RESPONSE IN OPPOSITION TO PETITION FILED BY TRIANGLE LITHOTRIPSY CORPORATION, LLC

Prepared by:

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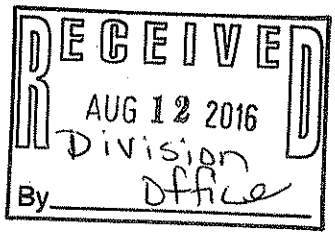

BACKGROUND

Piedmont Stone Center, PLLC ("Piedmont Stone Center") has provided lithotripsy services in North Carolina since 1985. Piedmont Stone Center offered the first outpatient-based lithotripter in the State and in 1989 became the first mobile lithotripsy vendor in North Carolina. Piedmont Stone Center currently operates four mobile lithotripters that provide services to patients in 25 different host sites throughout Western and Central North Carolina and Virginia. Piedmont Stone Center is now the largest lithotripsy provider in North Carolina, providing over 4,000 procedures each year on its existing lithotripters.

Pursuant to N.C. Gen. Stat. § 131E-183(a)(1), the need determinations in the State Medical Facilities Plan ("SMFP") provide a determinative limit on the provision of any covered health service. If there is no need identified for a covered service, then any application filed with the Certificate of Need Section ("CON Section") for that service must be denied. Lithotripsy is a covered health service.

The *Proposed 2017 SMFP* does not include a need determination for an additional lithotripter in the State. However, the *2016 SMFP* did include a need determination for one additional lithotripter in the statewide service area. This would be the fifteenth lithotripter in the State. Applications for the additional lithotripter were filed on June 15, 2016, by Piedmont Stone Center and Eastern Carolina Lithotripsy, Inc. ("ECL") (an associate of petitioner Triangle Lithotripsy Corporation, LLC ("Triangle")).[1] Those applications are currently under review with the CON Section. There are currently 14 total mobile and fixed lithotripters being operated across North Carolina by eight different providers. Collectively, those 14 operational units performed 10,019 procedures in 2014-2015. *See* Chapter 9 of the *Proposed 2017 SMFP*, attached hereto as Exhibit B. Based upon the methodology set forth in the *Proposed 2017 SMFP*, there is no need for any additional lithotripters in 2017.

[1] Triangle is repeatedly identified as an associate of ECL throughout the ECL application. Examples reflecting the close relationship of Triangle and ECL are contained in Exhibit A, attached hereto.

Nonetheless, despite the fact that there are applications for a new lithotripter currently under review in response to the 2016 need determination, on July 28, 2016, Triangle filed a petition to amend the *Proposed 2017 SMFP* (the "Petition"), seeking to add yet another need determination for a new statewide lithotripter. According to the Petition, the lithotripter could only be used to serve North Carolina host sites. It would be highly unusual (and possibly unprecedented) for the SHCC to determine a need for additional lithotripters two years in a row. If approved, Triangle's proposal would mean that the total statewide inventory for mobile and fixed lithotripters would increase to sixteen. As explained in greater detail below, Triangle's Petition is without merit and should be denied.

REASONS WHY THE PETITION SHOULD BE DISAPPROVED

A. Triangle's Petition is an untimely attack on the need methodology in the SMFP.

Triangle's Petition is nothing more than an attempt to challenge the need methodology for lithotripsy equipment that is established in the SMFP. This attack is both untimely and unsupported.

The SMFP provides that proposed changes to a need methodology that may have a statewide effect are to be submitted by petition no later than March 2, 2016. *See 2016 SMFP* Ch. 2, page 7 (an excerpt of which is attached hereto as Exhibit C). Triangle's Petition, which was not submitted until July 28, 2016, challenges the current need methodology and proposes to change that methodology with an additional adjustment of procedures completed out of state. *See* Petition, page 4. The planning area for lithotripsy is statewide, so Triangle's petition unquestionably has a statewide effect. *See 2016 SMFP*, page 122. Further, as stated on page 7 of the *2016 SMFP*: "[c]hanges with the potential for a statewide effect are the addition, deletion, and revision of policies or projection methodologies." The change proposed by Triangle does not challenge the accuracy of the data utilized nor does it allege any error in the application of the need methodology in the *Proposed 2017 SMFP*; rather, it would have the SHCC add a completely new step to the methodology, adjusting an already-adjusted utilization calculation by another factor which it deems to be the "inventory not available to North Carolinians." *See* Petition, page 4. This additional proposed step in the need methodology leads to a double adjustment and would result in unnecessary duplication of the 15 accounted for operational and pending lithotripters in use around the State, as explained in greater detail below.

Aside from its substantive lack of merit, Triangle's Petition simply does not meet the requirements for special need petitions filed in the summer petitioning cycle. Page 9 of the *2016 SMFP* provides:

> People who believe that unique or special attributes of a particular geographic area or institution give rise to resource requirements that differ from those provided by application of the standard planning procedures and policies may submit a written petition requesting an adjustment be made to the need

> determination given in the North Carolina Proposed State Medical Facilities Plan.

2016 SMFP, page 9.

The "particular geographic area" referred to above is a more localized geography, such as a county, not the entire State of North Carolina, which is the lithotripsy planning area. Moreover, Triangle is not proposing to apply the standard planning procedures and policies; rather, it is proposing to *change* the standard planning procedures and policies by "adjusting" for service performed in other states. *See* Petition, page 4. Triangle expressly acknowledges this on page 2 of its Petition: "[t]he proposed lithotripsy need methodology in Chapter 9 of the *2017 State Medical Facilities Plan* does not include an adjustment to account for lithotripter units that owners put in service outside North Carolina sites." As can be seen from Chapter 9 of the *2016 SMFP* and also in Chapter 9 of the *Proposed 2017 SMFP*, *all* of the sites served and *all* of the procedures performed by a mobile lithotripter are accounted for in calculating the need methodology. This is logical and appropriate because it provides a true picture of the machine's utilization. Triangle proposes to "adjust" this to make the number of lithotripters serving North Carolina appear smaller than it actually is. Specifically, Triangle's proposed adjustment would impact Step 4 of the need methodology, which says:

> Sum the number of existing lithotripters in the State, lithotripters not yet operational but for which a certificate of need has been awarded, and lithotripter need determinations from previous years for which a certificate of need has yet to be awarded.

See 2016 SMFP, page 123.

According to Triangle, the "real" number of existing lithotripters in North Carolina is 12.33, not 14, which is what the SMFP says. *See* Petition, page 4. The SMFP does not make "adjustments" in the number of existing lithotripters and exclude lithotripters that serve other states. Triangle's Petition acknowledges this basic fact. *See* Petition, page 2. Changing the number of existing lithotripters used in the calculation of need is a fundamental change in a statewide need methodology. If Triangle had wanted to propose this change to take effect in the *2017 SMFP*, it missed the deadline to do so by more than five months.

Triangle's proposal to amend the statewide need methodology is untimely and should have been submitted for consideration along with all other proposals to change need methodologies, no later than March 2, 2016. Triangle's tardy submission should be denied.

Moreover, Triangle's Petition is inconsistent with the position it took less than six months ago concerning another petition. In early 2016, Hampton Roads Lithotripsy, LLC, a Virginia-based mobile lithotripsy provider, submitted a petition to the SHCC proposing a new Policy TE-3 that would have granted special privileges to certain out-of-state mobile lithotripsy providers (the "Hampton Roads Petition"). The Hampton Roads Petition, much like the current Petition by Triangle, would have resulted in yet another new lithotripter being added to

the statewide inventory. Triangle, among others, filed a response *opposing* the Hampton Roads Petition. Triangle argued that the addition of yet another lithotripter to the statewide inventory in a year where applications for a new unit are pending, would amount to a duplication of resources. *See* Triangle Response, attached hereto as Exhibit D.

In its Response to the Hampton Roads Petition, Triangle stated that timing of the Hampton Roads Petition was inappropriate:

> As the petitioner notes, the *2016 SMFP* shows a statewide need for one additional lithotripter. Applications are due mid-year 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 Response, page 3. The review Triangle mentioned in its Response is currently in progress. Triangle's associate, ECL, is one of the applicants. The same concern Triangle expressed in March applies today. Triangle advocated in March that the Hampton Roads Petition "should be tabled until the conclusion of the 2016 Lithotripsy CON review cycle." Triangle Response, page 3. Triangle does not explain what has happened since March that makes its petition different from the Hampton Roads Petition.

Though Triangle now wishes to switch sides, the same argument Triangle made in March holds true for Triangle's Petition. There are currently two CON Applications under review in response to the need determination for one additional statewide lithotripter in the *2016 SMFP*. The end result of that competitive process will not be known for several months and even if a new machine becomes operational in 2017, its impact upon utilization and need will not be known for some time. To create a need for an additional lithotripter at this time will result in the unnecessary duplication of existing resources in direct contravention of the CON Law.

Furthermore, as noted above, ECL, an affiliate of Triangle, is one of two applicants for the CON in response to the 2016 lithotripsy need determination, where two of its four proposed host sites are in the Eastern part of the State. *See* Excerpts from ECL application, attached hereto as Exhibit E. Triangle's simultaneous proposal to again increase the inventory of lithotripters in the State during a review of its affiliated CON Application is merely an attempt by Triangle to hedge its bets on the outcome of the current review. If Triangle believes the Eastern part of the State needs more lithotripsy services, then the ECL application responds to that perceived need and the State will have the opportunity to review and make a determination on that proposal in the ongoing review cycle.

The need methodology in the SMFP, which was not timely challenged, takes into consideration the proposed new lithotripter (to be the 15th in the State) and that methodology controls this review cycle. There is no need for an additional lithotripter at this time and the Triangle Petition fails to prove otherwise.

B. Triangle's arguments about access are unpersuasive.

Triangle's Petition claims that there is uneven and limited access to lithotripsy services across the State. However, its arguments are misleading and unsupported.

First, there is no support for Triangle's assertion that the existing (and pending) lithotripsy inventory is "not available" to North Carolinians. Both fixed and mobile lithotripters serve patients across the State and Triangle provides no data or support from urologists or patients to suggest that existing lithotripsy services are "unavailable" to any patients in the State. Triangle's lack of evidence and support from urologists or patients speaks volumes in this regard. Notably, urologists from Eastern North Carolina spoke very forcefully against ECL's CON application, pointing out that there was no need for additional lithotripsy service in Eastern North Carolina. *See* Exhibit F attached hereto, Comments in Opposition filed by Carolina Lithotripsy. At CarolinaEast Medical Center in New Bern, for example, one of the urologists practicing there, Dr. Thomas Stewart, stated that utilization of the existing lithotripsy provider is only 41%. *See* Exhibit F, page 7 of Exhibit B to the Comments. Another urologist at CarolinaEast, Dr. Reed Underhill, stated: "I would like to say it [is] false that Litho services are so busy that we in Eastern NC need another machine. The number of procedures has actually gone down significantly over the last number of years so there is no need for another machine." *See* Exhibit F, page 8 of Exhibit B to the Comments.

Triangle also alleges that statewide distribution of lithotripsy services is "uneven" and that almost half of North Carolina counties "have no service." *See* Petition, page 5. This statement is misleading and intentionally misconstrues the true picture of available services for North Carolinians. Though it admits that it is not feasible for every single county in the State to support a lithotripter, that there is no official patient origin data for lithotripsy procedures and that many North Carolinians cross county borders for medical services, Triangle alleges that there is uneven access to services. *See* Petition, page 5. However, Triangle looked only at county utilization of lithotripsy services without regard to patient origin for those services. *See* Petition, page 5. In other words, Triangle provides no evidence or data to show that patients from those counties where a lithotripter is not physically located are not actually receiving needed lithotripsy services somewhere else. Triangle provides no data, no letters from physicians and no communications from patients to support its supposition that there is a dearth of services in those areas such that patients are entirely going without treatment, having difficulty receiving timely treatment at locations other than in the county in which they reside and/or being forced to seek treatment through other more invasive procedures.

It is also important to recognize that without urologists to order and perform lithotripsy procedures, lithotripsy services are not sustainable. Again, Triangle does not provide a single letter from a patient or urologist from any area in the State to support its assumptions regarding the access and availability of lithotripsy services. Instead, Triangle provides a letter from the Honorable Gary H. Pendleton, a member of the North Carolina legislature and Chairman of the Health Committee, and a copy of the remarks of Nancy Lane, the healthcare consultant hired by Triangle to prepare its Petition (as well as the ECL CON application). *See* Petition,

Attachment A. Mr. Pendleton is not a physician and provides no insight to support the suppositions in the Petition. His remarks state that there is a general lack of medical care in Eastern North Carolina and states that northeastern North Carolina "as TLC's petition shows, has a deficit of access to lithotripsy." Triangle's petition does not show this. In addition, and as Exhibit F shows, urologists who actually practice in Eastern North Carolina do not share Mr. Pendleton's view as far as lithotripsy is concerned. Vidant Medical Center in Greenville has a broad service area covering much of eastern and northeastern North Carolina. The Chief of Urology at Vidant Medical Center in Greenville, Dr. Gregory Murphy, stated in opposition to the ECL application: "Simply put there is NO unmet need in eastern NC as is erroneously contended in the application. We have created a 'spoke and wheel' concept for health care in our 29 county catch basin and provide the full range of appropriate services for kidney stones for our patients." *See* Exhibit F, page 2 of Exhibit C to the Comments.

Triangle's Petition focuses on its observation that 1,196 of the 10,019 procedures performed on the existing 14 lithotripters (not taking into account the pending applications for an additional mobile lithotripter) were performed outside the State of North Carolina. *See* Petition, page 2. Just because the existing lithotripters are available to serve patients in other States does not mean that they are unavailable to serve North Carolinians in need of their services. The best illustration of this fact is that most of the existing lithotripters in the State are operating well below capacity and could easily provide additional procedures to patients. The SMFP estimates the annual capacity of a lithotripter to be between 1,000 to 1,500 procedures. *See* Exhibit B, *Proposed 2017 SMFP*. That estimate of capacity is not a determinative limit of the capabilities of any given machine—it is rather the low floor of useful capacity.

Based upon the 2014-2015 data reported in the *Proposed 2017 SMFP*, which data Triangle does not challenge, there is more than sufficient excess capacity in underperforming, existing lithotripters to account for the number of out-of-state procedures performed.

Provider	**Number of Lithotripters**	**Total 2015 Procedures Data**	**Excess Capacity* (capacity – no. of procedures performed)**
Carolina Lithotripsy	2	1,306	694
Catawba Valley Medical Center	2	406	1594
Fayetteville Lithotripters Limited Partnership (Western NC)	1	558	442
Fayetteville Lithotripters Limited Partnership (Eastern NC)	1	264	736
Mission Hospital	1	259	741

* Capacity is defined as 1,000 procedures per lithotripter. *See Proposed 2017 SMFP.*

Only the existing lithotripters operated by Triangle (1), Stone Institute of the Carolinas (2) and Piedmont Stone Center (4) are operating at or near the minimum 1,000 procedure capacity per unit floor.[2]

With a number of existing lithotripters already underutilized, Triangle fails to demonstrate the need for yet another lithotripter to be added to the inventory, particularly before the unit available under the *2016 SMFP* goes online, and fails to demonstrate the unavailability or uneven access to the existing inventory.

C. Triangle's Petition proposes to restrain the utilization of the proposed lithotripter to only the State of North Carolina.

Triangle's Petition is essentially the converse of the proposal filed by Hampton Roads that it opposed earlier this year. Whereas the Hampton Roads Petition proposed a machine that could only be operated by a non-North Carolina entity, Triangle proposes to restrain the utilization of an approved new lithotripter to serve only North Carolina host sites. Just as the State of North Carolina does not grant special privileges to out of state providers, the State has not historically prohibited mobile providers from serving host sites outside the State of North Carolina. Given the available capacity for service that already exists, there is no need to restrict any lithotripter to serving only North Carolina host sites. More concerning, however, is that Triangle is proposing that the State regulate activities outside the State of North Carolina, which it cannot legally do. While Triangle may see its proposal as benefitting North Carolinians, it also potentially harms residents of other states, who also need lithotripsy services. Erecting barriers to care based on geography is not an appropriate use of the health planning process. Further, as a practical matter, there is no need for Triangle's proposed restriction as both of the pending CON applications for the 2016 need determination propose to serve only North Carolina host sites. *See* Exhibit E, excerpts from the ECL CON application and Exhibit G, excerpts from the Piedmont Stone Center CON application.

D. Triangle's Petition is inconsistent with the Basic Principles.

A petition to modify a need methodology or adjust a need determination must provide "evidence that the requested adjustment is consistent with the three Basic Principles governing the development of the North Carolina State Medical Facilities Plan: Safety and Quality, Access and Value." *See* 2016 SMFP, Ch. 2, page 9. Triangle insufficiently addresses this essential requirement.

With respect to safety and quality, the Petition posits in one sentence that it "responds to this principle's direction to respond to persistent and significant deficiencies." Petition, page 9. It is entirely unclear what "persistent and significant deficiencies" in quality and safety are being referenced, as neither is addressed by the Petition. Triangle's response is inadequate and merely repeats the question presented.

[2] The Stone Institute's lithotripters operate at slightly below the minimum 1,000 procedure per lithotripter floor.

With respect to access, Triangle states again that its petition "clearly promotes access to a service that would be feasible at the most conservative of value standards." Petition, page 9. This conclusory statement is more accurately characterized as a non-response. Again, the Petition does not support the promotion of access; rather, it supports a premature attempt at oversaturation and actually inhibits access by limiting the host sites that a provider may serve.

Finally, Triangle discusses generally the value of a non-invasive treatment such as lithotripsy. *See* Petition, page 10. That is not the metric of value referenced in the Basic Principles. The Petition includes no discussion of costs and provides no data of specific areas of the State to demonstrate an unmet need for lithotripsy services. It includes no letters of support from urologists or patients. Again, the Triangle Petition misses the mark.

CONCLUSION

Piedmont Stone Center fully supports the State's health planning process and the determination that there is no additional need for a statewide lithotripter as stated in the *Proposed 2017 SMFP*. Piedmont Stone Center respectfully requests that the petition filed by Triangle for an additional lithotripter be denied.