

**Technology and Equipment Committee
Agency Report
Adjusted Need Petition for One Mobile Lithotripter
in the Statewide Service Area
2017 State Medical Facilities Plan**

Petitioner:

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Request:

Triangle Lithotripsy requests an adjusted need for one additional mobile lithotripter statewide.

Background Information:

Extracorporeal Shock Wave Lithotripsy (ESWL) has been governed by the Certificate of Need (CON) law since 1993. The State Health Coordinating Council (SHCC) established a need determination methodology for lithotripters in the *1998 State Medical Facilities Plan (SMFP)*.

The methodology assumes an annual incidence of 16 cases of urinary stone disease per 10,000 population, with 85-90% of cases appropriate for lithotripsy. It established 1,000 procedures as the annual treatment capacity for a lithotripsy unit. Given that mobile units provide most lithotripsy procedures, the SHCC defined the service area to be the entire state. The methodology has not changed since that time.

In 1998, North Carolina had 14 lithotripsy units, 11 of which were mobile. The remainder were fixed units based at hospitals. Based on the methodology, the state initially needed a maximum of 11 lithotripters. Thus, the SHCC concluded that North Carolina had sufficient units to serve the population, and that there was no need for additional lithotripters. The inventory has fluctuated, but the current inventory of lithotripters is 14. Thirteen are now mobile and one is fixed. Although the state population has increased by 29% since 1998, the *2016 SMFP* represents the first time that the methodology has calculated a need for a lithotripter.

Chapter Two of the *SMFP* allows persons to petition for an adjusted need determination to allow consideration of "...unique or special attributes of a particular geographic area or institution..."

if they believe that their needs are not appropriately addressed by the standard methodology. Triangle Lithotripsy has submitted a petition to adjust the need determination to address a special statewide need. It should be noted that any person might submit a certificate of need (CON) application for a need determination in the Plan. The CON review could be competitive and there is no guarantee that the petitioner would be the approved applicant.

Analysis/Implications:

The petitioner proposes a threefold rationale for the adjusted need determination: (1) North Carolina does not have full use of the 14 mobile units in the inventory because some lithotripter sites are out of state; (2) statewide distribution of lithotripsy is uneven, thereby limiting access; and (3) as a result, the methodology underestimates need.

Out of State Lithotripsy Sites

The petition asserts that the *SMFP* overlooks critical factors that limit access to NC's inventory of lithotripters. According to the *Proposed 2017 SMFP*, 17.5% of sites are located and 14.0% of procedures are performed in either South Carolina or Virginia.

Just as with other health services, it is likely that some proportion of ESWL patients served in NC are residents of other states. Likewise, some NC residents probably receive ESWL in other states. No patient origin data is available to test the accuracy of either this proposition or the petitioner's assertion. Ambulatory surgery can serve as a base of comparison because it is the health service most similar to ESWL. An examination of the 2015 patient origin data for the 30 NC counties that border other states and that offer ambulatory surgical services indicates that 9.8% of patients who received services in these counties resided in other states. Similarly, some proportion of patients in border counties are likely to go to neighboring states to receive health services.

Distribution of Lithotripsy Services

The petition notes that several lithotripters have low use rates. It asserts that these low use rates reflect access problems, primarily because 55 counties do not offer lithotripsy services. Although this number is accurate, Figure 1 (at the end of this report) shows that only three counties lack a lithotripsy site either in the county or in a contiguous county. Given that almost all lithotripters are mobile, it is virtually impossible to have a unit in a specific county at the exact time it is needed, unless it is on site in every county on every day of the year.

The petitioner claims that, in general, the use rate is evidence that access (i.e., number and location of lithotripter sites) is limited, by pointing out that the calculated use rate (8.77 per 10,000) is lower than the standard use rate in the methodology (14.4 per 10,000, or 90% of 16 per 10,000). The petitioner concludes that uneven use rates signal access limitations, but this argument may be spurious. Other factors may influence both use rates and access. Possible factors include, e.g., actual need for ESWL, physician practice patterns, business decisions of lithotripter owners and/or sites, reimbursement models, and patient preference. Moreover, to assure an adequate inventory statewide, the standard methodology would be expected to reflect a use rate that is higher than the average. Of course, given that the methodology is statewide, the use rate in some areas may exceed the use rate assumed in the methodology.

The *Proposed 2017 SMFP* statewide use rate is 8.77 per 10,000 residents; the metropolitan use rate is 9.34 and nonmetropolitan use rate is 6.78. The petitioner claims that the difference in use rates between urban and rural areas indicates limited access, especially in rural areas. Without patient origin data, it is not possible to test this assertion directly, but it is possible to examine the proportion of procedures performed in rural areas.

Table 1 summarizes the number of procedures performed at each location and identifies the sites as either rural or urban, based on the Census Bureau’s standard definition of “urban” as “urbanized Areas of 50,000 or more people and urban clusters of at least 2,500 and less than 50,000 people.”¹ It shows that 38.4% of the procedures were performed in rural areas and 61.6% were performed in urban areas. The 2015 census estimates show that 34% of North Carolina’s population is rural and 66% is urban. Therefore, the proportion of procedures performed in rural areas is a bit higher than the rural proportion of the state population.

Table 1. Mobile Lithotripsy Procedures

Provider (number of machines)	Number of Procedures				
	North Carolina			Out of State Sites	Total Procedures
	Rural	Urban	Total NC		
Carolina Lithotripsy (2)	577	729	1,306	0	1,306
Catawba Valley Medical Center (2)	128	278	406	0	406
Fayetteville Lithotripters (1)	324	171	495	63	558
Fayetteville Lithotripters (1)	72	0	72	192	264
Piedmont Stone Center (4)	1,742	1,692	3,434	746	4,180
Stone Institute of the Carolinas (2)	360	1,434	1,794	195	1,689
Triangle Lithotripsy Corp. (1)	61	996	1,057	0	1,057
Total	3,288	5,276	8,564	1,196	9,760
% of Procedures by Type of NC Area	38.4%	61.6%	100.0%		

Source: Table 9A, *Proposed 2017 SMFP*

Need Determination

Mobile lithotripsy units serve quite a few sites in neighboring states, but, as the petition accurately points out, the methodology assumes that they serve only NC sites. The petition calculates utilization based on NC sites only, and finds a deficit of 1.67 lithotripters (taking into account the placeholder for the lithotripter need in the *2016 SMFP*).

The need determination methodology is based on the annual incidence of kidney stones appropriate for ESWL. The proportion of the population that reports ever having a kidney stone has increased since implementation of the methodology. The National Health and Nutrition Examination Study (NHANES), which uses a nationally representative sample of adults 20 years and older, reported an increase in kidney stone prevalence from 5.2% in 1994 to 8.8% in a

¹ <https://www.census.gov/geo/reference/ua/urban-rural-2010.html>.

combined sample from 2007-2010. (The stones reported could be symptomatic or asymptomatic.)²

The incidence of kidney stones is more difficult to estimate. A review of studies shows the following progression of kidney stone incidence in the United States:³

- 122 per 100,000 population in 1971
- 208 per 100,000 population in 1977
- 164 per 100,000 population in 1978
- 116 per 100,000 population in 2000

Incidence data is very sparse and generally reported for relatively small and specific populations only. No data using representative samples from the U.S. or North Carolina populations could be located. The available data indicates that the incidence is likely decreasing, while the prevalence is increasing. This observation is common in epidemiological data. As the population ages, a larger proportion will have had a kidney stone at least once in their lives.

NC has increased the availability of lithotripter services during the period during which prevalence has increased. Access to lithotripter sites in NC has increased from 76 in 2008 to 80 in 2015. Also, 19.5% of procedures were at South Carolina or Virginia sites in 2008 compared to 13.1% in 2015 (based on the *Proposed 2017 SMFP*). Utilization has decreased during this time, however. The statewide ESWL use rate in NC has declined 11% in the past 10 years, even though the population has increased.

Concomitant with the decrease in utilization in North Carolina, ESWL use also declined nationwide from 2002-2007 in both the Medicare-covered and privately insured populations.⁴ Also, a longitudinal study of over 100,000 residents of Ontario, Canada showed that ESWL use decreased between 1991 and 2010 from 69% of procedures to 34%. Increasing use of alternatives to ESWL (e.g., medical expulsive therapy, ureteroscopy) is cited as a reason for the decline.⁵

Agency Recommendation:

Given available information and comments submitted by the August 12, 2016 deadline for comments on petitions and comments, and in consideration of factors discussed above, the Agency recommends denial of the petition. The Agency supports the standard methodology for lithotripsy services. In addition, the SHCC cannot require a lithotripter owner to limit its services to North Carolina sites, as requested in the petition. The petitioner has not demonstrated that the

² Scales, C.D., Smith, A. C., Hanley, J. M., & Saigal, C. S. (2012). Prevalence of kidney stones in the United States. *European Urology*, 62: 160-165.

³ Romero, V., Akpinar, H., & Assimos, D.G. (2010). Kidney Stones: A Global Picture of Prevalence, Incidence, and Associated Risk Factors. *Reviews in Urology*. Vol. 12, No. 2/3, e86-e96.

⁴ Litwin, M.S. & Saigal, C.S. (eds.). (2012). *Urologic Diseases in America*. U.S. Department of Health and Human Services, Public Health Service, National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases. Washington, DC: U.S. Government Printing Office. NIH Publication No. 12-7865.

⁵ Ordon, M., Urbach, D., Mamdani, M., Saskin, R., Honey, R.J.D'A., & Pace, K.T. (2014). The surgical management of kidney stone disease: A population based time series analysis. *The Journal of Urology*. 192(5), 1450-1456.

methodology suppresses the need nor that access to ESWL services is limited. Further, the 2016 *SMFP* contained a need determination for one lithotripter. In light of the information presented above, it is likely that one additional lithotripter will be more than adequate to meet the need for ESWL services in North Carolina.

Figure 1. Lithotripter Sites, 2015

