Carolina counties have no service." (Triangle's Petition, page 5) In essence, Triangle assumes that there is an access problem for persons located in rural areas to obtain lithotripsy services.

However, in its comments concerning the Hampton Roads Petition Triangle criticized Hampton Roads because its "petition makes a blanket assumption that no provider could serve rural areas . . . ." (Exhibit C, Triangle Comments, page 2) Triangle further noted on the same page of its comments concerning the Hampton Roads' Petition that several North Carolina counties do not have a hospital (and gave examples) noting that the Hampton Roads' Petition acknowledged on its page 9 that such counties would not be appropriate for mobile lithotripsy.

However, Triangle is now arguing the reverse of its previous position. In addition to counties that lack hospitals, Triangle does not recognize that there are many more counties that do not have a urologist. Absent a host site for a lithotripter and at least one urologist to provide the procedure, how could service be provided in those counties? As Exhibit A shows, the current providers of lithotripsy services operate at 80 sites inside North Carolina (Triangle Petition, page 2, subtracting from the total number of host sites those located outside of North Carolina). That is a large number of host sites in a state that has 100 counties. Even if lithotripsy services are not offered in a particular county, they are available within a reasonable driving distance.[2]

The Technology and Equipment Committee Agency Report (Exhibit E) prepared in response to the Hampton Roads' Petition addressed this very question. Its grounds for the Agency recommendation for denial of the Hampton Roads' Petition stated the following grounds:

> On a statewide basis, there does not appear to be a substantial disproportion in procedures performed in rural versus urban areas. The small imbalance indicates that more procedures are performed in rural areas than suggested by their proportion of the state population. Therefore, an access issue suggested by petitioner does not appear to exist. Moreover, the 2016 SMFP reports a statewide need determination for one lithotripter, bringing the projected inventory to 15 machines. With the addition of the new machine, and given that the service area for lithotripters is statewide, the proposed policy may lead to duplication of resources.

Agency Report, page 4.

While Triangle <u>now</u> makes the unsupported assertion of a rural access problem (which Triangle criticized when Hampton Roads made the same unsupported assertion), it has not offered support for this assertion from a single urologist. In contrast, Commenters has provided letters from urologists addressing the fact that there is no access issue in rural eastern North Carolina[3] (attached as Exhibit F) showing that this argument advanced by Triangle now, but not a few months ago, is a false one.

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[2] Triangle argues in its petition on pages 6-7 that lithotripsy is a superior treatment to the alternatives discussed in Exhibit B without providing any support for that assertion. If Triangle's argument were true, then Triangle should have been able to provide some literature in support of it.

[3] The letters from urologists addressed eastern North Carolina access only because that was the geographic area targeted by Hampton Roads' Petition to which they were prepared in response. However, given the lithotripsy volume levels of South Carolina II and Catawba Valley previously discussed, there is every reason to believe that urologists in rural western North Carolina would agree with their opinions.