



August 12, 2016

Christopher Ullrich, M.D.
Chair, State Health Coordinating Council
Chair, Technology and Equipment Committee
North Carolina Division of Health Service Regulation
Healthcare Planning and Certificate of Need Section
2704 Mail Service Center
Raleigh, NC 27699-2704

VIA EMAIL

RE: Triangle Lithotripsy's Petition to for a Special Need Determination for One Additional Lithotripter in the 2017 State Medical Facilities Plan

Dear Dr. Ullrich:

On behalf of Hampton Roads Lithotripsy and the North Carolina patients we currently serve at sites in Virginia, I want to comment on the petition filed by Triangle Lithotripsy for a special need determination for an additional lithotripter in the state. As you are aware, we filed a methodology change petition in the spring, which would have allowed providers like us to bring existing equipment into the state to serve rural areas more effectively. That petition was denied, based in part on the Agency report, which asserted that rural access does not appear to be an issue, and that the need determination in the 2016 SMFP may improve access in rural areas of the state. As presented in the Triangle Lithotripsy petition, an analysis of the use rates in rural areas (as best can be determined without patient origin data) shows that rural areas do appear to have access issues. Further, the review for the lithotripter in the 2016 SMFP began July 1, and neither of the competing applicants proposes to significantly expand access in underserved rural areas.

While we support the concepts presented in the Triangle Lithotripsy petition, many of which echo the analysis presented in our spring petition, we believe that the allocation proposed in the petition will not necessarily be effective in addressing these issues. In particular, the allocation of another statewide lithotripter, without any meaningful restrictions or limitations focused on access for rural and underserved areas, would likely result in applications similar to those currently under review, which propose to predominately serve sites that already have lithotripsy service, often from multiple

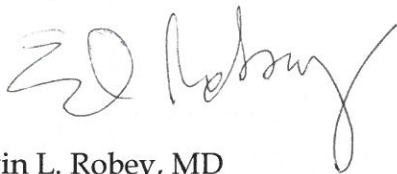
Hampton Roads Lithotripsy

lithotripters. While the petition requests that the need determination would limit the approved applicant to serving only North Carolina sites (as opposed to using the unit to serve sites in neighboring states), we do not find this restriction reasonable, as it is largely unenforceable and potentially illegal, since North Carolina has no authority to prohibit lawfully-acquired equipment from also providing services in another state. Moreover, the approval of another unit that would be required under the CON performance standards to reasonably project 1,000 additional lithotripsy procedures within three years would likely force the applicant to propose serving urban sites, as the number of rural sites needed to support 1,000 additional procedures would require the unit to serve a large portion of the state, making travel and schedule coordination difficult to demonstrate in the CON application, much less to actually effectuate.

While we appreciate the renewed focus on lithotripsy services, we continue to believe that a more effective way to improve access to underserved areas of the state, without unnecessarily duplicating existing units, is to allow providers with existing equipment with available capacity to serve those sites. Comments on our spring petition took issue with our proposal to allow units outside North Carolina to come into the state; however, clearly any existing provider in North Carolina can already serve sites within the state, and any applicant for a CON for a lithotripter in North Carolina must demonstrate it can serve 1,000 patients—within North Carolina—which may exceed the need for additional capacity. We also note that Triangle Lithotripsy could have applied for the need determination in the 2016 SMFP to accomplish the goals expressed in its petition, yet inexplicably failed to do so. Therefore, the most effective way to expand access to underserved sites without risking the unnecessary duplication of the capacity of another entire lithotripter would be to allow providers in other states to apply for a CON to serve sites in the state, if they can demonstrate that the sites they propose to serve are in underserved areas.

Although I base my practice in Virginia today, I have deep connections to North Carolina and would like to see a helpful solution to these issues affecting patients with urinary stone disease. Specifically, I received my undergraduate degree from NC State and my medical degree from the Bowman Gray School of Medicine at Wake Forest University, so North Carolina is where I first learned to care for patients. As part of Hampton Roads Lithotripsy, I am honored to provide care to North Carolina patients at the locations we serve in southeastern Virginia. We will continue to do so in the future; however, we believe it would be better for these residents of North Carolina, as well as the many others who do not have sufficient access to lithotripsy services, if we were able to provide this care within their home state. If the SHCC approves the Triangle Lithotripsy petition, we urge you to allow providers like us the opportunity to apply for a CON to use existing equipment to provide care to underserved residents of the state.

Sincerely,



Edwin L. Robey, MD

Hampton Roads Lithotripsy