



North Carolina Department of Health and Human Services  
Division of Health Service Regulation

Pat McCrory  
Governor

Aldona Z. Wos, M.D.  
Ambassador (Ret.)  
Secretary DHHS

Drexdal Pratt  
Division Director

May 5, 2014

Allyson Jones Labban  
300 North Greene Street, Suite 1400  
Greensboro, NC 27401

**No Review**

Facility or Business: InSight Health Corp.  
Project Description: Temporarily store MRI scanner at storage facility  
County: Buncombe  
FID #: 020752

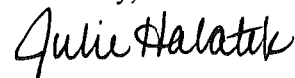
Dear Ms. Labban:


The Certificate of Need Section (CON Section) received your letter of March 27, 2014, regarding the above referenced proposal. Based on the CON law **in effect on the date of this response to your request**, the proposal described in your correspondence is not governed by, and therefore, does not currently require a certificate of need. However, please note that if the CON law is subsequently amended such that the above referenced proposal would require a certificate of need, this determination does not authorize you to proceed to develop the above referenced proposal when the new law becomes effective.

It should be noted that this determination is binding only for the facts represented by you. Consequently, if changes are made in the project or in the facts provided in your correspondence referenced above, a new determination as to whether a certificate of need is required would need to be made by the Certificate of Need Section. Changes in a project include, but are not limited to: (1) increases in the capital cost; (2) acquisition of medical equipment not included in the original cost estimate; (3) modifications in the design of the project; (4) change in location; and (5) any increase in the number of square feet to be constructed.

Please contact the CON Section if you have any questions. Also, in all future correspondence you should reference the Facility I.D. # (FID) if the facility is licensed.

Sincerely,

  
Julie Halatek  
Project Analyst

  
Martha J. Frisone, Interim Chief  
Certificate of Need Section

cc: Medical Facilities Planning Branch, DHSR

**Certificate of Need Section**

[www.ncdhhs.gov](http://www.ncdhhs.gov)

Telephone: 919-855-3873 • Fax: 919-733-8139

Location: Edgerton Building • 809 Ruggles Drive • Raleigh, NC 27603

Mailing Address: 2704 Mail Service Center • Raleigh, NC 27699-2704

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# SMITH MOORE LEATHERWOOD

March 27, 2014

Received by  
the CON Section  
MAR 27 2014

Martha Frisone, Interim Chief  
N.C. Department of Health & Human Services  
Division of Health Service Regulation  
Certificate of Need Section  
2704 Mail Service Center  
Raleigh, NC 27699-2704

Re: Project ID # B-6643-02, Fixed MRI Scanner, Buncombe Co.  
Replacement of equipment and relocation/storage of equipment

Dear Ms. Frisone:

We submit this request on behalf of our client, InSight Health Corp. ("InSight") regarding the proposed replacement, relocation, and storage of the existing fixed magnetic resonance imaging ("MRI") scanner currently located at Marquis Diagnostic Imaging of North Carolina, LLC ("Marquis Diagnostic") in Asheville, North Carolina. Marc Hewitt spoke with you earlier regarding this unique situation, and we are following up on that discussion with this written request. The pertinent facts supporting this request are outlined below.

## Background

In 2003, InSight was granted a certificate of need ("CON") to operate a fixed MRI scanner in Asheville, Buncombe County. The MRI was operated at an orthopedic physician practice in Asheville until 2012, when InSight obtained the written acknowledgement of the CON Section that replacement and relocation of the equipment to Marquis Diagnostic's practice location was exempt from CON review. Consistent with its representations to the CON Section, InSight entered into a contract with Marquis Diagnostic to provide MRI services, and located the 1.5 T Siemens MRI at Marquis Diagnostic's practice location on Centre Drive in Asheville.

Unfortunately, despite having signed a seven year contract with InSight, Marquis Diagnostic sold its assets to another provider and has ceased operations, defaulting on its contract. As a result of this unforeseen situation over which InSight had no control, it must now find an alternate location at which to place its previously-approved MRI scanner. InSight remains committed to providing MRI services in Buncombe County, consistent with its CON, and is working to identify a new location. In the interim, the landlord at Marquis Diagnostic's location is requiring InSight to remove the MRI scanner. Because a new site in Buncombe Co. has not yet been identified, and because even a short term interruption in the scanner's power

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Martha Frisone, Chief  
March 27, 2014  
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supply can cause extensive damage, InSight needs to store the scanner until a new site can be identified.

InSight maintains a storage facility with appropriate power supply in Harmony, NC, outside Buncombe County, and proposes storing the unit there until another services site can be identified. The MRI will not be used to scan patients or otherwise provides services while outside Buncombe County. InSight seeks confirmation from the CON Section that temporarily placing the existing MRI unit at its Harmony, NC storage facility until an alternate location can be identified does not constitute a new institutional health service or otherwise require CON review and approval.

The situation faced by InSight is similar to that of North Carolina Radiation Therapy Management Services, Inc. ("NCRRTMS"), which lost its practice location in Asheville through no fault of its own following a fire in the medical office building in which it was located. NCRRTMS was forced to store the two linear accelerators that had been operated at its practice location until it could identify a new site from which to operate the equipment. The CON Section allowed NCRRTMS to store the equipment until a new location was identified without losing its CON, and ultimately approved a subsequent exemption request to re-activate one of the linear accelerators and place it at a new site in Weaverville. *See* July 19, 2012 CON Section Determination. (Attachment A) Like NCRRTMS, InSight lost its location through the unforeseen actions of another party, and is seeking to store its existing, CON-approved equipment until an alternative location is identified.

#### Replacement Equipment

Additionally, InSight requests that the CON Section confirm that the replacement of the existing MRI unit with another unit already owned by InSight is exempt from CON review pursuant to N.C.G.S. § 131E-184(a)(7). In evaluating its options in light of Marquis Diagnostic's sudden cessation of operations and contract default, InSight identified a customer site in another state at which the unit could be put to productive use. InSight proposes to replace the existing 1.5T Siemens MRI unit with a 1.5T General Electric MRI unit already owned by InSight and move the existing Siemens MRI unit out of North Carolina. Accordingly, the replacement of the existing Siemens MRI unit with the proposed General Electric MRI unit will not result in an increase in the number of MRI units in the Buncombe County inventory.

In support of this request, we are attaching a completed Equipment Comparison Chart (Attachment B), which reflects that the existing unit and the proposed replacement unit are comparable medical equipment. Both units are 1.5T MRI scanners with comparable

Martha Frisone, Chief  
March 27, 2014  
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functionality that are used for the same diagnostic purposes. The replacement of the existing Siemens MRI with the proposed General Electric MRI already owned by InSight will not result in an impermissible increase in patient charges or operating expenses, consistent with 10A N.C.A.C. 14C.0303(d)(3).

We appreciate your review of and response to this request. Please let us know if you have any questions or need additional information from us.

Sincerely,

SMITH MOORE LEATHERWOOD LLP

  
Allyson Jones Labban

Enclosures



North Carolina Department of Health and Human Services  
Division of Health Service Regulation  
Certificate of Need Section  
2704 Mail Service Center • Raleigh, North Carolina 27699-2704  
<http://www.ncdhhs.gov/dhsr/>

Beverly Beves Perdue, Governor  
Albert A. Della, Acting Secretary

Drexdal Pratt, Director

Craig R. Smith, Section Chief  
Phone: (919) 855-3873  
Fax: (919) 733-8139

July 19, 2012

Mr. William R. Shenton  
PoynerSpruill  
PO Box 1801  
Raleigh, NC 27602

RE: No Review / North Carolina Radiation Therapy Management Services, Inc. / Relocation of linear accelerator and CT scanner / Buncombe County

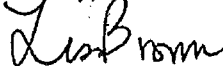
Dear Mr. Shenton:


The Certificate of Need (CON) Section received your letter of July 5, 2012 regarding the above referenced proposal. Based on the CON law in effect on the date of this response to your request, the proposal described in your correspondence is not governed by, and therefore, does not currently require a certificate of need. However, please note that if the CON law is subsequently amended such that the above referenced proposal would require a certificate of need, this determination does not authorize you to proceed to develop the above referenced proposal when the new law becomes effective.

It should be noted that this determination is binding only for the facts represented by you. Consequently, if changes are made in the project or in the facts provided in your correspondence referenced above, a new determination as to whether a certificate of need is required would need to be made by the Certificate of Need Section. Changes in a project include, but are not limited to: (1) increases in the capital cost; (2) acquisition of medical equipment not included in the original cost estimate; (3) modifications in the design of the project; (4) change in location; and (5) any increase in the number of square feet to be constructed.

In addition, you should contact the Construction Section to determine if they have any requirements for development of the proposed project. Please contact the CON Section if you have any questions. Also, in all future correspondence you should reference the Facility I.D.# (FID) if the facility is licensed.

Sincerely,

  
Les Brown  
Project Analyst

  
Craig R. Smith, Chief  
Certificate of Need Section

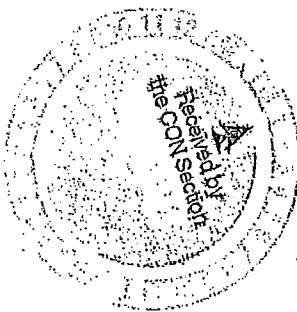
cc: Medical Facilities Planning Section, DHSR  
Construction Section, DHSR



Location: 809 Ruggles Drive, Dorothea Dix Hospital Campus, Raleigh, N.C. 27603  
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Attachment A



Poyner Spruill<sup>LLP</sup>

July 5, 2012

William R. Shenton  
Partner  
D: 919.783.2947  
F: 919.783.1075  
wshenton@poynerspruill.com

**HAND DELIVERY**

Craig R. Smith  
Chief  
CON Section  
809 Ruggles Drive  
Raleigh, NC 27603

Martha Frisone  
Assistant Chief  
CON Section  
809 Ruggles Drive  
Raleigh, NC 27603

RE: North Carolina Radiation Therapy Management Services, Inc.  
Relocation of Linear Accelerator to Weaverville

Dear Mr. Smith and Ms. Frisone:

I am writing on behalf of North Carolina Radiation Therapy Management Services, Inc. ("NCRRTMS") to follow up on prior communications about the linear accelerators that it operated at 445 Biltmore Avenue in Asheville. This letter describes plans by NCRRTMS to re-activate one of these linear accelerators, and locate it on a site in Weaverville, a town in Buncombe County located about 15 miles north of Asheville. After you have had an opportunity to review this proposal, we request that you confirm that the activities described do not constitute a new institutional health service at all and that NCRRTMS does not need to obtain a certificate of need to proceed with its plans for the Weaverville site.

**BACKGROUND**

You may recall that the Regional Operations Director for NCRRTMS in North Carolina, Rosa Maynor, and I met with you early in March and during our meeting she explained that NCRRTMS was actively exploring options for the sites of the two linear accelerators that were displaced from the Biltmore Avenue location in July of 2011 when a fire caused significant damage to the building. NCRRTMS had operated a Siemens Oncor linear accelerator ("the Siemens Linac") and a Varian 600 linear accelerator at 445 Biltmore Avenue before the fire. Once it got access to the building, NCRRTMS removed the linear accelerators from their ground floor location while NCRRTMS awaited news about the building owner's plans to make the space useable again.

As Ms. Maynor explained during our meeting in early March, when a good bit of time already had elapsed since the fire, there was no definite word on when the 445 Biltmore building would be available. Unfortunately, that is still the case. At the time of our meeting, there was a tentative indication that the building might be ready for occupancy sometime in July of this year, almost a full year after the fire. However, the latest word as of early this month is that it will be about five more months before NCRRTMS could even begin renovations at the 445 Biltmore Avenue location. The continued unavailability of these two linacs has created a significant burden on patients and physicians since the fire. As you know, the CON Section confirmed that NCRRTMS could purchase ownership interests associated with the operation of a linear accelerator at 20 Medical Park in Asheville. This made more capacity available, but it is not adequate to treat all the patients referred to NCRRTMS while the other two linacs have been out of service. As a result, NCRRTMS has been making arrangements since the fire to refer some patients to its centers in Marion, Park Ridge and Clyde, but while these two linacs have been out of commission, a number of patients also had to be referred to other providers for radiation therapy.

Craig R. Smith  
Martha Frisone  
July 5, 2012  
Page 2

Poyner Spruill<sup>LLP</sup>

As Ms. Maynor explained at our meeting, NCRTMS is committed to continue to operate three linear accelerators in Buncombe County; and above all else, it does not want to proceed with any actions that would jeopardize its ability to continue to do so. After explaining the circumstances surrounding the fire during our meeting, we did not understand you to indicate that you foresee any immediate circumstance in which the ability of NCRTMS to continue to operate all three linear accelerators in the future would be compromised.

As we indicated back in March, as the timeline for occupancy at 445 Billmore Avenue continued to grow, NCRTMS had begun to explore alternative locations for the two linear accelerators that had been deployed there. After consideration of alternatives, and taking account of the continued uncertainty about when the 445 Billmore premises can be restored to their pre-fire condition, NCRTMS has developed detailed plans to deploy the Siemens Linac to a site in Weaverville, which is still in Buncombe County, where a medical office building will be constructed. Deploying the Siemens Linac on this Weaverville site will allow its capacity to come back on line, and establish a site in northern Buncombe County where patients can receive radiation therapy.

This letter presents the basis for determining that the steps necessary to operate the Siemens Linac in Weaverville will not constitute a new institutional health service. We request your earliest possible review and consideration of this proposal in order to restore these vitally needed treatment resources.

#### **I. THE WEAVERVILLE SITE**

The Weaverville Site is a 1.4 acre parcel of land located on Old Mars Hill Hwy at the Exit 17 interchange of US Highway 19 and 23. It is available at a cost of \$325,000. A development company that has done construction for NCRTMS in the past but which is not a subsidiary of NCRTMS has a contractual right to purchase the site but has not done so as yet. It plans to construct a physician office building consisting of a total of 11,000 square feet. Approximately 2,819 square feet in this building will be used to support the operation of the Siemens Linac. Included in this radiation therapy space is a 1600 square-foot bunker that will house the Siemens Linac. Approximately 6,309 square feet in the building will be used as medical office space. The building also will have a front desk/waiting area consisting of 1,872 square feet, which will be used by patients who come to be seen by the physician group or for radiation therapy. The document attached to this letter as Exhibit 1 summarizes the cost information presented below.

##### ***A. Overview of All Construction Costs***

Details of the construction costs of the areas in the building are provided in Exhibit 2, which includes an affidavit from Mr. John Ellis, providing background details about the costs described in his letter, which also is included in Exhibit 2:

- The projected construction cost associated with the 2819 square feet of space that would be used in connection with the operation of the Siemens Linac is \$1,234,750;
- The projected construction cost for 6,309 square feet of general medical office space that is not associated with the provision of radiation therapy services is \$1,577,250;
- The projected construction cost of the Front Desk/Waiting Area of 1,872 square feet that will be jointly used by all patients, is \$468,000; and
- Projected site work and architectural and engineering fees for the building totaling \$700,000.

The sum of these four components of the building match the total amount of \$3,980,000 identified by Mr. Ellis in his letter for all construction costs associated with the entire building.

#### ***B. The Physician Office Building***

The medical office space in the building will consist of 6,309 square feet which will be used for physician practice offices, and will not support the operation of the linear accelerator in any way. A letter is being submitted on behalf of the developer of the physician office building to present the grounds for an exemption under N.C. Gen. Stat. § 131E-184(a)(9). NCR TMS has a management services agreement with the physician practice which includes medical oncologists and radiation oncologists. Under the terms of that agreement, NCR TMS will make this office space available to the physician group for the operation of their medical practice. Since none of these activities constitute a new institutional health service, the construction costs for the medical office space should be viewed under the physician office building exemption, as described in Section II A below, and none of the costs associated with construction of these physician office areas are pertinent to the cost review thresholds in the CON Law.

#### ***C. Radiation Therapy Areas in the Building***

The attached Exhibit 3 includes a first page which identifies the costs associated with each of the radiation therapy-related areas as well as the square footage of each; and a floor plan showing these areas as a second page. All of this space will be leased from the building developer by NCR TMS in a fair market lease. Under the terms of its management services agreement with the physician group, NCR TMS will make these areas available to the physician practice for treatment of patients on the Siemens Linac.

All of the space needed to support the linac operation has been included. The linear accelerator vault and its control room are included (1600 square feet), as well as all of the other areas needed for operation of the radiation therapy service. The radiation therapy area will be designed to accommodate a CT scanner that has been operated at the NCR TMS oncology treatment center located on the campus of Park Ridge Hospital (see further details in Section E, below), and the area needed for the CT scanner (500 square feet) also is included in the computation. All of the construction costs that are described in this letter have been reviewed and confirmed by Mr. John S. Ellis, an architect licensed to practice in North Carolina. The affidavit of Mr. Ellis and other materials in Exhibit 2 present his confirmation that the cost projection of \$1,234,750 for the construction of the radiation therapy related areas is reasonable, based on his experience.

#### ***D. Apportioning Construction Costs for Shared Areas and Features***

To apportion the costs of the radiation therapy area in the building, the total cost of the land and the construction expense was apportioned according to the proportional size of the areas in the building. To obtain the proportional size of the Radiation Therapy Area and the medical office space, we have excluded the Front Desk/Waiting Area that will be used jointly by radiation therapy patients and patients visiting the medical offices, and added the total square footage of the radiation therapy space with the areas that will be exclusively used for medical office space to obtain the appropriate ratio:

$$(Radiation Therapy - 2,819) + (Medical Office - 6,309) = 9,128 \text{ Square feet.}$$

That total of 9,128 was used as the denominator to determine the relative proportion of the two areas:



Radiation Therapy Area:  $2,819 / 9128 = .3088299$  rounded up to 31.0 %; and

Medical Office Space;  $6,309 / 9128 = .69117$  rounded down to 69.0 %.

This computation provides the basis for apportioning construction costs for areas or features that are shared between the physician office and radiation therapy areas in the building at the Weaverville Site. The basis for the total cost of the Front Desk/Waiting Area is the application of the same \$250 per square foot cost as the other non-specialized areas of the building.

Since the cost of the land, site work and the architectural and engineering fees will be included in the rent charged by the developer to NCRTMS to lease the radiation therapy space, and the rent will not be treated by NCRTMS as a capital cost at all, it could be argued that none of these costs need to be included in an overall computation for the purpose of determining whether a certificate of need will be required. Nevertheless, the following computations apportion 31 percent of the total value of each component to Radiation Therapy, based on the pro rata calculation above:

Front Desk/Waiting (\$468,000)	X.31 =	\$ 145,080.00
Land Cost (\$ 325,000)	X.31 =	\$ 100,750.00
A & E (\$250,000)	X.31 =	\$ 77,500.00
Site Work (\$450,000)	X.31 =	\$ 139,500.00
<b>TOTAL</b>		<b>\$ 462,830.00</b>

#### *E. The Equipment to be Deployed at the Weaverville Site*

The medical equipment to be moved to Weaverville consists of the Siemens Linac and a CT scanner, each of which already is owned by NCRTMS. The CT scanner will be relocated from the NCRTMS Park Ridge Center in Hendersonville. When the fire occurred, NCRTMS had been operating a CT scanner at the 445 Biltmore Avenue location. Due to the need for the authorities to investigate the fire and make other arrangements to clear the building to be re-entered, there was a delay before NCRTMS could even enter the building to assess damage and remove any of its equipment. In the meantime, CT scanner capacity was needed, and so NCRTMS proceeded to purchase a reconditioned CT machine. This CT machine was installed at the NCRTMS center in Hendersonville and has been operated there since then. NCRTMS is proposing to relocate that CT machine from Hendersonville to the Weaverville Site.

The Siemens Linac had been operated at the 445 Biltmore Avenue location since July of 2007, until the fire last July. It and the Varian 600 Linac were placed in storage after the fire, once the investigation was complete and NCRTMS could re-enter the building for the first time to assess damage. Since their removal from 445 Biltmore Avenue, both linacs have been stored in the Asheville area.

Since neither the Siemens Linac nor the CT machine will be acquired for the first time for deployment in Weaverville, there will be no acquisition cost for either machine at the Weaverville site. However, for reference purposes, this CT machine had a book value of \$209,565 at the time it was purchased after the fire in 2011, and its book value as of May 31 was \$183,184. In purchasing this CT machine, NCRTMS did not acquire equipment that would require a certificate of need because CT machines are not among the equipment for which a certificate of need is required as a matter of course, and because the value of this CT machine was much less than the cost threshold for Major Medical Equipment in the CON Law.

In addition, once NCRTMS was able to re-enter the 445 Billmore Avenue location, it moved the CT scanner that had been operated there out of state, and so the purchase and deployment of the CT machine in Hendersonville did not result in the creation of any additional diagnostic capacity.

***F. Costs to Deploy the Siemens Linac and CT Scanner in Weaverville***

The attached Exhibit 3 identifies the costs associated with moving and installing the CT Scanner (\$30,000) and also documents the cost to move and install the Siemens Linac (\$130,000). However, for reasons discussed below in Section II C, the cost to relocate the Siemens Linac should not be included in computing the total cost of radiation therapy activities on the Weaverville site.

***G. Other Associated Costs***

NCRTMS also has reviewed the other costs that are associated with its development of plans for the Weaverville site. As the architect, Mr. John Ellis, confirms in his affidavit, the costs associated with the work of his firm are included in the cost totals that are presented in his letter. Other than engaging the architectural firm, NCRTMS did not employ any other outside consultants but there was some internal staff time involved in the following activities: 1) Site assessment; 2) Feasibility studies; and 3) Development of cost estimates and other supporting materials. These activities were carried out by NCRTMS staff who work in the Asheville area, and by staff from an office in Florida. All of these costs were incurred as these employees carried out their job functions; and the expense of their employment would be incurred regardless of the Weaverville Proposal, and so the limited employee costs need not even be included in the computation. Nevertheless, the total cost of all staff time and expenses, including travel expenses, has been computed to be \$11,525, and in order to eliminate any concern about the exclusion of these costs, they all are included in the computation of capital costs associated with the Weaverville site, in Section I H, below.

***H. The total of all the costs identified above is less than \$ 2 Million.***

The following computation aggregates the specific construction costs for the radiation therapy area with the additional apportioned construction costs and other expenses identified. When all the costs identified above in Sections C, D, F, and G are combined, the total is less than the capital expenditure threshold of \$ 2 Million in N.C. Gen. Stat. § 131E-176(16)(b):

Radiation Therapy Construction Costs	\$ 1,234,750.00	
Radiation Therapy Apportioned Costs	\$ 462,830.00	
CT Transportation & Installation Costs	\$ 30,000.00	
Internal Staff Time and Expense	\$ 11,525.00	
<b>TOTAL</b>		<b>\$ 1, 739,105.00</b>

**II. ANALYSIS OF ISSUES UNDER THE CON LAW**

Based on the information provided in, and attached to, this letter, it is clear that the plans to offer radiation therapy services at the Weaverville site through its two Siemens Linacs ("the Weaverville Proposal") do

not constitute a "New Institutional Health Service" and that no certificate of need is required. The information provided about the Weaverville Proposal comprehensively documents all of the costs associated with the establishment of radiation therapy services on the Weaverville site. The linear accelerator and CT scanner that are to be deployed there already are owned by NCRTMS. Therefore, no acquisition cost is associated with the equipment. Furthermore, the costs of reactivating the Siemens Linac, including transportation and installation at the Weaverville site, also should be excluded from the cost computation because these activities constitute nothing more than reactivating equipment that had to be removed and stored as a direct result of a natural disaster, the fire at the 445 Biltmore location.

What follows is a point-by-point analysis of all of the activities described above, in light of pertinent components of the definition of new institutional health services in the Certificate of Need Law.

***A. The general medical office space in the building is exempt from CON review.***

The construction of the 6,309 square feet of medical office space in the building and the associated costs should be exempted under the provision for exemption of construction of physician office building space set forth in N.C. Gen. Stat. § 131E-184(a)(9). This provision exempts from certificate of need review any activities or costs associated with the development or acquisition of a physician office building, regardless of cost, and so long as no new institutional health service (other than a capital expenditure exceeding \$2,000,000) is to be offered or developed in the building. As the following analysis establishes, a careful review of each of the other components of the definition of new institutional health service, shows that no new institutional health service will be developed or offered in the building. By the express terms of the exemption itself, capital expenditures exceeding \$2 Million are excluded from consideration. Therefore, none of the costs attributable to the construction of the general medical office space should be considered as part of the computation. The capital costs to construct the Radiation Therapy Area, or which are proportionately attributed to that area in the building, are addressed below in Section II C.

***B. The Weaverville Proposal does not constitute the establishment of a new health service facility.***

No aspect of the Weaverville Proposal can be interpreted as the establishment of a new "health service facility," defined in N.C. Gen. Stat. § 131E-176(9b):

"Health service facility" means a hospital; long term care hospital; psychiatric facility; rehabilitation facility; nursing home facility; adult care home; kidney disease treatment center, including freestanding hemodialysis units; intermediate care facility for the mentally retarded; home health agency office; chemical dependency treatment facility; diagnostic center; hospice office, hospice inpatient facility, hospice residential care facility; and ambulatory surgical facility.

None of these types of facilities will be established in Weaverville. The CT scanner may be used for some diagnostic procedures, in addition to treatment planning for the linear accelerator. But even when the CT scanner's current value is added to the construction costs for the CT area at the Weaverville site, the total is below the \$500,000 level at which a diagnostic center would be deemed to be established:

"Diagnostic center" means a freestanding facility, program, or provider, including but not limited to, physicians' offices, clinical laboratories, radiology centers, and mobile diagnostic programs, in which the total cost of all the medical diagnostic equipment utilized by the facility which cost ten thousand dollars (\$10,000) or more exceeds five hundred thousand dollars (\$500,000). In determining whether the medical diagnostic equipment in a diagnostic center costs more than five hundred thousand dollars (\$500,000), the costs of the equipment, studies, surveys, designs, plans, working

Craig R. Smith  
Martha Frisone  
July 5, 2012  
Page 7

Poyner Spruill<sup>LLP</sup>

drawings, specifications, construction, installation, and other activities essential to acquiring and making operational the equipment shall be included. The capital expenditure for the equipment shall be deemed to be the fair market value of the equipment or the cost of the equipment, whichever is greater.

The deployment of the CT scanner in Weaverville will not result in the establishment of a diagnostic center. Even when the construction cost for the CT area and control room (\$175,000) and the cost of its transportation and installation (\$30,000), is added to the current value of the CT scanner (\$183,184 as indicated above in Section I E), the resulting total of \$388,184 is well below the \$500,000 threshold that would constitute the establishment of a diagnostic center. The only other item of diagnostic equipment costing more than \$10,000 that may be deployed in the building is an ultrasound machine, which has a value of no more than \$70,000, and which will be installed in the physician office space. This ultrasound machine will serve patients of the physician practice and will not be operated in conjunction with the radiation therapy equipment. However, in order to address this issue simply, even when the value of this ultrasound machine is added to the costs computed previously, the total is below the \$500,000 threshold at which a diagnostic center would be established: (\$388,184 + \$70,000 = \$458,184). Thus, it is clear that neither a diagnostic center nor any of the other types of health service facilities identified in the CON Law are involved in the Weaverville Proposal.

Finally, since no health service facility is involved at all, the Weaverville Proposal also will not involve a relocation of a health service facility from one service area to another that is subject to review under N.C. Gen. Stat. § 131E-176(16)(q). In fact, the equipment will remain in Buncombe County and would not be leaving the service area at any rate.

***C. The Weaverville Proposal will not involve capital expenditures that constitute new institutional health services subject to review.***

The total amount derived from all the computations in Section I of this letter is \$1,739,105. It is noteworthy that this computation actually apportions parts of the costs of the architectural and engineering costs, site work, base building costs, and even the land purchase, although all of these costs will be incurred by the developer. This approach is significantly more inclusive than the methodology adopted in the Final Agency Decision in a case involving an Asheville oncology practice's proposal to install and operate a linear accelerator and CT scanner in a new physician office building. See *Mission Hosps., Inc. v. N.C. DHHS*, 205 N.C. App. 35, 696 S.E.2d 163 (2010).

In the appeal stemming from that case, the Court of Appeals upheld the Division's approach of evaluating the applicable CON threshold dollar amounts based solely upon costs that were truly essential to acquiring and making operational the linear accelerator and CT scanner. Under the approach affirmed in this case, a developer's base costs to construct an exempt physician office building are disregarded and need not be included in determining whether a cost threshold in the CON Law has been exceeded. *Id.* at 50-55, 696 S.E.2d at 174-77. If that approach were carried through to the analysis of costs associated with the Weaverville Site, then all of the developer's base costs would be excluded and the only costs to be included would be the specialized construction for the Siemens Linac and the CT scanner. However, to simplify the analysis of this issue, NCRTMS has adopted a much more conservative approach to computing the costs for its Weaverville Proposal, and has included a broad range of the base building costs.

From this information, it is clear that even after including a number of costs which need not be computed at all in examining the costs "essential" to the Weaverville Proposal -- within the meaning of the CON Law--the total still falls below the \$2,000,000 threshold established in N.C. Gen. Stat. § 131E-176(16)(b).

Craig R. Smith  
Martha Frisone  
July 5, 2012  
Page 8

Poyner Spruill<sup>LLP</sup>

It also is clear that the Weaverville Proposal will not involve an acquisition of major medical equipment that would be subject to review under that capital expenditure threshold in the CON Law. N.C. Gen. Stat. § 131E-176(16)(p). All of the equipment already is owned by NCRTMS.

The cost of transporting and installing the Siemens Oncor linear accelerator has not been included in the computation to this point because the need to relocate and install this linear accelerator arose as a result of the fire at 445 Biltmore Avenue. In transporting the Siemens Linac from storage and installing it in a location where it can resume operations, NCRTMS will be undertaking activities, and incurring expenses, that will only serve to re-establish the operation of an asset that already was in operation and already had been capitalized on the NCRTMS accounts. On the first day it began operations at 445 Biltmore Avenue, all of the costs of its acquisition, transport, and installation at the 445 Biltmore Avenue location already had been incurred and were on the books and subject to amortization as capital expenditures, accounted for over the projected useful life of the machine. Thus, in transporting and installing the Siemens Linac in Weaverville, NCRTMS will simply be incurring an expense to restore operational capacity that already was on the books. The cost to remove it from 445 Biltmore Avenue and store it over these past months has been covered in large part by an insurance policy, which also will cover at least part of the cost of moving it and making it operational again in Weaverville. Any remaining costs not covered by insurance will be accounted for as an expense of operation and maintenance and will not be a capital expenditure that falls within the capital cost thresholds set out in the CON Law. Therefore, none of the costs associated with deployment of the Siemens Linac in Weaverville are capital costs at all.

***D. No specified equipment or services subject to review will be involved.***

Since the linear accelerator and CT scanner that will be deployed in Weaverville already are owned by NCRTMS, there will be no acquisition of equipment as part of the proposal. None of the equipment items listed in N.C. Gen. Stat. § 131E-176(f1) will be acquired as part of the Weaverville Proposal. Likewise, none of the services listed in N.C. Gen. Stat. § 131E-176(f) will be involved in the Weaverville Proposal.

***E. No other component of the definition of New Institutional Health Service is implicated.***

It also is clear that there will be no health service facility beds, no dialysis, hospice or home health services involved, no operating rooms or ambulatory surgery facilities, and no mobile medical equipment involved and hence, none of the other presently codified and effective components of the definition of new institutional health service have any application to any aspect of the Weaverville Proposal. See N.C. Gen. Stat. § 131E-176(16) (c),(d),(e),(l),(m),(n),(o),(r),(s),(u), and (v).

Craig R. Smith  
Martha Frisone  
July 5, 2012  
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Poyner Spruill<sup>LLP</sup>

### III. CONCLUSION

The detailed information provided in this letter and in the attached materials establishes that a total cost projection of \$1,739,105 for all activities associated with the deployment of the linac and CT scanner to Weaverville is reasonable. Accordingly, based on the information provided, and in light of that cost projection, which is supported by the affidavit and other materials from Mr. Ellis, there is no reason to include a contingency factor.

However, even if one adds every bit of the \$130,000 cost to transport and install the Siemens Linac to the total cost of \$1,739,105 identified above, the resulting sum of \$1,869,105 still clearly falls below the \$2 Million capital expenditure threshold that would trigger review.

Based on the information provided in this letter and the enclosed material, NCRTMS does not require a certificate of need to proceed with its plans for Weaverville, which do not constitute a new institutional health service. We expect to be able to get back in touch with you in the next few weeks concerning the deployment of a replacement machine for the older, Varian 600 linear accelerator that had been in operation at 445 Biltmore Avenue and which will remain in storage until more concrete information is available about deployment back to 445 Biltmore Avenue, or to another, as yet unidentified site.

Thank-you again for your attention to this matter, and in light of the lengthy delay that has already occurred since the fire, we respectfully request your consideration of expediting your decision on this matter.

Very truly yours,



**William R. Shenton**  
Partner

WRS:klh

## EXECUTIVE SUMMARY OF KEY DETAILS OF THE WEAVERVILLE SITE

### I. Overview Of Construction Costs

Approximately 2,819 square feet in this building will be used to support the operation of the Siemens Linac. Included in this radiation therapy space is a 1600 square-foot bunker that will house the Siemens Linac.

Approximately 6,309 square feet in the building will be used as medical office space.

The building also will have a front desk/waiting area consisting of 1,872 square feet, which will be used by patients who come to be seen by the physician group or for radiation therapy.

Details of the construction costs of the areas in the building are provided in Exhibit 1, which includes an affidavit from Mr. John Ellis, providing background details about the costs described in his letter, which also is included in Exhibit 1:

- The projected construction cost associated with the 2819 square feet of space that would be used in connection with the operation of the Siemens Linac is \$1,234,750;
- The projected construction cost for 6,309 square feet of general medical office space that is not associated with the provision of radiation therapy services is \$1,577,250;
- The projected construction cost of the Front Desk/Waiting Area of 1,872 square feet that will be jointly used by all patients, is \$468,000; and
- Projected site work and architectural and engineering fees for the building totaling \$700,000.

### II. Apportioning The Non-Radiation Therapy Costs

To apportion the costs of the radiation therapy area in the building, the total cost of the land and the construction expense was apportioned according to the proportional size of the areas in the building. To obtain the proportional size of the Radiation Therapy Area and the medical office space, we have excluded the Front Desk/Waiting Area that will be used jointly by radiation therapy patients and patients visiting the medical offices, and added the total square footage of the radiation therapy space with the areas that will be exclusively used for medical office space to obtain the appropriate ratio:

- $(\text{Radiation Therapy} - 2,819) + (\text{Medical Office} - 6,309) = 9,128$  Square feet.

That total of 9,128 square feet was used as the denominator to determine the relative proportion of the two areas in the computation which follows.

- Radiation Therapy Area:  $2,819 / 9128 = .3088299$  rounded up to 31.0 %; and
- Medical Office Space:  $6,309 / 9128 = .69117$  rounded down to 69.0 %.
- Since the cost of the land, site work and the architectural and engineering fees will be included in the rent charged by the developer to NCRTMS to lease the radiation therapy space, and the rent will not be treated by NCRTMS as a capital cost at all, it could be argued that none of these costs need to be included in an overall computation for the purpose of determining whether a certificate of need will be required. Nevertheless, the following computations apportion 31 percent of the total value of each component to Radiation Therapy, based on the pro rata calculation above:

FrontDesk/Waiting (\$468,000)	X.31 =	\$ 145,080.00
Land Cost (\$ 325,000)	X.31 =	\$ 100,750.00
A & E (\$250,000)	X.31 =	\$ 77,500.00
Site Work (\$450,000)	X.31 =	\$ 139,500.00
<b>TOTAL</b>		<b>\$ 462,830.00</b>

**III. The Total Of All The Costs Identified Is Less Than \$ 2 Million.**

The following computation aggregates the specific construction costs for the radiation therapy area with the additional apportioned construction costs and other expenses identified. When all the costs identified are combined, the total is less than the capital expenditure threshold of \$ 2 Million in N.C. Gen. Stat. § 131E-176(16)(b):

Radiation Therapy Construction Costs	\$ 1,234,750.00	
Radiation Therapy Apportioned Costs	\$ 462,830.00	
CT Transportation & Installation Costs	\$ 30,000.00	
Internal Staff Time and Expense	\$ 11,525.00	
<b>TOTAL</b>		<b>\$ 1,739,105.00</b>



EXHIBIT 2

AFFIDAVIT OF JOHN S. ELLIS, AIA

John S. Ellis, being first duly sworn, deposes and says:

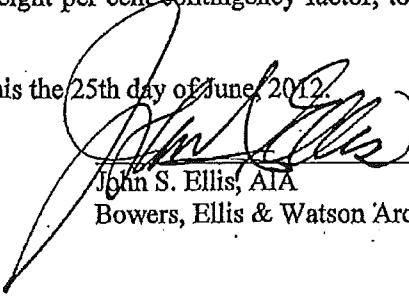
1. My name is John S. Ellis, and I am a member of the American Institute of Architects and a licensed architect in the State of North Carolina.
2. I am a shareholder in Bowers, Ellis & Watson Architects, PA which has an office in Asheville, North Carolina. Our firm has experience in planning and designing buildings and structures for health care facilities, including radiation therapy services. We have participated in the design and construction of at least six radiation therapy projects here in western North Carolina that included linear accelerators.
3. As a result of our firm's experience and my own personal experience, I have detailed knowledge of the costs incurred to construct structures for health care services in the Asheville area, including radiation therapy services provided through linear accelerators.
4. At the request of Mr. Ricardo Andisco of Radiation Therapy Services, Inc., I prepared the letter dated June 15, 2012, that is attached as Exhibit A, to present our firm's architectural and engineering proposal and the probable construction costs for a building to be built on a site located north of Asheville at the intersection of Jupiter Road and US Routes 19 & 23 in Weaverville, North Carolina.
5. The attached Exhibit B shows the planned location of the building and parking area on the Weaverville site. The building planned for this site would contain a total usable area of 11,000 square feet, with 6,309 square feet to be used as general medical office space, 2,819 square feet to be used for the radiation therapy services, and the remaining 1,872 square feet consisting of a front desk and waiting area, jointly used by patients seen in either the medical practices in the building, or in the radiation therapy area.
6. The letter attached as Exhibit A presents the probable construction cost that will be incurred to construct the 8,181 square feet of the building that will be used as general medical office space, and the front desk/waiting area. The probable construction cost estimate of \$250 per square foot is a reasonable probable cost to build general medical office space in Buncombe County, North Carolina.
7. The attached letter also contains a breakdown of the areas in the building that will be used to provide radiation therapy services through the linear accelerator, along with associated construction costs. Based on my experience, I find each of the following space allocations and probable construction costs per square foot to be reasonable:
  - Construction of a vault and control room area for the linear accelerator, consisting of a total of 1,600 square feet at a cost of \$550 per square foot, resulting in a total cost of \$880,000;

- Construction of a 500 square foot area to house a computed tomography scanner with its associated control area, consisting of a total of 500 square feet, at a cost per square foot of \$350 for a total cost of \$175,000.
- Construction of an area of 719 square feet for radiation oncology consisting of: 1) a holding room; 2) a dark room, 3) dosimetry area, 4) an exam room, 5) two dressing rooms and two restrooms (one each for male and female); 6) a mechanical room; and 7) corridor space in the radiation oncology area; all at a cost of \$250 per square foot, the same cost as the non-radiation oncology medical office space.

The total of all these probable construction costs is \$1,234,750, as indicated my letter attached as Exhibit A.

8. In the letter attached as Exhibit A, I also included a probable cost of \$250,000 for architectural & engineering fees (which includes the expenses incurred for providing this Affidavit and the attached exhibits), as well as a probable cost of \$450,000 for all site work and the construction of parking areas, each of which is reasonable based on my experience.
9. Each of the probable cost figures set out in this Affidavit and in my attached letter already includes a seven to eight per cent contingency factor, to allow for unanticipated conditions.

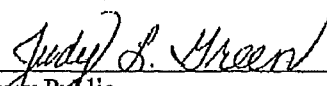
Further, Affiant sayeth not this the 25th day of June, 2012.

  
 John S. Ellis, AIA  
 Bowers, Ellis & Watson Architects, PA

STATE OF NORTH CAROLINA  
 COUNTY OF BUNCOMBE

I hereby certify that John S. Ellis, AIA, did personally appeared before me this day and, after first being duly sworn, did acknowledge to me that he voluntarily signed the foregoing document, knows the contents thereof, and that each of the statements contained in the foregoing document is true to the best of his knowledge and belief.

This the 25 day of June, 2012

  
 Notary Public

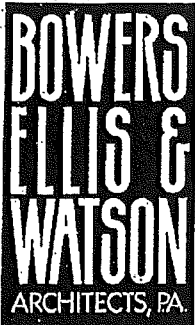
[OFFICIAL SEAL]

Judy L. Green  
 Printed or Typed Name of Notary

JUDY L. GREEN  
 NOTARY PUBLIC  
 BUNCOMBE COUNTY, N.C.  
 My Commission Expires \_\_\_\_\_

My Commission Expires: 4-19-14

June 15, 2012



Mr. Ricardo Andisco  
Radiation Therapy Services, Inc.  
2234 Colonial Blvd.  
Ft. Myers, FL 33907

RE: Weaverville Site Study for  
21<sup>st</sup> Centruy Oncology

Dear Ricardo:

I am writing this letter to serve as our architectural and engineering proposal and probable construction cost on the above referenced project as outlined on the enclosed sketch. It is as follows:

STEVEN W. BOWERS AIA  
JOHN S. ELLIS AIA  
W. MICHAEL WATSON AIA

168 PATTON AVENUE  
ASHEVILLE, NC 28801

828/236-9982

facsimile:  
828/236-9996

e-mail:  
info@bewarch.com

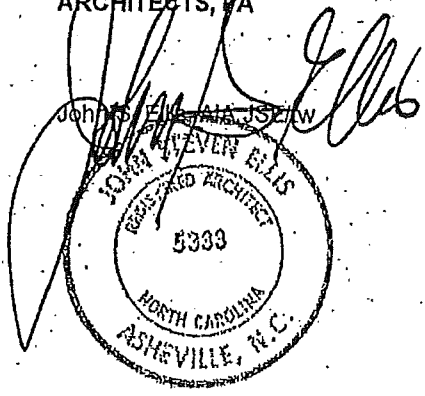
web site:  
www.bewarch.com

<u>Total Project Cost</u>	<u>Sq Ft</u>	<u>Cost Sq Ft</u>	<u>Total Cost</u>
Vault / control Room	1,600	\$550	\$ 880,000
CT Scanner / Control Room	600	\$350	\$ 175,000
Radiation Only Rooms			
Holding Room	78		
Dark Room	66		
Dosimetry	160		
Exam Room	110		
Dressing Room (men)	31		
Dressing Room (women)	31		
Restroom (men)	47		
Restroom (women)	52		
Mechanical Room	60		
Corridors	94		
Total Rad Onc Only	<u>719</u>	\$250	\$ 179,750
Total Vault, CT, Rad Onc	<u>2,819</u>		<u>\$1,234,750</u>
Remaining Non-Rad Onc	<u>8,181</u>	\$250	<u>\$2,045,250</u>
Total Building	<u>11,000</u>		<u>\$3,280,000</u>
Architectural & Engineering			\$ 250,000
Site Work (Parking, Exterior)			\$ 450,000
Total Building and Site Work Cost			<u>\$3,980,000</u>

If you have any questions, please do not hesitate to contact me. Hoping this meets with your approval, I remain

Sincerely,

BOWERS, ELLIS & WATSON  
ARCHITECTS, PA



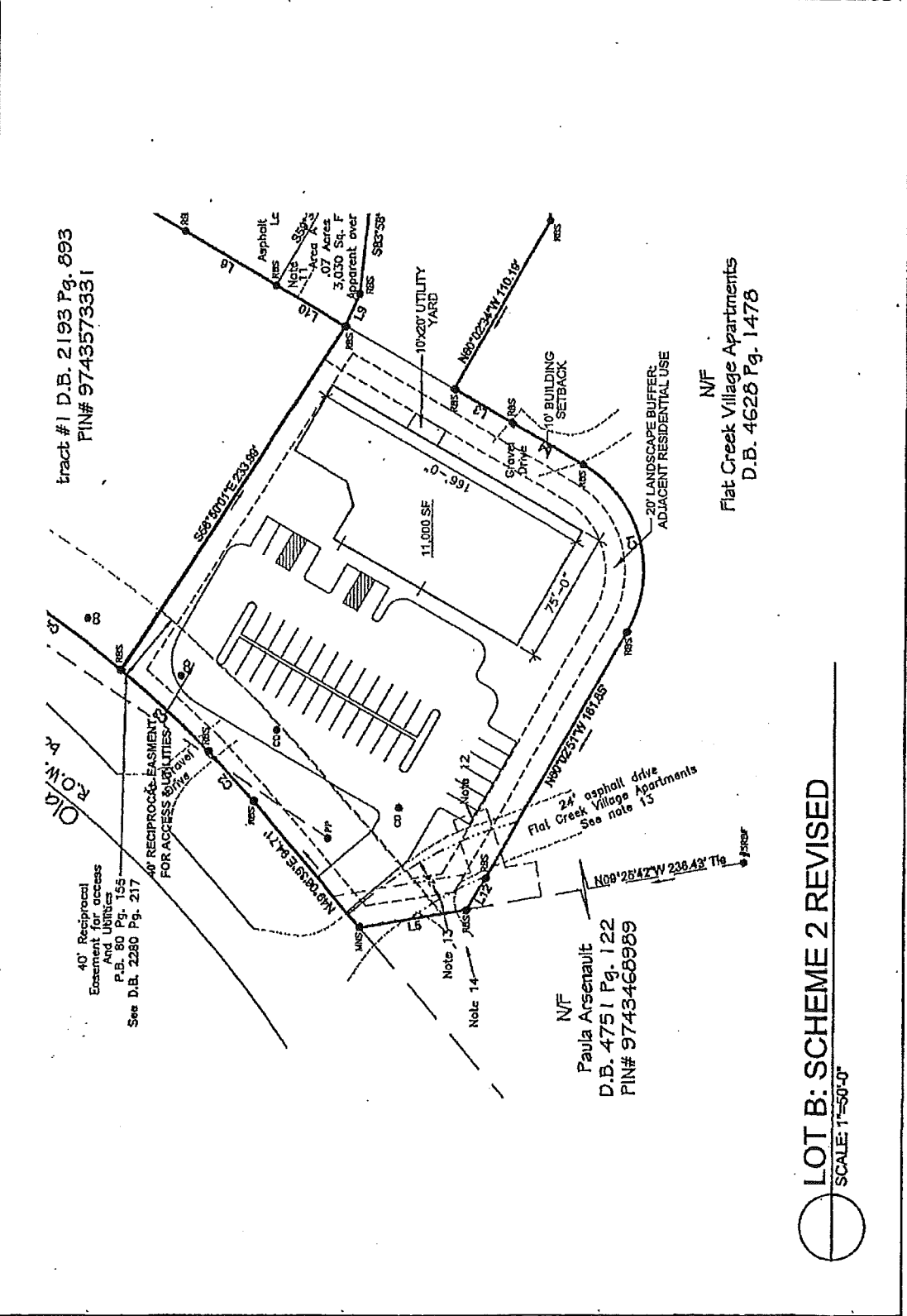
12016\proposal.1  
Enclosure

169 PATTON AVENUE  
 ASHVILLE, NC 28601  
 B.E.W.  
 B.E.W.  
 B.E.W.  
 B.E.W.  
 AS NOTED  
 May 31, 2012

**BOYERS**  
**ELLIS G. WATSON**  
 ARCHITECTS, INC.  
 828 / 238-9996  
 828 / 238-9992

WEAVERVILLE SITE STUDY  
 FOR  
 21st CENTURY ONCOLOGY  
 PRELIMINARY SITE STUDY, LOT B, SCHEME 2 REVISED

LOT B



tract #1 D.B. 2193 Pg. 893  
 PIN# 9743573331

N/F  
 Flat Creek Village Apartments  
 D.B. 4626 Pg. 1478

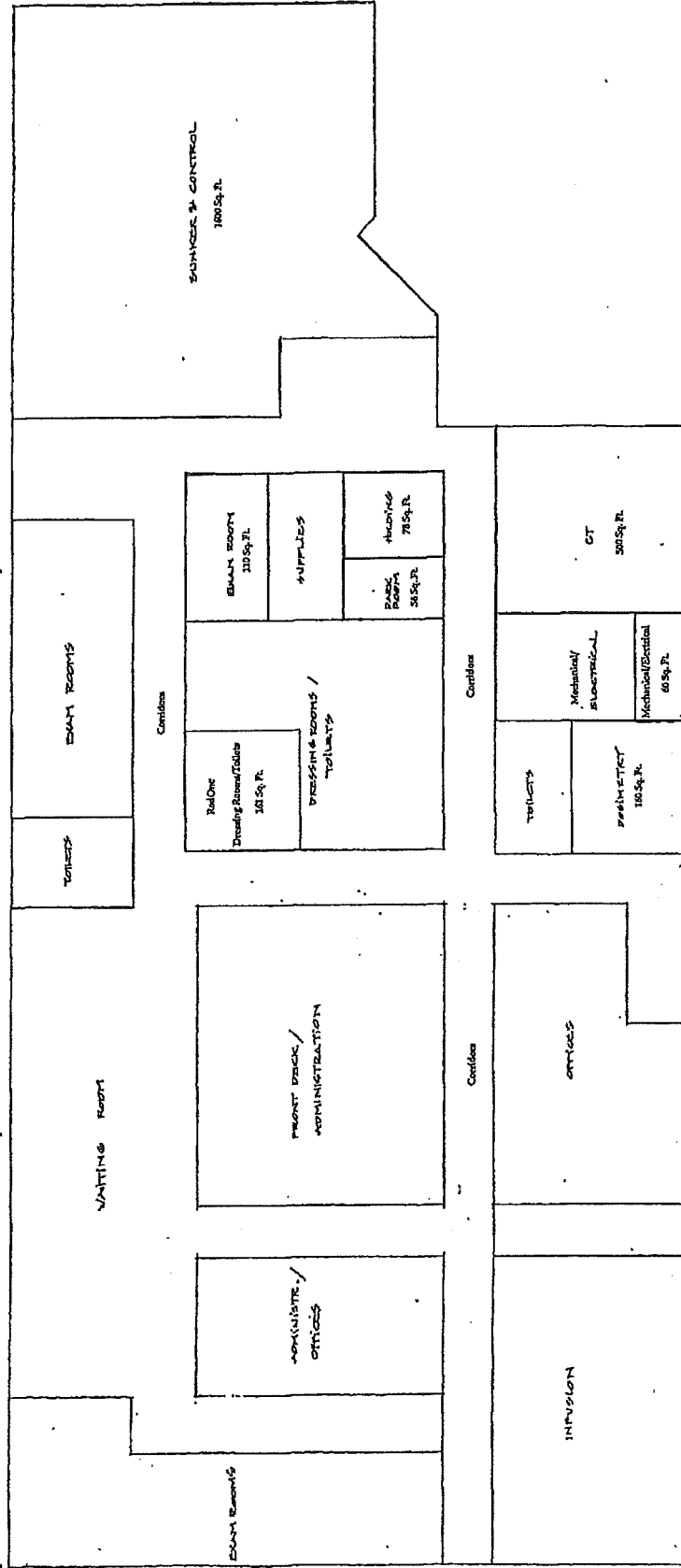
N/F  
 Paula Arsenault  
 D.B. 4751 Pg. 122  
 PIN# 974346889

LOT B: SCHEME 2 REVISED  
 SCALE: 1"=50'-0"



Exhibit 3

Weaverville Cost Summary			
<b>Total Building Cost</b>	<b>11,000 sq. ft.</b>		<b>\$ 3,280,000</b>
Architectural & Engineering			\$ 250,000
Site Work (Parking, Exterior)			\$ 450,000
<b>Total Building and Site Work Cost</b>			<b>\$ 3,980,000</b>
Land			\$ 325,000
<b>Total Project Cost</b>			<b>\$ 4,305,000</b>
<b>Radiation Therapy Costs</b>			
	Sq Ft	Cost Sq Ft	Total Cost
Vault/Control Room	1,600	\$ 550	\$ 880,000
CT Scanner / Control Room	500	\$ 350	\$ 175,000
<b>Radiation Only Rooms</b>			
Holding Room	78		
Dark Room	56		
Dosimetry	160		
Exam Room	110		
Dressing Room (men)	31		
Dressing Room (women)	31		
Restroom (men)	47		
Restroom (women)	52		
Mechanical Room	60		
Corridors	94		
<b>Total Radiation Therapy Only</b>	<b>719</b>	<b>\$ 250</b>	<b>\$ 179,750</b>
<b>Total Vault, CT, Rad Therapy</b>	<b>2,819</b>		<b>\$ 1,234,750</b>
<b>Allocation of Costs to Radiation Therapy</b>			
	Rad	Total Non-Shared	Rad %
Square Feet	2,819	9,128	31.0%
<b>Cost</b>			
Total Vault, CT, Rad Onc.	100%	\$ 1,234,750	\$ 1,234,750
Internal Staff Time (Radiation Specific)	100%	\$ 9,200	\$ 9,200
Internal Staff Time (General)	31%	\$ 7,500	\$ 2,325
Front Desk and Waiting Area	31%	\$ 468,000	\$ 145,080
Land	31%	\$ 325,000	\$ 100,750
Architectural & Engineering	31%	\$ 250,000	\$ 77,500
Site Work (Parking, Exterior)	31%	\$ 450,000	\$ 139,500
<b>Subtotal Rad Onc Cite</b>			<b>\$ 1,709,105</b>
Transport/Install CT Scanner			\$ 30,000
<b>Total Project Costs - Radation Therapy</b>			<b>\$ 1,739,105</b>
[Transport/Install Siemens Oncor Linac]			[ \$ 130,000]



1

EQUIPMENT COMPARISON

	EXISTING EQUIPMENT	REPLACEMENT EQUIPMENT
Type of Equipment (List Each Component)	MRI	MRI
Manufacturer of Equipment	Siemens	General Electric
Tesla Rating for MRIs	1.5	1.5
Model Number	Espre	Signa
Serial Number	30602	R2959
Provider's Method of Identifying Equipment	S1347M	G1305A
Specify if Mobile or Fixed	Fixed*	Fixed*
Mobile Trailer Serial Number/VIN #	1M9A3A8228H022437	1S9FAA482X31182624
Mobile Tractor Serial Number/VIN #	N/A	N/A
Date of Acquisition of Each Component	2/7/2008	9/27/2003
Does Provider Hold Title to Equipment or Have a Capital Lease?	Hold Title	Hold Title
Specify if Equipment Was/Is New or Used When Acquired	New when acquired	New when acquired
Total Capital Cost of Project (Including Construction, etc.) <Use Attached Form>	\$0.00	\$0.00
Total Cost of Equipment	\$0.00	\$0.00 <sup>+</sup>
Fair Market Value of Equipment	N/A	\$250,000.00
Net Purchase Price of Equipment	N/A	
Locations Where Operated	Buncombe County	Buncombe County
Number Days In Use/To be Used in N.C. Per Year	365	365
Percent of Change in Patient Charges (by Procedure)	N/A	0%
Percent of Change in Per Procedure Operating Expenses (by Procedure)	N/A	0%
Type of Procedures Currently Performed on Existing Equipment	All MRI exams	N/A
Type of Procedures New Equipment is Capable of Performing	N/A	All MRI exams

\* While both the existing and the replacement units are housed in mobile coaches, the 2003 CON was issued for a fixed MRI, so the existing unit and the replacement unit are classified and operated as fixed units.  
 + The replacement unit is already owned by InSight.