



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

CORRECTION LETTER

November 19, 2013

William R. Shenton
Poyner Spruill
301 Fayetteville Street
Suite 1900
Raleigh, NC 27602

No Review

Facility or Business: Roanoke Valley Cancer Center

Project Description:

- Transfer of 100% of Roanoke Valley Cancer Center, P.A ownership interests in the linear accelerator and other assets to New LLC
- Acquisition of 100% of New LLC by NCRTMS
- Ground Lease Agreement with Halifax Regional Medical Center

County: Halifax
FID #: 130385

Dear Mr. Shenton:

You received a letter from the Certificate of Need Section (CON) dated November 15, 2013 concerning the above referenced proposal. The letter mistakenly stated:

Per the telephone conversation that you had with Mr. Smith and Mrs. Thorne-Williams on October 25, 2013, the fact that NCRTMS will enter into a ground lease agreement with Halifax Regional Medical Center for the site (land) in which the cancer center will operate does change the decision made by the CON Section in a No Review letter dated August 27, 2013.

However, the letter should have stated:

Per the telephone conversation that you had with Mr. Smith and Mrs. Thorne-Williams on October 25, 2013, the fact that NCRTMS will enter into a ground lease agreement with Halifax Regional Medical Center for the site (land) in which the cancer center will operate **does not** change the decision made by the CON Section in a No Review letter dated August 27, 2013.



Certificate of Need Section

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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Mr. Shenton
November 19, 2013
Page 2

If you have any questions regarding this matter, please feel free to contact me. Please refer to the Project I.D. # and Facility I.D.# (FID) in all correspondence.

Sincerely,



Bernetta Thorne-Williams, Project Analyst



Craig R. Smith, Chief
Certificate of Need Section

cc: Medical Facilities Planning Section, DHSR
Acute and Home Care Licensure and Certification Section, DHSR



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November 15, 2013

William R. Shenton
Poyner Spruill
301 Fayetteville Street
Suite 1900
Raleigh, NC 27602

No Review

Facility or Business: Roanoke Valley Cancer Center

Project Description:

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- Acquisition of 100% of New LLC by NCRTMS
- Ground Lease Agreement with Halifax Regional Medical Center

County: Halifax
FID #: 130385

Dear Mr. Shenton:

The Certificate of Need Section (CON Section) received your letters of July 25, 2013, October 25, 2013 and October 31, 2013 regarding the above referenced proposal. Per the telephone conversation that you had with Mr. Smith and Mrs. Thorne-Williams on October 25, 2013, the fact that NCRTMS will enter into a ground lease agreement with Halifax Regional Medical Center for the site (land) in which the cancer center will operate does change the decision made by the CON Section in a No Review letter dated August 27, 2013. Therefore, 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.

Moreover, you need to contact the Acute and Home Care Licensure and Certification Sections of the Division of Health Service Regulation to determine if they have any requirements for development of the proposed project.

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Mr. Shenton
August 27, 2013
Page 2

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,



Bernetta Thorne-Williams, Project Analyst



Craig R. Smith, Chief
Certificate of Need Section

cc: Medical Facilities Planning Section, DHSR
Acute and Home Care Licensure and Certification Section, DHSR



Poyner Spruill^{LLP}

October 31, 2013

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

VIA HAND DELIVERY

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

Bernetta Thorne-Williams
Project Analyst
CON Section
809 Ruggles Drive
Raleigh, NC 27603

RE: Acquisition of Linear Accelerator Operated by Roanoke Valley Cancer Center

Dear Ms. Frisone and Ms. Thorne-Williams:

I am writing on behalf of North Carolina Radiation Therapy Management Services, Inc. ("NCRRTMS") to confirm that the purchase of the Linear Accelerator Operated by Roanoke Valley Cancer Center has been completed and to confirm one additional point that was mentioned in my attached letter of October 25.

The building occupied by the cancer center was constructed on land owned by Halifax Regional Medical Center, which has had a ground lease arrangement with the owner, Roanoke Valley Cancer Center, P.A. Under the ground lease arrangement, the hospital leased the site to the P.A. which built and owned the building and vault prior to closing of the transaction.

As I indicated in my letter on October 25, and explained in a telephone call with Mr. Smith and Ms. Thorne-Williams on October 25, as the final arrangements for the purchase were being worked out, the possibility arose of having another affiliate of NCRRTMS enter a ground lease with Halifax Regional Medical Center for the building in which the linear accelerator has been operated.

That in fact has occurred. As part of the overall purchase arrangements, Radiation Therapy Associates of Western North Carolina, P.A., an affiliate of NCRRTMS, has entered a ground lease with Halifax Regional Medical Center for the site. As I indicated in my letter of October 25, and as Mr. Smith confirmed in the telephone call on October 25, this additional facet of the transaction does not change the conclusion that the transaction is not subject to further CON review, since it does not entail the purchase or deployment of any additional medical equipment, any capital expenditure, or the offering of any additional health services.

I am writing this final letter, as Mr. Smith requested during the telephone call on October 25, to confirm that this was part of the completed transaction and thank-you for your attention to this matter.

Very truly yours,

William R. Shenton
Partner

Enc.

cc: Craig R. Smith

October 25, 2013

Received by
the CON Section
10/25/2013

William R. Shenton
Partner
D: 919.783.2947
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VIA HAND DELIVERY

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

Bernetta Thorne-Williams
Project Analyst
CON Section
809 Ruggles Drive
Raleigh, NC 27603

RE: Acquisition of Linear Accelerator Operated by Roanoke Valley Cancer Center

Dear Ms. Frisone and Ms. Thorne-Williams:

I am writing a follow up letter on behalf of North Carolina Radiation Therapy Management Services, Inc. ("NCRRTMS") to provide one additional detail concerning the purchase of ownership interests in Roanoke Valley Cancer Center that was not discussed in a prior letter of July 25 (See attached copy of July 25 letter, minus exhibits).


The building occupied by the cancer center was constructed on land owned by Halifax Regional Medical Center, which has had a ground lease arrangement with the current owner, Roanoke Valley Cancer Center, P.A. Under the ground lease arrangement, the hospital leased the site and the P.A. built and owns the building and vault. At the time the July 25 letter was written, the parties thought that with the purchase by NEW LLC of the ownership interests in a successor company to Roanoke Valley Cancer Center, P.A, the existing ground lease would simply continue.

However, since writing the July 25 letter to you, and receipt of your attached letter of August 27, in which the CON Section confirmed that the transaction does not require a certificate of need, the possibility of having another affiliate of NCRRTMS purchase the building and enter a ground lease with the hospital has come up. Since this additional facet of the transaction would not involve the acquisition of any additional equipment, and would simply entail the purchase of the existing building where this health service has been operated for a number of years, we can not foresee any reason that a purchase of the building would present any basis to determine that the transaction requires a certificate of need; but since this has become a possibility, we wanted to advise you of this potential additional facet of the transaction, because there are plans to close the transaction on Monday, as soon as the parties decide how to proceed in regard to the building purchase and resolve any other final details.

Thank you for your attention to this and please advise as soon as possible if you perceive any reason that the acquisition of the building by the NCRRTMS affiliate and its assumption of the lessee role in the ground lease from the hospital would raise any certificate of need issues.

With best wishes, I am

Very truly yours,



William R. Shenton
Partner

Enc.

cc: Craig R. Smith

RALEIGH / CHARLOTTE / ROCKY MOUNT / SOUTHERN PINES

Received by
the CON Section
OCT 25 2013

Poyner Spruill^{LLP}

October 25, 2013

William R. Shenton
Partner
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VIA HAND DELIVERY

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

Bernetta Thorne-Williams
Project Analyst
CON Section
809 Ruggles Drive
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RE: Acquisition of Linear Accelerator Operated by Roanoke Valley Cancer Center

Dear Ms. Frisone and Ms. Thorne-Williams:

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However, since writing the July 25 letter to you, and receipt of your attached letter of August 27, in which the CON Section confirmed that the transaction does not require a certificate of need, the possibility of having another affiliate of NCRTMS purchase the building and enter a ground lease with the hospital has come up. Since this additional facet of the transaction would not involve the acquisition of any additional equipment, and would simply entail the purchase of the existing building where this health service has been operated for a number of years, we can not foresee any reason that a purchase of the building would present any basis to determine that the transaction requires a certificate of need; but since this has become a possibility, we wanted to advise you of this potential additional facet of the transaction, because there are plans to close the transaction on Monday, as soon as the parties decide how to proceed in regard to the building purchase and resolve any other final details.

Thank you for your attention to this and please advise as soon as possible if you perceive any reason that the acquisition of the building by the NCRTMS affiliate and its assumption of the lessee role in the ground lease from the hospital would raise any certificate of need issues.

With best wishes, I am

Very truly yours,



William R. Shenton
Partner

Enc.

cc: Craig R. Smith

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Received by
the CON Section
JUL 25 2013

July 25, 2013

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VIA 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: Acquisition of Linear Accelerator Operated by Roanoke Valley Cancer Center

Dear Mr. Smith and Ms. Frisone:

We are writing on behalf of North Carolina Radiation Therapy Management Services, Inc. ("NCRTMS"), to inform the Certificate of Need Section of its plans to purchase the ownership interests in an organization that operates a linear accelerator located at 212 Smith Church Road in Roanoke Rapids, North Carolina. As a result of the transaction described in this letter, NCRTMS will acquire ownership of the entity that now operates the linear accelerator. Based on the CON Section's treatment of similar arrangements in the past, the transaction described in this letter does not involve an activity for which a certificate of need should be required. In a separate letter to be submitted at a later date, NCRTMS will describe its plans to replace the current linear accelerator operated in Roanoke Rapids and present the basis for an exemption of that replacement from certificate of need review under NC 10 Stat. § 131E-184(a)(7) and 10A NCAC 14C .0303.

OVERVIEW

Roanoke Valley Cancer Center, P.A.

The current owner of the linear accelerator in operation in Roanoke Rapids is Roanoke Valley Cancer Center, P.A. This facility treated its first patient with a Cobalt 60 linear accelerator on April 8, 1988, and thus was in operation and became an "Oncology Treatment Center" before the Certificate of Need Law was amended in 1993 to require a certificate of need before an Oncology Treatment Center is established. Exhibit 1 has excerpts from each State Medical Facilities Plan since 1997, the first SMFP that presented a linear accelerator inventory. This data shows that Roanoke Valley Cancer Center's linear accelerator has operated continuously throughout this period. We understand that late in 1995, it acquired the refurbished Varian Clinac 6/100 linear accelerator, which it operates now, at a total cost of \$295,000, which included all associated construction and upfit costs. Since the purchase of the Varian Clinac 6/100, the following additional equipment purchases associated with the operation of the linear accelerator have occurred, with the stated costs and dates of purchase, where available:

- Acrylic base plate with Silverman support (\$390.00)
- Breast boards (2 model MT-250WC) \$6,190.00
- Cassette holder model MT-300 (\$2,400.00 – May/1996)
- Crosshair laser (\$4,358.72 – July 31, 2001)
- Digital electro meter (\$1,200.00)
- Simulator manufactured by Cascade (\$59,000.00 – July 24, 1998)

As best as can be presently determined, the purchase of the Varian 6/100 linear accelerator was not presented to the CON Section for consideration as a Replacement Equipment exemption under N.C. Gen. Stat. § 131E-184(a)(7). However, as already noted, the center already was in operation and was an established oncology treatment center before the statutory amendment, and so the purchase of the Varian machine did not constitute the initial development or establishment of an oncology treatment center that would require obtaining a certificate of need. In addition, the total cumulative expenditures for all of these equipment purchases, from acquisition of the Varian 6/100 linear accelerator forward to the present time, is \$368,538.72. Thus, the total cost of the current Varian Clinac 6/100 and all other equipment in place at the center since purchase of the Varian Clinac 6/100 falls well below the Major Medical Equipment threshold of \$750,000 defined in N.C. Gen. Stat. § 131E-176 (14o). Accordingly, none of the equipment purchases at the center to date have required a certificate of need.

The Transfer of Ownership Interest in Roanoke Valley Cancer Center, P.A.

The transaction presented in this letter will involve only a transfer of the underlying ownership interests of the center. As its name indicates, Roanoke Valley Cancer Center, P.A., is a professional association. The sole owner of its stock is Dr. C.A. Thannikkary, a licensed physician. Roanoke Valley plans to establish a limited liability company whose interests can be acquired by non-physicians. The linear accelerator and other associated operating assets would be transferred to this **NEW LLC**, and simultaneously with the transfer, NCRTMS would acquire all of the ownership interests in the NEW LLC.

ANALYSIS

The CON Law was enacted to prevent the development and operation of unneeded health services, equipment and facilities. This is made explicit in the first section of the law, where the General Assembly finds: "That the proliferation of unnecessary health service facilities results in costly duplication and underuse of facilities, with the availability of excess capacity leading to unnecessary use of expensive resources and overutilization of health care services." N.C. Gen. Stat. § 131E-175(4). Accordingly, the CON Law essentially focuses on the development and offering of those "new institutional health services" that are listed in N.C. Gen. Stat. § 131E-176(16), and which would create additional health service capacity. Each of the listed new institutional health services entails the establishment of an additional health service or facility, the operation of additional equipment, or an expansion or relocation of existing services. Each of these events could have an impact on the capacity, or service area, of a type of health service and thereby affect how it is utilized. In keeping with its fundamental goals, the CON Law expressly recognizes that certain activities are not subject to review, such as purchases of existing health services, or the repair or replacement of existing facilities or equipment, since these actions do not change the overall capacity of the health care system. Based upon the clear terms of the CON Law and prior declaratory rulings by the Department that have recognized this fundamental principle, the Proposed Transaction does not require a certificate of need.

The Proposed Transaction Will Not Result in a New Institutional Health Service

The CON Law provides that no person shall offer or develop a "new institutional health service" without first obtaining a CON. N.C. Gen. Stat. § 131E-178. However, none of the components of the "new institutional health service" definition addresses, directly or indirectly, the acquisition of ownership interests in an organization that already offers a health service. The CON Law also identifies changes in ownership among the "administrative and other activities that are not integral to clinical management," and which are specifically excluded from the definition of "health service" in the CON Law. N.C. Gen. Stat. § 131E-176(9a). Therefore, based on the text of the law, the acquisition of NEW LLC's ownership interests does not involve a new service at all and should not be subject to CON review.

The Proposed Transaction Does Constitute the Acquisition of a Linear Accelerator or Simulator Subject to Review Under N.C. Gen. Stat. § 131E-176(16)(f1).

The list of new institutional health services does include "the acquisition by purchase, donation, lease, transfer or comparable arrangement" of a linear accelerator or simulator "by or on behalf of any person," N.C. Gen. Stat. § 131E-176(16)(f1)5a, 9; but the proposed acquisition by NCRTMS of all the ownership interests of NEW LLC does not constitute the acquisition of a linear accelerator. As explained above, the transaction is limited to the acquisition of the underlying ownership interests in the corporate entity owning the existing radiation center and its associated equipment. The ownership of the NEW LLC will change to NCRTMS, but its legal status as an existing business entity will not change. Since NEW LLC will remain the same legal entity, the same "person" will own and operate the linear accelerator and other equipment following the Proposed Transaction. See N.C. Gen. Stat. §131E-176(19). Accordingly, and consistent with the rulings issued since the August 2005 amendment, there is no basis to treat the Proposed Transaction as a purchase of a linear accelerator under the provisions of N.C. Gen. Stat. § 131E-176(16)(f1) 5a and to require a certificate of need before it may occur.

The Agency's Past Responses to Similar Transactions Confirm that This Does Not Require a CON.

This request follows prior declaratory rulings which have interpreted the applicability of the CON Law to the purchase of ownership interests in corporate entities that already are operating a health service. In at least four rulings that were issued after the enactment of the August 2005 amendment to the CON Law, the Department has determined that the transfer of ownership interests in organizations that own linear accelerators does not require a certificate of need.

- On August 18, 2011, the Department issued a declaratory ruling finding that Radiation Oncology Centers of the Carolinas, Inc.'s transfer of two CON-approved radiation oncology centers to two wholly-owned subsidiaries did not constitute a new institutional health service or require a certificate of need. See *In re: Request for Declaratory Ruling by Radiation Oncology Centers of the Carolinas, Inc.* (Exhibit 2).
- On September 27, 2010, the Department issued a declaratory ruling confirming that the acquisition by Cancer Centers of North Carolina, P.C. of the majority of the ownership interests in Wake Radiology Oncology Services did not require a certificate of need. See *In re: Request for Declaratory Ruling by Wake Radiology Oncology Services, PLLC, Cancer Centers of North Carolina, P.C., US Oncology, Inc. et al.* (Exhibit 3).

In addition to the two rulings attached as exhibits, the Department also issued a declaratory ruling on December 21, 2007, finding that Rex Healthcare, Inc.'s purchase of the membership interests of Smithfield Radiation Oncology, LLC, was not subject to CON review; and a declaratory ruling on September 14, 2007, confirming that certificate of need review was not required for the sale to another entity of 100% of the stock of a company that owned a linear accelerator.

Craig R. Smith
Martha Frisone
July 25, 2013
Page 4

Poyner Spruill^{LLP}

Finally, in transactions involving acquisitions by NCRTMS of ownership interest in entities that operated linear accelerators in Goldsboro and Clinton, the CON Section has issued no review letters confirming that transactions structured in a similar way to the one described in this letter may proceed without certificate of need review. Attached as **Exhibit 4** is the letter that was issued by the CON Section on April 2, 2012 with regard to the transactions involving the linear accelerator in Clinton.

Thus, the Department and CON Section have consistently determined that events such as the Proposed Transaction do not trigger certificate of need review. The transactions involved in the above-described declaratory rulings are exactly analogous to the Proposed Transaction at issue in this request. Under the Proposed Transaction, NCRTMS will acquire all of the ownership interests in NEW LLC, which will continue to own the Roanoke Valley Cancer Center and its associated equipment, including the Varian 6/100 Linac.

***The Proposed Transaction Does Not Involve the Development
or Expansion of a Health Service Facility***

The Proposed Transaction will not entail a capital expenditure to develop or expand a health service or health service facility because the same equipment will continue to be operated at the same location, and no expansion of services is proposed. Likewise, the Proposed Transaction will not entail "a capital expenditure . . . which relates to the provision of a health service" under N.C. Gen. Stat. § 131E-176(16)(b). The only change that will result from the Proposed Transaction will be in the ownership of NEW LLC, and that change in ownership is not a health service.

As the Department must have determined in the prior declaratory rulings discussed above, the purchase of ownership interests in an existing enterprise, which already is lawfully operating medical equipment and offering services, is not a capital expenditure that "relates to the provision of a health service" under N.C. Gen. Stat. § 131E-176(16)(b). The definition of "health service" in the CON Law specifically excludes "administrative and other activities that are not integral to clinical management." N.C. Gen. Stat. § 131E-176(9a). The ownership of the Roanoke Valley Cancer Center is not integral to its clinical management, and the center's operations will not change as a result of the Proposed Transaction. Therefore, the purchase of ownership interests in NEW LLC is not an activity that is "integral to clinical management," and accordingly is not "a capital expenditure . . . which relates to the provision of a health service" within the meaning of N.C. Gen. Stat. § 131E-176(16)(b).

CONCLUSION

As explained above, since 1995, Roanoke Valley Cancer Center has been operated as a radiation oncology center for many years and that will continue after completion of the Proposed Transaction. The Proposed Transaction would only involve a transfer of the underlying ownership interests in the corporate entity that owns the linear accelerator. The equipment will continue to serve patients at the same location, and there will be no change in the scope of services provided by the Cancer Center as a result of the Proposed Transaction. The Proposed Transaction does not involve the offering or expansion of any new facility, service or equipment, and the State's inventory of linear accelerators will not change as a result of the transaction.

For all of the foregoing reasons, the regulation of events like the Proposed Transaction, involving an existing oncology center and its associated equipment, which does not otherwise implicate the fundamental purposes of the CON Law stated in N.C. Gen. Stat. § 131E-175, is beyond the scope of the CON Law, and should not require a CON. North Carolina courts have recognized that because the CON Law interferes with the normal right to do business, it must be narrowly construed. See *HCA Crossroads*

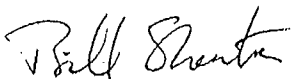
Craig R. Smith
Martha Frisone
July 25, 2013
Page 5

Poyner Spruill^{LLP}

Residential Centers, Inc. v. N.C. Dep't of Human Resources, 327 N.C. 573, 579, 398 S.E.2d 466, 470 (1990) ("When viewed in its entirety, Article 9 of Chapter 131E of the General Statutes, the Certificate of Need Law, reveals the legislature's intent that an applicant's fundamental right to engage in its otherwise lawful business be regulated but not be encumbered with unnecessary bureaucratic delay.") Failure to issue the requested no-review determination would delay and impede the Parties that are requesting this determination in proceeding with a lawful business transaction.

We have enclosed a copy of the Exhibits referenced in this letter (see attached Index). We request your earliest possible attention to this request and look forward to your confirmation that the Proposed Transaction is not a new institutional health service and that it may proceed without a certificate of need. Thank-you for your attention to this matter, and please let me know if there is any additional information you may require.

Very truly yours,



William R. Shenton
Partner



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

August 27, 2013

William R. Shenton
Poyner Spruill
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No Review

Facility or Business: Roanoke Valley Cancer Center

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- o Transfer of 100% of Roanoke Valley Cancer Center, P.A ownership interests in the linear accelerator and other assets to New LLC
- o Acquisition of 100% of New LLC by NCRTMS

County: Halifax
FID #: 130385

Dear Mr. Shenton:

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Moreover, you need to contact the Acute and Home Care Licensure and Certification Sections of the Division of Health Service Regulation to determine if they have any requirements for development of the proposed project.

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



Certificate of Need Section

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Mr. Shenton
August 27, 2013
Page 2

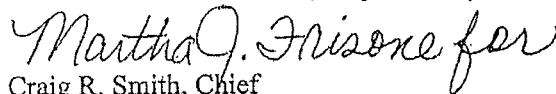
original cost estimate; (3) modifications in the design of the project; (4) change in location; and (5) any increase in the number of square feet to be constructed.

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,



Bernetta Thorne-Williams, Project Analyst



Craig R. Smith, Chief
Certificate of Need Section

cc: Medical Facilities Planning Section, DHSR
Acute and Home Care Licensure and Certification Section, DHSR