

**JULY 26, 2023 ORAL REMARKS IN SUPPORT OF PETITION TO ELIMINATE THE NEED DETERMINATION
FOR TWO ADDITIONAL LITHOTRIPTORS IN THE DRAFT 2024 SMFP
PRESENTED BY CHARLES HAUSER OF PIEDMONT STONE CENTER**

- Lithotripsy uses shock waves to treat kidney stones. It is noninvasive, relatively painless and highly effective.
- Currently, there are eight providers of lithotripsy in North Carolina, seven of which are mobile providers.
- Petitioners (Piedmont Stone Center, Stone Institute and Healthtronics d/b/a Carolina Lithotripsy, Fayetteville Lithotriptors- SC II and Fayetteville Lithotriptors-VA I) are five of the seven mobile providers. Combined, the petitioners:
 - Own 11 of the 14 lithotriptors that serve North Carolina;
 - Serve 64 host sites throughout North Carolina according to the Draft 2024 SMFP;
 - Represent 181 treating urologists; and
 - Performed 5,756 of the 6,738 (85%) lithotripsy procedures performed in North Carolina according to the data in the Draft 2024 SMFP.
- There is access to mobile lithotripsy in all areas of North Carolina, including rural areas. Given its mobile nature, the service can be easily adapted to serve any area of the State needing the service, as long as there are urologists in the area.
- Petitioners support and respect North Carolina’s health planning process, and the important work performed by staff and SHCC members. Petitioners support eliminating the need determination for two additional lithotriptors in the draft 2024 SMFP for the following reasons:
 - There is significant excess capacity in the 14 lithotriptors in North Carolina now. No single lithotripter is at or near the SMFP-defined full utilization of 1,000 cases.
 - Lithotripsy is the only SMFP-regulated technology that does not consider utilization at all in its need methodology.
 - The need methodology is population based and has been in place since 1998.
 - The methodology assumes lithotripsy is appropriate in 90% of the cases of urinary stone disease.
- There have been significant changes since 1998 that warrant: (1) eliminating the need determination in the Draft 2024 SMFP; and (2) changing the need methodology for lithotripsy.
- The changes since 1998 are: (1) increased use of ureteroscopy, another noninvasive procedure used to treat kidney stones; (2) a shortage of urologists; (3) increasing specialization of urologists who do not perform lithotripsy; and (4) decreased opportunities for urologists in residency to receive training in lithotripsy.
- These factors have led to a steady decrease in lithotripsy procedures in North Carolina since the 2017 SMFP. **According to data from the 2017 SMFP through the draft 2024 SMFP, the number of procedures reported over this time period has declined by 26.4%. The number of procedures per lithotripter has declined by 26.5%.**
- This situation is not likely to change.
- We suggest that the need methodology be revised to consider utilization. For example, there is no need unless a machine has reached SMFP-defined full utilization of 1,000 cases.

- Recognizing the SHCC may not wish to reconsider the need methodology at this time, we ask the SHCC to eliminate the need determination for two machines from the draft 2024 SMFP. As an alternative to changing the need methodology, the SHCC may want to form a work group to study the need methodology in 2024.
- We thank the SHCC and staff for their time and consideration. Our petition goes into greater detail. We are pleased to answer any questions that SHCC members or staff may have.