COMMENTS REGARDING
Petition for New Technology and Equipment Policy (Hampton Roads Lithotripsy, LLC)

Commenters: Carolina Lithotripsy, a Limited Partnership ("Carolina Lithotripsy")
Fayetteville Lithotripters Limited Partnership – South Carolina II ("South Carolina II")
Fayetteville Lithotripters Limited Partnership – Virginia I ("Virginia I")

Through their general partners, ESL, Inc. and Lithotripters, Inc.

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On behalf of the three above-named Commenters, ESL, Inc. as general partner of Carolina Lithotripsy and Lithotripers, Inc. as general partner of South Carolina II and Virginia I, provide the following comments concerning the above-referenced Petition. In short, Commenters oppose adoption of the requested Policy TE-3 proposed by Hampton Roads Lithotripsy, LLC ("HRL") for the 2017 State Medical Facilities Plan ("SMFP"). The reasons for Commenters' disagreement with HRL's request are responded to in the order that HRL presented them in the Petition.

1. The current methodology does not understate the need.

The standard methodology for determining the need for lithotripters consists of multiple factors, of which determination of the State's population is not a controversial one. HRL does, however, question the appropriateness of the use of 16 incidents of urinary stone disease per 10,000 persons as a potential understatement of the annual incidence of urinary stone disease suggesting (on page 2 of the Petition) that the actual incidence of disease is actually 888 per 10,000 without relating this statement to the need for the performance of lithotripsy procedures.

In addition, HRL notes that over time the rate of kidney stones is increasing due to negative trends in diabetes and obesity. While the literature does suggest that there has been a trend towards an increased incidence of kidney stones for reasons HRL has identified, that is not suggestive that the standard methodology understates the need for lithotripsy procedures as the chart on page 4 of the Petition shows reflecting the number of lithotripsy procedures reported for the years 2012-2016. There has been a small increase in the number of procedures for the period reported in the chart.

Without considering more information, that gradual increase in the number of procedures performed would appear to be consistent with the general notion that there is a trend towards greater incidence of kidney stone disease, although it is apparent that the factor of 888 compared to 16 per 10,000 is not a relevant number for determining need or the existing lithotripsy providers would have much higher volumes of procedures performed than they actually do. HRL notes on page 8 of the Petition that existing equipment currently provides an average of

only 747 procedures per unit, while the standard methodology provides that 1,000 is the low range of the annual treatment capacity of a lithotripter.

Since population growth has resulted in the current methodology authorizing an additional lithotripter within the State to be awarded in 2016, then there is nothing to suggest that there may be an understatement of need given the actual volume of procedures currently performed. Since the reported volume of procedures includes all actual procedures (both newly-diagnosed cases and repeat procedures for persons with a chronic condition that is not cured), actual volumes of procedures performed demonstrate that there is not an understatement of need.

A factor that HRL does not discuss in the Petition is that the technology used to treat kidney stones has changed over time. The SMFP standard methodology assumes that 90% of those persons who have an episode of urinary stone disease will be treated by lithotripsy. While that was the case at the time that the standard methodology was adopted, it is no longer the case. Over time, the use of ureteroscopic procedures have displaced the use of lithotripsy as the primary treatment for ureteral stones, and this trend of the increasing use of ureteroscopic procedures (with a corresponding decline in the use of lithotripsy) may continue as is reflected in the five articles that are attached to these comments.

Of those articles, two very specifically address the role that obesity and diabetes play in the development of kidney stone disease and (this unfortunate) growth of such disease noting that such patients are better treated by ureteroscopic procedures than by lithotripsy. See "Ureteroscopy and Stones: Current Status and Future Expectations" (World Journal of Nephrology) and "Ureteroscopic of Renal Calculi" (Urologic Clinics of North America).

By failing to acknowledge the technological changes that have occurred in the treatment of kidney stones in recent years, HRL's suggestion that there may be an understated need misrepresents not only the current need but also realistic expectations of need in the future.

2. Because the actual number of lithotripsy procedures is lower than the number the standard methodology would project, there is no reason to believe that there is an access issue.

As HRL notes, all of the lithotripters within the State except for the one operated by Mission Hospital in Asheville are mobile. The providers of the service can take the lithotripter wherever they are needed to serve patients within the State. When one reviews the locations at which the mobile lithotripsy providers (both these Commenters and the other mobile lithotripsy providers which provide services) listed in the 2016 SMFP, one will note that many of the locations throughout the State at which services are provided would qualify as being rural using any reasonable definition of the term, including the USDA definition. It is illogical to suggest that the current mobile lithotripsy providers are resistant to offering their services in other similar rural communities in which there is need for the services.

As HRL notes in its proposed Policy TE-3, it is proposing that the out-of-state providers be allowed to only serve a hospital in a town with fewer than 50,000 inhabitants and is not proximate to an urbanized area. For reasons not mentioned by HRL, many such communities cannot support lithotripsy service because they would not generate enough incidents of needed service within a reasonable interval of time to meet its suggested standard of performing four procedures for every day that a mobile lithotripter is on site (page 11 of Petition).

Furthermore, the critical resource in being able to provide the service in a community is the availability of a urologist to perform the procedure. Many rural areas do not have a urologist who performs lithotripsy. Therefore, without regard to how many lithotripters might be authorized within the State, service would not be made available because any "access" issue arises not from the lack of the equipment, but the lack of volume and/or a urologist to treat the patients.

3. The current methodology does not assume that capacity is unavailable to most areas of the State.

Since all of the lithotripters in the State except for the fixed-based unit in Asheville can and do travel, determination of need on a statewide basis is logical. Again, a review of the locations served by the mobile lithotripters in the State listed in the 2016 SMFP demonstrates good geographic distribution of services throughout the State, including in less populous communities.

4. Nothing stated by HRL suggests a need for additional access to lithotripsy in more isolated, rural areas.

Rather than identifying any rural hospital within the State that complains of being unable to access a lithotripsy provider, HRL assumes that there must be such areas, focusing primarily on the northeastern portion of the State to which its equipment is proximate.

HRL does not identify a community hospital located in that area which seeks access to lithotripsy services but has been unable to obtain it. These Commenters, two of which serve eastern North Carolina, treated between 312 and 680 persons per lithotripter in 2014 respectively, as is reflected in the 2016 SMFP. Obviously, more than adequate capacity currently exists there (and also in western North Carolina) to meet any needs.

Again, HRL has not addressed the primary reasons why lithotripsy service may not be available in a particular area, which are an inadequate volume of patients requiring treatment and/or no urologist to treat patients. None of the Commenters have received reports from hospitals of unmet needs for service. Furthermore, given the modern transportation system that our highways provide, persons in rural areas frequently travel reasonable distances to more populous communities for a variety of goods and services, including specialists' medical services and the technology that specialists use.

Traveling a reasonable distance to a larger community to obtain lithotripsy service is no different as HRL notes on page 6 of the Petition that approximately 10% of its patients live in North Carolina, but were treated at sites in Virginia. Lithotripsy services are performed on an outpatient basis. The service is non-invasive, and it can be generally completed in a few hours. Consequently, reasonable travel for lithotripsy services is not burdensome. Throughout areas of the State, whether urban or rural, where a community borders another State, it is not unusual for someone to cross State lines to receive a service or to purchase a good. To the extent that the reason is that the service or good (including lithotripsy) cannot be made available in the local community (e.g., lack of volume or a urologist), adding more lithotripsy providers cannot address that.

5. Whether the incidence of urinary kidney stones is likely (slightly) higher in the northeastern portion of the State is not relevant to the question.

The charts contained on pages 6 and 7 of the Petition are mildly suggestive that the incidence of obesity and diabetes in the northeastern portion of the State is slightly higher than the State average. Presumably that might mean that the incidence of kidney stone disease in that portion of the State might be slightly higher than the State average. Given that ureteroscopic treatment is the preferred method for obese patients (who are more likely to be diabetic), as stated in attached articles, HRL's argument in this section sheds no light on the need for its proposed Policy TE-3.

6. There is no reason to believe that the standard methodology is not adequately addressing the needs of the citizens of the State.

The addition of the lithotripter in 2016 included in this year's SMFP would certainly create the opportunity for additional services to be made available if they are needed. Presumably, any provider which would pursue obtaining a certificate of need for a lithotripter would do so with the objective of treating as many kidney stones as it could. To the extent that there are hospitals within the State (whether located in a rural or urban area) that need service, presumably the additional machine would be used as efficiently as possible to provide that service.

Conclusion

In its rationale for the specific components of the proposed Policy TE-3, HRL essentially repeats some version of its numbered arguments contained in the Petition. It should be noted, however, that HRL has included in the proposed Policy (in Item 4) that in order for an out-of-state lithotripsy provider to be able to obtain a certificate of need that it would need to demonstrate that providing service would be reasonably expected to improve the "quality of, access to, or value of lithotripsy services in the area served . . . . ." It is unclear how that determination is to be made since it is not explained in the Petition.

The Commenters provide their services using the latest lithotripsy technology, as is reflected in the information identifying their lithotripters authorized to operate within the State. The access issues have already been discussed, so there is nothing additional for the commenters to add on that point. Concerning the value of the lithotripsy services, HRL does reference "more competition in underserved areas" on page 6 of the Petition. In that regard, there is nothing to prevent any of the current mobile lithotripsy operators from providing services throughout the State, and the various providers do compete with each other for business opportunities.

If there are any quality, access or value issues, then one would expect that there are hospitals that would suggest what they are and how Policy TE-3 might address their needs. Absent such a suggestion from hospitals (not HRL), it appears that HRL's proposal is nothing more than an attempt to expand its own market reach which it could more appropriately pursue by filing an application for the certificate of need for the new lithotripter which is authorized in the 2016 SMFP.