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Healthcare Planning

RESPONSE TO PETITION FILED BY HAMPTON ROADS LITHOTRIPSY, LLC

Prepared by:

Piedmont Stone Center, PLLC
3825 Forrestgate Drive
Winston-Salem, NC 27103

Charles Hauser, CEO
chauser@pdllc.com
(336) 714-2600

BACKGROUND

Piedmont Stone Center, PLLC (PSC) has provided lithotripsy services in North Carolina since 1985. Presently, PSC has 4 mobile lithotripters that cover Western and Central North Carolina and Virginia. PSC's mobile lithotripters serve host sites in urban, suburban and rural areas of North Carolina and Virginia. PSC, like every mobile lithotripsy provider proposing to offer service in North Carolina, can propose to add additional mobile lithotripters to the North Carolina inventory only if two conditions are present: (1) there is a need determination in the State Medical Facilities Plan (SMFP) for an additional mobile lithotripter; and (2) PSC files a CON application in which it demonstrates that it meets the performance standards found at 10A NCAC 14C.3203.

Pursuant to Criterion (1) of the CON Law, N.C. Gen. Stat. § 131E-183(a)(1), the need determination in the SMFP is a "determinative limitation" on the provision of any health service (including lithotripsy) in North Carolina. This means that if there is no need for a service in the SMFP, any CON application proposing to provide the service will be denied. The performance standards are integral to the determination of need under Criterion (3) of the CON Law, N.C. Gen. Stat. § 131E-183(a)(3).

On March 2, 2016, Hampton Roads Lithotripsy, LLC (HRL), a mobile lithotripsy company based in Virginia Beach, Virginia, filed a petition with the State Health Coordinating Council (SHCC) in which it seeks to eliminate these conditions, but only for a certain class of providers. In its proposed Policy TE-3, HRL's petition urges the SHCC to take the unprecedented step of granting special privileges to certain out of state mobile lithotripsy providers while maintaining the status quo for in-state providers and other out of state providers that do not operate in states adjacent to North Carolina. In other words, lithotripsy providers would be treated differently based on where they operate and whether they have existing equipment, with in-state providers being subject to requirements that certain out of state providers do not have to meet. As explained below, HRL's petition is seriously flawed and should be denied.

REASONS WHY PETITION SHOULD BE DISAPPROVED

A. The Petition Allows HRL to Avoid the Establish Planning Process and a Competitive CON Review.

HRL states that it is aware that the 2016 SMFP contains a need determination for an additional lithotripter. *See* Petition, page 4. HRL states that it has decided not to apply to meet the need determination. *See* Petition, page 8. This was HRL's choice. The 2016 SMFP affords HRL a process to serve North Carolina residents in North Carolina, but HRL has chosen not to avail itself of this process. Instead, it asks the SHCC to flout the established planning process and invent a way for HRL to serve North Carolina residents in North Carolina but without following the requirements that other providers must follow. PSC respectfully submits that the SHCC should not invent a new and highly questionable process for a provider that simply does not want to participate in the existing process.

HRL likely recognizes that one or more CON applications will be filed to meet the need determination for one additional lithotripter in the 2016 SMFP. By circumventing the need determination in the 2016 SMFP, HRL appears to want to avoid a competitive CON review. HRL figures that if it does not have to comply with a need determination or the performance standard, its chances of success are likely improved. By using its existing equipment, HRL will also avoid making the capital commitment that providers applying under the 2016 SMFP need determination will need to make. PSC respectfully submits that it is not the SHCC's role to customize an exception for a provider that simply does not want to participate in the existing process.

B. The SMFP and the CON Law Do Not Discriminate Based on Where the Provider Operates.

Chapter 9 of the SMFP defines lithotripsy as ". . . the pulverization of urinary stones by means of a lithotripter. Extracorporeal lithotripsy is lithotripsy that occurs outside the body. . . . A lithotripter is a device that uses shock waves to pulverize urinary stones, which can then be expelled in the urine. An emitter is placed in contact with the patient's abdomen and the shock waves are focused on the stone, which is shattered by the force." 2016 SMFP, Chapter 9, page 122.

As reflected in the SMFP, there are currently eight providers with a total of 14 lithotripters serving North Carolina citizens. Thirteen of these machines are mobile units. One lithotripter is a fixed unit located at Mission Hospital in Asheville. Collectively, all eight providers serve sites from the Outer Banks to far Western North Carolina and numerous cities and towns in between. *See* Table 9A of the 2016 SMFP, attached as Exhibit A. Some of the areas served by the existing lithotripsy providers are predominantly rural. Under the heading "Access," the 2016 SMFP states:

> Due to the mobility of lithotripter services, and the subsequent number of sites from which the service is provided, it may be concluded that geographic access is available to the maximum economically feasible extent.

2016 SMFP, page 122.

As shown in Table 9A, some of the lithotripsy providers are North Carolina-based companies that serve sites exclusively located in North Carolina, and some are not. Regardless, each of these providers has to meet the same rules. None of them can propose to acquire an additional lithotripter for use in North Carolina unless there is a need determination in the SMFP and the provider files a CON application in which it demonstrates that it meets the performance standards.

To give a concrete example, there is a need determination in the 2016 SMFP for one additional lithotripter, to be located anywhere in the State of North Carolina. *See* 2016 SMFP, page 129. Any of the eight existing providers could file a CON application to meet this need, and any new entrant (including HRL) could also file a CON application to meet this need. All applicants would complete the same application form, all applicants would have to satisfy each applicable criterion in the CON Law, and all applicants would have to demonstrate compliance with the performance standards at 10A NCAC 14C.3203. The CON Section would review each application the same; it would not apply different standards based on whether the applicant operates in North Carolina or Hawaii or whether the applicant proposes to serve rural areas, urban areas or a mix of both.

To the best of PSC's knowledge and belief, the SMFP and the CON Law have never treated providers differently because they operate in certain states. PSC is not aware of the SHCC ever granting special privileges only to certain out of state providers. There is no policy in the SMFP or any language in the CON Law that supports different treatment based on where a provider operates. And there is certainly nothing in the SMFP or the CON Law to support the notion that in-state providers should be subject to requirements that certain out of state providers are not required to meet.

If the HRL petition is approved, a new and unprecedented element of discriminatory treatment based on geography would be introduced into North Carolina health planning. Certain out of state providers – those who are operating in states contiguous to North Carolina and have existing lithotripsy equipment – would be enabled to add to the inventory of lithotripters in North Carolina without a need determination in the SMFP. Every other provider wishing to add to the inventory of lithotripters in North Carolina would be subject to the need determination in the SMFP. All providers would still be required to file CON applications, but only those with existing equipment operating in contiguous states would be exempt from the performance standard. Proposed Policy TE-3 therefore has the effect of establishing four different classes of lithotripsy providers: North Carolina based providers; existing providers that operate in contiguous states; new providers in contiguous states; and

providers operating in non-contiguous states.[1] The following chart illustrates the distinctions in proposed Policy TE-3:

State Where Operating	Must Meet Need Determination in SMFP	Must Meet Performance Standard
North Carolina	Yes	Yes
Virginia, South Carolina, Georgia and Tennessee (with existing equipment)	No	No
Virginia, South Carolina, Georgia and Tennessee (new providers)	Yes	Yes
Every other state that is not contiguous to NC	Yes	Yes

The petition does not explain why lithotripsy providers need to be divided into four classes, nor can PSC discern a health policy or health planning rationale for this division. The petition does not explain why it makes sense to exempt, for example, a Virginia provider with existing equipment from a need determination and a performance standard while a Texas based provider with existing equipment is not exempt. The petition claims that patients in rural areas need better access to lithotripsy, but the petition does not explain why an existing provider in a contiguous state would be better able to serve rural patients than a North Carolina provider that already serves rural North Carolinians.[2]

The following hypothetical illustrates the problems that arise from such discriminatory and arbitrary distinctions. Assume that there is no need in the 2017 SMFP for additional lithotripters anywhere in North Carolina. If proposed Policy TE-3 is adopted, HRL could still file a CON application, even though there is no need in the SMFP for additional lithotripters in North Carolina. HRL would not have to meet any performance standard. A North Carolina based provider could not file a CON application to add another lithotripter in 2017 (or if it did,

[1] The title of proposed Policy TE-3 is "Use of Existing Mobile Lithotripsy Units to Increase Access in Rural Areas of the State." Therefore, new providers are not eligible. This could lead to a result in which two different Virginia providers (one with existing equipment and the other that plans to acquire equipment) would be treated differently under the SMFP.

[2] Ostensibly, HRL chose contiguous states for special treatment on the theory that providers from contiguous states would return to their "home" state and therefore not increase the inventory of lithotripters in North Carolina, whereas providers from more distant states would find it more difficult to return to their "home" states. HRL's theory is pure artifice. Whether a Virginia based provider with existing equipment provides service in North Carolina for 1 day or 365 days per year, that provider is still "in" North Carolina and therefore increasing the inventory of lithotripsy equipment in North Carolina. Thus, the provider is subject to the need determination in the SMFP.

the application would be denied because it does not meet the need determination in the SMFP, which is a "determinative limitation" on the number of lithotripters in the State). *See* N.C. Gen. Stat. § 131E-183(a)(1). Similarly, a Texas based provider could not file an application in North Carolina in 2017, even if it proposed to use existing equipment as HRL proposes to do. The Texas based provider might well question why the Virginia provider received special treatment. It would not be possible to offer a coherent explanation for this different treatment. Nor would it be possible to explain why an existing Virginia provider should be treated differently from a new Virginia provider. By employing an arbitrary distinction based on geography, proposed Policy TE-3 is entirely inconsistent with the integrity and data-driven analysis the SHCC normally employs in the planning process.

Aside from the complete lack of a health policy or planning rationale for giving some out of state providers benefits that in-state providers do not enjoy, HRL's proposal actually creates a constitutional problem because it discriminates in interstate commerce. This is not allowed under Article I, § 8, cl. 3. of the U.S. Constitution. North Carolina cannot give special privileges to certain out of state lithotripsy providers unless there is a rational basis for doing so. The petition provides no such justification. In addition to undermining the historical integrity of the SHCC's decision making process, HRL's idea could actually expose the State of North Carolina to litigation from providers who are not able to take advantage of proposed Policy TE-3.

Moreover, to the best of PSC's knowledge, the states that are contiguous to North Carolina do not extend preferential treatment to North Carolina providers. In Virginia, for example, anyone (regardless of where they are from) proposing to develop a new lithotripsy service must meet the applicable performance standard. "A new renal lithotripsy service may be approved if the applicant can demonstrate that the proposed service can provide at least 750 renal lithotripsy procedures annually." 12 VAC 5-230-660(B).

Thus, the petition creates an unlevel playing field. There is no basis for the unlevel playing field, and PSC respectfully asks the SHCC to deny the petition.

C. HRL's Definition of "Rural" is Problematic.

HRL's proposed Policy TE-3 would require the applicant to serve "only hospital sites in areas defined as rural by the United State 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."

Petition, page 2 (emphasis in original).

The petition provides a link to a search engine on the USDA website that allows a user to type in various addresses to determine whether a location is rural or urban. Using this search engine, PSC was able to determine that the USDA regards the UNC Hillsborough hospital as a "rural" location. *See* Exhibit B. Clearly, this location, situated between the Triad and the Triangle, is not what one would reasonably consider rural. Residents in that area enjoy abundant access to health care at multiple facilities such as UNC Hillsborough, UNC Hospitals in Chapel Hill, Duke University Medical Center in Durham and Alamance Regional Medical Center in Burlington. The search engine also classifies Rex Healthcare's facility in Holly Springs as "rural." *See* Exhibit C. Holly Springs is a growing community south of Raleigh. It also enjoys abundant access to health care from a variety of providers. Holly Springs is not "rural." While the petition may express a desire to improve access for rural North Carolinians, its proposed definition of "rural" is highly problematic and may encourage manipulation.

When the SHCC was considering Policy TE-1 (conversion of fixed PET scanners to mobile PET scanners) in 2014, the SHCC ultimately decided not to include a requirement that an applicant serve rural areas of the State. As shown in HRL's petition, defining "rural" can be challenging and may lead to unintended consequences such as adding more lithotripters – without any need determination in the SMFP for more lithotripters - to areas that already enjoy ample access to health care.

D. HRL's Assumptions About Access Are Unsubstantiated.

HRL spends several pages criticizing the current lithotripsy need methodology, stating that the current methodology may understate the need and that there may be potential access issues. However, as HRL acknowledges, this methodology in fact generated a need in 2016. *See* Petition, page 4. HRL has chosen not to meet this need. *See* Petition, page 8. The SHCC should view HRL's attacks with skepticism. HRL states that adding one more machine is not likely to expand access to all areas of the state. *See* Petition, page 4. HRL does not explain why a total of 15[3] geographically dispersed lithotripters in North Carolina, some of which have additional capacity now, are insufficient to meet the need.

HRL states that it is not reasonable to expect residents in most of North Carolina to use the fixed lithotripter in Asheville. *See* Petition, page 5. HRL neglects to mention that Mission, where the Asheville lithotripter is located, is a regional referral center that serves 18 counties in Western North Carolina. Moreover, it does not seem reasonable or likely that HRL, based in Virginia Beach, Virginia, will be providing service hundreds of miles away in Western North Carolina.

HRL suggests that North Carolina is losing capacity and access because some mobile providers serve sites in Virginia and South Carolina. *See* Petition, page 5. No evidence, other than HRL's "belief," is offered to support this point. With 4 lithotripters, PSC devotes most of its capacity to North Carolina. As shown on Table 9A of the 2016 SMFP, page 126, of the

[3] 14 existing machines plus the machine in the 2016 SMFP.

4,226 procedures performed on PSC's lithotripters in FFY 2014, 3,450 procedures (82%) were performed in North Carolina.

HRL argues that the need for additional access to the service area appears particularly great in more isolated, rural areas of the state. Yet as Table 9A of the 2016 SMFP discloses, the existing fixed and mobile lithotripters cover many of these "isolated, rural areas." This includes far Western North Carolina, Elizabeth City, Edenton and the Outer Banks. *See* page 125 of the SMFP. HRL complains that the unit that serves Northeastern North Carolina "was in the state only 47 days in 2014," performing a total of 92 procedures. Petition, page 5. If there is a problem with the provider offering "only 47 days" of service in North Carolina, one might ask why HRL does not apply in 2016 to provide more days of service? HRL cannot sit on the sidelines criticizing the methodology and the behavior of other providers when HRL itself is unwilling to participate in the established process to address what it perceives as an access problem. The need methodology in the SMFP and the CON Law do not limit HRL to serving a sparsely-populated area that makes it difficult to meet the performance standard; HRL imposed the service area limitation on itself.

HRL states that it has treated "some" patients who reside in Northeastern North Carolina "but have minimal access to lithotripsy in their state." Petition, page 5. HRL provides no data concerning the number of patients or information about why these patients chose to receive service from HRL.[4] It is a fact that some residents of Northeastern North Carolina live closer to Virginia health care providers than to North Carolina health care providers. That does not mean that these residents lack access to health care services. There is nothing wrong with patients crossing state lines to receive health care. It could easily be the case that the patient's urologist is based in Virginia and referred the patient to a Virginia based lithotripsy provider. A urologist must prescribe lithotripsy.

Further, there are relatively few urologists in Northeastern North Carolina. According to the North Carolina Medical Board's website, in the ten counties HRL lists on page 5 of the petition, there are only 8 urologists with active North Carolina medical licenses.[5] The urologists' participation in the lithotripsy program is essential. HRL does not explain whether any of these 8 urologists support HRL's petition or would be likely to refer patients to HRL's lithotripter. Without the local urologists' support, HRL's proposal has little chance of improving the so-called access problem.

The petition also fails to discuss the availability of primary care physicians in Northeastern North Carolina. Primary care physicians typically refer patients to urologists

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[4] On page 6 of the petition, HRL states that "[a]ccording to 2015 records from Hampton Roads Lithotripsy's urologists, approximately 10 percent of their patients live in North Carolina but were treated at sites in Virginia." This does not mean that these patients were all lithotripsy patients. HRL is not a urology practice; rather, it is a provider of lithotripsy services. It is PSC's understanding that a urology practice, Urology of Virginia, PC, is associated with HRL. Both HRL and Urology of Virginia are located at 225 Clearfield Avenue in Virginia Beach. Urology of Virginia provides comprehensive urologic care. Its practice is not limited to lithotripsy. *See* http://www.urologyofva.net/contact-us/map-directions/ (visited March 13, 2016).

[5] http://wwwapps.ncmedboard.org/Clients/NCBOM/Public/LicenseeInformationResults.aspx (visited March 10, 2016).

who would in turn refer patients for lithotripsy. Patients cannot self-refer for lithotripsy. Exempting certain providers from the SMFP need determinations does not solve physician infrastructure issues; all it does it add capacity without a practical way for patients to use that capacity.

Apart from physician infrastructure issues, it is not clear from HRL's petition where exactly it would provide the mobile lithotripsy service. In most cases, the lithotripsy provider contracts with a hospital and uses a mobile pad provided by the hospital. But in some of the counties listed in the petition (*e.g.,* Camden, Currituck, Gates, Perquimans and Tyrell), there is no hospital. And in some others (*e.g.,* Chowan, Dare and Pasquotank), the hospital already contracts with a mobile lithotripsy provider. *See* page 125 of the 2016 SMFP.

HRL then asserts that patients from Northeastern North Carolina are either "forgoing treatment and enduring prolonged, extreme and unnecessary pain," or "are being forced to seek care at some distance from their home county, which requires unnecessary travel and expense." Petition, page 6. HRL provides no evidence to substantiate its proposition that patients are suffering physically or economically. And if HRL really believes that patients are suffering and would be better off with HRL providing services in Northeastern North Carolina, then HRL could file a CON application in 2016.

HRL then speculates that hospitals in rural areas lack choice in lithotripsy providers and may be forced to pay more for lithotripsy services. No evidence is offered to substantiate the point. *See* Petition, page 6. Again, if HRL really believes this to be true, then it has an opportunity in 2016 to address the perceived problem. HRL has chosen not to do so. Rather, HRL's proposed Policy TE-3 is the opposite of competition. Instead of participating in an open, competitive process in 2016 where all applicants will be treated the same, HRL wants a "closed" review in 2017 where HRL is likely to be the only applicant and will be positioned to receive a CON because it does not have to meet the performance standard. Thus, HRL is asking the SHCC to "stack the deck" in HRL's favor. This severely undermines the integrity of the SHCC's health planning process.

HRL's citation to the petitions for the Brunswick MRI and Policy TE-1 (mobile PET) are not helpful. *See* Petition, page 6. In the Brunswick petition, Dosher Hospital was seeking to have its own MRI scanner rather than contract with a vendor. HRL is not proposing to bring the service "in house" to the hospital. Rather, it would be a third party vendor which is precisely the situation Dosher was seeking to eliminate. The same is true of the 2015 Policy TE-1 review; the successful applicant in that review proposed to bring the mobile PET service "in house" so it would no longer have to contract with a vendor. Policy TE-1 also requires the applicant to convert an existing fixed PET scanner to mobile status, so Policy TE-1 is "inventory neutral." That is not the case with proposed Policy TE-3. Policy TE-3 adds to the inventory of lithotripters without a need determination in the SMFP. It does not matter that HRL's lithotripter already exists in Virginia; it is new to North Carolina and is therefore subject to the need determination in the SMFP.

On pages 6 and 7 of its petition, HRL states that health factors show that the incidence of urolithiasis is likely higher in Northeastern North Carolina than the rest of the state. HRL

relies on the obesity and diabetes rates in Northeastern North Carolina. However, HRL stops short of demonstrating that the incidence of urolithiasis is in fact higher in Northeastern North Carolina than the rest of the state. As discussed above, there are three locations in Northeastern North Carolina that offer mobile lithotripsy service.

HRL's petition is also internally inconsistent. On the one hand, it asks the SHCC to accept as facts that the incidence of urolithiasis is higher in Northeastern North Carolina than elsewhere in the State; that patients in this area of the State lack reasonable access to lithotripsy; and that some patients are either forgoing treatment or enduring expensive travel to get the treatment. *See* Petition, pages 5-7. At the same time, HRL says it declined to pursue a CON application pursuant to the need determination in the 2016 SMFP because it does not think it can meet the performance standard of 1,000 cases in Year 3 of its project. *See* Petition, page 8. If the demand as is great as HRL claims it is, then it would seem reasonably likely HRL should be able to satisfy the performance standard 3 years into the operation of its project. Moreover, the service area for lithotripsy is statewide. Neither the SMFP nor the CON Law restricts HRL to serving just 10 counties in Northeastern North Carolina. If HRL determined that serving just those 10 counties in Northeastern North Carolina would not enable it to meet the performance standard, it could propose to serve other locations in North Carolina.

The SHCC should not be misled by a provider's claim that an exception should be made when the provider has self-selected a limited and sparsely-populated service area.

E. The Rationale for Specific Components of the Proposed Policy Are Unsupported.

On pages 8 and 9 of its petition, HRL suggests that its mobile lithotripter would not be "new" equipment in North Carolina. That is incorrect. As far as North Carolina is concerned, HRL's machine would be new because it does not serve North Carolina now. It makes no difference that the machine serves sites in Virginia. The machine would be additive to the inventory of lithotripters in North Carolina. Thus, a need determination would have to be included in the SMFP to add an additional lithotripter. While HRL believes that its proposed Policy TE-3 would prevent providers from other states from "picking up and moving" their equipment to North Carolina, *see* Petition, page 9, the proposed policy gives no parameters concerning how often the machine must be in other states versus North Carolina. The policy only requires the applicant to serve "at least one host site" in a contiguous state. The policy does not establish how frequently the provider must serve the one host site in a contiguous state. This creates significant opportunities for gamesmanship and manipulation.

It is also important to consider what might happen if the provider's contracts with host sites in contiguous states ended, leaving the provider with only North Carolina host sites. While proposed Policy TE-3 purports to require a provider to commit to continue to provide service in contiguous states following completion of the project, the provider cannot reasonably represent that it will *always* have contracts with host sites in contiguous states. Contracts rarely last forever and may end for a variety of reasons. Neither the CON Section nor the

SHCC can regulate a provider's behavior outside of North Carolina. A promise that a provider will continue to serve host sites in contiguous states is not enforceable.

HRL believes that its proposed policy should be limited to lithotripsy and should have no broader implications. *See* Petition, page 9. Once the door is open to exceptions such as HRL proposes, it is difficult, if not impossible, to limit further requests for more exceptions. It also becomes more difficult to successfully argue against granting exceptions. Following the precedent set by proposed Policy TE-3, it would be relatively easy for a provider of mobile MRI (or PET or cardiac catheterization) in South Carolina, for example, to argue that it should be allowed to serve rural host sites in North Carolina without a need determination and without having to meet performance standards. Ultimately, proposed Policy TE-3 erodes the integrity of the SHCC's health planning process and encourages the unnecessary duplication of health care services that the SMFP and the CON Law seek to avoid.

On page 10 of its petition, HRL states that "[t]o require applicants to achieve the same volume standards would effectively negate the ability of providers to offer service to rural areas under the policy." This is untrue. Many existing providers, including PSC, serve both rural and urban areas. The current need methodology and CON performance standard do not deny lithotripsy access to rural areas of North Carolina, as evidenced by the fact that many units are serving rural areas of the State.

On page 10 of its petition, under the heading "Adverse Effects if Petition is Not Approved," HRL again asserts that patients in rural areas will continue to forego treatment or will have to leave the state to receive treatment. As discussed earlier, the petition provides no evidence that patients are foregoing lithotripsy treatment. Regardless of whether HRL provides lithotripsy service in North Carolina, some patients in Northeastern North Carolina will continue to outmigrate to Virginia for a variety of reasons, including historical practice and the relative lack of hospitals and physicians in their area.

On page 11 of its petition, HRL claims that proposed Policy TE-3 would not lead to unnecessary duplication. This is untrue. First, by allowing certain out of state providers to skirt the need determination in the SMFP entirely, Policy TE-3 inherently promotes unnecessary duplication. Under Policy TE-3, additional lithotripsy capacity will be added to North Carolina without any data to determine whether there is a need for this additional capacity. Second, by eliminating the performance standard for certain out of state providers, Policy TE-3 deprives the CON Section of an effective tool to measure need. Based on HRL's criticism that the provider that now serves Northeastern North Carolina "only" provided 47 days of service in 2014, one could reasonably say that particular lithotripter would be dramatically underutilized if it served Northeastern North Carolina exclusively. HRL admits in its petition that it does not think it could meet the performance standard by serving only Northeastern North Carolina. *See* Petition, page 8. Thus, HRL is seeking to add capacity to an area that does not currently support utilization remotely close to the performance standard. This is the essence of unnecessary duplication.

F. The Proposed Change is Not Consistent With the Basic Principles.

Petitions to change need methodologies are required to provide "*[e]vidence* that the requested change is consistent with the three Basic Principles governing the development of the North Carolina State Medical Facilities Plan: Safety and Quality, Access and Value." *See* 2016 SMFP, page 8 (emphasis added). Conclusory assertions without supporting data are not evidence. The petition spends only one paragraph discussing the Basic Principles and does not provide the required evidence. *See* Petition, bottom of page 11. In that one paragraph, the petition makes no effort to demonstrate that proposed Policy TE-3 enhances safety and quality. Likewise, the petition does not explain how Proposed Policy TE-3 increases value. As the Value discussion in the SMFP states, "[m]aximizing the health benefit for the entire population of North Carolina that is achieved by expenditures for services regulated by the State Medical Facilities Plan will be a key principle in the formulation and implementation of SHCC recommendations for the State Medical Facilities Plan." 2016 SMFP, page 3. The petition, premised on serving rural communities only, does not demonstrates that it maximizes value for the entire population of North Carolina.

With respect to access, the goal of North Carolina's health planning process is to ensure that needed services are widely available, and as Table 9A of the SMFP shows, lithotripsy is widely available in North Carolina. *See also* 2016 SMFP, page 122 (". . . geographic access is available to the maximum economically feasible extent."). The need in the 2016 SMFP for an additional lithotripter is statewide. Thus, applicants can propose to serve rural areas, urban areas or a mix of both. As can be seen from Table 9A, most providers, including PSC, serve a mix of rural and urban areas so that the service is available to as many people in North Carolina as possible. Creating an exemption for certain out of state providers so that these providers can serve only rural areas is not warranted.

CONCLUSION

PSC supports the State health planning process and the 2016 SMFP need determination for additional lithotripsy capacity in North Carolina. PSC respectfully requests that HRL's petition be denied.

CHAPTER 9
TECHNOLOGY AND EQUIPMENT

Summary of Service Supply and Utilization
The number of lithotripsy procedures reported on lithotripters registered in North Carolina for 2013-2014 was 10,459. There were 14 lithotripsy units operated by eight providers.

The present gamma knife located at North Carolina Baptist Hospital in Health Service Area (HSA) II serves the western portion of the state (HSAs I, II, and III). During 2013-2014, 375 gamma knife procedures were reported. Vidant Medical Center received a certificate of need pursuant to a need determination in the North Carolina 2003 State Medical Facilities Plan for one gamma knife to serve the eastern portion of the state (HSAs IV, V and VI). Vidant Medical Center began offering service as of October 2005, and reported 133 gamma knife procedures provided during 2013-2014. The two gamma knives assure that the western and eastern portions of the state have equal access to gamma knife services.

Linear accelerators provided 584,630 Equivalent Simple Treatment Visit procedures that are counted for need determination purposes in 2013-2014. The average number of procedures statewide per linear accelerator as shown in Table 9G is 4,677. There are 125 linear accelerators in North Carolina that are operational, have a certificate of need, or for which there is a prior year need determination.

Twenty-one hospitals and two outpatient facilities reported a total of 32,381 procedures for fixed Positron Emission Tomography (PET) Scanners that were operational in the reporting period. Thirty sites reported 5,870 procedures in total for mobile PET service.

In 1983, there were only two magnetic resonance imaging (MRI) programs in North Carolina, performing a total of 531 procedures. In 2013-2014, fixed and mobile scanners were reported as providing 800,182 procedures.

A total of 49 hospitals and cardiac diagnostic centers provided fixed cardiac catheterization services during fiscal year 2013-2014. Also, during fiscal year 2013-2014 mobile cardiac catheterization services were reported at 5 hospitals and cardiac diagnostic centers across the state.

Changes from the Previous Plan
No substantive changes in basic principles and methodologies have been incorporated into the Technology and Equipment Chapter in the North Carolina 2016 State Medical Facilities Plan. There is one new policy incorporated into Chaper 4 of the the North Carolina 2016 State Medical Facilities Plan for Technology and Equipment. Policy TE-2-Intraoperative Magnetic Resonance Scanners has been added by a recommendation of the State Health Coordinating Council. This policy will allow facilities that meet the outlined requirements to apply for an intraoperative magnetic resonance scanner (iMRI). Language has been added to Chapter 9: MRI section which clarifies that equipment obtained through Policy TE-2 will not be counted in the inventory and the CPT procedures will be excluded from the need determination calculation.

Throughout the chapter, data have been revised to reflect services provided during FY 2013-2014, and dates have been advanced by one year, where appropriate.

LITHOTRIPSY

Introduction
Lithotripsy is defined as the pulverization of urinary stones by means of a lithotripter. Extracorporeal lithotripsy is lithotripsy that occurs outside the body. Extracorporeal shock wave lithotripsy (ESWL) is the non-invasive procedure with which this section will concern itself.

A lithotripter is a device that uses shock waves to pulverize urinary stones, which can then be expelled in the urine. An emitter is placed in contact with the patient's abdomen and the shock waves are focused on the stone, which is shattered by the force.

A lithotripter's service area is the lithotripter planning area in which the lithotripter is located. The lithotripter planning area is the entire state.

Lithotripter Utilization
Lithotripter utilization can be reasonably estimated by the incidence of urinary stone disease. Urinary stone disease, or urolithiasis, is a disease in which urinary tract stones or calculi are formed. The annual incidence of urinary stone disease is approximately 16 per 10,000 population[1]. Not all cases of urinary stone disease would be appropriately treated by lithotripsy. It has been estimated that 85 to 90 percent of kidney stone patients, when surgery is indicated, can be treated successfully by ESWL treatment. The annual treatment capacity of a lithotripter has been estimated to be 1,000 to 1,500 cases.

The number of lithotripsy procedures reported in North Carolina for the period of 2013-2014 was 10,459 procedures. There were 14 lithotripsy units operated by eight providers. Procedures were provided by a fixed unit at one facility, and by 13 mobile units operated by seven providers. Given the 14 lithotripsy units, the average number of procedures per lithotripter for the 2013-2014 fiscal year is 747.

Access
Due to the mobility of lithotripter services, and the subsequent number of sites from which the service is provided, it may be concluded that geographic access is available to the maximum economically feasible extent.

Lithotripsy Need Determination Methodology
North Carolina uses a methodology based on the incidence of urinary stone disease. The need is linked to the estimate of urinary stone disease cases and is based on the assumption that 90 percent could be treated by ESWL.

The standard methodology used for determining need for lithotripters is calculated as follows:

Step 1: Divide the July 1, 2016 estimated population of the state, available from the North Carolina Office of State Budget and Management, by 10,000 and multiply the result by 16, which is the estimated incidence of urinary stone disease per 10,000 population.

[1] Pahiri, J.J. & Razack, A.A. (2001) "Chapter 9: Nephrolithiasis". In Clinical Manual of Urology, by Philip M. Hanno, Alan J. Wein, S. Bruce Malkowicz. McGraw-Hill Professional Publisher.

Step 2: Multiply the result from Step 1 by 90 percent to get the number of patients in the state who have the potential to be treated by lithotripsy in one year.

Step 3: Divide the result of Step 2 by 1,000, which is the low range of the annual treatment capacity of a lithotripter, and round to the nearest whole number.

Step 4: Sum the number of existing lithotripters in the state, lithotripters not yet operational but for which a certificate of need has been awarded, and lithotripter need determinations from previous years for which a certificate of need has yet to be awarded.

Step 5: Subtract the result of Step 4 from the result of Step 3 to calculate the number of additional lithotripters needed in the state.

Lithotripsy Services in North Carolina

There are eight providers that offer lithotripsy services in North Carolina. On the following pages, Table 9A and Table 9B provide information on the number of procedures as well as the location of the facilities served by these eight providers.

Table 9A: Mobile Lithotripsy Providers and Locations Served

(From 2014 data as reported on the "2015 Lithotripsy Registration and Inventory Form for Mobile Equipment")

Provider: Carolina Lithotripsy, LTD, 2014 Litho Place, Fayetteville, NC 28304-

Machines 2; #1137 (11/15/2000); #01179 (12/15/2011)

Areas Generally Served: Eastern North Carolina

Facility and Location	*Procedures*
CarolinaEast Medical Center, New Bern, NC	103
Carteret General Hospital, Morehead City, NC	53
Columbus Regional Healthcare System, Whiteville, NC	12
Duke Raleigh Hospital, Raleigh, NC	10
FirstHealth Moore Regional Hospital, Pinehurst, NC	162
FirstHealth Richmond Memorial Hospital, Rockingham, NC	25
Halifax Regional Medical Center, Roanoke Rapids, NC	30
Highsmith-Rainey Specialty Hospital, Fayetteville, NC	177
Johnston Health, Smithfield, NC	81
Lenoir Memorial Hospital, Kinston, NC	21
New Hanover Regional Medical Center, Wilmington, NC	201
Novant Health Brunswick Medical Center, Supply, NC	12
Onslow Memorial Hospital, Jacksonville, NC	4
Rex Hospital, Raleigh, NC	125
Southeastern Regional Medical Center, Lumberton, NC	73
Vidant Beaufort Hospital, Washington, NC	28
Vidant Medical Center, Greenville, NC	138
WakeMed, Raleigh, NC	50
Wayne Memorial Hospital, Goldsboro, NC	17
Wilson Medical Center, Wilson, NC	38
Total Procedures:	**1,360**
Average Number of Procedures per Lithotripter:	**680**

Provider: Catawba Valley Medical Center, 810 Fairgrove Church Road, SE, Hickory, NC 28602-

Machines 2; #1355 (11/2010); TC-2051 (03/2001)

Areas Generally Served: Western and Central North Carolina

Facility and Location	*Procedures*
Carolinas HealthCare System- Blue Ridge, Morganton, NC	39
Catawba Valley Medical Center, Hickory, NC	321
Rutherford Regional Medical Center, Rutherfordton, NC	68
Scotland Memorial Hospital, Laurinburg, NC	135
Total Procedures:	**563**
Average Number of Procedures per Lithotripter:	**282**

Table 9A: Mobile Lithotripsy Providers and Locations Served

(From 2014 data as reported on the "2015 Lithotripsy Registration and Inventory Form for Mobile Equipment")

Provider: Fayetteville Lithotripters Limited Partnership-South Carolina II, 9825 Spectrum Drive, Bldg 3, Austin, TX 78717-

Machines 1; SID OR-197 (01/17/2011)

Areas Generally Served: Western North Carolina and South Carolina

Facility and Location	*Procedures*
Charles George VA Medical Ctr, Asheville, NC	25
Harris Regional Hospital, Sylva, NC	118
Haywood Regional Medical Center, Clyde, NC	112
Margaret R Pardee Memorial Hospital, Hendersonville, NC	93
Park Ridge Health, Hendersonville, NC	60
St. Luke's Hospital, Columbus, NC	7
The McDowell Hospital, Marion, NC	32
Transylvania Regional Hospital, Brevard, NC	46
Oconee Medical Center, Seneca, SC	100
Total Procedures:	**593**
Average Number of Procedures per Lithotripter:	**593**

Provider: Fayetteville Lithotripters Limited Partnership-Virginia I, 9825 Spectrum Drive, Bldg 3, Austin, TX 78717-

Machines 1; SID OR-519 (11/9/2013) replaced SID 1147

Areas Generally Served: Eastern North Carolina and Virginia

Facility and Location	*Procedures*
Sentara Albemarle Medical Center, Elizabeth City, NC	24
The Outer Banks Hospital, Nags Head, NC	17
Vidant Chowan Hospital, Edenton, NC	51
Harborview Medical Center, Suffolk, VA	20
Louise Obici Memorial Hospital, Suffolk, VA	2
Mary Immaculate Hospital, Newport News, VA	157
Maryview Medical Center, Portsmouth, VA	8
Riverside Tappahannock Hospital, Tappahannock, VA	9
Riverside Walter Reed Hospital, Newport News, VA	4
Southside Community Hospital, Farmville, VA	19
Spotsylvania Regional Medical Center, Fredricksburg, VA	1
Total Procedures:	**312**
Average Number of Procedures per Lithotripter:	**312**

Table 9A: Mobile Lithotripsy Providers and Locations Served

(From 2014 data as reported on the "2015 Lithotripsy Registration and Inventory Form for Mobile Equipment")

Provider: Piedmont Stone Center, PLLC, 1907 S Hawthorne Road, Winston-Salem, NC 27103-

Machines 4; 01138 (03/26/2002); 01175 (04/10/2003); 01171 (04/24/2003); 1925 (12/26/2006)

Areas Generally Served: Western and Central North Carolina and Virginia

Facility and Location	*Procedures*
Carolinas HealthCare System-Blue Ridge, Valdese,	94
Davis Regional Medical Center, Statesville,	45
High Point Regional Health System, High Point,	498
Hugh Chatham Memorial Hospital, Elkin,	182
Iredell Memorial Hospital, Statesville,	144
Lexington Medical Center, Lexington,	64
Maria Parham Medical Center, Henderson,	60
Morehead Memorial Hospital, Eden,	172
Northern Hospital of Surry County, Mount Airy,	50
Novant Health Forsyth Medical Center, Winston-Salem,	116
Novant Health Rowan Medical Center, Salisbury,	213
Novant Health Thomasville Medical Center, Thomasville,	41
Randolph Hospital, Asheboro,	115
Wake Forest Baptist Medical Center, Winston-Salem,	103
Watauga Medical Center, Boone,	144
Wesley Long Hospital, Greensboro,	326
Wilkes Regional Medical Center, North Wilkesboro,	75
Alamance Regional Medical Center, Burlington, NC	186
Annie Penn Hospital, Reidsville, NC	14
Piedmont Stone Center, Winston-Salem, NC	799
Yadkin Valley Community Hospital, Yadkinville, NC	9
Lynchburg General Hospital, Lynchburg, VA	254
Martha Jefferson Hospital, Charlottesville, VA	204
Memorial Hospital of Martinsville, Martinsville, VA	110
Montgomery Regional Hospital, Blacksburg, VA	131
Piedmont Day Surgery Center, Danville, VA	43
Twin County Regional Hospital, Galax, VA	74
Total Procedures:	**4,266**
Average Number of Procedures per Lithotripter:	**1,067**

Table 9A: Mobile Lithotripsy Providers and Locations Served

(From 2014 data as reported on the "2015 Lithotripsy Registration and Inventory Form for Mobile Equipment")

Provider: Stone Institute of the Carolinas, LLC, 215 S Main Street, Suite 201, Davidson, NC 28036-

Machines 2; 2053 (10/2006); 1048 & 01384 (01/2001)

Areas Generally Served: Western and Central North Carolina

Facility and Location	*Procedures*
Carolinas HealthCare System-Lincoln, Lincolnton, NC	60
Carolinas Medical Center, Charlotte, NC	153
Carolinas Medical Center-Huntersville, Charlotte, NC	72
Carolinas Medical Center-Northeast, Concord, NC	220
Carolinas Medical Center-Pineville, Charlotte, NC	217
Carolinas Medical Center-Union, Monroe, NC	115
Carolinas Medical Center-University, Charlotte, NC	211
Caromont Regional Medical Center, Gastonia, NC	126
Cleveland Regional Medical Center, Shelby, NC	108
Lake Norman Regional Medical Center, Mooresville, NC	184
Novant Health Matthews Medical Center, Matthews, NC	197
Novant Health Presbyterian Medical Center, Charlotte, NC	87
Piedmont Medical Center, Rock Hill, SC	161
Surgery Center at Edgewater, Fort Mill, SC	34
Total Procedures:	**1,945**
Average Number of Procedures per Lithotripter:	**973**

Provider: Triangle Lithotripsy Corp, 7003 Chadwick Dr #321, Brentwood, TN 37027-

Machines 1; 10142940 (04/01/2010)

Areas Generally Served: East Central North Carolina

Facility and Location	*Procedures*
Central Carolina Hospital, Sanford, NC	126
Duke Regional Hospital, Durham, NC	28
Durham Ambulatory Surgical Center, Durham, NC	104
Nash General Hospital, Rocky Mount, NC	127
North Carolina Speciality, Durham, NC	13
Rex Hospital, Raleigh, NC	217
Rex Surgery Center, Cary, NC	168
Sampson Regional Medical Center, Clinton, NC	15
WakeMed, Raleigh, NC	253
Wayne Memorial Hospital, Goldsboro, NC	74
Total Procedures:	**1,125**
Average Number of Procedures per Lithotripter:	**1,125**

Total Mobile Procedures: **10,164**

Table 9B: Fixed Lithotripsy Providers and Locations Served

(From 2014 data as reported on the "2015 Hospital License Renewal Application")

Provider: Mission Hospital, Inc./Mission, 509 Biltmore Ave., Asheville, NC 28801

Machines: 1 . 08/2000

Area Served:

Facility and Location	*Procedures*
WNC Stone Center, Asheville, NC	295
Total Number of Procedures:	**295**
Average Number of Procedures per Lithotripter:	295

Table 9C: Mobile and Fixed Lithotripsy

(Total Procedures/Units Reported)

Total Procedures Reported	Units Reported	Average Procedures Per Unit
10,459	14	747

Need Determination
Application of the standard methodology for the North Carolina 2016 State Medical Facilities Plan determined the need for one lithotripter as shown in Table 9D. There is no need anywhere else in the state and no other reviews are scheduled.

Table 9D: Lithotripter Need Determination

(Scheduled for Certificate of Need Review Commencing in 2016)

It is determined that the service areas listed in the table below need additional lithotripters as specified.

Lithotripters	Lithotripter Need Determination*	Certificate of Need Application Due Date**	Certificate of Need Beginning Review Date
Statewide	1	June 15, 2016	July 1, 2016
It is determined that there is no need for additional lithotripters anywhere else in the state and no other reviews are scheduled.			

* Need determinations shown in this document may be increased or decreased during the year pursuant to Policy GEN-2 (see Chapter 4).

** Application due dates are absolute deadlines. The filing deadline is 5:30 p.m. on the application due date. The filing deadline is absolute (see Chapter 3).

USDA Rural Development
Committed to the future of rural communities.

US Department of Agriculture, Rural Development
Initial Eligibility Determination

EXHIBIT
B
Blumberg No. 6208

Matched Address 430 Waterstone Dr, Hillsborough, NC 27278

This address IS located in an eligible area.

User Entered Point:

User Located
Latitude 36.038433238863945
Longitude -79.09042730927467

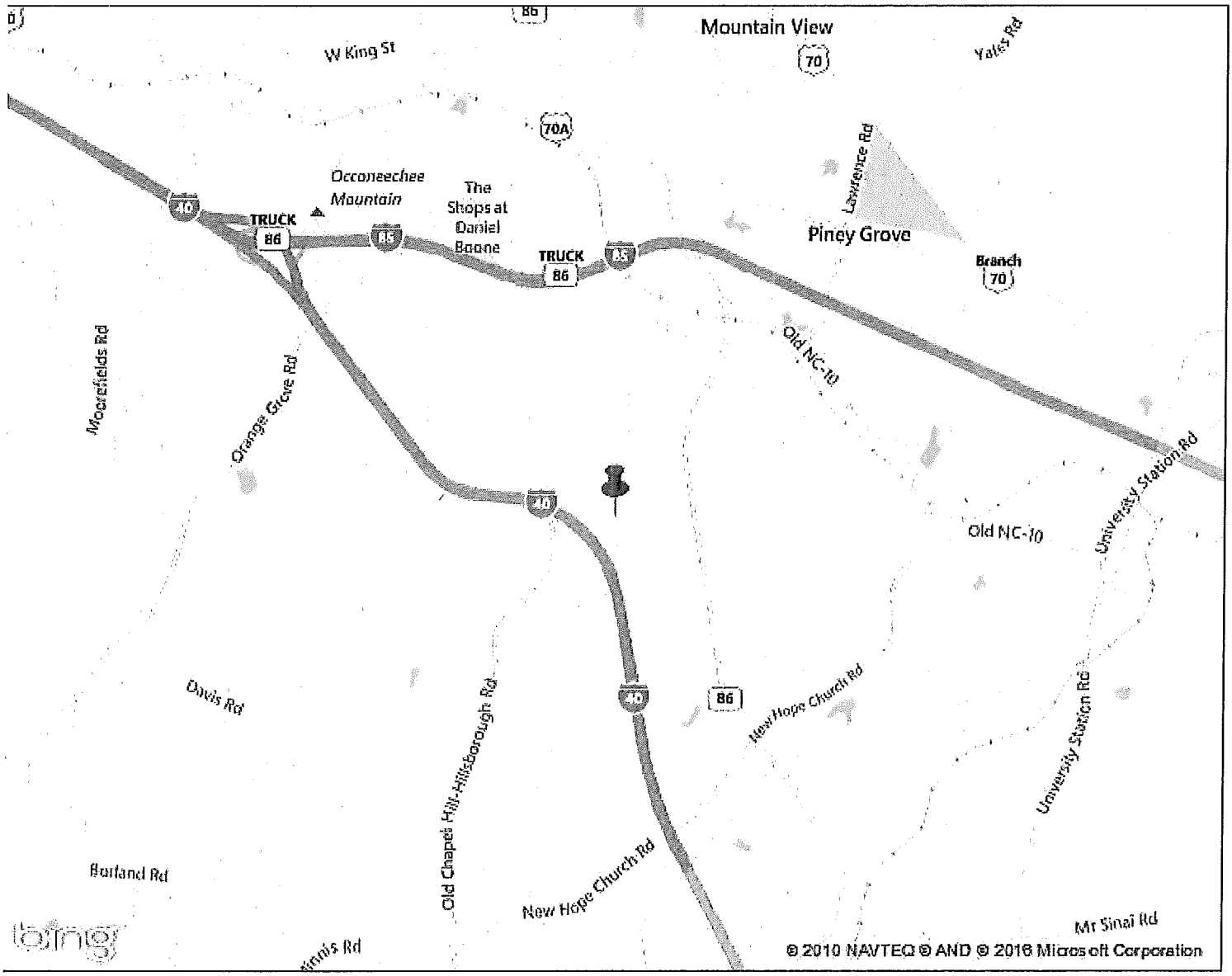
This address IS located in an eligible area. for properties in the US

* Keep in mind that this is only an initial determination on the eligibility of your address. There are other eligibility factors for this program which cannot be confirmed through this tool.

Address of UNC Hillsborough

pointLayer

RHS SFH MFH
Ineligible Area



Date created: Monday, March 07, 2016 - 3:46:27 PM (Central Daylight Time)

USDA Rural Development
Committed to the future of rural communities.

US Department of Agriculture, Rural Development
Initial Eligibility Determination

EXHIBIT
Blumberg No. 5208
C

Matched Address 781 Avent Ferry Rd, Holly Springs, NC 27540

This address IS located in an eligible area.

User Entered Point:

User Located **Latitude** 35.642875 **Longitude** -78.837203

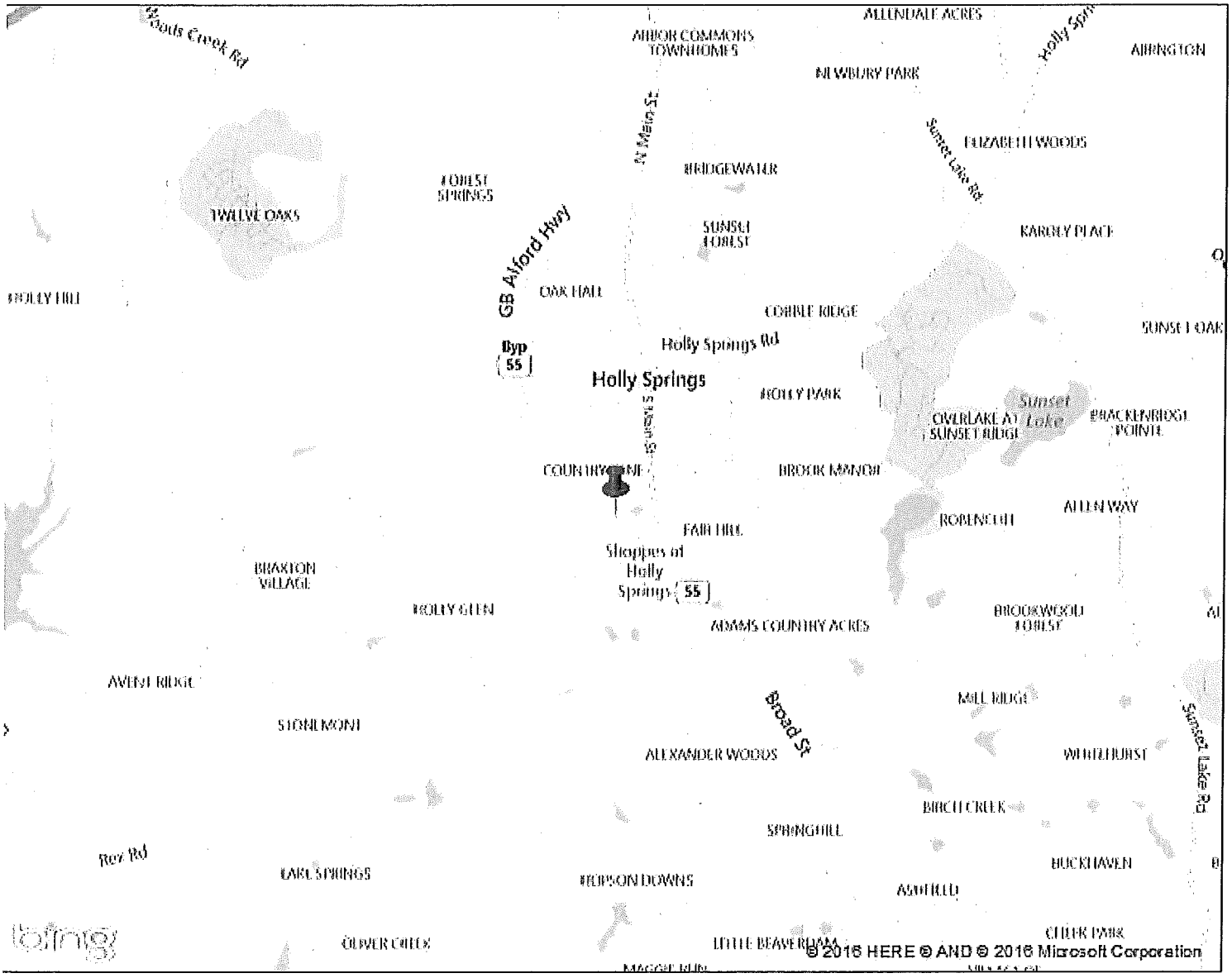
This address IS located in an eligible area. for properties in the US

* Keep in mind that this is only an initial determination on the eligibility of your address. There are other eligibility factors for this program which cannot be confirmed through this tool.

Address of Rex Healthcare facility in Holly Springs

pointLayer

RHS SFH MFH
Ineligible Area



Date created: Thursday, March 17, 2016 - 9:40:29 AM (Central Daylight Time)