Comments on Petition to the State Health Coordinating Council Regarding New Technology and Equipment Policy TE-3
2017 State Medical Facilities Plan

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Commenter:		***Contact:***	
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SUMMARY OF REQUESTED ADJUSTMENT

Hampton Roads Lithotripsy, LLC, a Virginia company based in Norfolk, filed a petition requesting a new Policy TE-3 for the 2017 State Medical Facilities Plan.

The petition's stated intent is to permit applicants who own mobile lithotripsy equipment to increase access to rural areas in North Carolina. The proposed policy would:

- Benefit only companies that operate outside the state of North Carolina, in contiguous states including states as far away as Georgia;
- By-pass the Need Methodology for Lithotripsy in Chapter 9 of the *State Medical Facilities Plan*;
- Not require the applicant to be serving North Carolina at the time it applies for a Certificate of Need under the proposed policy; and
- Permit operation only at hospital sites.

We appreciate the state's consideration of our comments on the petition and welcome any questions.

COMMENTS

UNFRIENDLY TO NORTH CAROLINA

Petition Policy Elements 1 and 2 would prohibit a mobile lithotripsy company that serves only North Carolina from applying. Specifically the petition requires the following:

> *… has regulatory approval if needed, to operate in a state contiguous to North Carolina*
>
> *..currently provides services to at least one host site in one of the states that is contiguous to North Carolina*

The petition had no letters of support from North Carolina and the petitioner chose not to exercise the opportunity to make a case in person before the State Health Coordinating Council at its meeting in March 2016.

UNFRIENDLY TO RURAL NORTH CAROLINA

The petition's third Policy Element requires that a Certificate of Need application filed under the proposed new policy TE-3 to serve only rural hospital sites.

> *Will serve only hospital sites in areas defined as rural…*

Several North Carolina counties do not have a hospital; Alexander, Graham, and Warren are a few examples. The petition actually notes that these counties would not be appropriate for mobile lithotripsy (page 9 of 12).

INSIGHTFUL CONSIDERATIONS

The petition raises good questions about access to lithotripsy in rural North Carolina. However, the petition favors only the solution that benefits this one out-of-state company. The petition would give Hampton Roads Lithotripsy, and other out-of-state companies, unrestricted access to grow business in North Carolina at the expense of companies that are in North Carolina and serve North Carolina. A North Carolina company that operates at full capacity could not apply for a CON under the policy as written, but an out of state company with no track record, would have permission to create a case and that applicant would not be subject to the standard performance requirement. It would only need to serve an area defined as rural. It could compete where others could not. The proposed policy would create two classes of lithotripsy providers.

The petition's arguments that the 1994 use rates merit re-examination are valid, but the petition falls short of resolution on alternatives. However, it appropriately opens the door for additional discussion. The petition makes an excellent case that service to out of state locations should be discounted in the state methodology, even noting without so saying that the out-of-state cases exceed the state threshold for an additional lithotripter. However, the petition makes a blanket assumption that no provider could serve rural areas, instead proposes a solution that serves the petitioner's interest in Northeastern North Carolina. It appropriately notes the planning obstacles associated with the state's missing patient origin data, but only generally references its own data on service to North Carolina residents. It notes that patients of urologists in the Hampton Roads area could be served by lithotripters in rural North Carolina, but fails to discuss whether those urologists would go to the rural North Carolina lithotripter.

The proposed policy is incomplete with regard to the narrative. The narrative suggests using a placeholder to count service to counties the out of state unit would serve, but does not apply the same to North Carolina units that go out of state. Over time, this will create an imbalance that favors the out of state unit.

INAPPROPRIATE TIMING

As the petitioner notes, the *2016 SMFP* shows a statewide need for one additional lithotripter. Applications are due mid-year and the review may not finish before the end of the year. Consideration of the policy now, before filing the batch applications, would put the state in an untenable position. Certificate of Need staff would be constrained in their comments because of a review in progress.

STATEMENT OF ADVERSE EFFECTS ON PROVIDERS AND CONSUMERS IF THE ADJUSTMENT IS MADE

The petition would permit duplication of resources. For example, it could permit location in a county, at the border of very urban county Thoughtful review and consideration could eliminate such unintended consequences.

REMEDY

The petitioner clearly raises issues that merit consideration.by a group that understands the full spectrum of lithotripsy treatment, disease indicators, cost of operations and quality program requirements. A work group could be appointed and could convene in late fall, to provide recommendations to the Technology Committee in spring 2017.

The petition correctly notes that the development of the current methodology occurred in 2001. Now, fifteen years later, it is appropriate to revisit the methodology and its research foundations.

A new methodology could include more current nephrolithiasis disease incidence and kidney stone prevalence information, as well as utilization patterns and underserved areas. It could make adjustments for fixed and mobile unit status, as is the case with MRI. The methodology could exclude counts of procedures provided outside the state by adding one extra step to the current methodology.

As a first step, in 2016, the SHCC could remedy the problem of missing patient origin data, by asking DHSR Planning to add one table to the required Registration and Inventory of Equipment forms. When the SHCC expanded the MRI methodology, a similar panel looked at underserved areas and adjusted thresholds to favor redistribution of resources. A study group could look at that.

CONCLUSION

The petition raises important questions about the methodology for calculating need for lithotripter capacity and the best ways to serve rural communities in North Carolina. The Hampton Roads Lithotripsy petition should be tabled until the conclusion of the 2016 Lithotripsy CON review cycle. A work group should then be created to review the petition and make recommendations to the SHCC. This allows the work group to account for the 2016 application decision and yield the best recommendations.