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Eastern Carolina Lithotripsy, Inc.
8161 Highway 100, PMB 170
Nashville, TN 37221

Ms. Martha Frisone, Assistant Chief
Ms. Tanya Rupp, Project Analyst
Healthcare Planning and Certificate of Need
Division of Health Service Regulation
2704 Mail Service Center
Raleigh, North Carolina 27699-2704

Re: Comments on Competing Applications for a Certificate of Need for one new Lithotripter in North Carolina; CON Project ID Numbers:

G-011200-16, Piedmont Stone Center
J-011201-16, Eastern Carolina Lithotripsy, Inc.

Dear Ms. Rupp and Ms. Frisone,

On behalf of Eastern Carolina Lithotripsy, Inc. ("ECL") Project ID# J-011201-16, thank you for the opportunity to comment on the above referenced applications for a new lithotripter to serve a statewide need in North Carolina.

We recognize that the Agency must base the decision for a Certificate of Need (CON) award for the proposed lithotripter on the CON health planning criteria, as outlined in G.S. 131E-183. We appreciate the complexity of reviewing competitive applications, and the careful thought it requires on the part of Agency staff. We request that the Agency give careful consideration to not only the standard competitive criteria that have been used in past competitive reviews for other services, but also to other critical factors that affect quality, value, and access in this important project.

Need for Lithotripsy in North Carolina

The Agency should pay particular attention to the need for lithotripsy services across various geographies in North Carolina. The planning service area for lithotripsy is the entire state of North Carolina; the two applications, one by ECL, and one by Piedmont Stone Center, LLC ("PSC"), propose to serve very different geographies. Both applications allow the Agency to adequately compare each proposal's response to need in their project service areas and determine which application will meet the needs of the greatest number of North Carolinians. Specifically:

- ECL's application calculates both total procedures needed and unmet need for lithotripsy procedures by county for all counties in North Carolina.

- PSC's application calculates unmet need in only two counties, Caldwell and Orange. PSC's estimates of need for these counties match the estimates of need provided by ECL exactly, suggesting that both applicants have a similar underlying approach to determining need (See Table 1).

Table 1 - Comparison of 2020 Total Need for Lithotripsy Procedures in Caldwell and Orange Counties

County	ECL Application (a)	PSC Application (b)
Caldwell	118	118
Orange	216	216

Sources:

a. *Referenced data in table called "Projected Expected Procedures at 2016 SMFP Use Rate, 2016-2020" in Exhibit 10 of ECL Application.*

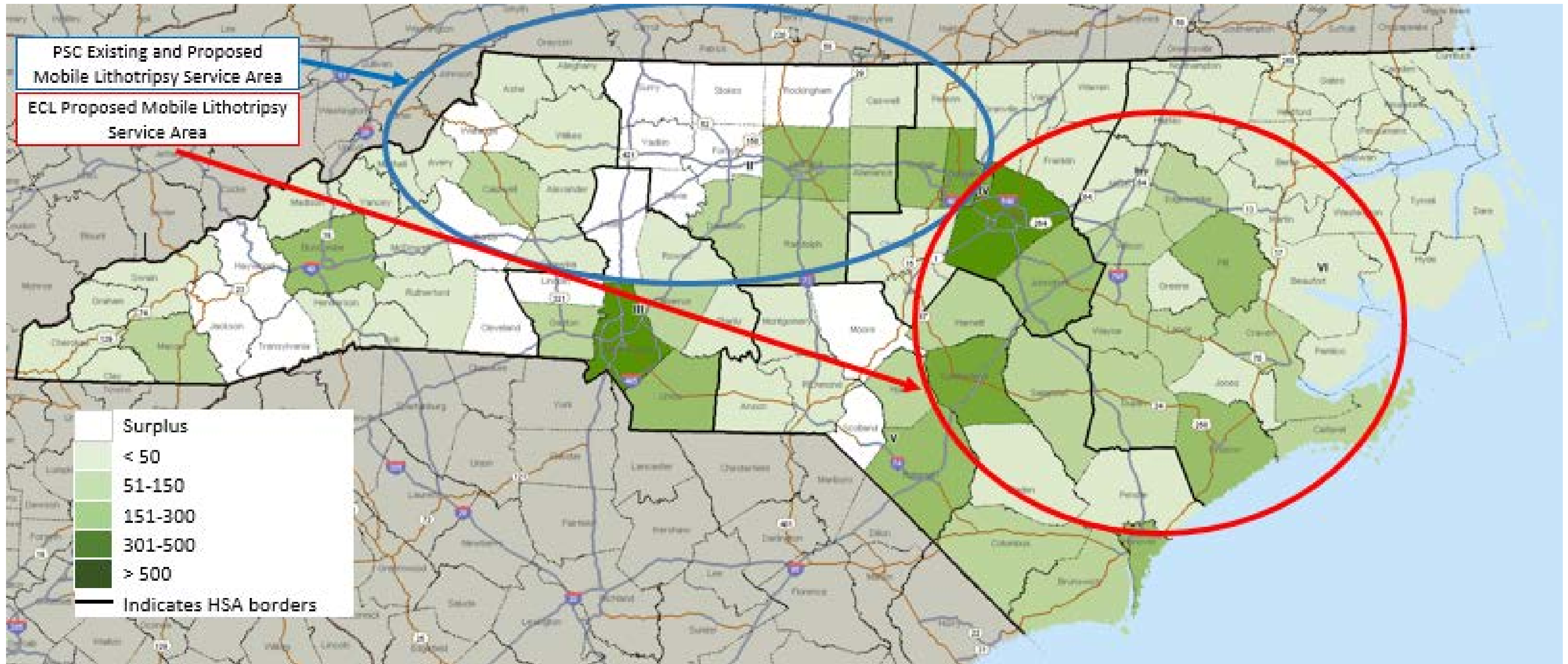
b. *PSC application, page 61, table "Urinary Stone Cases Appropriate for Lithotripsy."*

- While PSC's application *did not* calculate the need in any counties other than Orange and Caldwell, its methodology for calculating need in the population starts from the same basis as that of ECL. Because both applications endorse the same approach, the forecast use for *all counties* provided in ECL's application applies to both applications.
- ECL goes a step beyond PSC by estimating the number of lithotripsy procedures that current providers would absorb at historical service patterns. Exhibit 10 of ECL's application contains the difference between need and current use patterns by county.[1] Figure 1 in this letter uses Figure III.1 in ECL's application to illustrate the difference in county-level unmet need between the two applications.

As Figure 1 shows, PSC's existing and proposed service areas, with Caldwell and Orange counties added, are currently well served (white counties) in comparison to ECL's proposed service area in eastern North Carolina. Moreover, as shown in Table 2, ECL proposes to serve the county with the highest unmet need statewide, Wake.

[1] Referenced data in table "Projected Annual Procedure Surplus / (Deficit) by County" in Exhibit 10 of ECL Application.

Figure 1 - Unmet Need by County as Presented in Eastern Carolina Lithotripsy's Application



Notes:

a. *Source: ECL Application, Page 35, w/ Service Areas Circled.*

b. *Source data for map included in ECL Application, Exhibit 10.*

c. *Service Areas include proposed host and primary counties of patient origin.*

PSC does not specify the exact service area for its proposed new lithotripter. We assume it matches the counties in which it proposes to locate the new lithotripter. One could look at unmet need in PSC's apparent service area in two ways. Table 2 compares unmet need in the 12 PSC counties using data from ECL's application. Table 3 uses data from PSC's application to show unmet need in the same PSC counties.

Table 2 – Comparison of 2020 Unmet Need for Lithotripsy Procedures

County	ECL Proposed Service Area	PSC Apparent Service Area
Alamance		52
Beaufort	32	
Burke		(21)
Caldwell		78
Carteret	65	
Craven	82	
Cumberland	385	
Davidson		63
Duplin	80	
Durham	327	
Forsyth		(161)
Guilford		200
Harnett	125	
Johnston	170	
Jones	3	
Lenoir	51	
Nash	7	
Onslow	285	
Orange	192	192
Pamlico	12	
Randolph		52
Rockingham		(125)
Rowan		20
Sampson	67	
Surry		(75)
Wake	979	
Wilkes		11
Service Area Net Need	**2,863**	**286**

Source: ECL Application, Exhibit 10
Note: () = surplus

ECL application data clearly show that the ECL service area has the greater unmet need. Data included in the PSC application tell a similar story. Table 3 calculates the PSC unmet need from data on page 56 of the PSC application. Discussion of CON Review Criterion 3 in Attachment A contains further detail.

Both tables show that ECL will reach at least seven times more unmet need than PSC.

Table 3 - Unmet Need for Lithotripsy Procedures in PSC Service Area Using Information Provided in PSC Application

Proposed Host Site	County	Reported 2015 Procedures	Proposed Need in 2020	Unmet Need / Utilization Increase
		a	*b*	*c*
Novant Rowan	Rowan	220	226	6
Randolph Hospital	Randolph	138	142	4
Blue Ridge Valdese	Burke	184	189	5
Wesley Long	Guilford	315	323	8
Wilkes Regional	Wilkes	89	91	2
Alamance Regional	Alamance	175	180	5
Lexington Memorial	Davidson	50	51	1
Morehead Memorial	Rockingham	217	223	6
Hugh Chatham Memorial	Surry	149	153	4
Piedmont Stone Center	Forsyth	780	801	21
UNC Caldwell	Caldwell	0	118	118
UNCHHC	Orange	0	216	216
Total		***2,317***	***2,713***	***396***

Notes:

a. *PSC Application, Page 56*

b. *PSC Application, Pages 58-61, assumes no procedures were performed in Caldwell and Orange counties*

c. *b - a*

Out-of-State Service

ECL provides patient origin on page 68 of its application. Information on page 68 includes an "other" category, which includes both North Carolina counties and other states. Out-of-state origin was estimated using data from ECL Application, Exhibit 11. The maximum out of state origin reported for by the ASCs listed in Exhibit 11 was .02%. Therefore, ECL estimates no less than 99.8% of patients to be from North Carolina. PSC provided its proposed patient origin on page 79 of its application. It included six Virginia counties in the table on page 79. We conservatively assumed all of the "Other" reported on page 79 of the PSC application was other North Carolina counties. Clearly, serving less than 1 percent out-of-state is more responsive to North Carolina's statewide need than 12 percent.

CON Statute Findings of Fact: Considerations

Findings of Fact presented in the CON statute (G.S. 131E-175) stress the importance of providing services to communities with limited access.

Finding # 4 states:

> *"That the proliferation of unnecessary health service facilities results in costly duplication and underuse of facilities, with the availability of excess capacity leading to unnecessary use of expensive resources and overutilization of health care services."* Finding # 6 states: *"That excess capacity of health service facilities places an enormous economic burden on the public who pay for the construction and operation of these facilities as patients, health insurance subscribers, health plan contributors, and taxpayers."*

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Findings # 7 states:

> *"That the general welfare and protection of lives, health, and property of the people of this State require that new institutional health services to be offered…in order that only appropriate and needed institutional health services are made available in the area to be served.*

As noted previously and described throughout these comments, the area PSC proposes to serve is comparatively well served and has far less need for more capacity. Approving the PSC application would be inconsistent with Findings of Fact #4, #6, and #7, and multiple CON review criteria.

Competitive Overview

ECL was not able to find an example of a competitive lithotripsy CON review. As a result, we were not able to find precedent for comparative review criteria for lithotripsy. However, there are a number of comparison categories that the Agency typically uses to compare applications:

- Geographic accessibility;
- Access to underserved groups;
- Demonstration of need;
- Revenues;
- Operating expenses; and
- Competition (existing services operated by each applicant).

Other than the traditional comparative metrics for CON reviews, a few additional comparative measure categories will also be important in the lithotripsy review. These include:

- Patients served within North Carolina; and,
- Availability of anesthesia service.

The following summary presents a strong and reasonable comparison of the two applications with regard to value elements. It the gives the applicant with the preferable metric a score of "1," and gives the other a "0"; identical scores each receive a "1."

The Agency sometimes uses staffing metrics. However, in the case of Lithotripsy services, staffing related metrics would not yield a useful comparison. Lithotripsy providers often differ in the business model used to deliver services, as is the case with the two models proposed by ECL and PSC. Therefore, staffing metrics across the two applications are not comparable.

Table 4 - Comparison of Two Applications using Suggested Comparison Criteria: Scoring

Measure	ECL	PSC
Demonstrated 2020 Need for Lithotripsy Procedures in Proposed Service Area	1	0
Average Self-Pay Write-off (Charity)	1	0
Value of Charity Care	1	0
Medicare and Medicaid	1	0
Cost per procedure	1	0
Total Utilization	1	0
Capital Costs	1	0
Percentage of Proposed Patients from NC	1	0
Number of Lithotripters Currently Owned by Applicant or Affiliated Entity	1	0
Anesthesia Availability	1	0
Total Score	***10***	***0***

Table 4 shows the actual results for each metric. Important explanations or clarifications for some of the metrics follow the table.

Table 5 - Comparison of Two Applications using Suggested Comparison Criteria: Year Two Values

Notes	Measure	ECL	PSC
a	Demonstrated 2020 Need for Lithotripsy Procedures in Proposed Service Area	2,863	396
b	Average Year 2 Self-Pay Write-off (for a self-pay patient)	95.0%	23.0%
c	Total Year 2 Value of Charity Care	$41,749	$17,567
d	Year 2 Medicare and Medicaid Percent	42.5%	40.3%
e	Year 2 Cost per procedure	$986	$2,286
f	Year 3 Total Utilization	1,090	1,045
g	Capital Costs	$973,049	$1,368,634
h	Year 2 Percentage of Proposed Patients from NC	99.8%	87.8%
i	Number of Lithotripters Currently Owned by Applicant of Affiliated Entity	1	4
j	General Anesthesia Availability	Yes	No

Notes:

a. *See Table 2 for ECL and Table 3 for PSC, in these comments.*

b. *Write-off = (Avg. Self Pay Gross Rev (FORM D) – Avg. Self Pay Net Rev (FORM E)) / Avg. Self Pay Gross Rev. (FORM D).*

   ECL Write-off = ($1,900 - $95) / $1,900 = ***95%****.*

   PSC Write-off = ($4,500 - $3,465) / $4,500 = ***23%****.*

c. *Based on information for charity care provided in Section VI of both applications.*

d. *Based on information for payer mix provided in Section VI of both applications.*

e. *Cost per procedure = Total Operating Expenses (FORM B) / Total Procedures (FORM B).*

   ECL cost per procedure = $1,063,505 / 1,079 = ***$986.***

   PSC cost per procedure = $1,785,449 / 781 = ***$2,286.***

f. *Based on information for utilization provided in Section IV of both applications.*

g. *Based on information for total capital costs provided in Section XIII of both applications.*

h. *See discussion in section "Out of State Service".*

i. *For information purposes, Eastern Carolina Lithotripsy, Inc. does not own another lithotripter in North Carolina, however its management company, American Diagnostics, Inc. also manages Triangle Lithotripsy Corporation, which owns one lithotripter in North Carolina (see page 17 of ECL Application). PSC owns four lithotripters in North Carolina.*

j. *See discussion in Attachment A under "PSC Makes No Mention of the Provision of Anesthesiologist or CRNA Services*

Non-Conforming PSC Application

In addition to a lower comparative rating, the Agency should deny PSC's application because it is non-conforming with Statutory Review Criteria 3, 4, 6, 8, and 9. As noted above, we believe the Agency should pay particular attention to the issue of need. Criterion 3 asks that applicants identify a population to be served, and demonstrate need of that population for the services being proposed. PSC's application neither identifies its population to be served, nor demonstrates need in the population which it could be expected to serve. The need determination in the *2016 SMFP* alone is not enough to meet Criterion 3. Need for lithotripsy services in 2016 does not distribute across the state evenly. Some areas have a heavy concentration of services and use more lithotripsy services than others use. PSC failed to demonstrate that this is because those areas *need* more lithotripsy services due to a higher incidence of urinary stone disease. It is more likely because supply in those well-served areas is already high enough. Piedmont Stone Center operates in one of these areas. It owns four lithotripters, more than any other organization in the state. The data presented in ECL's application make it clear: Piedmont's existing service area, in the Triad, Northwestern North Carolina, and Southwestern Virginia, already receives a disproportionate amount of lithotripsy service.

Detailed discussions in Attachment A to this letter elaborate on this, and other reasons why the Agency should not award the lithotripsy Certificate of Need to Piedmont Stone Center, LLC. Attachment B contains a letter from Harnett Health indicating its interest in becoming a host site for ECL. Attachment C includes additional letters of support for ECL's application.

Conclusion

Based on facts presented in both applications, and additional factors discussed in these comments and attachments, it is clear that the Agency should award Eastern Carolina Lithotripsy, Inc. the Certificate of Need. Unlike the application filed by the Piedmont Stone Center, LLC, ECL's application:

- Adequately demonstrates need for the services it proposes;
- Proposes to bring a lithotripter to the most underserved part of the state: eastern North Carolina;
- Proposes to provide over 99 percent of service to North Carolinians;
- Provides for substantial discounts for the uninsured; and
- Provides an efficient, low cost service.

Thank you for your time and consideration. Please do not hesitate to contact me if you have any questions.

Sincerely,

David B. Driggs
President
Eastern Carolina Lithotripsy, Inc.

Attachment(s)

Attachments

Competitive Review of Piedmont Stone Center's Application...A
Letter of Support from Harnett Health...B
Additional Letters of Support C

Attachment A

Competitive Review of –
Piedmont Stone Center, application for Mobile Lithotripter
Project ID# G-011200-16

Competitive Review of –
Piedmont Stone Center, Application for Mobile Lithotripter
Project ID# G-011200-16

OVERVIEW

Piedmont Stone Center, PLLC's ("PSC") application to acquire a fifth mobile lithotripter to service primarily its existing service area, is non-conforming with GS 131E-183(a) CON statutory review criteria 3, 4, 6, 8, and 9.

CON REVIEW CRITERIA

3. The applicant shall identify the population to be served by the proposed project, and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and, in particular, low income persons, racial and ethnic minorities, women, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.

PSC Fails to Adequately Identify the Population It Proposes to Serve

PSC's projected patient origin on page 79 of its application appears to be patient origin for its entire business, *not* for the new lithotripter.

GS 131E-176(20) defines, in statute, "Project" as,

> *"a proposal to undertake a capital expenditure that results in the offering of a new institutional health service as defined by this Article."*

It goes on to state,

> *"[a] project, or capital expenditure project, or proposed project may refer to the project from its earliest planning stages up through the point at which the specified new institutional health service may be offered."*

The new institutional health service that PSC proposes is one new mobile lithotripter. PSC owns four mobile lithotripters. Therefore, the "proposed project" is the new lithotripter, and not the existing plus new lithotripter.

Criterion 3 requires that an applicant identify the population to be served by the "proposed project." On page 79 of its application, PSC provides the proposed patient origin for FY2018 and FY2019 for "Piedmont Stone Center," which presumably includes the patient origin for *all* PSC owned lithotripters. One cannot discern from this information the proposed patient origin for the proposed project. PSC did not provide the projected patient origin for the new lithotripter elsewhere in the application. As result, PSC does not adequately identify the population to be served by the proposed project.

If the information provided on page 79 is interpreted to match the proposed patient origin for the new lithotripter, then PSC proposes that 12.2 percent of its patients receiving service on the new lithotripter will be from Virginia, which is outside the health service area. Please see discussion under Criterion 9.

PSC Fails to Demonstrate Adequate Need in the Population Most Likely to be Served

PSC projects need in two ways. First, it projects need for lithotripsy at existing PSC host sites for which it proposes to expand service. Second, it projects need for lithotripsy at two new host sites, UNC Hospital Hillsborough Campus ("UNCHHC") and UNC Healthcare Caldwell ("UNC Caldwell").

On pages 54 through 59 of its application, PSC explains its methods for projecting lithotripsy need at the existing host sites. PSC uses a four-year projected compound annual population growth rate of 0.53 percent to forecast lithotripsy procedures from FY2015 to FY2020 for the counties in which the existing host sites are located. The table on pages 58 and 59 of the PSC application show the results of this method for each host site, shown as "*Procedures Based on 0.53% Growth Rate*." PSC also projects additional procedures, above and beyond those attributed to population growth. It categorizes these additional procedures as "incremental growth" for each host site.

Page 57 explains that the "Incremental Growth" is based on the assumption that lithotripsy procedures at the *"selected host sites will increase an average of two, three, and four procedures per day at the selected host sites [sic]."* PSC provides no further explanation for this increase. "Incremental Growth" does not represent need. It does not relate to population growth, incidence of urinary stone disease, or increasing demand for procedures at these selected host sites. The underlying assumption, though not stated, is if PSC adds days to its host sites, more lithotripsy procedures will simply appear, regardless of need. In fact, through its own population growth methodology, PSC illustrated only a modest amount of additional need for lithotripsy procedures at the selected existing host sites by 2020.

Page 60 of its application contains PSC's need methodology for lithotripsy procedures at the new sites, UNC Caldwell and UNCHHC. This methodology uses the annual incidence rate for urinary stone disease, 16 per 10,000 population, applied to population projections for Caldwell and Orange Counties, and the assumption that 90 percent of urinary stone disease cases are appropriate for lithotripsy. The result is a need for 118 lithotripsy cases in Caldwell County and 216 lithotripsy cases in Orange County. This methodology is reasonable for calculating need, though it may overstate unmet need.

Taken together, the two methods of need calculation presented in PSC's application indicate a maximum unmet need (and thus plausible increase in annual utilization) of 396 procedures for the 12 counties of its proposed host site locations. Table 1 summarizes data from the PSC application.

Table 1 - Total Unmet Need for Lithotripsy Procedures in Selected Host Sites Counties as Presented in PSC Application

Proposed Host Site	Host County	2015 Procedures	Need in 2020	Unmet Need / Possible Utilization Increase
		a	*b*	*c*
Novant Rowan	Rowan	220	226	6
Randolph Hospital	Randolph	138	142	4
Blue Ridge Valdese	Burke	184	189	5
Wesley Long	Guilford	315	323	8
Wilkes Regional	Wilkes	89	91	2
Alamance Regional	Alamance	175	180	5
Lexington Memorial	Davidson	50	51	1
Morehead Memorial	Rockingham	217	223	6
Hugh Chatham Memorial	Surry	149	153	4
Piedmont Stone Center	Forsyth	780	801	21
UNC Caldwell	Caldwell	0	118	118
UNCHHC	Orange	0	216	216
Total		***2,317***	***2,713***	***396***

Notes:

a. *PSC Application, Page 56*

b. *PSC Application, Pages 58-61, assumes no procedures were performed in Caldwell and Orange counties*

c. *b - a*

PSC Fails to Properly Calculate Need

PSC lays out a methodology for lithotripsy need for Caldwell and Orange Counties on page 60, culminating in a table showing *"Urinary Stone Cases Appropriate for Lithotripsy"* for the two counties. Its shows need for 118 and 216 cases in Caldwell and Orange Counties, respectively. PSC derived these figures from an estimated annual incidence rate of 16 urinary stone cases per 10,000 population. PSC fails to consider that many people from Orange and Caldwell Counties who have urinary stone disease may receive service in other counties. While patient origin data for existing lithotripsy services in North Carolina are not available, ECL estimated the number of procedures by county of origin in Exhibit 10 of its application by using a proximity allocation commonly used in population analysis.[1] From those data, ECL estimates residents of Caldwell and Orange counties received 40 and 22 lithotripsy procedures, respectively in 2015.

By failing to consider the number of procedures obtained by Caldwell and Orange County residents outside the county, PSC overestimates unmet need for those counties.

Criterion 3 Summary

PSC's need methodology is insufficient. PSC elected to create a need methodology for Caldwell and Orange Counties that differs from its methodologies for the other host site counties. Had it calculated and shown the *actual unmet need for lithotripsy services* in all the counties it proposes to serve, PSC would have shown there *is minimal need* in most of its proposed host site counties. Rather than illustrate minimal need, PSC chose to provide an incomplete analysis of need in its service area.

PSC fails to:

- identify the population to be served;
- demonstrate need for residents of PSC's existing host sites at which PSC will expand service; and
- properly calculate need for Caldwell and Orange Counties.

For these reasons, PSC's application does not conform to Criterion 3.

[1] Referenced data in table *"Estimated Patients Served 2015"* in Exhibit 10 of ECL Application. Method also used by County Health Rankings.

4. Where alternative methods of meeting the needs for the proposed project exist, the applicant shall demonstrate that the least costly or most effective alternative has been proposed.

PSC Fails to Demonstrate That Its Proposal Represents the Least Costly or Most Effective Option

On page 74 and 75 of its application, PSC identifies two alternatives:

1. *"Serve the Identified Population Via Existing Piedmont Stone Center Lithotripters",* and
2. "*Establish Different Host Sites for the Proposed Lithotripter."*

As discussed in Criterion 3, PSC did not adequately establish the need for the proposed project in its service area. Assuming need exists PSC is required to show that alternatives are less costly and more effective than the proposed project.

The first alternative is, indeed, less costly and more effective than the proposed project. According to page 38 of its application, PSC completed 707 lithotripsy procedures at host sites located in Virginia in 2015.

Table 2 - Piedmont Stone Center Mobile Lithotripsy Procedures in Virginia

PSC Virginia Host Site Location	2015 Procedures
Twin County	84
Lynchburg General	251
Martha Jefferson	203
Memorial Hospital of Martinsville	124
Montgomery Regional	26
Carilion New River	19
VA Total	***707***

Source: PSC Application, Page 38

As illustrated in the Criterion 3 discussion, and according to PSC's application, the proposed host site counties will need, at most, capacity for 396 additional lithotripsy procedures by 2020, well below the 707 annual procedures currently provided by PSC in Virginia. Shifting service from Virginia back to North Carolina would easily meet the need in the North Carolina counties that PSC proposes to serve with the new lithotripter.

PSC also dismissed the alternative to propose different host sites. The existing use rate for lithotripsy provides a measure of how well a county receives service. Using PSC's own data, we estimate that 13 of the 24 primary counties served by PSC in 2015 had use rates higher than the annual lithotripsy use rate in its own need calculation for Caldwell and Orange counties (14.4 per 10,000 population).[2] These counties are appropriately served *already*. Of PSC's selected host site counties, four had 2015 use-rates higher than 14.4. Two of PSC's current host site counties, Iredell (Iredell Memorial), and Watauga (Watauga Medical Center), appear to have lithotripsy use rates much lower than 14.4 per 10,000 population and therefore appear to be much better candidates for increased service. Moreover, many other counties across North Carolina that PSC does not currently serve have much greater need for the service than many of PSC's proposed host sites. Yet PSC proposes to serve existing sites in counties with already high rates of use. PSC owns four lithotripters and is accustomed to managing truck schedules in a large geographic region. PSC has scheduling components to provide service to different host sites, which would more effectively serve the needs of North Carolinians.

[2] On page 60 of its application PSC estimates the incidence rate for urinary stone disease to be 16 per 10,000 population. It further reduces the total estimated cases of urinary stone disease by 90 percent to represent the total cases appropriate for Lithotripsy. Using this method, the actual estimated lithotripsy use rates are 14.4 procedures per 10,000 population (16 * 90% = 14.4). Of note, ECL and the 2016 SMFP used the exact same methodology.

Table 3 - Estimated 2015 Lithotripsy Use Rates in Counties Currently Served by PSC

County	2015 Population	2015 PSC Procedures	Estimated Procedures per 10,000 Population	PSC New Lithotripter Host Site?
	a	*b*	*c*	*d*
Forsyth	367,853	514	13.98	x
Guilford	516,415	489	9.47	x
Davidson	164,927	272	16.47	x
Randolph	143,666	230	16.00	x
Surry	73,834	176	23.78	x
Wilkes	70,000	150	21.50	x
Alamance	157,624	184	11.67	x
Rowan	138,710	159	11.45	x
Pittsylvania (VA)	63,628	150	23.65	
Henry (VA)	54,166	138	25.47	
Rockingham	92,543	121	13.10	x
Iredell	169,281	138	8.15	
Burke	89,198	96	10.78	x
Campbell (VA)	56,318	121	21.52	
Yadkin	37,655	113	29.97	
Orange	141,599	-	0.00	x
Albemarle (VA)	106,982	96	8.99	
Stokes	46,787	92	19.66	
Davie	41,475	84	20.16	
Carroll (VA)	30,277	63	20.71	
Caldwell	82,391	54	6.60	x
Bedford (VA)	6,420	50	78.13	
Ashe	27,482	46	16.73	
Watauga	53,314	46	8.62	

Notes:

a. *NC Office of State Management and Budget for NC Counties; Virginia Labor Market Information*

b. *PSC Application, Page 38*

c. *b / a / 10,000; Conservative estimate; Assumes PSC has 100% market share*

d. *PSC Application, Pages 58, 59, and 62*

e. *Highlighted cells show use rates above 14.4 per 10,000.*

Table 3 assumes PSC provides all of the lithotripsy services obtained by residents of these counties. In truth, other providers may serve residents at locations in other counties. Therefore, the data in Table 3 are likely conservative estimates and understate use rates.

In summary, PSC's own, identified alternatives are both less costly and more effective solutions to serve the need for additional lithotripsy services in North Carolina. PSC fails to conform to Criterion 4.

6. The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

PSC Proposes to Duplicate Existing Resources

Many of the counties in which PSC proposes to locate its new scanner have high lithotripsy use rates suggesting each currently receives adequate service. By *adding* lithotripsy services to these, high-use counties, PSC would increase 2019 lithotripsy use-rates in some counties to over *twice* the standard, SMFP-based incidence rate of 14.4 per 10,000 population. Table 4 shows that, according to PSC's application, seven of the twelve proposed host site counties will have use rates over 14.4 per 10,000 population in 2019.

Table 4 - Projected 2019 Lithotripsy Use Rates in Counties Currently Served by PSC

County	2019 Population	2019 Projected PSC Procedures	Estimated Procedures per 10,000 Population	PSC New Lithotripter Host Site?
Notes:	***a***	***b***	***c***	***d***
Forsyth	383,601	559	14.58	x
Guilford	531,454	539	10.14	x
Davidson	166,815	458	27.48	x
Randolph	146,020	343	23.46	x
Surry	73,833	262	35.48	x
Wilkes	70,468	262	37.18	x
Alamance	165,388	217	13.10	x
Rowan	138,710	161	11.62	x
Pittsylvania (VA)	63,726	151	23.72	
Henry (VA)	54,179	136	25.11	
Rockingham	92,543	141	15.24	x
Iredell	177,765	136	7.65	
Burke	89,197	136	15.25	x
Campbell (VA)	57,528	121	21.02	
Yadkin	36,962	116	31.35	
Orange	148,257	156	10.53	x
Albemarle (VA)	113,856	96	8.41	
Stokes	46,787	91	19.38	
Davie	41,470	86	20.65	
Carroll (VA)	30,466	60	19.84	
Caldwell	82,250	76	9.19	x
Bedford (VA)	6,584	50	76.52	
Ashe	27,596	45	16.43	
Watauga	54,874	45	8.26	

Notes:

a. *NC Office of State Management and Budget for NC Counties; Virginia Labor Market Information*
b. *2019 PSC Patient Origin Percent for Each County (PSC Application, Page 79) * Total 2019 Piedmont Utilization (PSC Application, Page 84)*
c. *b / a / 10,000; Conservative estimate; Assumes PSC has 100% market share*
d. *PSC Application, Pages 58, 59, and 62*
e. *Highlighted cells exceed 14.4.*

Quite clearly, PSC is duplicating its own service in counties such as Davidson, Randolph, Surry, and Wilkes. PSC provides no information to demonstrate reasons why these counties need additional services. PSC provides no evidence that lithotripsy use rates would be as high as 37 per 10,000 population (Wilkes). The more likely scenario for PSC will be that its increased service does not result in the increased volumes it projects.

By deciding to locate its proposed lithotripter in multiple counties that exceed its own benchmark, PSC demonstrates that it *will* duplicate resources and therefore fails to conform to Criterion 6.

8. The applicant shall demonstrate that the provider of the proposed services will make available, or otherwise make arrangements for, the provision of the necessary ancillary and support services. The applicant shall also demonstrate that the proposed service will be coordinated with the existing health care system.

PSC Does Not Adequately Describe Provision of Ancillary Resources

Section II.2 of the CON application asks an applicant to provide evidence that it will provide necessary support and ancillary services. PSC provides a list of proposed ancillary services, but fails to describe how, or where, it will provide patient preparation and recovery. Lithotripsy patients require private space for procedure preparation activities such as changing clothes, education, and medication administration. Because lithotripsy procedures involve sedation or analgesic therapy, patients require recovery space accompanied by a nurse. Recovery is similar to minor surgeries. Preparation and recovery are vital components of lithotripsy service. PSC does not provide a description of how prep and recovery will be provided to its patients. It is impossible to determine where these activities occur and which will staff complete them.

PSC Does Not Adequately Describe Provision of Anesthesiologists or CRNA Services

On page 109 of its application, PSC states, *"The RN administers conscious sedation."* This is the only mention of sedation or anesthesia of any kind in the application. Although an RN, under the supervision of a physician, urologist in this case, may deliver conscious sedation via intravenous drugs such as midazolam or fentanyl, many lithotripsy patients can be better served by the use of general anesthesia. Many studies have confirmed the comparative effectiveness of general anesthesia in lithotripsy (ESWL) procedures.[3,4,5,6] These studies have found the success rate for ESWL, e.g. the percent of cases that result in destroyed stones, to be higher when general anesthesia is used, than when the procedure involves conscious or oral sedation.

ESWL creates powerful shocks to the kidney and ureters.[7] Studies hypothesize that patients not fully anesthetized during lithotripsy are more likely to move during the procedure, often through involuntary movements, or respiratory variation. When a patient moves during the procedure, focus of the shockwave is at risk of diverting away from the stone, causing unnecessary kidney tissue damage. Ultimately the choice of sedation versus anesthesia is between physician and patient. PSC does not appear to provide the option of general anesthesia for its patients. General anesthesia for ESWL is common. Anesthesia services, though not always necessary, should always be an option for lithotripsy patients.

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[3] **Sorensen C**, Chandhoke P, Moore M, et al. Comparison of intravenous sedation versus general anesthesia on the efficacy of the Doli 50 lithotriptor. J Urol. 2002;**168**:35-37.
[4] **Eichel L**, Batzold P, Erturk E. Operator experience and adequate anesthesia improve treatment outcome with third-generation lithotripters. J Endourol. 2001;**15**:671-673
[5] **Semins, J**, Matlaga B. Strategies to optimize shock wave lithotripsy outcome: Patient selection and treatment parameters. World J Nephrol 2015: **4(2):** 230-234
[6] **McClain P**, Lange J, Assimos D. Optimizing Shock Wave Lithotripsy: A Comprehensive Review. Rev Urol. 2013: **15(2)**:49-60.
[7] **Semins, J**, Matlaga B. Strategies to optimize shock wave lithotripsy outcome: Patient selection and treatment parameters. World J Nephrol 2015: **4(2):** 230-234

Criterion 8 Summary

To aid in the discussion of ancillary resources, Table 5 provides a comparison of patient flow between ECL and PSC, which operate distinctly different models:

Table 5 - Comparison of Patient Flow in Proposed PSC and ECL Applications

Step	PSC		ECL	
	Location	Staff	Location	Staff
Registration	Truck?	?	Hospital Registration	Hospital Staff
Preparation	Truck?	?	Hospital Pre-Procedure Surgical Prep	Hospital Surgical RNs
Anesthesia / Sedation Administration	Truck	RN	Truck	Anesthesiologist / CRNA
Procedure	Truck	Litho Tech	Truck	ECL Litho Tech
Recovery	Truck?	?	Hospital Post-Surgical Recovery	Hospital Surgical RNs
Discharge	Truck?	?	Hospital	Hospital Staff

PSC did not demonstrate that is has made arrangements for the necessary ancillary services. By not adequately demonstrating how prep and recovery services will be provided to patients or showing the availability of general anesthesia services, PSC fails to conform to Criterion 8.

9. An applicant proposing to provide a substantial portion of the project's services to individuals not residing in the health service area in which the project is located, or in adjacent health service areas, shall document the special needs and circumstances that warrant service to these individuals.

PSC Fails to Describe the Special Needs of Proposed Virginia Patients

Table 6 summarizes PSC's projected patient origin. As discussed in Criterion 3, PSC provided projected patient origin for what appears to be all PSC lithotripsy sites for FY2018 and FY2020. It did not state that the origin information provided was explicitly for the new lithotripter. If the patient origin information is for the new lithotripter, PSC will provide more than one in ten of its procedures to Virginia patients. Criterion 9 requires PSC to explain its service to patients residing out of area.

Table 6 - Piedmont Stone Center Patient Origin by State

County	2018	2019
Pittsylvania (VA)	3.10%	3.00%
Henry (VA)	2.90%	2.70%
Campbell (VA)	2.50%	2.40%
Albemarle (VA)	2.00%	1.90%
Carroll (VA)	1.30%	1.20%
Bedford (VA)	1.10%	1.00%
Total Virginia	**12.90%**	**12.20%**
Total North Carolina	**87.10%**	**87.80%**
Total	***100.00%***	***100.00%***

Source: PSC Application, Page 79

Criterion 9 uses the term "service area." Applicable definitions of "service area" include:

- NCGS 131E-176 (24a) -*"the area of the State, as defined in the State Medical Facilities Plan or in rules adopted by the Department, which receives services from a health service facility;"* and,
- Chapter 9, p122, of the *2016 State Medical Facilities Plan - "A lithotripter's service area is the lithotripter planning area in which the lithotripter is located. The lithotripter planning area is the entire state."*

Other services regulated by CON, such as Acute Care Beds and Linear Accelerators, use alternate definitions of service area, specifically defined by the current *SMFP*. Some alternatives include:

- A single county;
- *SMF*P designated county groups; or
- The six statewide defined "Health Service Areas" (HSAs).

However, no definition of "service area" in the *2016 SMFP* includes areas outside of North Carolina. Therefore, PSC did not document the special needs and circumstances for the 12.2 percent of its patients from Virginia, as required by Criterion 9. If its proposed patient origin is, indeed, for the proposed new lithotripter, PSC fails to conform to Criterion 9.

Attachment B

Letter of Support: Harnett Health

Harnett Health

P.O. Box 1706
Dunn, NC 28335
(910) 892-1000
www.HarnettHealth.org

Date: 7/29/2016

Ms. Martha Frisone
Assistant Chief
Healthcare Planning and Certificate of Need Section
Division of Health Service Regulation
2704 Mail Service Center
Raleigh, NC 27699-2704

RE: Host Site / Support Letter for the Certificate of Need application filed by Eastern Carolina Lithotripsy to develop and operate a new Mobile Lithotripsy Unit in North Carolina.

Dear Ms. Frisone:

I am the President of Harnett Health and am writing this letter to express support for the Certificate of Need application filed by Eastern Carolina Lithotripsy, an associate of Triangle Lithotripsy Corporation, to develop and operate a new Mobile Lithotripsy in North Carolina.

Triangle Lithotripsy Corporation has been providing extracorporeal shock wave lithotripsy (ESWL) services in North Carolina for over 25 years and has a strong reputation for delivering quality ESWL services. By drawing from the experience of Triangle Lithotripsy Corporation, and increasing access to services in central and eastern North Carolina, Eastern Carolina Lithotripsy will be able to expertly serve a growing patient demand for non-invasive kidney stone treatment.

There currently are no lithotripsy services provided in Harnett County. If approved, Harnett Health would consider a contract with Eastern Carolina Lithotripsy to provide access to these services for our patients. We have a pad prepared for mobile services at both our Betsy Johnson and Central Harnett Hospital campus locations.

We can provide the required ancillary services, such as billing, registration, housekeeping, patient recovery, radiology, anesthesia, and laboratory. Our transfer and blood product policies would apply to this service.

We have not experienced any licensure revocations or CMS Medicare / Medicaid termination of provider agreements.

This is an excellent proposal for an important service in an underserved area. I urge the Division of Health Service Regulation to approve the Eastern Carolina Lithotripsy application.

Sincerely,

Kevin Jackson
President
Harnett Health

Attachment C

Additional Letters of Support

CAROLINA UROLOGY HEALTHCARE, PLLC
417 Vance Street – Suite B, Clinton, NC 28328-4001
Phone: (910) 590-3569 Fax: (910) 592-3525
Robert W. Reagan, Jr. MD   Frankie L. Britt, FNP-BC

Date: 07/29/2016

Ms. Martha Frisone
Assistant Chief
Healthcare Planning and Certificate of Need Section
Division of Health Service Regulation
2704 Mail Service Center
Raleigh, NC 27699-2704

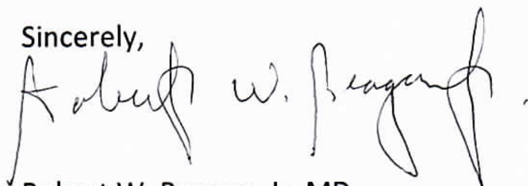
RE: Eastern Carolina Lithotripsy's application to develop and operate a new mobile lithotripsy unit serving eastern North Carolina, including Sampson County

Dear Ms. Frisone:

I recently submitted a letter to the Agency in support of Eastern Carolina Lithotripsy, Inc.'s proposal to add one new lithotripter in North Carolina. I am a urologist practicing in Sampson County, a county with over 60,000 people. I feel that having more options for times for ESWL treatment absolutely would be a benefit to the citizens of Sampson and surrounding counties. As noted in the earlier letter, I perform approximately 100 ureteroscopies per year on patients who would be candidates for less-invasive lithotripsy, if it were available. Unfortunately, the hospital at which I practice, Sampson Regional Medical Center ("SRMC"), has limited access to mobile lithotripsy services, sometimes only a few days a month. As a result, lithotripsy is often unavailable for my patients. Eastern Carolina Lithotripsy ("ECL") proposes to add two to four days per month at SRMC, a substantial increase in access. Increased referrals from my practice alone could justify two additional days per month.

As a general practice, SRMC board and administrative officials are reluctant to get involved and support one vendor over another in competitive Certificate of Need applications. However, I strongly support the inclusion of additional days from ECL and will work with SRMC administration and board to add service days from ECL when the Certificate of Need is granted. Having a unit at the hospital on a regular schedule will help my patients and the hospital. Because the price structure is so accommodating to charity and government patients, and because ECL rates are very market competitive, it should be easy to develop a contract. Having talked with administration, I believe SRMC shares my desire to improve the health of our community by providing the best healthcare resources possible right here in Sampson County. ECL will further this aim.

Sincerely,



Robert W. Reagan, Jr. MD
Carolina Urology Healthcare, PLLC

North Carolina General Assembly
House Of Representatives

REPRESENTATIVE GARY H. PENDLETON
49TH DISTRICT - WAKE COUNTY

July 27, 2016

Ms. Martha Frisone, Assistant Chief
Healthcare Planning and Certificate of Need Section
Division of Health Service Regulation
2704 Mail Service Center
Raleigh, NC 27699-2704

RE: Letter in support of Eastern Carolina Lithotripsy's CON Application for one lithotripter in the statewide service area in the 2016 State Medical Facilities Plan

Dear Ms. Frisone:

I am writing this letter to express support for the CON application filed by Eastern Carolina Lithotripsy ("ECL") for the pending 2016 CON. I grew up in Eastern North Carolina and spend a lot of time there. As you know, Eastern North Carolina is suffering from lack of medical care.

ECL is an affiliated company of Triangle Lithotripsy Corporation ("TLC"), which has been providing lithotripsy services in North Carolina for over 25 years and has a strong reputation for delivering quality services.

As anyone who has had a kidney stone knows, it is painful and treatment cannot come soon enough. While many with kidney stones receive alternative treatments such as invasive ureteroscopy, lithotripsy provides a non-invasive, highly effective treatment for kidney stones. Yet, access across the state is not uniform. Certain areas of the state enjoy better access than others. In particular, eastern North Carolina, as ECL's application shows, has a deficit of access to lithotripsy. The lack of availability in certain areas is due, in part, to the fact that lithotripsy providers in North Carolina are permitted to provide service to other states. As a result, a significant part of our inventory is being used out-of-state. The need methodology in the current *State Medical Facilities Plan* is not able to account for this loss of inventory. To close the gap in resources in a timely manner, ECL has applied for the present CON.

As a former board member of WakeMed, a US Army Medical Service Corp. officer, Wake County Commissioner, and a person who cares about health care access in the state, I urge the Division of Health Service Regulation to approve ECL's application for the pending CON.

Sincerely,

Gary H. Pendleton

Gary H. Pendleton,
Chairman, Health Committee

GHP/kmp
cc William Pinna

610 LEGISLATIVE OFFICE BUILDING, 300 N. SALISBURY ST., RALEIGH, NC 27603 • (919) 733-5860 • GARY.PENDLETON@NCLEG.NET

D.C. Esporas, M.D., FACS
Sanford Surgical Specialties
1816 Doctors Drive
Sanford, North Carolina 27330

July 25, 2016

Ms. Martha Frisone, Assistant Chief
Healthcare Planning and Certificate of Need Section
Division of Health Services Regulation
2704 Mail Service Center
Raleigh, NC 27699-2704

RE: Host Site / Support Letter for Eastern Carolina Lithotripsy's CON Application

Dear Ms. Frisone:

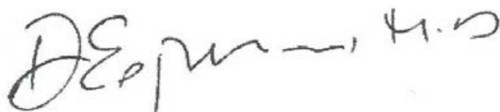
I am a urologist and have been in practice in Sanford, Lee County, North Carolina for the past thirty years. I am writing to support the application which has been filed by Eastern Carolina Lithotripsy Corporation for a mobile lithotripter to be deployed in eastern North Carolina.

The company that has been managing Triangle Lithotripsy Corporation ("TLC") since 1989 also proposes to manage Eastern Carolina Lithotripsy's lithotripter. When TLC first came to Central Carolina Hospital to offer to provide service, we told them that the best day to provide ESWL for our patients would be on Saturdays due to our existing surgical schedule and clinical demands during weekdays. In addition, it was more convenient for our patients as they would not have to take time off from work for their procedure and it would be easier to find someone who could drive them home after the procedure if it was on a Saturday.

They were extremely flexible and responsive and we have been treating on Saturdays for the past 27 years. They have been extremely professional and have always provided the highest quality of equipment and personnel thus giving us the ability to consistently rely on the highest caliber of ESWL treatments for our patients week-in and week-out.

I strongly support your approval of Eastern Carolina Lithotripsy's CON application, as I am certain they will bring the very best of services to all Eastern North Carolinians who currently do not have access to this non-invasive form of treating kidney stones. They will be the most responsive to the best way to bring their services to where it is needed the most in the most convenient and economical manner possible. They are great people with whom to work.

Sincerely yours,



Carteret Community College

"Education for Life"

3505 Arendell Street, Morehead City, NC 28557-2989

Tele: (252) 222-6000
www.carteret.edu

Date: June 20, 2016

Ms. Martha Frisone
Assistant Chief
Healthcare Planning and Certificate of Need Section
Division of Health Service Regulation
2704 Mail Service Center
Raleigh, NC 27699-2704

RE: Clinical Training Site / Support Letter for the Certificate of Need application filed by Eastern Carolina Lithotripsy to develop and operate a new Mobile Lithotripsy Unit in North Carolina.

Dear Ms. Frisone:

I am writing this letter to express support for the Certificate of Need application filed by Eastern Carolina Lithotripsy, an associate of Triangle Lithotripsy Corporation, to develop and operate a new Mobile Lithotripsy in North Carolina. I am also writing to express interest in utilizing its proposed mobile unit as a clinical observation site for our students in Radiography. I understand Eastern Carolina Lithotripsy will manage the proposed agency. I also understand that Triangle Lithotripsy Corporation has a reputation for providing quality lithotripsy services in North Carolina.

I look forward to working with Eastern Carolina Lithotripsy in any way possible to enhance our health education programs. I expect the collaboration to be a great asset to our program.

Many of our graduating students begin their healthcare careers in central and eastern North Carolina. A new mobile lithotripsy unit available in those areas would be welcomed.

Sincerely,

Elaine M. Postawa

Name Elaine Postawa Title Radiography Program Chairperson

School / Program Carteret Community College

Address 3505 Arendell St.

City Morehead City State NC Zip 28557

Phone 252-222-6165 Email postawae@carteret.edu

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