

**Presentation of Special Needs Petition for
Additional Lithotripter,
Proposed 2017 State Medical Facilities Plan
Wilmington, July 22, 2016**

Presented by:

*on behalf of
Triangle Lithotripsy*

Good afternoon, my name is Nancy Lane, and am here representing Triangle Lithotripsy, LLC. Triangle, a North Carolina company whose membership includes practicing urologists, has provided mobile lithotripsy in central and eastern North Carolina for more than 25 years. Its service locations extend from Wayne County to the Research Triangle and include hospitals and ambulatory surgery centers.

Triangle Lithotripsy is requesting that the *2017 State Medical Facilities Plan* show an adjusted special need for one additional mobile lithotripsy unit to address a statewide geography. The methodology in the Proposed Plan shows no need.

The reason for the request is simple. The Proposed Plan lists 14 lithotripters in North Carolina and these serve 80 North Carolina sites; one unit is fixed at Mission Hospital, one serves almost exclusively Virginia sites, four serve Virginia sites and one serves South Carolina. The remaining seven (7) serve only North Carolina sites. Combined, our North Carolina lithotripters are serving 17 sites out of state. This means 18 percent of our lithotripsy capacity provides service to non-North Carolinians. However, the methodology treats all 14 as if they served only North Carolina locations. The 80 North Carolina sites may get service only one day a month.

As a result of the need for one additional lithotripter in the Plan in 2016, Triangle looked closely at lithotripsy service use and capacity in North Carolina. We found that certain areas of the state have very low lithotripsy use rates. The low use appears to correlate with availability of the lithotripsy unit. This is

inconsistent with the state's epidemiology. As you may know, kidney stones occur frequently in North Carolina. The state is part of the national kidney stone belt. The causes of kidney stones are actually complex, and are associated with things like gender, mineral composition of the water supply, the amount of oxalic acid consumed in foods like iced tea, spinach, peanuts and chocolate, personal hydration practices, and weight. Kidney stones are painful. Some correct themselves. Many require treatment and the options are lithotripsy that uses shock waves to pulverize the stone and invasive procedures to remove the stone.

Access appears to make a difference in county use rate in North Carolina. It makes sense, with a lithotripter available only once a month, or even once a week, patients will request the invasive option, rather than wait in pain. Use rates in the state have 25-fold variation, with the higher rates in the better served areas. The North Carolina Plan methodology assumes that every unit is available to North Carolina, multiplies population by use rate and divides that by 1,000 procedures per unit to get the number of units the state needs. It is a simple methodology, based on need of the population and count of existing units. However, when you adjust number of units for the equivalent days spent outside North Carolina, the number of available lithotripters is 11.5, not 14.

Though prevalence of kidney stones is increasing, - up from 5.2 percent in the 1990's to 8.8 percent in 2010 according to a survey presented at the American Urological Association meeting in 2012, North Carolina SMFP has for years used the same 16 per 10,000 rate that was first used in 1994. The 2012 study reports that kidney stones affect one in 11 people in the US.

The 2016 Plan showed a need for one additional lithotripter statewide and there are two CON applications under review for that lithotripter. Members of Triangle are involved in one of these. I do not want to comment on those applications. What Triangle wants the SHCC to see is that one lithotripter in 2016 will not address the full current state need. We are not proposing to tinker with the methodology. We do not know the outcome of the review. We do know that the Plan could include one more lithotripter without any risk of providing excess capacity in the state. We plan to submit a petition with more detail later. My goal today is to introduce the issue and learn about any concerns you may have.

For the record, Triangle commented against a much more narrow petition filed by Hampton Roads in the spring. That petition favored out of state providers and limited the service locations. It will take years to collect new data and create a new methodology. This petition is very simple it will address a geographic need for one more lithotripsy unit in the state.

We have been asked if alternatively, some of the lithotripters that are operating at low volume could solve the problem. They have been at low volume for years and the state cannot intervene in their operations. Moreover, volume does not affect the Plan methodology.

Thank you. I will be happy to entertain questions. You may find my knowledge limited, but I will take questions to Triangle and get back to you with their response.