

**Petition to the State Health Coordinating Council
 Regarding Mobile Lithotripsy Equipment,
 Statewide Adjusted Need Determination
 2017 State Medical Facilities Plan**

July 28, 2016

Petitioner:		Contact:	
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STATEMENT OF REQUESTED ADJUSTMENT

Triangle Lithotripsy Corporation (TLC) requests the following change to the *2017 State Medical Facilities Plan (SMFP)* to address a special need for one additional mobile lithotripter statewide:

Table 9D: Lithotripter Need Determination
(Scheduled for Certificate of Need Review Commencing in 2017)

It is determined that the service areas listed in the table below need additional lithotripters as specified.

Lithotripters	Lithotripter Need Determination	Certificate of Need Application Due Date**	Certificate of Need Beginning Review Date
Statewide	1***	TBD	TBD

* Need determination shown in this document may be increased or decreased during the year pursuant to Policy GEN-2 (see Chapter 4).

** Application due dates are absolute deadlines. The filing deadline is 5:30 p.m. on the application due date. The filing deadline is absolute (see Chapter 3).

*** An application approved under this special need may only serve North Carolina sites.

REASONS FOR THE PROPOSED ADJUSTMENT

OVERVIEW

Triangle Lithotripsy Corporation, LLC (TLC) currently serves the Triangle and eastern North Carolina with a mobile lithotripter that serves hospitals and ambulatory surgery centers. In the course of evaluating the statewide need for lithotripsy services, TLC 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. One provider serves almost exclusively Virginia sites. The lithotripter at Mission Hospital in Asheville is fixed, and operates at about 26 percent capacity. The SMFP defines capacity of a lithotripter as 1,000 annual procedures.

The collective result is that North Carolina does not have full service of 14 lithotripters today. TLC conservatively estimates that, after adjusting for out-of-state service, adding the unit from the 2016 SMFP and treating the Mission unit the same as others, the deficit is actually 1.6 lithotripters.

The SMFP treats the whole state as a single geography. To improve access, TLC requests a special statewide need for one additional lithotripter to be included in the 2017 State Medical Facilities Plan to serve only North Carolina sites.

SMFP METHODOLOGY UNDERESTIMATES NEED

The 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. The methodology assumes that each lithotripter in the DHSR inventory serves North Carolina sites. The methodology did not anticipate that the state's lithotripters might not stay in the state. The methodology is simple. It multiplies a use rate by state population and divides the resulting estimated procedures by 1,000 to calculate lithotripters needed in the state. Then it subtracts the number of lithotripters in the state's inventory to get number needed in the plan.

The methodology does not involve patient origin and the state does not collect patient origin data. Without patient origin data from the current lithotripter units, the SMFP methodology cannot make assumptions regarding the number of North Carolinians served.

Today, North Carolina has 14 lithotripters. The 2016 SMFP need added one more bringing the inventory to 15. According to the Equipment Inventory Forms completed by lithotripter operators, in 2015, the 14 lithotripters served 97 sites and completed 10,019 procedures. However, 17 of the sites and 1,196 of the procedures completed were in Virginia or South Carolina locations.

Most of the lithotripter units pre-date CON law. The state has no authority to direct where they go.

**Table 1 - Comparison of North Carolina Lithotripter Performance:
In-State and Out-of-State Locations, 2015**

	# of Service Sites	Procedures
In-state	80	8,823
Out-of-state	17	1,196
Total	97	10,019
% Out-of-state	17.5%	11.9%

Source: 2016 Registration and Inventory of Medical Equipment

The SMFP methodology applies an adjusted estimated urinary stone incidence rate to calculate estimated lithotripsy procedures for the entire North Carolina population. To calculate supply, it assumes all lithotripters will serve need of only North Carolinians and that a single lithotripter has a practical capacity of 1,000 procedures per year. As a result, the proposed 2017 SMFP methodology shows no need for new lithotripters.

Table 2 - 2017 Proposed SMFP Lithotripsy Methodology and Need for Additional Lithotripters

Notes	Description	Value
a	July, 2017 NC Population	10,261,956
b	Urinary Stone Incidence per 10,000 Pop	16
c	Estimated Urinary Stone Cases	16,419
d	Estimated Urinary Stone Cases Adjusted by 90 %	14,777
e	Procedures per Lithotripter	1,000
f	Number of Lithotripters Needed	15
g	2015 Inventory	14
h	2016 CON	1
i	Need per 2017 Plan	0

Notes:

- a. North Carolina Office of State Management and Budget
- b. 2017 SMFP, Chapter 9
- c. $a / 10,000 * b$
- d. $c * .9$
- e. 2017 SMFP, Chapter 9
- f. $e / 1,000$ (rounded to nearest whole number)
- g. 2017 SMFP, Chapter 9
- h. 2017 SMFP, Chapter 9
- i. $f - g - h$

However, the true inventory available to North Carolinians is lower than the 14 reported in the 2017 SMFP. Table 3 below shows the 2017 statewide need for lithotripters after reducing the inventory to account for capacity that goes out of state. Out of state sites include South Carolina and Virginia. To be conservative, TLC adjusted the inventory on the lower percentage out of state from Table 1. In Table 3, the inventory not available to North Carolinians equals 11.9 percent of the total inventory. The resulting need for additional lithotripters is 1.67. Had TLC adjusted on sites served, the deficit would have been even larger. The inventory would reduce by 17.5 percent and the deficit would be 2.45.

Table 3 - 2017 Lithotripsy Need after Adjusting for Out-of-state Use

Notes	Description	Value
a	July, 2017 NC Population	10,261,956
b	Urinary Stone Incidence per 10,000 Pop	16
c	Estimated Urinary Stone Cases	16,419
d	Estimated Urinary Stone Cases Adjusted by 90 %	14,777
e	Procedures per Lithotripter	1,000
f	Number of Lithotripters Needed	15
g	2015 Inventory	14
h	Percent Lithotripsy Procedures Completed Out-of-state	11.9%
i	Adjusted 2015 Inventory	12.33
j	2016 CON	1
k	Additional Lithotripters Needed	1.67

Notes:

- a. North Carolina Office of State Management and Budget
- b. 2017 SMFP, Chapter 9
- c. $a / 10,000 * b$
- d. $c * .9$
- e. 2017 SMFP, Chapter 9
- f. $e / 1,000$ (rounded to nearest whole number)
- g. 2017 SMFP, Chapter 9
- h. Table 1
- i. $g * h$
- j. 2017 SMFP, Chapter 9
- k. $f - i - j$

An adjusted statewide special need for one additional lithotripter unit would provide capacity to make this treatment option more uniformly accessible in the state. It would recognize the SMFP definition of geographic area for this service and it would provide maximum flexibility for providers to respond.

STATEWIDE DISTRIBUTION OF LITHOTRIPSY SERVICES IS UNEVEN

North Carolina Registration and Inventory of Medical Equipment Forms (EIFs) show that not all counties in North Carolina receive lithotripsy services in equal proportion to population. In fact, 45 counties have no lithotripsy services within the county. Although it is not feasible for every small county to support a lithotripter, it is not reasonable that almost half of North Carolina counties have no service. Even within the 55 counties with services, use differs significantly. Having no official patient origin data, TLC looked at procedures at host sites, as if they served residents of the host site county. Under this assumption, 2015 use rates for the counties with service ranged from 0.36 procedures per 10,000 population to 27.62. Even with its limitations, the calculation shows uneven access. The 2017 SMFP methodology uses 14.4 per 10,000 as the use rate obtained after it adjusts the need to 90 percent.¹ Only a quarter of counties with lithotripsy service, 14 of the 55, showed lithotripsy procedures at rates above 14.4 per 10,000 population. All others were below 14.4.

Of course, many North Carolinians cross county borders for medical service. It is better to look at aggregated use rates. The 2015 statewide average use rate of procedures completed in North Carolina was 8.77 procedures per 10,000 population. Although urban area rates were slightly higher than rural rates, in aggregate both urban and rural counties had use rates well below the standard used in the Proposed SMFP.

Table 4 - Estimated 2015 Lithotripsy Use Rates – Statewide, Urban, and Rural

OMB Designation	Number of Counties	2015 Population	Litho Procedures Completed Within Counties (2016 EIFs)	Procedures per 10,000 Residents
<i>Notes</i>	<i>a</i>	<i>b</i>	<i>c</i>	<i>d</i>
Metro	46	7,828,437	7,313	9.34
Non-Metro	54	2,226,285	1,510	6.78
Total		10,054,722	8,823	8.77

Notes:

- a. U.S. Census Bureau, Population Division, based on Office of Management and Budget, July 2015 delineations (Urban counties are those in an MSA,*
- b. Rural are those not in a North Carolina Office of State Management and Budget Metropolitan Statistical Area (aggregated for each county group)*
- c. 2016 North Carolina Registration and Inventory of Medical Equipment Forms (aggregated for each county group)*
- d. $b / 10,000 / c$*

¹ The 2017 SMFP estimates the incidence rate for urinary stone disease to be 16 per 10,000 population. It further reduces the total estimated cases of urinary stone disease by 90 percent to represent the total cases appropriate for Lithotripsy. Using this method, the actual estimated lithotripsy use rates are 14.4 procedures per 10,000 population ($16 * 90\% = 14.4$).

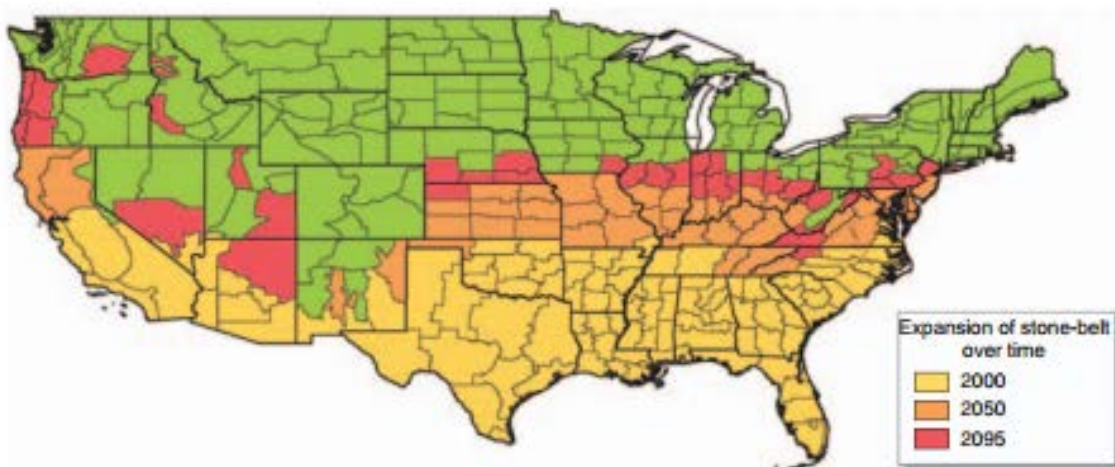
IMPACT OF LIMITED ACCESS

The impacts of limited access in most parts of the state are threefold: (1) when lithotripter service is not available, practice patterns for urologists shift from non-invasive lithotripsy to invasive ureteroscopy (2) patients may wait in pain longer than necessary, and (3) patient's choices are limited.

Practice Patterns and Epidemiology

As you may know, kidney stones occur frequently in North Carolina, reportedly at higher rates than elsewhere in the country. The state is part of the national kidney stone belt. Causes of kidney stones are complex and not fully understood, but stones are associated with things like gender, mineral composition of the water supply, the amount of oxalic acid consumed in foods like iced tea, spinach, peanuts and chocolate, a person's weight, and hydration practices. Places with hotter summer months have increased risk for kidney stones. This is one reason why southern United States has a much higher incidence of kidney stones and is known as the "kidney belt". Some recent studies indicate temperature is major risk factor for kidney stones, suggesting that the incidence rate of kidneys stones will rise as global temperatures rise.

Figure 1 - Kidney Stone Belt in the US and Impact of Climate Change



Growth of the US "kidney stone belt in response to projected climate change. Risk increases with time from red to orange to yellow." International Society of Nephrology²

Kidney stones are painful. Some correct themselves. Many require treatment. Kidney stones have multiple treatment options. Extra Corporeal Shockwave Lithotripsy (ESWL) is a procedure that uses shock waves to pulverize the stone. ESWL is not invasive, and with proper equipment and good technicians, the patient walks out after recovering from sedation. Ureteroscopy is an invasive procedure that uses a flexible scope inserted into the bladder to remove the stone. Laser scope based ureteroscopy is another, invasive alternative. Medical schools tend to train more for the invasive procedures, while physicians learn use of shock waves or Extracorporeal Shock Wave Lithotripsy (ESWL) once they are in practice, by completing special training.

² <http://ncpedia.org/kidney-stone-belt> Slide from National Academy of Sciences

For urologists practicing in areas without good access to lithotripsy, invasive procedures are the only option. If a patient is in pain and needs an intervention, and the lithotripter will not be available for a week or more, urologists will seek an alternative therapy.

Pain

Pain from kidney stones can be excruciating. Affected patients understandably have little tolerance to wait a week or more for the mobile unit to arrive, and transitioning patients from one urologist to another in pursuit of the mobile unit requires substantial care coordination. Patients with kidney stones usually make the ER their first point of call, unless they have had prior experience and know to seek a urologist. An ER visit may result in “watchful waiting” followed by another visit when the pain passes the toleration point.

Patient Choice

Without access to lithotripsy, patients and their physicians lose access to a valuable treatment alternative. While some patients may choose an invasive procedure, the majority of patients who require an intervention for kidney stones choose lithotripsy. Additional lithotripters will open up lithotripsy as an option, or provide more timely access to the service, for many North Carolinians.

STATEMENT OF ADVERSE EFFECTS ON PROVIDERS AND CONSUMERS IF THE ADJUSTMENT IS NOT MADE

Without an adjustment, the SMFP methodology will not generate need for another lithotripter for years. The one unit in the 2016 SMFP is not adequate to fill the deficit of lithotripters in North Carolina. The state will remain short on capacity, and access disparities will continue, and invasive procedures will increase. Many North Carolinians in undersupplied areas will have limited choices while others in adequately supplied areas will enjoy better access and more choice.

STATEMENT OF ALTERNATIVES CONSIDERED AND FOUND NOT FEASIBLE

OVERVIEW

TLC looked at several alternatives including changing the lithotripsy need methodology and focusing the need in one area of the state.

ALTERNATIVE 1: UPDATE THE SMFP LITHOTRIPSY METHODOLOGY

TLC considered proposing a change to the lithotripsy methodology. This would take a long time, would involve new data collection by the state, and cost hundreds of hours of staff and committee time. Today, the next opportunity to update the SMFP policies or methodology will occur in the 2017 Spring Comments Period. Comments would address for methodology changes that the State Health Coordinating Council might include in the 2018 SMFP or a later one. If the SHCC waits to implement a methodology change, the deficit in lithotripsy service would continue at least one year and possibly more. TLC supports an updated methodology eventually, but a special need determination in the 2017 SMFP would address a need that exists today and that occurs statewide. As such, the special need determination is the best option. If the methodology changes in the 2018 SMFP or later, the 2017 special need determination will be included in the overall inventory. As this petition shows, the state needs more than one extra lithotripter today. A special need determination will not create a surplus.

ALTERNATIVE 2: FOCUS THE NEED IN ONE SUB-REGION

There are more counties with no lithotripter services in the far eastern and western parts of the state. However, the need does not neatly concentrate in a single cluster of counties, or in rural versus urban counties. A special need for a statewide geography puts the burden on applicants to define service areas, and to be flexible in meeting the need. It also gives the state the option to benefit from whatever applicant pool is ready to make a response.

ALTERNATIVE 3: ELIMINATE THE NORTH CAROLINA RESTRICTION

Without a restriction to serve North Carolina sites only, applicants who respond to the need could provide only some of the time to North Carolina locations. The state needs more than one unit. Partial service would not be responsive to the special need.

EVIDENCE OF NON-DUPLICATION OF SERVICES

As noted earlier, the state has a deficit of lithotripter capacity and evidence of low access. One more lithotripter unit will not provide excess supply statewide. A statewide need, restricted to service in North Carolina will direct applicants to serve areas with unmet need.

EVIDENCE OF CONSISTENCY WITH NORTH CAROLINA STATE MEDICAL FACILITIES PLAN

BASIC GOVERNING PRINCIPLES

Safety and Quality

This basic principle notes:

“...priority should be given to safety, followed by clinical outcomes, followed by satisfaction.

“...As experience with the application of quality and safety metrics grows, the SHCC should regularly review policies and need methodologies and revise them as needed to address any persistent and significant deficiencies in safety and quality in a particular service area.”

This petition clearly responds to this principle’s direction to respond to persistent and significant deficiencies.

Access

This basic principle notes:

“...The first priority is to ameliorate economic barriers and the second priority is to mitigate time and distance barriers.

“...The SHCC planning process will promote access to an appropriate spectrum of health services at a local level, whenever feasible under prevailing quality and value standards.”

This petition clearly promotes access to a service that would be feasible at the most conservative of value standards. The petition requests fewer additional lithotripter units than it demonstrates are needed on a procedure basis. A site basis would forecast even more need.

Value

This basic principle notes:

“The SHCC defines health care value as the maximum health care benefit per dollar expended.

“...Cost per unit of service is an appropriate metric...

”...At the same time overutilization of more costly and/or highly specialized low-volume services without evidence-based medical indication may contribute to escalating health costs without commensurate population-based health benefit.”

A non-invasive procedure has a much lower risk of infection. The new lithotripter units create shock waves without putting patients in a water bath. The procedure is simple, costs of equipment are well below \$1 million, and simple prep and recovery reduce the total cost of the procedure. This petition demonstrates that some areas of the state are exceptionally well served, while other areas lack access to this service. More patients choose lithotripsy to over invasive alternatives precisely because of its value. Therefore, this petition promotes the consistency with the SMFP’s governing principle of value.

CONCLUSION

The proposed changes are consistent with and support the Basic Principles that govern the SMFP.

ATTACHMENTS:

Letter of Support Senator Pendleton..... A

Attachment A

Letter of Support: Rep. Gary H. Pendleton, Chairman Health Committee



North Carolina General Assembly
House Of Representatives

REPRESENTATIVE GARY H. PENDLETON
49TH DISTRICT - WAKE COUNTY

July 22, 2016

Christopher Ulrich, MD
Chair, State Health Coordinating Council
Healthcare Planning and Certificate of Need Section
Division of Health Service Regulation
2704 Mail Service Center
Raleigh, NC 27699-2704

RE: Letter in support of Triangle Lithotripsy Corporation's petition for a special need determination for one lithotripter in the statewide service area in the 2017 State Medical Facilities Plan

Dear Dr. Ulrich:

I am writing this letter to express support for the petition filed by the Triangle Lithotripsy Corporation for a special need determination for one, statewide lithotripter in the *2017 State Medical Facilities Plan*. I grew up in Eastern North Carolina and spend a lot of time there. As you know, Eastern North Carolina is suffering from lack of medical care.

Triangle Lithotripsy Corporation ("TLC") has been providing lithotripsy services in North Carolina for over 25 years and has a strong reputation for delivering quality services. Through its experience and its recent evaluation of the statewide market, TLC has determined there is deficit of lithotripters in the state.

As anyone who has had a kidney stone knows, it is painful and treatment cannot come soon enough. While many with kidney stones receive alternative treatments such as invasive ureteroscopy, lithotripsy provides a non-invasive, highly effective treatment for kidney stones. Yet, access across the state is not uniform. Certain areas of the state enjoy better access than others. In particular, northeastern North Carolina, as TLC's petition shows, has a deficit of access to lithotripsy. The lack of availability in certain areas is due, in part, to the fact that lithotripsy providers in North Carolina are permitted to provide service to other states. As a result, a significant part of our inventory is being used out-of-state. The need methodology in the current *State Medical Facilities Plan* is not able to account for this loss of inventory. To close the gap in resources in a timely manner, TLC has proposed a viable solution: need for one additional lithotripter in the 2017 Plan.

As a former board member of WakeMed, a US Army Medical Service Corp. officer, and Wake County Commissioner, I urge the Division of Health Service Regulation to approve TLC's petition.

Sincerely,

A handwritten signature in black ink that reads "Gary H. Pendleton".

Gary H. Pendleton
Chairman, Health Committee

GHP/kmp

cc Paige Bennett, Assistant Chief, Healthcare Planning
William Pinna, JD

