

**Technology and Equipment Committee**  
**Agency Report**  
**Lithotripsy Technology and Equipment Policy**  
**Proposed 2017 State Medical Facilities Plan**

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***Petitioner:***

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***Contact:***

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***Request:***

Hampton Roads Lithotripsy, LLC requests that the *North Carolina 2017 State Medical Facilities Plan (SMFP)* include a new policy regarding lithotripsy.

***Background Information:***

Chapter 2 of the State Medical Facilities Plan (SMFP) describes the purpose and process for submitting petitions to amend the SMFP during its development. Early in the planning year petitions related to basic SMFP policies and methodologies that have a statewide impact may be submitted. The SMFP defines changes with the potential for a statewide impact as “*the addition, deletion, and revision of policies and revision of the projection methodologies.*” The review requested by this petitioner could affect a methodology or policies in the SMFP and should be considered before publication of the Proposed 2017 SMFP.

The policy proposed by Hampton Roads Lithotripsy is as follows:

*Policy TE-3: Use of Existing Mobile Lithotripsy Units to Increase Access in Rural Areas of the State*

*Applicants that own existing mobile lithotripsy units that are approved to operate in states contiguous to North Carolina may apply for a Certificate of Need (CON) to serve host sites in North Carolina if the applicant(s) demonstrates in the CON application that the mobile lithotripsy unit:*

- 1. Has regulatory approval, if needed, to operate in a state contiguous to North Carolina, including Georgia, South Carolina, Tennessee or Virginia;*
- 2. Currently provides services to at least one host site in one of the states that is contiguous to North Carolina and commits to continue doing so following completion of the project;*
- 3. Will serve only hospital sites in areas defined as rural by the United States Department of Agriculture, which includes areas other than:*

- a. *A city or town that has a population greater than 50,000 inhabitants; and,*
  - b. *The urbanized area contiguous and adjacent to such a city or town.*
4. *It is reasonably expected to improve the quality of, access to, or value of lithotripsy services in the area served by the host site.*

*The performance standards in 10A NCAC 14C .3202 would not be applicable.*

Lithotripsy has been governed by the Certificate of Need (CON) law since 1993. The 1997 SMFP began to include inventories of lithotripsy equipment and the number of procedures performed. During this time, the State Health Coordinating Council (SHCC) sought comments on the need for lithotripters. As a result, beginning with the 1998 SMFP, the SHCC first articulated a need determination methodology for lithotripsy.

The methodology assumed an annual incidence of 16 cases of urinary stone disease per 10,000 population, with 85-90 percent of cases appropriate for lithotripsy. In addition, given that mobile units provide most lithotripsy procedures, the SHCC defined the service area to be the entire state. To gauge the sufficiency of the current inventory of equipment, the SMFP compared North Carolina's inventory to two nearby states that governed lithotripters under their CON law. Specifically, the Kentucky State Health Plan's methodology did not identify a need unless all units performed "at least 1,000 procedures in the previous year. One thousand procedures represents 50 percent utilization of 50 weeks of operation at 40 hours per week allowing an average of one hour per procedure" (1998 SMFP, p. 76). Based on this information, North Carolina determined the treatment capacity of a lithotripter to be between 1,000 and 1,500 procedures per year. The methodology has not changed since that time.

In 1998, North Carolina had 14 lithotripsy units, 11 of which were mobile. The remainder were fixed units based at hospitals. Given the methodology and the 1998 population, the state needed a maximum of 11 lithotripters at that time – 3 fewer than the inventory. Thus the SHCC concluded that North Carolina had sufficient units to serve the population, and that there was no need for additional lithotripters in 1998.

One unit was sold in 2003, leaving the state with 13 lithotripters. In 2006, Stone Institute of the Carolinas filed a petition for an adjusted need determination for Mecklenburg County. The petitioner argued that the one unit available in Mecklenburg County could not support the area's continued population growth. As a result, the 2007 SMFP contained a need determination for one lithotripter in Mecklenburg County, returning the inventory to the original 14 units.

The total inventory of lithotripters remains unchanged, but 13 are now mobile and 1 is fixed. Although the state population has increased substantially since 1998, the 2016 SMFP represents the first time that the methodology has triggered a need for a lithotripter.

***Analysis/Implications:***

A primary rationale for the proposed policy expresses the concern that the current complement of lithotripsy equipment in North Carolina may not meet the needs of patients in rural areas. To solve this problem, the petitioner recommends a new policy that limits a mobile lithotripsy unit to rural areas. Because these mobile units would serve patients in sparsely populated areas, the petitioner

proposed that they should be exempt from the standards in 10A NCAC 14C .3203. This rule requires a CON applicant to show that in the third year of operation the unit is projected to perform 1,000 procedures per year and that it will perform an average of 4.0 procedures per day per site.

An analysis of lithotripsy procedures in the 2016 SMFP shows that of the 10,164 procedures performed on mobile equipment 8,833 were performed in North Carolina. The remaining 1,331 were performed out of state. The petitioner correctly observes that the residence location of lithotripsy patients is not available on the Registration and Inventory forms. As a proxy for patient residence, the agency’s analysis of access to lithotripsy services used the location where the procedures were performed.

To determine whether the procedures were performed in a rural area, the agency’s analysis used the definition proposed by the petitioner – the U.S. Department of Agriculture’s (USDA) Business and Industry Guaranteed Loan program. “Rural areas are any areas other than:

- (1) A city or town that has a population of greater than 50,000 inhabitants; and
  - (2) The urbanized area contiguous and adjacent to such a city or town, as defined by the U.S. Bureau of the Census using the latest decennial census of the United States.”
- <http://eligibility.sc.egov.usda.gov/eligibility/welcomeAction.do?pageAction=rbs>

The designation of a place as rural or urban was based on the street address of the hospital where the mobile lithotripsy unit operated during 2013-2014. Lithotripsy equipment that operates in North Carolina may also operate in adjacent states. These proportions include only the procedures performed in North Carolina. Table 1 summarizes the number of procedures performed at each location and identifies the areas as either rural or urban (as of the 2010 Census). It shows that 39.4% of the procedures were performed in rural areas and 60.6% were performed in urban areas. Attachment A shows the number of procedures for each facility, by provider.

**Table 1. Mobile Lithotripsy Procedures Performed in North Carolina**

Provider (number of machines)	Number of Procedures				
	North Carolina			Out of State	Total Procedures
	Rural	Urban	Total North Carolina		
Carolina Lithotripsy (2)	655	705	1,360	0	1,360
Catawba Valley Medical Center (2)	563	0	563	0	563
Fayetteville Lithotripters (1)	315	178	493	100	593
Fayetteville Lithotripters (1)	92	0	92	220	312
Piedmont Stone Center (4)	1,290	2,160	3,450	816	4,266
Stone Institute of the Carolinas (2)	352	1,398	1,750	195	1,945
Triangle Lithotripsy Corp. (1)	215	910	1,125	0	1,125
<b>Total</b>	<b>3,482</b>	<b>5,351</b>	<b>8,833</b>	<b>1,331</b>	<b>10,164</b>
<b>% of Procedures by Type of NC Area</b>	<b>39.4%</b>	<b>60.6%</b>	<b>100.0%</b>		

Source: Table 9A, 2016 North Carolina State Medical Facilities Plan

The petitioner claims that rural areas are not well served by lithotripters. Since the lithotripter service area is the entire state, procedures performed in rural versus urban areas should be proportional to the population in rural and urban areas of the state.

Based on the 2010 census (see Table 3), 66 percent of North Carolina’s population is urban, using the Census Bureau’s standard definition of “urbanized Areas of 50,000 or more people and urban clusters of at least 2,500 and less than 50,000 people” (<https://www.census.gov/geo/reference/ua/urban-rural-2010.html>). This definition differs slightly from that used by the USDA.

**Table 2. North Carolina Urban and Rural Population, 2010**

	<b>N</b>	<b>Percent</b>
Urban	6,301,756	66.1%
Rural	3,233,727	33.9%
<b>Total Population</b>	<b>9,535,483</b>	<b>100.0%</b>

Source: U.S. Census Bureau.

([http://factfinder.census.gov/faces/tableservices/jsf/pages/productview.xhtml?pid=DEC\\_10\\_SF1\\_P2&prodType=table](http://factfinder.census.gov/faces/tableservices/jsf/pages/productview.xhtml?pid=DEC_10_SF1_P2&prodType=table))

Table 1 shows that 60.6 percent of procedures were conducted in urban areas and 39.4 percent were conducted in rural areas of North Carolina during 2013-2014. Table 2 shows that 66.1 percent of North Carolina’s population resides in urban areas and 33.9 percent resides in rural areas. The slight variation in the definition of rural and urban between the 2010 Census and that used by the USDA may yield slight variation in results. In addition, the lithotripsy procedure data does not identify the residence of the patients, but rather identifies the location of the service.

On a statewide basis, there does not appear to be a substantial disproportion in procedures performed in rural versus urban areas. The small imbalance indicates that more procedures are performed in rural areas than suggested by their proportion of the state population. Therefore, an access issue suggested by the petitioner does not appear to exist. Moreover, the 2016 SMFP reports a statewide need determination for one lithotripter, bringing the projected inventory to 15 machines. With the addition of the new machine, and given that the service area for lithotripters is statewide, the proposed policy may lead to duplication of resources. Finally, the petitioner may apply for the 2016 statewide need determination.

***Agency Recommendation:***

Given available information and comments submitted by the March 18, 2016 deadline for comments on petitions and comments, and in consideration of factors discussed above, the Agency recommends denial of the petition. The Agency supports the standard methodology for lithotripsy services.

## Attachment A: Mobile Lithotripsy Providers and Locations Served in North Carolina

### *Machines 2; Areas Generally Served: Eastern North Carolina*

<i>Facility and Location</i>	<i>Procedures</i>	<i>Rural</i>	<i>Urban</i>
CarolinaEast Medical Center, New Bern, NC	103	103	
Carteret General Hospital, Morehead City, NC	53	53	
Columbus Regional Healthcare System, Whiteville, NC	12	12	
Duke Raleigh Hospital, Raleigh, NC	10		10
FirstHealth Moore Regional Hospital, Pinehurst, NC	162	162	
FirstHealth Richmond Memorial Hospital, Rockingham, NC	25	25	
Halifax Regional Medical Center, Roanoke Rapids, NC	30	30	
Highsmith-Rainey Specialty Hospital, Fayetteville, NC	177		177
Johnston Health, Smithfield, NC	81	81	
Lenoir Memorial Hospital, Kinston, NC	21	21	
New Hanover Regional Medical Center, Wilmington, NC	201		201
Novant Health Brunswick Medical Center, Supply, NC	12	12	
Onslow Memorial Hospital, Jacksonville, NC	4		4
Rex Hospital, Raleigh, NC	125		125
Southeastern Regional Medical Center, Lumberton, NC	73	73	
Vidant Beaufort Hospital, Washington, NC	28	28	
Vidant Medical Center, Greenville, NC	138		138
WakeMed, Raleigh, NC	50		50
Wayne Memorial Hospital, Goldsboro, NC	17	17	
Wilson Medical Center, Wilson, NC	38	38	
<b>Total Procedures:</b>	<b>1,360</b>	<b>655</b>	<b>705</b>

### *Machines 2; Areas Generally Served: Western and Central North Carolina*

<i>Facility and Location</i>	<i>Procedures</i>	<i>Rural</i>	<i>Urban</i>
Carolinas HealthCare System- Blue Ridge, Morganton, NC	39	39	
Catawba Valley Medical Center, Hickory, NC	321	321	
Rutherford Regional Medical Center, Rutherfordton, NC	68	68	
Scotland Memorial Hospital, Laurinburg, NC	135	135	
<b>Total Procedures:</b>	<b>563</b>	<b>563</b>	

### *Machines 1; Areas Generally Served: Western North Carolina and South Carolina*

<i>Facility and Location</i>	<i>Procedures</i>	<i>Rural</i>	<i>Urban</i>
Charles George VA Medical Ctr, Asheville, NC	25		25
Harris Regional Hospital, Sylva, NC	118	118	
Haywood Regional Medical Center, Clyde, NC	112	112	
Margaret R Pardee Memorial Hospital, Hendersonville, NC	93		93
Park Ridge Health, Hendersonville, NC	60		60
St. Luke's Hospital, Columbus, NC	7	7	
The McDowell Hospital, Marion, NC	32	32	
Transylvania Regional Hospital, Brevard, NC	46	46	
<b>Total Procedures:</b>	<b>493</b>	<b>315</b>	<b>178</b>

***Machines 1; Areas Generally Served: Eastern North Carolina and Virginia***

<b><i>Facility and Location</i></b>	<b><i>Procedures</i></b>	<b><i>Rural</i></b>	<b><i>Urban</i></b>
Sentara Albemarle Medical Center, Elizabeth City, NC	24	24	
The Outer Banks Hospital, Nags Head, NC	17	17	
Vidant Chowan Hospital, Edenton, NC	51	51	
<b><i>Total Procedures:</i></b>	<b>92</b>	<b>92</b>	

***Machines 4; Areas Generally Served: Western and Central North Carolina and Virginia***

<b><i>Facility and Location</i></b>	<b><i>Procedures</i></b>	<b><i>Rural</i></b>	<b><i>Urban</i></b>
Alamance Regional Medical Center, Burlington, NC	186	186	
Annie Penn Hospital, Reidsville, NC	14	14	
Carolinas HealthCare System-Blue Ridge, Valdese, NC	94	94	
Davis Regional Medical Center, Statesville, NC	45	45	
High Point Regional Health System, High Point, NC	498		498
Hugh Chatham Memorial Hospital, Elkin, NC	182	182	
Iredell Memorial Hospital, Statesville, NC	144	144	
Lexington Medical Center, Lexington, NC	64		64
Maria Parham Medical Center, Henderson, NC	60	60	
Morehead Memorial Hospital, Eden, NC	172	172	
Northern Hospital of Surry County, Mount Airy, NC	50	50	
Novant Health Forsyth Medical Center, Winston-Salem, NC	116		116
Novant Health Rowan Medical Center, Salisbury, NC	213		213
Novant Health Thomasville Medical Center, Thomasville, NC	41		41
Piedmont Stone Center, Winston-Salem, NC	799		799
Randolph Hospital, Asheboro, NC	115	115	
Wake Forest Baptist Medical Center, Winston-Salem, NC	103		103
Watauga Medical Center, Boone, NC	144	144	
Wesley Long Hospital, Greensboro, NC	326		326
Wilkes Regional Medical Center, North Wilkesboro, NC	75	75	
Yadkin Valley Community Hospital, Yadkinville, NC	9	9	
<b><i>Total Procedures:</i></b>	<b>3,450</b>	<b>1,290</b>	<b>2,160</b>

***Machines 2; Areas Generally Served: Western and Central North Carolina***

<b><i>Facility and Location</i></b>	<b><i>Procedures</i></b>	<b><i>Rural</i></b>	<b><i>Urban</i></b>
Carolinas HealthCare System-Lincoln, Lincolnton, NC	60	60	
Carolinas Medical Center, Charlotte, NC	153		153
Carolinas Medical Center-Huntersville, Charlotte, NC	72		72
Carolinas Medical Center-Northeast, Concord, NC	220		220
Carolinas Medical Center-Pineville, Charlotte, NC	217		217
Carolinas Medical Center-Union, Monroe, NC	115		115
Carolinas Medical Center-University, Charlotte, NC	211		211
Caromont Regional Medical Center, Gastonia, NC	126		126
Cleveland Regional Medical Center, Shelby, NC	108	108	
Lake Norman Regional Medical Center, Mooresville, NC	184	184	
Novant Health Matthews Medical Center, Matthews, NC	197		197
Novant Health Presbyterian Medical Center, Charlotte, NC	87		87
<b><i>Total Procedures:</i></b>	<b>1,750</b>	<b>352</b>	<b>1,398</b>

***Machines 1; Areas Generally Served: East Central North Carolina***

<b><i>Facility and Location</i></b>	<b><i>Procedures</i></b>	<b><i>Rural</i></b>	<b><i>Urban</i></b>
Central Carolina Hospital, Sanford, NC	126	126	
Duke Regional Hospital, Durham, NC	28		28
Durham Ambulatory Surgical Center, Durham, NC	104		104
Nash General Hospital, Rocky Mount, NC	127		127
North Carolina Speciality, Durham, NC	13		13
Rex Hospital, Raleigh, NC	217		217
Rex Surgery Center, Cary, NC	168		168
Sampson Regional Medical Center, Clinton, NC	15	15	
WakeMed, Raleigh, NC	253		253
Wayne Memorial Hospital, Goldsboro, NC	74	74	
<b><i>Total Procedures:</i></b>	<b>1,125</b>	<b>215</b>	<b>910</b>

***Total Mobile Procedures Performed in North Carolina:*** 8,833

*From 2014 data as reported on the "2015 Lithotripsy Registration and Inventory Form for Mobile Equipment"  
Source: Table 9A, 2016 North Carolina State Medical Facilities Plan*