

**Technology and Equipment Committee Agency Report
Petition to Remove the Need Determination for Two Lithotriptors
in the 2024 State Medical Facilities Plan**

Petitioners:

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Request:

The Petitioners request elimination of the proposed need determination for two new lithotripsy units from the *2024 State Medical Facilities Plan (SMFP or “Plan”)*.

Background Information:

Chapter Two of the *SMFP* provides, in relevant part, that “[a]nyone who finds that the *North Carolina State Medical Facilities Plan* policies or methodologies, or the results of their application, are inappropriate may petition for changes or revisions. Such petitions are of two

general types: those requesting changes in basic policies and methodologies, and those requesting adjustments to the need projections.” Petitions requesting adjustments to need projections are reviewed in the summer. Any person may 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.

The need determination methodology for lithotriptors is based on population, a use rate of 16 extracorporeal shockwave lithotripsy (ESWL) cases per 10,000 population and a further assumption that 90% of kidney stones can be treated by ESWL. While the need determination methodology describes the capacity of a lithotripter as up to 1,500 cases, it does not consider utilization of existing machines.

There are currently eight lithotripsy providers statewide. Together, they operate thirteen mobile lithotriptors in addition to one fixed lithotripter located in Asheville, NC. The Petitioners own eleven of the thirteen mobile units. There are currently nine mobile lithotriptors serving areas of the western and central regions of NC, and four serving eastern and central areas of the state. Some of these mobile units also serve host sites in Virginia. The *SMFP* defines the service area for mobile lithotriptors as statewide.

Analysis/Implications

The Petitioners request removal of the need determination for two lithotriptors from the *2024 SMFP* due, in part, to their assertion that there is an insufficient number of urologists within the state. However, according to the American Urological Association Census for 2022,¹ North Carolina has 4.36 urologists per 100,000 population, which the association considered “medium high” and above the national average of 4.21 per 100,000 population.

Also, the Petitioners state that the need determination should be removed because ureteroscopy (URS) procedures have increased while ESWL procedures have decreased. Shockwave lithotripsy and URS are the most commonly utilized procedures for the treatment of kidney stones.² The Petitioners contend there has been a steady decline in ESWL in the North Carolina, and that there is currently sufficient lithotripsy capacity in all areas of the state, including rural communities. Research by Agency staff corroborates an increase in URS procedures nationwide, and that the number of URS procedures performed surpassed the number of ESWL procedures.³ However, this trend may be concentrated in areas well-served by hospital facilities, possibly overlooking the needs of areas less-well served⁴. Additionally, most URS procedures are inpatient procedures performed under anesthesia, while ESWL is usually an outpatient procedure suitable to a mobile

¹ <https://www.auanet.org/research-and-data>

² Assimos, D., Krambeck, A., Miller, N. L., Monga, M., Murad, M. H., Nelson, C. P., ... & Matlaga, B. R. (2016). Surgical management of stones: American urological association/endourological society guideline, PART I. *The Journal of urology*, 196(4), 1153-1160.

³ Haas, C. R., Li, S., Knoedler, M. A., Penniston, K. L., & Nakada, S. Y. (2023). Ureteroscopy and shock wave lithotripsy trends from 2012 to 2019 within the US Medicare dataset: sharp growth in ureteroscopy utilization. *Journal of Endourology*, 37(2), 219-224.

⁴ Kaplan-Marans, E., Jivanji, D., Vazquez-Rivera, K., Martinez, M., Lee, J., Shpeen, B. H., ... & Schulman, A. (2023). National Utilization, Reimbursement, and Urban Versus Rural Trends of Extracorporeal Shockwave Lithotripsy and Ureteroscopic Laser Lithotripsy. *Urology*, 174, 48-51.

unit.^{5,6} Therefore, while there have been more URS procedures performed in recent years, this alone does not necessarily diminish the need for mobile lithotripters using ESWL.

The Petitioners state that there has been an overall decline in ESWL procedures from 2015 - 2022. However, Agency staff reviewed the data on lithotripter utilization across the state and found that while utilization had declined from 2015 to 2019, it began rebounding in 2021 (Table 1). Additionally, there is anecdotal information offered by practicing urologists in the Raleigh area that there is a 4-6 week waiting period for lithotripsy appointments in urology offices serving Wake County.

Table 1. Lithotripsy Procedures

Data Year	Lithotriptors	Procedures	Procedures per Lithotripter	Percent Change
2015	14	10,019	716	-
2016	14	9,529	681	-4.89%
2017	15	9,253	617	-9.40%
2018	15	8,710	581	-5.83%
2019	15	8,952	597	2.75%
2020	14	7,268	519	-13.07%
2021	14	7,310	522	0.58%
2022	14	7,926	566	8.43%

From 2017 SMFP - 2024 Proposed SMFP

Agency Recommendation:

The Agency supports the standard need methodology for lithotriptors. Based on the available information and comments submitted by the August 9, 2023 deadline, and in consideration of the factors discussed above, the Agency recommends denial of the petition.

⁵ <https://my.clevelandclinic.org/health/treatments/16582-shockwave-lithotripsy>

⁶ <https://urology.wustl.edu/patient-care/kidney-stones/surgery-for-kidney-stones/>