



NC DEPARTMENT OF
**HEALTH AND
HUMAN SERVICES**

ROY COOPER • Governor

KODY H. KINSLEY • Secretary

MARK PAYNE • Director, Division of Health Service Regulation

VIA EMAIL ONLY

June 21, 2023

Denise M. Gunter
denise.gunter@nelsonmullins.com

No Review

Record #: 4226
Date of Request: June 15, 2023
Facility Name: Novant Health Breast Center Mint Hill
FID#: 060857
Business Name: Novant Health Norfolk, LLC
Business #: 3726
Project Description: Contribution of imaging assets from Novant Health Breast Center Mint Hill and lease back from a joint venture which is held with a controlling interest
County: Mecklenburg

Dear Ms. Gunter:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency) received your correspondence regarding the project described above. Based on the CON law **in effect on the date of this response to your request**, the project as described is not governed by, and therefore, does not currently require a certificate of need. 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.

This determination is binding only for the facts represented in your correspondence. If changes are made in the project or in the facts provided in the correspondence referenced above, a new determination as to whether a certificate of need is required would need to be made by this office.

Please do not hesitate to contact this office if you have any questions.

Sincerely,

Julie M. Faenza
Project Analyst

Micheala Mitchell
Chief

cc: Acute and Home Care Licensure and Certification Section, DHSR
Radiation Protection Section, DHSR

NC DEPARTMENT OF HEALTH AND HUMAN SERVICES • DIVISION OF HEALTH SERVICE REGULATION

HEALTHCARE PLANNING AND CERTIFICATE OF NEED SECTION

LOCATION: 809 Ruggles Drive, Edgerton Building, Raleigh, NC 27603
MAILING ADDRESS: 809 Ruggles Drive, 2704 Mail Service Center, Raleigh, NC 27699-2704
<https://info.ncdhhs.gov/dhsr/> • TEL: 919-855-3873

AN EQUAL OPPORTUNITY / AFFIRMATIVE ACTION EMPLOYER

Denise M. Gunter
T: 336.774.3322 F: 336.774.3372
denise.gunter@nelsonmullins.com

The Knollwood, 380 Knollwood Street Suite 530
Winston-Salem, North Carolina 27103
T: 336.774.3300 F: 336.774.3299
nelsonmullins.com

June 15, 2023

VIA EMAIL ONLY

Micheala Mitchell, Chief
North Carolina Department of Health and Human Services
Division of Health Service Regulation
Healthcare Planning and Certificate of Need Section
809 Ruggles Drive
Raleigh, North Carolina 27603

Re: Novant Health Norfolk, LLC and Acquisition of Novant Health Breast
Imaging Center Mint Hill
Mecklenburg County
FID: 060857

Dear Ms. Mitchell:

On behalf of Novant Health Norfolk, LLC, Inc. (“NH Norfolk”), I am writing to request the Agency’s written confirmation that the following proposed transaction (the “Transaction”) does not require CON review.

Background

As you may recall, in November 2022, I wrote to the Agency to advise of a proposed transaction in which NH Norfolk would acquire certain imaging assets of Novant Health, Inc. See **Exhibit A**. Novant Health owns 50.1% of the NH Norfolk joint venture. In December 2022, the Agency determined that NH Norfolk was permitted to acquire, without further CON review, certain imaging assets of Novant Health, Inc. Copies of the Agency’s letters stating that no CON was required are attached as **Exhibit B**. The facts represented in my November 2022 letter have not changed.

Description of Current Transaction

The NH Norfolk transaction closed on December 31, 2022. NH Norfolk now proposes to acquire Novant Health Breast Center Mint Hill (“NH BCMH”). NH BCMH is a

hospital outpatient department (“HOPD”) imaging center on the campus of Novant Health Mint Hill Medical Center in Mint Hill, North Carolina. NH BCMH offers screening and diagnostic mammography, breast biopsy, breast ultrasound, and bone density testing. See <https://www.novanthealth.org/breastcenterminthill>. No CON was required for NH BCMH because no CON regulated equipment was purchased and no applicable CON thresholds were crossed.

The structure of the Transaction will be the same as that described in my November 2022 letter. No new or additional health services will be offered as a result of the Transaction. The Transaction does not involve any construction, relocation or acquisition of other imaging assets that Novant Health does not presently own. At all times, the imaging assets at NH BCMH will be under Novant Health’s sole control and will be used solely by Novant Health to provide health care services to Novant Health’s patients, using Novant Health’s charity care and related financial assistance policies to ensure access by medically underserved patients.

Analysis

Pursuant to N.C. Gen. Stat. § 131E-178(a), the CON Law regulates “new institutional health services,” which include, *inter alia*:

- (1) The construction, development, or other establishment of a new health service facility, such as a diagnostic center (N.C. Gen. Stat. § 131E-176(16)a.);
- (2) The obligation by any person of a capital expenditure of more than \$4 million to develop or expand a health service or a health service facility, or which relates to the provision of a health service (N.C. Gen. Stat. § 131E-176(16)b.);
- (3) The acquisition by purchase, donation, lease, transfer, or comparable arrangement of MRI scanners (N.C. Gen. Stat. § 131E-176(16)f1.7); and
- (4) The acquisition by purchase, donation, lease, transfer, or comparable arrangement of major medical equipment, *i.e.*, a single unit or system of components that cost more than \$2 million (N.C. Gen. Stat. § 131E-176(16)p.).

This Transaction does not implicate any of the definitions of “new institutional health services.” With respect to (1) above, the Transaction does not involve the construction, development or other establishment of a new health service facility. With respect to (2) above, the Transaction does not involve the obligation by any person of a capital expenditure of more than \$4 million to develop or expand a health service or health service facility, or which relates to the provision of a health service. With respect to (3) and (4), no CON regulated assets such as MRI scanners are involved, and the transaction does not involve the acquisition of major medical equipment.

Micheala Mitchell
June 15, 2023
Page 3

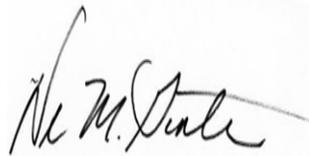
The authorities cited in my November 2022 letter also apply to this Transaction.
See **Exhibit C**.

Accordingly, NH Norfolk respectfully requests the Agency's written confirmation that the foregoing Transaction does not require CON review.

If you should need any further information, please do not hesitate to let me know.

Thank you for your time and consideration.

Sincerely,

A handwritten signature in black ink, appearing to read "Denise M. Gunter", is written over a light gray rectangular background.

Denise M. Gunter

Enclosures



NC DEPARTMENT OF
**HEALTH AND
HUMAN SERVICES**

ROY COOPER • Governor
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MARK PAYNE • Director, Division of Health Service Regulation

VIA EMAIL ONLY

December 7, 2022

Denise M. Gunter
Denise.gunter@nelsonmullins.com

No Review

Record #: 4074
Date of Request: November 28, 2022
Business Name: Novant Health, Inc.
Business #: 1341
Project Description: Contribution of imaging assets and lease back from a joint venture which is held with a controlling interest
County: Statewide

Dear Ms. Gunter:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency) received your correspondence regarding the project described above. Based on the CON law **in effect on the date of this response to your request**, the project as described is not governed by, and therefore, does not currently require a certificate of need. 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.

This determination is binding only for the facts represented in your correspondence. If changes are made in the project or in the facts provided in the correspondence referenced above, a new determination as to whether a certificate of need is required would need to be made by this office.

Please do not hesitate to contact this office if you have any questions.

Sincerely,

Michael J. McKillip
Team Leader

Micheala Mitchell
Chief

NC DEPARTMENT OF HEALTH AND HUMAN SERVICES • DIVISION OF HEALTH SERVICE REGULATION
HEALTHCARE PLANNING AND CERTIFICATE OF NEED SECTION

LOCATION: 809 Ruggles Drive, Edgerton Building, Raleigh, NC 27603
MAILING ADDRESS: 809 Ruggles Drive, 2704 Mail Service Center, Raleigh, NC 27699-2704
<https://info.ncdhhs.gov/dhsr/> • TEL: 919-855-3873

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MARK PAYNE • Director, Division of Health Service Regulation

VIA EMAIL ONLY

December 7, 2022

Denise M. Gunter
Denise.gunter@nelsonmullins.com

Material Compliance Approval - Transfer of Ownership for Good Cause

Project ID #: F-11990-20
Facility: Novant Health Presbyterian Breast Center
Project Description: Relocate diagnostic center to new site within the county, replace some existing equipment, and add additional mammography equipment and an ultrasound unit
County: Mecklenburg
FID #: 200894
Certificate Holder: Novant Health, Inc.
New Owner: Novant Health-Norfolk, LLC

Dear Ms. Gunter:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency) received your notice of transfer of ownership during development of the project identified above. The Agency has determined that good cause exists based on the fact that Novant Health, Inc. will contribute the imaging assets and lease them back from a joint venture in which it holds a controlling interest. Consequently, the Agency shall not withdraw the certificate of need as a result of this transfer.

Please be advised that pursuant to G.S. 131E-181(b), any person who subsequently acquires a certificate of need is required to materially comply with the representations made in the certificate of need application. Further, in accordance with G.S. 131E-190(i), the Agency may bring action in Superior Court for injunctive relief requiring the successor to operate the service in material compliance with those representations.

If the proposed transfer of ownership does **not** happen as described above, the certificate holder must notify the Agency in writing.

It should be noted that this Agency's position is based solely on the facts represented by you and that any change in facts as represented would require further consideration by this office and a separate determination. If you have any questions concerning this matter, please feel free to contact this office.

NC DEPARTMENT OF HEALTH AND HUMAN SERVICES • DIVISION OF HEALTH SERVICE REGULATION
HEALTHCARE PLANNING AND CERTIFICATE OF NEED SECTION

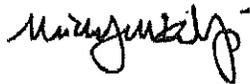
LOCATION: 809 Ruggles Drive, Edgerton Building, Raleigh, NC 27603
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AN EQUAL OPPORTUNITY / AFFIRMATIVE ACTION EMPLOYER

Ms. Gunter
December 7, 2022
Page 2

Please refer to the Project ID # and Facility ID # (FID) in all correspondence.

Sincerely,

A handwritten signature in black ink, appearing to read "Michael J. McKillip". The signature is written in a cursive style with a horizontal line at the end.

Michael J. McKillip
Team Leader

A handwritten signature in black ink, appearing to read "Micheala Mitchell". The signature is written in a cursive style.

Micheala Mitchell
Chief



NC DEPARTMENT OF
**HEALTH AND
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ROY COOPER • Governor
KODY H. KINSLEY • Secretary
MARK PAYNE • Director, Division of Health Service Regulation

VIA EMAIL ONLY

December 7, 2022

Denise M. Gunter
Denise.gunter@nelsonmullins.com

Material Compliance Approval - Transfer of Ownership for Good Cause

Project ID #: G-12208-22
Facility: Novant Health Imaging Piedmont
Project Description: Replace a dedicated breast MRI scanner with a general use MRI scanner and relocate it to Novant Health Imaging Piedmont
County: Forsyth
FID #: 955506
Certificate Holder: Novant Health, Inc.
New Owner: Novant Health-Norfolk, LLC

Dear Ms. Gunter:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency) received your notice of transfer of ownership during development of the project identified above. The Agency has determined that good cause exists based on the fact that Novant Health, Inc. will contribute the imaging assets and lease them back from a joint venture in which it holds a controlling interest. Consequently, the Agency shall not withdraw the certificate of need as a result of this transfer.

Please be advised that pursuant to G.S. 131E-181(b), any person who subsequently acquires a certificate of need is required to materially comply with the representations made in the certificate of need application. Further, in accordance with G.S. 131E-190(i), the Agency may bring action in Superior Court for injunctive relief requiring the successor to operate the service in material compliance with those representations.

If the proposed transfer of ownership does **not** happen as described above, the certificate holder must notify the Agency in writing.

It should be noted that this Agency's position is based solely on the facts represented by you and that any change in facts as represented would require further consideration by this office and a separate determination. If you have any questions concerning this matter, please feel free to contact this office.

NC DEPARTMENT OF HEALTH AND HUMAN SERVICES • DIVISION OF HEALTH SERVICE REGULATION
HEALTHCARE PLANNING AND CERTIFICATE OF NEED SECTION

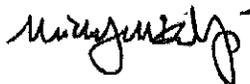
LOCATION: 809 Ruggles Drive, Edgerton Building, Raleigh, NC 27603
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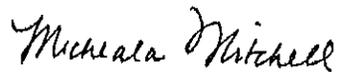
Ms. Gunter
December 7, 2022
Page 2

Please refer to the Project ID # and Facility ID # (FID) in all correspondence.

Sincerely,

A handwritten signature in black ink, appearing to read "Michael J. McKillip".

Michael J. McKillip
Team Leader

A handwritten signature in black ink, appearing to read "Micheala Mitchell".

Micheala Mitchell
Chief

Denise M. Gunter
T: 336.774.3322 F: 336.774.3372
denise.gunter@nelsonmullins.com

The Knollwood, 380 Knollwood Street Suite 530
Winston-Salem, North Carolina 27103
T: 336.774.3300 F: 336.774.3299
nelsonmullins.com

November 28, 2022

VIA EMAIL ONLY

Micheala Mitchell, Chief
North Carolina Department of Health and Human Services
Division of Health Service Regulation
Healthcare Planning and Certificate of Need Section
809 Ruggles Drive
Raleigh, North Carolina 27603
micheala.mitchell@dhhs.nc.gov

Re: Outpatient Imaging Joint Venture

Dear Ms. Mitchell:

On behalf of Novant Health, Inc. (“Novant”), I am writing to request the Agency’s written confirmation that the following proposed transaction (the “Transaction”) does not require CON review. Since the Transaction involves two open CONs, and to the extent that the Transaction implicates N.C. Gen. Stat. § 131E-189, this letter also requests a good cause transfer of these CONs pursuant to N.C. Gen. Stat. § 131E-189(c).

Description of the Transaction

Novant owns various imaging assets located in hospital outpatient departments (“HOPD”) and Independent Diagnostic Testing Facilities (“IDTF”), as well as mobile MRI scanners that serve various host sites throughout North Carolina. Collectively, the HOPD and IDTF locations are referred to as “Centers.” The imaging assets at the Centers consist of different modalities, such as CT, ultrasound, mammography, C-Arm, DEXA, x-ray, fluoroscopy, and MRI (collectively, “Imaging Assets”). A spreadsheet identifying the Centers and their imaging assets is attached hereto as **Exhibit A**¹. Some of the mobile MRI scanners are not located at the IDTF locations shown in Rows 18-35 of **Exhibit A**. These mobile MRI scanners are included as part of the Transaction and are also Imaging Assets. They are included in Rows 39-46 of **Exhibit A**.

¹ Exhibit A is provided in both .pdf and Excel formats.

Novant intends to contribute the Imaging Assets to a new joint venture company, of which Novant will own a controlling interest of 50.1%. The remaining 49.9% of the joint venture company will be owned by Norfolk Management Services, LLC.² The joint venture company is proposed to be called Novant Health-Norfolk, LLC. A copy of the certificate of formation for Novant Health-Norfolk, LLC is attached as **Exhibit B**. Novant Health-Norfolk, LLC will then lease the Imaging Assets back to Novant where they will continue to be used at the Centers identified on **Exhibit A** to provide the same services they currently provide at the same locations. The mobile MRI scanners listed on Rows 39-46 of **Exhibit A** will also be leased back to Novant where they will provide the same services they currently provide at the same host sites they currently serve. A diagram describing the transaction is attached as **Exhibit C**.

No new or additional health services will be offered as a result of the Transaction. The Transaction does not involve any construction, relocation, or acquisition of other Imaging Assets that Novant does not presently own.³ At all times, the Imaging Assets will be under Novant's sole control and will be used solely by Novant to provide health care services to Novant's patients, using Novant's charity care and related financial assistance policies to ensure access by medically underserved patients. To the extent there are CONs for any of the Imaging Assets, Novant, as either a CON holder or the ultimate parent entity of a CON holder, will continue to materially comply with these CONs. The legal names of the Centers, their tax identification and NPI numbers will not change as a result of this transaction; rather, the Centers will continue to operate as they always have. Likewise, the mobile MRI scanners shown on Rows 39-46 of **Exhibit A** will continue to operate as they always have.

Analysis

Pursuant to N.C. Gen. Stat. § 131E-178(a), the CON Law regulates "new institutional health services," which include, *inter alia*:

- (1) The construction, development, or other establishment of a new health service facility, such as a diagnostic center (N.C. Gen. Stat. § 131E-176(16)a.);
- (2) The obligation by any person of a capital expenditure of more than \$4 million to develop or expand a health service or health service facility, or which relates to the provision of a health service (N.C. Gen. Stat. § 131E-176(16)b.);
- (3) The acquisition by purchase, donation, lease, transfer, or comparable arrangement of MRI scanners (N.C. Gen. Stat. § 131E-176(16)f1.7); and
- (4) The acquisition by purchase, donation, lease, transfer, or comparable arrangement of major medical equipment, *i.e.*, a single unit or system of components that cost more than \$2 million (N.C. Gen. Stat. § 131E-176(16)p.).

² Norfolk Management Services, LLC does not own any health care facilities or services in North Carolina and does not provide health care services.

³ Should that occur in the future, Novant will notify the Agency as necessary.

This Transaction does not implicate any of the definitions of “new institutional health services.” With respect to (1) above, the Transaction does not involve the construction, development, or other establishment of a new health service facility. With respect to (2) above, the Transaction does not involve the obligation by any person of a capital expenditure of more than \$4 million to develop or expand a health service or health service facility or provide a new or additional health service. With respect to (3) and (4) above, to the extent the acquisition of CON regulated assets is involved, Novant will own the majority of Novant Health-Norfolk, LLC and continue to have exclusive possession, use and control of the Imaging Assets, just as it does today.

The Agency has previously determined that a similar joint venture arrangement did not require CON review. See **Exhibit D** attached hereto. In 2015, Vidant Radiation Oncology (“VRO”) notified the Agency that two entities, Vidant Medical Center (“Vidant”) and North Carolina Radiation Therapy Management Services, LLC (“NCRT”), planned to contribute their existing linear accelerators to a single joint venture, VRO. The two contributing members, Vidant and NCRT, each owned 50% of VRO. The initial establishment of VRO and the contribution of the linear accelerators to VRO did not require a CON. Later, in 2019, the Agency reaffirmed its earlier position and allowed VRO to acquire, without CON review, two additional linear accelerators and a CT scanner. The VRO no review letters in **Exhibit D** cite ample precedent to support the position that no CON is required for similar arrangements, and that precedent also applies here.

Similar to VRO, Novant Health-Norfolk, LLC merely serves as a conduit for ownership. Notably, Novant’s percentage ownership of Novant Health-Norfolk, LLC will be the majority percentage, whereas in VRO, the ownership percentage was divided equally between the members.

Good Cause Transfer

Novant and its affiliates have received CONs for two projects which are not yet complete. In Project I.D. No. G-12208-22, Novant and Piedmont Imaging LLC received a CON to replace a dedicated breast MRI scanner with a general use MRI scanner and relocate it to Novant Health Imaging Piedmont in Winston-Salem. See **Exhibit E**. In Project I.D. No. F-11990-20, Novant and Presbyterian Breast Center, LLC received a CON to relocate a diagnostic center to a new site in Mecklenburg County, replace some existing equipment and add certain additional equipment. See **Exhibit F**. Each CON is currently being developed. The Transaction involves both of these projects. These CONs will continue to be developed by Novant exactly as described in the CON applications. Novant will materially comply with any conditions on these CONs and will control the projects as 50.1% owner of the Novant Health-Norfolk, LLC. Nevertheless, to the extent that this Transaction may implicate N.C. Gen. Stat. § 131E-189, Novant respectfully asks the Agency to deem this a good cause transfer of these CONs to the joint venture pursuant to N.C. Gen. Stat. § 131E-189(c).

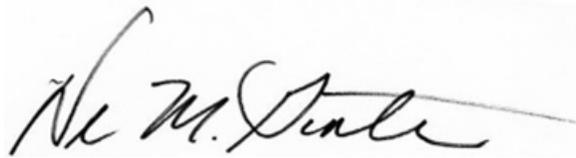
Micheala Mitchell
November 28, 2022
Page 4

Accordingly, Novant respectfully requests the Agency's written confirmation that the foregoing Transaction does not require CON review. Novant further requests confirmation that the good cause transfer provision of N.C. Gen. Stat. § 131E-189(c) applies to the CONs for Project I.D. No. G-12208-22 and Project I.D. No. F-11990-20.

If you should need any further information, please do not hesitate to let me know.

Thank you for your time and consideration.

Sincerely,

A handwritten signature in black ink, appearing to read "Denise M. Gunter", is centered on the page. The signature is written in a cursive style with a long horizontal flourish extending to the right.

Denise M. Gunter

DMG:pfb
Enclosures
cc: Derek L. Hunter, Esq. (with enclosures)(via email)



NC DEPARTMENT OF
HEALTH AND
HUMAN SERVICES

ROY COOPER • Governor

Exhibit C

MANDY COHEN, MD, MPH • Secretary

MARK PAYNE • Director, Division of Health Service Regulation

October 9, 2019

Gary Qualls
430 Davis Drive
Suite 400
Morrisville, NC 27560

No Review

Record #: 3078
Business Name: Vidant Radiation Oncology, LLC
Business #: 2324
Project Description: Vidant Radiation Oncology, LLC (VRO) acquisition of two Linacs and one CT scanner from VRO's current members, Vidant Medical Center and North Carolina Radiation Therapy Management Services, LLC
County: Pitt

Dear Mr. Qualls:

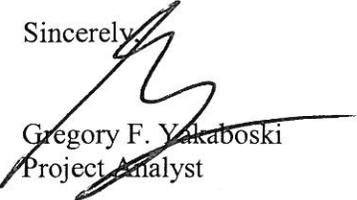
The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency) received your correspondence regarding the above referenced proposal. Based on the CON law **in effect on the date of this response to your request**, the proposal described in that correspondence is not governed by, and therefore, does not currently require a certificate of need. 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.

You may need to contact the Agency's Acute and Home Care Licensure and Certification Section to determine if they have any requirements for development of the proposed project.

This determination is binding only for the facts represented in your correspondence. If changes are made in the project or in the facts provided in the correspondence referenced above, a new determination as to whether a certificate of need is required would need to be made by this office.

Please do not hesitate to contact this office if you have any questions.

Sincerely,


Gregory F. Yakaboski
Project Analyst


Martha J. Frisone
Chief

cc: Acute and Home Care Licensure and Certification Section, DHSR

NC DEPARTMENT OF HEALTH AND HUMAN SERVICES • DIVISION OF HEALTH SERVICE REGULATION
HEALTHCARE PLANNING AND CERTIFICATE OF NEED SECTION

LOCATION: 809 Ruggles Drive, Edgerton Building, Raleigh, NC 27603
MAILING ADDRESS: 809 Ruggles Drive, 2704 Mail Service Center, Raleigh, NC 27699-2704
<https://info.ncdhhs.gov/dhsr/> • TEL: 919-855-3873

AN EQUAL OPPORTUNITY / AFFIRMATIVE ACTION EMPLOYER

Yakaboski, Greg

From: Qualls, Gary <Gary.Qualls@klgates.com>
Sent: Wednesday, October 02, 2019 3:20 PM
To: Yakaboski, Greg
Subject: [External] RE: additional question

CAUTION: External email. Do not click links or open attachments unless you verify. Send all suspicious email as an attachment to report.spam@nc.gov

Greg:

In response to your question by phone earlier today, this e-mail clarifies that, once the transaction described in my August 22, 2019 VRO No Review Request occurs:

1. VRO will have 100% ownership of the two linacs and one CT scanner described in the August 22 letter (in Ahoskie and Roanoke Rapids); and
2. As represented on page 1 of my August 22 letter, VRO is -- and will continue to be -- a joint venture between Pitt County Memorial Hospital, Incorporated, d/b/a Vidant Medical Center (“Vidant”) and North Carolina Radiation Therapy Management Services, LLC (“NCRT”).

Let me know if I can assist with any other questions.

Thanks

Gary

From: Yakaboski, Greg <greg.yakaboski@dhhs.nc.gov>
Sent: Wednesday, October 2, 2019 8:56 AM
To: Qualls, Gary <Gary.Qualls@klgates.com>
Subject: additional question

Morning Gary,

An additional question has come up re: VRO No Review request. Is there a good time for a phone call either today or tomorrow?

Thanks,
Greg

Sincerely,

Gregory F. Yakaboski

Gregory F. Yakaboski

Project Analyst

[Division of Health Service Regulation](#), Certificate of Need
[NC Department of Health and Human Services](#)

Office: 919-855-3873

Greg.Yakaboski@dhhs.nc.gov

809 Ruggles Drive, Edgerton Building
2704 Mail Service Center
Raleigh, NC 27699-2704

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Yakaboski, Greg

From: Qualls, Gary <Gary.Qualls@klgates.com>
Sent: Tuesday, October 01, 2019 10:48 AM
To: Yakaboski, Greg
Subject: RE: [External] RE: Question re: VRO Acquisition of additional LINAC and CT Scanner

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Correct

Thanks

Gary

From: Yakaboski, Greg <greg.yakaboski@dhhs.nc.gov>
Sent: Tuesday, October 1, 2019 10:47 AM
To: Qualls, Gary <Gary.Qualls@klgates.com>
Subject: RE: [External] RE: Question re: VRO Acquisition of additional LINAC and CT Scanner

Hey Gary,

One last question. I have to put down a County on the letter.... I put Pitt County since it is my understanding that VRO is operated out of Vidant in Greenville... is this correct?

Thanks,
Greg

From: Qualls, Gary <Gary.Qualls@klgates.com>
Sent: Monday, September 30, 2019 3:43 PM
To: Yakaboski, Greg <greg.yakaboski@dhhs.nc.gov>
Subject: RE: [External] RE: Question re: VRO Acquisition of additional LINAC and CT Scanner

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919-466-1182

Thanks

From: Yakaboski, Greg <greg.yakaboski@dhhs.nc.gov>
Sent: Monday, September 30, 2019 3:42 PM
To: Qualls, Gary <Gary.Qualls@klgates.com>
Subject: RE: [External] RE: Question re: VRO Acquisition of additional LINAC and CT Scanner

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Yakaboski, Greg

From: Qualls, Gary <Gary.Qualls@klgates.com>
Sent: Wednesday, September 18, 2019 11:24 AM
To: Yakaboski, Greg
Subject: [External] RE: No Review Request dated 8/22/19 for VRO's acquisition of additional Linear Accelerators and a CT Scanner from current members

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Greg:

Sorry, I got tied up.

This is a different project, in different locations, than the ones you referenced below. The projects you referenced below involve radiation oncology equipment in Greenville. The two sites at issue in my August 22 letter are in Ahoskie and Roanoke Rapids, and my August 22 request deals exclusively with equipment in those two locations. However, the same entity is involved, Vidant Radiation Oncology (“VRO”), as in the projects you referenced below.

As background in my August 22 request, I referenced the Agency’s 2015 approval to merge the radiation oncology assets of Vidant and NCRT into VRO to remind the Agency of how VRO was formed and the assets VRO currently holds. I also referenced the 2015 approval because it is precedent for allowing this new request for the Ahoskie and Roanoke Rapids sites.

Let me know if you have any further questions.

Thanks

Gary

From: Yakaboski, Greg <greg.yakaboski@dhhs.nc.gov>
Sent: Tuesday, August 27, 2019 10:27 AM
To: Qualls, Gary <Gary.Qualls@klgates.com>
Subject: No Review Request dated 8/22/19 for VRO's acquisition of additional Linear Accelerators and a CT Scanner from current members

Good Morning Gary,

Actually just left you a voice mail, then discovered I had a follow up question, so sent this email.

Questions re: the No Review Request that you sent over...

#1) Does this involve the facility “Vidant Radiation Oncology Center at VMC FID #170020” or is this something different?

#2) Does this involve Project ID # Q-11292-17 re: “Vidant Radiation Oncology Center at VMC FID #170020” Project Description “Relocate five existing linear accelerators, two from NC Radiation Therapy Center and three from Leo Jenkins Cancer Center (replacing four) to a new outpatient cancer center at Vidant Medical Center which is currently under construction for a total of five linear accelerators upon project completion”

Overall, as part of your response, please explain the relationship of the No Review request with the facility and project identified above.

Thanks,
Greg

Sincerely,

Gregory F. Yakaboski

Gregory F. Yakaboski
Project Analyst
[Division of Health Service Regulation](#), Certificate of Need
[NC Department of Health and Human Services](#)

Office: 919-855-3873
Greg.Yakaboski@dhhs.nc.gov

809 Ruggles Drive, Edgerton Building
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Yakaboski, Greg

From: Qualls, Gary <Gary.Qualls@klgates.com>
Sent: Wednesday, September 11, 2019 1:09 PM
To: Yakaboski, Greg
Subject: RE: [External] RE: No Review Request dated 8/22/19 for VRO's acquisition of additional Linear Accelerators and a CT Scanner from current members

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Thanks. Will respond very soon.

Gary

From: Yakaboski, Greg <greg.yakaboski@dhhs.nc.gov>
Sent: Wednesday, September 11, 2019 12:56 PM
To: Qualls, Gary <Gary.Qualls@klgates.com>
Subject: FW: [External] RE: No Review Request dated 8/22/19 for VRO's acquisition of additional Linear Accelerators and a CT Scanner from current members

Hey Gary,

Just a very low key reminder re: this letter and my questions/additional information request. Realize that you have been very busy....I am under no time deadline but just wanted to bring this back to your attention in case you had a time deadline.

Greg

From: Qualls, Gary <Gary.Qualls@klgates.com>
Sent: Tuesday, August 27, 2019 10:32 AM
To: Yakaboski, Greg <greg.yakaboski@dhhs.nc.gov>
Subject: [External] RE: No Review Request dated 8/22/19 for VRO's acquisition of additional Linear Accelerators and a CT Scanner from current members

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Will do

Thanks

Gary

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Yakaboski, Greg

From: Qualls, Gary <Gary.Qualls@klgates.com>
Sent: Tuesday, August 27, 2019 10:32 AM
To: Yakaboski, Greg
Subject: [External] RE: No Review Request dated 8/22/19 for VRO's acquisition of additional Linear Accelerators and a CT Scanner from current members

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Will do

Thanks

Gary

From: Yakaboski, Greg <greg.yakaboski@dhhs.nc.gov>
Sent: Tuesday, August 27, 2019 10:27 AM
To: Qualls, Gary <Gary.Qualls@klgates.com>
Subject: No Review Request dated 8/22/19 for VRO's acquisition of additional Linear Accelerators and a CT Scanner from current members

Good Morning Gary,

Actually just left you a voice mail, then discovered I had a follow up question, so sent this email.

Questions re: the No Review Request that you sent over...

#1) Does this involve the facility "Vidant Radiation Oncology Center at VMC FID #170020" or is this something different?

#2) Does this involve Project ID # Q-11292-17 re: "Vidant Radiation Oncology Center at VMC FID #170020" Project Description "Relocate five existing linear accelerators, two from NC Radiation Therapy Center and three from Leo Jenkins Cancer Center (replacing four) to a new outpatient cancer center at Vidant Medical Center which is currently under construction for a total of five linear accelerators upon project completion"

Overall, as part of your response, please explain the relationship of the No Review request with the facility and project identified above.

Thanks,
Greg

K&L GATES



Gary S. Qualls
 D 919.466.1182
 F 919.516.2072
 gary.qualls@klgates.com

August 22, 2019

Via Hand Delivery

Martha J. Frisone, Chief
 Healthcare Planning and Certificate of Need Section
 Division of Health Service Regulation
 N.C. Department of Health and Human Services
 809 Ruggles Drive
 Raleigh, NC 27603

Re: No Review Request for VRO's Acquisition of Additional Linear Accelerators and a CT Scanner from Current Members

Dear Ms. Frisone:

The purpose of this request is to inform the North Carolina Department of Health and Human Services, Division of Health Service Regulation, Healthcare Planning and Certificate of Need Section (the "Agency") of the contribution of existing radiation oncology equipment and services by the two existing members of Vidant Radiation Oncology ("VRO") into VRO.

As you know from a prior No Review Decision approval (Exhibit A), VRO is an existing joint venture between Pitt County Memorial Hospital, Incorporated, d/b/a Vidant Medical Center ("Vidant") and North Carolina Radiation Therapy Management Services, LLC ("NCRT"). NCRT is a controlled affiliate of 21st Century Oncology. We ask that the Agency confirm that Vidant's and NCRT's respective contributions of two existing linear accelerators ("linacs"), and NCRT's contribution of a CT scanner, to VRO are not reviewable as a new institutional health service under the North Carolina Certificate of Need ("CON") law.

I. Prior CON Approval for VRO.

By letter dated August 12, 2015, the Agency approved Vidant's and NCRT's initial contribution of linacs and related radiation oncology assets to VRO ownership (the "Original VRO Transaction"). See Exhibit A (Agency's August 12, 2015 VRO No Review Decision Approval and July 31, 2015 Request, and related exhibits thereto). VRO has now operated those assets for a number of years.

Martha J. Frisone, Chief
August 22, 2019
Page 2

II. Obtaining VRO's Interest in the Equipment Does Not Require a CON.

VRO now seeks to acquire 100% ownership of two additional linacs and one CT scanner (collectively the "New VRO Equipment") currently owned by VRO members, Vidant and NCRT, respectively. Specifically, the New VRO Equipment is comprised of:

1. A linear accelerator operated by a Vidant-related entity¹ in Ahoskie (the "Ahoskie Equipment"); and
2. A linear accelerator and CT scanner operated by NCRT in Roanoke Rapids (the "Roanoke Rapids Equipment").

This is a related-party transaction. In other words, a separate, third party will not be obtaining ownership of the New VRO Equipment. Instead:

1. For the Ahoskie Equipment, Vidant, the Ahoskie Equipment 100% owner, will become the 50% owner. NCRT will become the other 50% owner through VRO ownership.
2. Likewise, for the Roanoke Rapids Equipment, NCRT, the Roanoke Rapids Equipment 100% owner, will become the 50% owner. Vidant will become the other 50% owner through VRO ownership.

The New VRO Equipment will continue to be operated at the same locations at which they are currently being operated. VRO's ownership of the New VRO Equipment does not involve the offering or expansion of any new health service facility, service or equipment, and the State's inventory of linacs and CT scanners will not change. No new or additional linacs (or other regulated equipment) will be acquired or placed in operation in the State. As detailed below in Section III below, this is similar to other membership changes in regulated equipment ownership, which did not require a CON.

¹ Ahoskie Imaging, LLC and Radiation Services of North Carolina, LLC (the "Vidant Affiliates") collectively own the Ahoskie Linac a/k/a the Ahoskie Equipment. Those Vidant Affiliates are controlled affiliates of East Carolina Health. In turn, East Carolina Health and Vidant are both part of the Vidant Health System as related entities. The Vidant Affiliates currently allow the Ahoskie Equipment to be operated by its affiliate East Carolina Health d/b/a Vidant Roanoke-Chowan Hospital, pursuant to a service agreement, in separate business occupancy physical space from the main hospital building.

Martha J. Frisone, Chief
August 22, 2019
Page 3

III. Continuing to Use VRO as a Conduit for Linac Ownership is Not Regulated Under CON Law.

Vidant and NCRT contributing their respective equipment to VRO does not require a CON. The CON statute provides a lengthy and exclusive list of activities that constitute development of a new institutional health service, requiring a CON. The contribution of equipment by a joint venture member to its own joint venture that already actively provides health services is not included on that list.

Pursuant to a well-established maxim of statutory construction, *expressio unius est exclusio alterius*, those transactions not included in N.C. Gen. Stat. § 131E-176(16) do not require a CON. *See, e.g., In re Miller*, 357 N.C. 316, 325, 584 S.E.2d 772, 780 (2003) (stating that “[u]nder the doctrine of *expressio unius est exclusio alterius*, when a statute lists the situations to which it applies, it implies the exclusion of situations not contained in the list”); *see also Jackson v. A Woman’s Choice, Inc.*, 130 N.C. App. 590, 594, 503 S.E.2d 422, 425 (1998) (internal citations omitted) (“Where a statute is explicit on its face, the courts have no authority to impose restrictions that the statute does not expressly contain.”).

Via their initial joint venture established by the Original VRO Transaction, Vidant and NCRT placed ownership rights of five (5) of their collective linacs into the joint venture, VRO. Vidant and NCRT each own 50% of VRO. As we observed in that Original VRO Transaction Request (which the Agency approved), Vidant and NCRT continued to own those five (5) linacs through their respective ownership of VRO. See Exhibit A.

Now, Vidant and NCRT, through their VRO venture, wish to add the New VRO Equipment (i.e., the Ahoskie Equipment and Roanoke Rapids Equipment) to that same venture and each VRO member will continue to own a 50% interest in their newly contributed equipment.

IV. Prior Analogous Precedent.

The most relevant precedent for this approval is the initial establishment of VRO and the contribution of the five (5) linacs discussed in Part III above. See Exhibit A, pp. 1-10. However, many other previous Declaratory Rulings and No Review Decisions demonstrate that a CON is not required for similar membership interest changes pertaining to CON regulated equipment or there is no CON policy advanced by a review where:

1. All of the regulated equipment or other items (and associated space) to be part of the redesignation transaction at issue already exists and is currently being operated (particularly when the existing owner will continue to have an ownership role in the future).
2. No regulated equipment will be added to or removed from the site at issue.
3. No new service lines will be added to the site at issue.

Martha J. Frisone, Chief
 August 22, 2019
 Page 4

4. No regulated equipment or services will be relocated to or otherwise added to the relevant State Medical Facilities Plan (“SMFP”) service area.

In those instances, the Agency and Division have reasoned that the CON law is not intended to result in unnecessary CON reviews when the existing regulated asset or service will continue to serve the same patient base in the same location, albeit through a different ownership structure. *See HCA Crossroads Residential Centers, The North Carolina Department of Human Resources, 327 N.C. at 579, 398 S.E. 2d at 470.*

A. Original VRO Transaction Approval and Other Radiation Therapy Facility Analogues.

In addition to the approval establishing VRO and the contribution of the five (5) linacs discussed in Part III above (Exhibit A, pp. 1-10), the remainder of Exhibit A consists of numerous Declaratory Rulings and No Review Determinations from the Division and the Agency approving, without CON review, ownership structure changes to *per se* reviewable linear accelerators and related assets. See N.C. Gen. Stat. § 131E-176(16)(f1)(5a).

B. Heart Lung Bypass Equipment Analogues

Another category of relevant precedent is found at pages 56-68 of Exhibit A.² Those No Review Decision approvals pertained to WakeMed’s and Rex’s acquisition of heart-lung bypass machines through ownership of the physician-owned entities that owned the equipment. Like linear accelerators, the acquisition of a heart-lung bypass machine is technically *per se* CON-reviewable. See N.C. Gen. Stat. § 131E-176(16)(f1)(5). However, as in other examples cited throughout this Part IV, the Agency concluded that the CON law is not intended to be implicated when existing equipment (otherwise *per se* reviewable) changes ownership, yet is already counted in the CON and SMFP inventory and simply remains in the same place serving the same patient base.

C. Nursing Facility Analogues

Another category of such precedent is found in Exhibit B to this Request. Exhibit B consists of Agency No Review Decision approvals for Rex Hospital (Ex. B, pp. 1-5) and Hugh Chatham Memorial (Ex. B, pp. 6-18). See Agency’s April 7, 2014 Rex Hospital No Review Decision Approval and March 24, 2014 Request to Obtain Separate License for Rex Rehabilitation Center of Raleigh (and exhibits thereto).

² These examples are contained in Exhibit A because they were cited in support of, and attached to, the Original VRO Transaction No Review Request.

Martha J. Frisone, Chief
August 22, 2019
Page 5

In both instances, the Agency found that no CON review was required where a skilled nursing facility was removed from its associated hospital license and the nursing facility obtained its own separate license from the hospital. Even though a new licensed health service facility was technically created in both situations,³ the Agency made the non-reviewability determination. In these nursing facility examples, as in the instant request, the CON law is not intended to result in unnecessary CON reviews when the existing CON-regulated equipment, beds, or services will continue to serve the same patient base, in the same location. *See HCA Crossroads Residential Centers, The North Carolina Department of Human Resources*, 327 N.C. at 579, 398 S.E. 2d at 470 ("[w]hen viewed in its entirety . . . 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").

In both transactions, the CON and SMFP inventory of nursing home beds remained the same, and those beds remained in the same place serving the same patient base. In the High Chatham Memorial example, the ownership structure was also changing.

D. Hospital Splits

Exhibits C and D to this Request catalogue yet another area of similar agency interpretations. Those Division Declaratory Rulings involved The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas HealthCare System and Mercy Hospital, Inc. (collectively "CHS") and WakeMed, and their respective requests to change the licensure status of hospital segments. In CHS's November 2, 2012 Declaratory Ruling, the Division approved, without a CON, the redesignation of the Mercy Vail Avenue Campus to be relicensed from the Mercy Hospital license (License # H0042) to the Carolinas Medical Center license (License # H0071). See Exhibit C, Declaratory Ruling for the Charlotte-Mecklenburg Hospital Authority d/b/a/Carolinas Healthcare System and Mercy Hospital, Inc., November 2, 2012.

In the CHS Ruling, the Division cited a July 15, 2002 WakeMed Declaratory Ruling (Exhibit D), in which the Division determined that no CON was required for WakeMed to split the WakeMed Raleigh and WakeMed Cary campuses into two separate licensed hospitals, where those facilities had previously operated under a single license. That was true even though the WakeMed transaction technically constituted the creation of a newly licensed health service facility. See N.C. Gen. Stat. §§ 131E-176(9b) and 176(16)(a). In the WakeMed Declaratory Ruling, the Division reasoned that requiring a CON "would be an overly technical interpretation of the Certificate of Need law and not in furtherance of any statutory purpose."

³ See N.C. Gen. Stat. §§ 131E-176(9b) and 176(16)(a).

Martha J. Frisone, Chief
August 22, 2019
Page 6

E. Applying Prior Analogous Precedent

Likewise, here, Vidant and NCRT's contributions of the New VRO Equipment do not constitute the acquisition of a linac or major medical equipment. In fact, the underlying equipment ownership will be essentially the same. Unlike some of the prior situations referenced above that were determined not to be subject to CON review, but similar to the initially approved VRO contributions in 2015, Vidant and NCRT will still retain an ownership interest in the linacs and the CT scanner. No separate third party will be acquiring any ownership interest in the equipment. The same parties will retain ownership of the New VRO Equipment -- just as with all five linacs in the original approval establishing VRO -- and the New VRO Equipment will remain in the same location, and will still be used to serve patients in the same manner.

A "new institutional health service" includes "the acquisition by purchase, donation, lease, transfer, or comparable arrangement . . . by or on behalf of any person" a linear accelerator and simulator. See N.C. Gen. Stat. § 131E-176(16)(f1)(5a) and (f1)(9). However, the transaction contemplated here will not constitute the acquisition of a linear accelerator as defined by N.C. Gen. Stat. § 131E-176(16). As with the Original VRO Transaction:

1. ownership of the radiation therapy equipment will largely be unaffected by this transaction;
2. that equipment will continue to be owned, in part, by the same entities both before and after this transaction; and
3. VRO will merely be the new ownership conduit through which NCRT and Vidant continue to own the New VRO Equipment.

A fundamental concept of corporate law is that the owners of corporate stock are distinct from the corporation itself. *See* Robinson on North Carolina Corporate Law, § 2.08 ("A corporation is a legal entity separate and distinct from its shareholders.") By design, LLC members also stand in a position similar to corporate shareholders. *Id.* at § 34.03[3]. Consequently, under the general principles of business organizations law governing LLC membership interests, the members of an LLC are legally distinct from the LLC itself. *Id.* at § 34.05[1] ("A membership interest may be acquired directly from the LLC or by assignment from another holder").

Vidant and NCRT are merely placing their collective ownership interests into one joint venture and will then each retain a percentage share of the ownership of the joint venture. Therefore, this transaction cannot constitute the acquisition of a linear accelerator because Vidant and NCRT will retain ownership of their respective equipment through VRO.

Martha J. Frisone, Chief
August 22, 2019
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CONCLUSION

Based upon the foregoing information, we request that the Agency:

1. confirm that contribution of the New VRO Equipment into VRO by its members is not reviewable as a new institutional health service under the CON law because it is simply a related entity transaction; or
2. in the alternative, confirm that the New VRO Equipment contributions into VRO are exempt from review under the CON law's exemption provisions in N.C. Gen. Stat. § 131E-184(a)(8).

Thank you for your assistance in regard to this matter. Please feel free to contact me at the number above if you have any questions or need further information.

Sincerely,

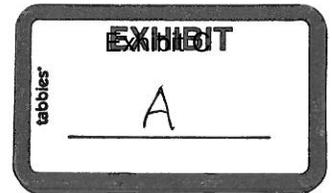


Gary S. Qualls

Martha J. Frisone, Chief
August 22, 2019
Page 8

EXHIBITS

- A. Agency's August 12, 2015 VRO No Review Decision Approval and July 31, 2015 Request, and related exhibits thereto (all Bates Stamped)
1. Certificate of Need CON Project I.D. Q-8562-10
 2. Exemption Request (without exhibits) and Approval to Replace CT Simulator
 3. Certificate of Need CON Project I.D. Q-8558-10
 4. Material Compliance Letter dated May 19, 2011
 5. NC Radiation Therapy-Greenville 2007 Declaratory Ruling
 6. NC Radiation Therapy-Greenville's 2009 Certificate of Need Exemption
 7. Declaratory Ruling for the Charlotte-Mecklenburg Hospital Authority d/b/a/Carolinas Healthcare System, November 4, 2011
 8. In re: Request for Declaratory Ruling by Wake Radiology Oncology Services, PLLC, et al.
 9. In re: Request for Declaratory Ruling by Radiation Therapy Services, Inc. et. al.
 10. No Review/WakeMed/Acquisition of Ownership Interest of CSA-1, Owners of Five Heart-Lung Bypass Machines Located in WakeMed/Wake County
 11. No Review /Rex Hospital, Inc./Acquisition of Ownership Interests of CSAMS Lake Boone, LLC, Owners of three Heart-Lung Bypass Machines Located at Rex Hospital/Wake County
- B. Agency's April 7, 2014 Rex Hospital No Review Decision Approval and March 24, 2014 Request to Obtain Separate License for Rex Rehabilitation Center of Raleigh
- C. Declaratory Ruling for the Charlotte-Mecklenburg Hospital Authority d/b/a/Carolinas Healthcare System and Mercy Hospital, Inc., dated November 2, 2012
- D. Declaratory Ruling for WakeMed, dated July 15, 2002



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 12, 2015

Gary S. Qualls
K&L Gates, LLP
Post Office Box 14210
Research Triangle Park, North Carolina 27709-4210

William R. Shenton
Poyner Spruill
Post Office Box 1801
Raleigh, North Carolina 27602-1801

No Review

Record #: 1683
Business Name: Vidant Radiation Oncology
Business #: 2249
Project Description: Vidant Medical Center becoming 100% owner of NewCo Cancer Services, LLC
County: Pitt

Dear Messrs. Qualls and Shenton:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency) received your letter of July 31, 2015 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.

However, you need to contact the Agency's Construction and Acute and Home Care Licensure and Certification Section, DHSR Sections to determine if they have any requirements for development of the proposed project.



Healthcare Planning and Certificate of Need Section
www.ncdhhs.gov
Telephone: 919-855-3873 • Fax: 919-715-4413
Location: Edgerton Building • 809 Ruggles Drive • Raleigh, NC 27603
Mailing Address: 2704 Mail Service Center • Raleigh, NC 27699-2704
An Equal Opportunity/ Affirmative Action Employer

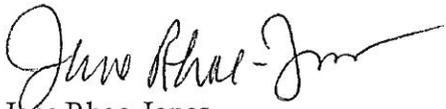


Gary S. Qualls and William R. Shenton
August 12, 2015
Page 2

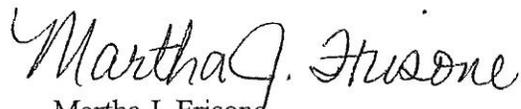
It should be noted that this determination is binding only for the facts represented in your correspondence. Consequently, if changes are made in the project or in the facts provided in your correspondence referenced above, a new determination as to whether a certificate of need is required would need to be made by this office. 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 this office if you have any questions. Also, in all future correspondence you should reference the Business # if the facility is licensed.

Sincerely,



Jane Rhoe-Jones
Project Analyst



Martha J. Frisone
Assistant Chief, Certificate of Need

cc: Acute and Home Care Licensure and Certification Section, DHSR
Construction Section, DHSR
Assistant Chief, Healthcare Planning

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Martha Frisone
Assistant Chief, Certificate of Need
Department of Health and Human Services
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Health Planning and Certificate of Need
Section
809 Ruggles Drive
Raleigh, North Carolina 27603

RE: No Review Request - Joint Venture between Vidant and 21st Century Oncology Affiliate

Dear Ms. Carraway and Ms. Frisone:

On behalf of our client, Pitt County Memorial Hospital, Incorporated, d/b/a Vidant Medical Center ("Vidant"), along with William Shenton, who is counsel for 21st Century Oncology and its North Carolina affiliate, North Carolina Radiation Therapy Management Services, LLC ("NCRT"), enclosed please find an attachment describing a No Review Request for a potential joint venture between Vidant and NCRT.

As indicated in the No Review Request, we do not believe that this joint venture is subject to certificate of need review. Thank you in advance for your attention, and please let me know if you have any questions.

Sincerely,

Gary S. Qualls
Gary S. Qualls

cc: William Shenton

Attachments

Poyner Spruill^{LLP}

July 31, 2015

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

Shelley Carraway
Chief
Healthcare Planning and Certificate of Need Section
NC Department of Health and Human Services
2704 Mail Service Center
Raleigh, NC 27699-2704

Martha Frisone
Asst. Chief
Certificate of Need
NC Department of Health and Human Services
2704 Mail Service Center
Raleigh, NC 27699-2704

RE: No Review Request – Joint Venture between Vidant and 21st Century Oncology Affiliate

Dear Ms. Carraway and Ms. Frisone:

I am writing as counsel for 21st Century Oncology and its North Carolina affiliate, North Carolina Radiation Therapy Management Services, LLC ("NCRT"), to transmit, along with Gary Qualls and Colleen Crowley, who are counsel for Vidant Medical Center, a No-Review request for your consideration. Vidant and NCRT are planning to implement a joint venture which will entail the combination of their respective freestanding radiation equipment and services in the Greenville area into a new limited liability company, called Vidant Radiation Oncology.

The enclosed document describes the steps in the transaction, and as we indicate this joint venture should not be subject to certificate of need review. We appreciate your attention to this request and please feel free to contact counsel for either of the parties if you should have any questions or need further clarification.

Very truly yours,



William R. Shenton
Partner

**No Review Request for Joint Venture between
Vidant Health and 21st Century Oncology**

The purpose of this request is to inform the North Carolina Department of Health and Human Services, Division of Health Service Regulation, Healthcare Planning and Certificate of Need Section (the “Agency”) of a planned joint venture between Pitt County Memorial Hospital, Incorporated, d/b/a Vidant Medical Center (“Vidant”) and North Carolina Radiation Therapy Management Services, LLC (“NCRT”),¹ involving the combination of their existing, freestanding radiation oncology equipment and services into a single joint venture limited liability company to be named Vidant Radiation Oncology (“VRO”). We ask that the Agency confirm that this joint venture is not reviewable as a new institutional health service under the North Carolina Certificate of Need (“CON”) law.

STATEMENT OF FACTS

By way of background, NewCo Cancer Services LLC (“NewCo”), d/b/a Leo Jenkins Cancer Center (“Cancer Center”), a 50/50 joint venture between East Carolina University Brody School of Medicine (“ECU”) and Vidant, owns and operates two existing linear accelerators (“linacs”) and CT simulators, pursuant to CON Project I.D. Q-8562-10. See Certificate of Need attached as Exhibit 1 and Exemption Request and Approval to Replace a CT Simulator attached as Exhibit 2. Vidant also owns and operates a Cyberknife linac, which is operated as a freestanding radiation treatment service at the Cancer Center, pursuant to CON Project I.D. Q-8558-10 and Material Compliance letter dated May 19, 2011. See Certificate of Need attached as Exhibit 3 and Material Compliance Letter attached as Exhibit 4.

NCRT owns and operates two existing linacs as part of NC Radiation Therapy-Greenville. See Declaratory Ruling and Exemption attached as Exhibits 5 and 6.

¹ NCRT is a controlled affiliate of 21st Century Oncology.

First, Vidant seeks to obtain full ownership of the two linacs and CT simulators currently owned by NewCo and located at the Cancer Center. NewCo will continue to exist after Vidant obtains 100% ownership of the linacs and simulators. Once Vidant obtains full ownership, the same equipment will be used to provide the same radiation oncology services, in the same location.

Second, as part of a joint venture, Vidant and NCRT will be combining and contributing their existing freestanding radiation oncology services, medical equipment (including the 5 linacs, one of which is a Cyberknife linac) and related assets to the newly created VRO. After the joint venture transaction occurs, all of the equipment will continue to be operated in the same two locations as described above.² Therefore, as a result of these two steps (collectively, the “Transaction”), no linacs will be relocated or added to Linear Accelerator Service Area 27, as defined by the 2015 State Medical Facilities Plan (“SMFP”).

DISCUSSION

I. Obtaining NewCo’s Interest in the Equipment Does Not Require a CON.

As Step #1 to the Transaction, Vidant seeks to acquire 100% ownership of the two linacs and simulators currently owned by NewCo. A separate, third party will not be obtaining ownership of the linacs and simulators. Instead, Vidant, the 50% owner of the equipment, will now become the 100% owner. The linacs and simulators will continue to be operated at the Cancer Center in the same manner they are currently being operated.

The purchase of NewCo’s interest in the two linacs and simulators does not involve the offering or expansion of any new facility, service or equipment, and the State’s inventory of linacs will not change. No new or additional linacs will be acquired or placed in operation in the

² While at some point in the future VRO may seek to relocate equipment, it would not do so unless and until all necessary approvals are obtained from the Agency.

State. As detailed below in Section II, this is similar to membership change in the ownership of regulated equipment and a CON is not required.

II. Creating VRO as a Conduit for Ownership is Not Regulated Under CON Law.

Likewise, Step 2 in the Transaction -- Vidant and NCRT contributing their respective linacs to VRO -- does not require a CON. The CON statute provides a lengthy and exclusive list of activities that constitute development of a new institutional health service, requiring a CON. The joint venture of two existing entities that already actively provide health services is not included on that list. Pursuant to a well-established maxim of statutory construction, *expressio unius est exclusio alterius*, those transactions not included in N.C. Gen. Stat. § 131E-176(16) do not require a CON. *See, e.g., In re Miller*, 357 N.C. 316, 325, 584 S.E.2d 772, 780 (2003) (stating that “[u]nder the doctrine of *expressio unius est exclusio alterius*, when a statute lists the situations to which it applies, it implies the exclusion of situations not contained in the list”); *see also Jackson v. A Woman’s Choice, Inc.*, 130 N.C. App. 590, 594, 503 S.E.2d 422, 425 (1998) (internal citations omitted) (“Where a statute is explicit on its face, the courts have no authority to impose restrictions that the statute does not expressly contain.”).

Here, Vidant and NCRT will place the ownership rights of all five linacs into the joint venture, VRO. NCRT will own 50% of VRO and Vidant will own 50% of VRO. Therefore, both Vidant and NCRT will continue to own the linacs through their respective ownership of VRO.

Previous Declaratory Rulings and No Review Decisions demonstrate that the Agency and the Division of Health Service Regulation have already determined that a CON is not required for similar membership interest changes pertaining to CON regulated equipment. *See Id.*, attached as Exhibit 7; *In re: Request for Declaratory Ruling by Wake Radiology Oncology*

Services, PLLC, et al., attached as Exhibit 8; *In re: Request for Declaratory Ruling by Radiation Therapy Services, Inc. et. al.*, attached as Exhibit 9; *No Review/WakeMed/Acquisition of Ownership Interest of CSA-1, Owners of Five Heart-Lung Bypass Machines Located in WakeMed/Wake County* attached as Exhibit 10; and *No Review /Rex Hospital, Inc./Acquisition of Ownership Interests of CSAMS Lake Boone, LLC, Owners of Three Heart-Lung Bypass Machines Located at Rex Hospital/Wake County* attached as Exhibit 11.

Likewise, here, Vidant and NCRT's joint venture does not constitute the acquisition of a linac. In fact, the underlying linac ownership will be essentially the same. Unlike some of the prior situations referenced above that were determined not to be subject to CON review, Vidant and NCRT will still retain an ownership interest in the linacs. No separate third party will be acquiring any ownership interest in the equipment. The same parties will retain ownership of all five linacs (now through the joint conduit of VRO); and the linacs will remain in the same location, and will still be used to serve patients in the same manner.

A "new institutional health service" includes "the acquisition by purchase, donation, lease, transfer, or comparable arrangement . . . by or on behalf of any person" a linear accelerator and simulator. N.C. Gen. Stat. § 131E-176(16)(f1)(5a) and (f1)(9). However, the transaction contemplated here will not constitute the acquisition of a linear accelerator as defined by N.C. Gen. Stat. § 131E-176(16). Ownership of the radiation therapy equipment will largely be unaffected by this transaction. That equipment will continue to be owned, in part, by the same entities both before and after this transaction. VRO will be owned by Vidant and NCRT. VRO will merely be the new ownership conduit through which NCRT and Vidant continue to own the radiation oncology treatment equipment.

A fundamental concept of corporate law is that the owners of corporate stock are distinct from the corporation itself. *See* Robinson on North Carolina Corporate Law, § 2.08 (“A corporation is a legal entity separate and distinct from its shareholders.”) By design, LLC members also stand in a position similar to corporate shareholders. *Id.* at § 34.03[3]. Consequently, under the general principles of business organizations law governing LLC membership interests, the members of an LLC are legally distinct from the LLC itself. *Id.* at § 34.05[1] (“A membership interest may be acquired directly from the LLC or by assignment from another holder”).

Vidant and NCRT are merely placing their collective ownership interests into one joint venture and will then each retain a percentage share of the ownership of the joint venture. Therefore, this transaction cannot constitute the acquisition of a linear accelerator because Vidant and NCRT will retain ownership of their respective equipment through the VRO.

CONCLUSION

Based on the discussion herein, Vidant and NCRT request that the Agency provide confirmation that no CON is required for the proposed Transaction described above.

EXHIBITS

1. Certificate of Need CON Project I.D. Q-8562-10
2. Exemption Request (without exhibits) and Approval to Replace CT Simulator
3. Certificate of Need CON Project I.D. Q-8558-10
4. Material Compliance Letter dated May 19, 2011
5. NC Radiation Therapy-Greenville 2007 Declaratory Ruling
6. NC Radiation Therapy-Greenville's 2009 Certificate of Need Exemption
7. *Declaratory Ruling for the Charlotte-Mecklenburg Hospital Authority d/b/a/Carolinas Healthcare System, November 4, 2011*
8. *In re: Request for Declaratory Ruling by Wake Radiology Oncology Services, PLLC, et al.*
9. *In re: Request for Declaratory Ruling by Radiation Therapy Services, Inc. et. al.*
10. *No Review/WakeMed/Acquisition of Ownership Interest of CSA-1, Owners of Five Heart-Lung Bypass Machines Located in WakeMed/Wake County*
11. *No Review /Rex Hospital, Inc./Acquisition of Ownership Interests of CSAMS Lake Boone, LLC, Owners of three Heart-Lung Bypass Machines Located at Rex Hospital/Wake County*

STATE OF NORTH CAROLINA

*Department of Health and Human Services
Division of Health Service Regulation*

CERTIFICATE OF NEED

for

Project Identification Number #Q-8562-10

FID #100878

ISSUED TO: NewCo Cancer Services, LLC
P.O. Box 6028
Greenville, NC 27835

Pursuant to N.C. Gen. Stat. § 131E-175, et. seq., the North Carolina Department of Health and Human Services hereby authorizes the person or persons named above (the "certificate holder") to develop the certificate of need project identified above. The certificate holder shall develop the project in a manner consistent with the representations in the project application and with the conditions contained herein and shall make good faith efforts to meet the timetable contained herein. The certificate holder shall not exceed the maximum capital expenditure amount specified herein during the development of this project, except as provided by N.C. Gen. Stat. § 131E-176(16)e. The certificate holder shall not transfer or assign this certificate to any other person except as provided in N.C. Gen. Stat. § 131E-189(c). This certificate is valid only for the scope, physical location, and person(s) described herein. The Department may withdraw this certificate pursuant to N.C. Gen. Stat. § 131E-189 for any of the reasons provided in that law.

SCOPE: NewCo Cancer Services shall acquire two existing linear accelerators, CT simulator, and related equipment, and multispecialty oncology physician practices from East Carolina University Brody School of Medicine/ Pitt County.

CONDITIONS: See Reverse Side

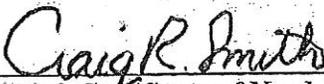
PHYSICAL LOCATION: Pitt County Memorial Hospital
600 Moye Boulevard
Greenville, NC 27834

MAXIMUM CAPITAL EXPENDITURE: \$9,700,000

TIMETABLE: See Reverse Side

FIRST PROGRESS REPORT DUE: May 1, 2011

This certificate is effective as of the 30th day of December, 2010



Chief, Certificate of Need Section
Division of Health Service Regulation

CONDITIONS:

1. NewCo Cancer Services, LLC shall materially comply with all representations made in its application.
2. NewCo Cancer Services, LLC shall not acquire, as part of this project, any equipment that is not included in the project's proposed capital expenditure in Section VIII of the application or which would otherwise require a certificate of need.
3. NewCo Cancer Services, LLC shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Certificate of Need Section in writing prior to the issuance of the certificate of need.

A letter acknowledging acceptance of and agreeing to comply with all conditions stated in the conditional approval letter was received by the Certificate of Need Section on December 6, 2010.

TIMETABLE:

Occupancy/Offering of service(s) _____ April 1, 2011



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

September 13, 2013

Jeffrey Shovelin, Director of Corporate Planning
Vidant Health
Post Office Box 2068
Greenville, North Carolina 27835-6028

Exempt from Review - Replacement Equipment

Facility or Business: Vidant Medical Center
Project Description: Replace CT Scanner and CT Simulator at the Leo Jenkins Cancer Center
County: Pitt
FID #: 933410

Dear Mr. Shovelin:

In response to your letter of August 14, 2013, the above referenced proposal is exempt from certificate of need review in accordance with N.C.G.S 131E-184(a)(7). Therefore, you may proceed to acquire, without a certificate of need, the GE Optima CT580 16 Slice CT Simulator to replace the existing Siemens SimView CT Scanner. This determination is based on your representations that the existing unit will be removed from North Carolina and will not be used again in the State without first obtaining a certificate of need. Further please be advised that as soon as the replacement equipment is acquired, you must provide the CON Section and the Medical Facilities Planning Section with the serial number of the new equipment to update the inventory, if not already provided.

Moreover, you need to contact the Acute and Home Care Licensure and Certification Section and the Construction Section to determine if they have any requirements for development of the proposed project.

It should be noted that this Agency's position is based solely on the facts represented by you and that any change in facts as represented would require further consideration by this Agency and a separate determination. If you have any questions concerning this matter, please feel free to contact this office.



Certificate of Need Section

www.ncdhhs.gov

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

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

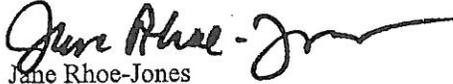
Mailing Address: 2704 Mail Service Center • Raleigh, NC 27699-2704

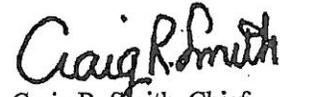
An Equal Opportunity/ Affirmative Action Employer



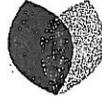
Jeffrey Shovelin
September 13, 2013
Page 2

Sincerely,


Jane Rhoe-Jones
Project Analyst


Craig R. Smith, Chief
Certificate of Need Section

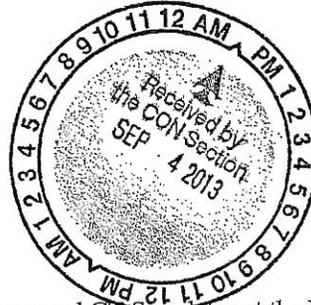
cc: Acute and Home Care Licensure and Certification, DHSR
Construction Section, DHSR
Medical Facilities Planning Branch, DSHR



VIDANT HEALTH™

August 29, 2013

Ms. Jane Rhoe-Jones
 Certificate of Need Section
 Division of Health Service Regulation
 NC Department of Health and Human Services
 2704 Mail Service Center
 Raleigh, NC 27699-2704



RE: Request for "No Review" for Replacement CT Scanner and CT Simulator at the Leo Jenkins Cancer Center

Dear Ms. Rhoe-Jones:

NewCo Cancer Services, LLC (NewCo), a joint venture between Vidant Medical Center and ECU's Leo Jenkins Cancer Center, plans to replace an existing CT simulator with new equipment. NewCo believes that the proposed equipment replacement is not subject to review under North Carolina's Certificate of Need (CON) laws.

The proposed project includes the replacement of a Siemens SimView CT scanner with a GE Optima CT580 16 slice CT simulator (see Appendix A for vendor quotes and Appendix B for equipment comparison table and brochure). The equipment will be secured through accumulated reserves. The reason for this replacement is due to age and the need for upgraded technology to provide optimal care. Only minor renovations are needed for the existing CT simulator suite (See Appendix C for drawings and construction estimate). The total capital costs for the proposed replacement is estimated to be \$ 1,147,781 (see Appendix D for the Capital Cost Sheet). These costs include all expenses associated with the equipment and minor renovations. After the new scanner is operational, the existing equipment will be permanently removed from the facility and will no longer be exempt from CON law (see Appendix E for required documentation of equipment removal).

NewCo's proposed project meets the definition of replacement equipment found in G.S. 131E-176(22a). The total capital expenditure for the equipment is less than \$2,000,000 and the equipment being purchased is for the sole purpose of replacing comparable medical equipment. Since NewCo's proposal meets the definition of "replacement equipment", G.S. 131E-184(a)(7) exempts this project from review. Therefore, NewCo requests approval of a no review status for the proposed project.

If you require additional information or clarification, please contact me at (252)-847-3631.

Jeffrey Shovelin
 Director of Corporate Planning
 Vidant Health

STATE OF NORTH CAROLINA

*Department of Health and Human Services
Division of Health Service Regulation*

CERTIFICATE OF NEED

for

Project Identification Number #Q-8558-10

FID #933410

ISSUED TO: Pitt County Memorial Hospital, Inc.
P.O. Box 6028
Greenville, NC 27835

Pursuant to N.C. Gen. Stat. § 131E-175, et. seq., the North Carolina Department of Health and Human Services hereby authorizes the person or persons named above (the "certificate holder") to develop the certificate of need project identified above. The certificate holder shall develop the project in a manner consistent with the representations in the project application and with the conditions contained herein and shall make good faith efforts to meet the timetable contained herein. The certificate holder shall not exceed the maximum capital expenditure amount specified herein during the development of this project, except as provided by N.C. Gen. Stat. § 131E-176(16)e. The certificate holder shall not transfer or assign this certificate to any other person except as provided in N.C. Gen. Stat. § 131E-189(c). This certificate is valid only for the scope, physical location, and person(s) described herein. The Department may withdraw this certificate pursuant to N.C. Gen. Stat. § 131E-189 for any of the reasons provided in that law.

SCOPE: Pitt County Memorial Hospital shall acquire a CyberKnife radiosurgery system and related equipment from East Carolina University Brody School of Medicine/ Pitt County

CONDITIONS: See Reverse Side

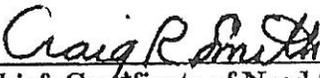
PHYSICAL LOCATION: Pitt County Memorial Hospital
600 Moye Boulevard
Greenville, NC 27834

MAXIMUM CAPITAL EXPENDITURE: \$4,750,000

TIMETABLE: See Reverse Side

FIRST PROGRESS REPORT DUE: May 1, 2011

This certificate is effective as of the 30th day of December, 2010



Chief, Certificate of Need Section
Division of Health Service Regulation

STATE OF NORTH CAROLINA
Department of Health and Human Services
Division of Health Service Regulation

CERTIFICATE OF NEED

for
 Project Identification Number #Q-8558-10

FID #933410

ISSUED TO: Pitt County Memorial Hospital, Inc.
 P.O. Box 6028
 Greenville, NC 27835

Pursuant to N.C. Gen. Stat. § 131E-175, et. seq., the North Carolina Department of Health and Human Services hereby authorizes the person or persons named above (the "certificate holder") to develop the certificate of need project identified above. The certificate holder shall develop the project in a manner consistent with the representations in the project application and with the conditions contained herein and shall make good faith efforts to meet the timetable contained herein. The certificate holder shall not exceed the maximum capital expenditure amount specified herein during the development of this project, except as provided by N.C. Gen. Stat. § 131E-176(16)e. The certificate holder shall not transfer or assign this certificate to any other person except as provided in N.C. Gen. Stat. § 131E-189(c). This certificate is valid only for the scope, physical location, and person(s) described herein. The Department may withdraw this certificate pursuant to N.C. Gen. Stat. § 131E-189 for any of the reasons provided in that law.

SCOPE: Pitt County Memorial Hospital shall acquire a CyberKnife radiosurgery system and related equipment from East Carolina University Brody School of Medicine/ Pitt County

CONDITIONS: See Reverse Side

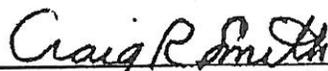
PHYSICAL LOCATION: Pitt County Memorial Hospital
 600 Moye Boulevard
 Greenville, NC 27834

MAXIMUM CAPITAL EXPENDITURE: \$4,750,000

TIMETABLE: See Reverse Side

FIRST PROGRESS REPORT DUE: May 1, 2011

This certificate is effective as of the 30th day of December, 2010


 Chief, Certificate of Need Section
 Division of Health Service Regulation

CONDITIONS:

1. Pitt County Memorial Hospital, Incorporated shall materially comply with all representations made in its application.
2. Pitt County Memorial Hospital, Incorporated shall not acquire, as part of this project, any equipment that is not included in the project's proposed capital expenditure in Section VIII of the application or which would otherwise require a certificate of need.
3. Pitt County Memorial Hospital, Incorporated shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Certificate of Need Section in writing prior to the issuance of the certificate of need.

A letter acknowledging acceptance of and agreeing to comply with all conditions stated in the conditional approval letter was received by the Certificate of Need Section on December 6, 2010.

TIMETABLE:

Occupancy/Offering of service(s) _____ January 1, 2011



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

Beverly Eaves Perdue, Governor
 Lanier M. Cansler, Secretary

www.ncdhhs.gov/dhsr

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

May 19, 2011

Mr. Jeff Shovelin, Director of Corporate Planning
 Pitt County Memorial Hospital
 2100 Stantonsburg Road
 Greenville, NC 27835

RE: Material Compliance/ Project I.D. # Q-8558-10 Pitt County Memorial Hospital shall acquire a CyberKnife radiosurgery system and related equipment from East Carolina University Brody School of Medicine/ Change from operating the CyberKnife as a hospital-based service to a freestanding radiation treatment center/ Pitt County
 FID # 933410

Dear Mr. Shovelin:

In response to your correspondence dated April 18, 2011 regarding the above referenced project, the Certificate of Need Section has determined that the proposed change is in material compliance with representations made in the application. These changes include obtaining an additional NPI number and new Medicare and Medicaid identification numbers to operate the CyberKnife service as a freestanding radiation treatment center at the same location in the Leo W. Jenkins Cancer Center. This change in operating status does not constitute a change in the equipment to be acquired from East Carolina University Brody School of Medicine. However, you should contact the Construction Section of the Division of Health Service Regulation to determine if they have any requirements pertinent to the proposed change.

It should be noted that this Agency's position is based solely on the facts represented by you and that any change in facts as represented would require further consideration by this Agency and a separate determination.

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

Sincerely,

Bernetta Thorne-Williams
 Bernetta Thorne-Williams, Project Analyst

Craig R. Smith
 Craig R. Smith, Chief
 Certificate of Need Section

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



Location: 701 Barbour Drive ■ Dorothea Dix Hospital Campus ■ Raleigh, N.C. 27603
 An Equal Opportunity / Affirmative Action Employer




PITT COUNTY MEMORIAL HOSPITAL
University Health Systems of Eastern CarolinaSM

April 18, 2010

Mr. Craig Smith, Chief
 Certificate of Need Section, Division of Health Service Regulation
 North Carolina Department of Health and Human Services
 2704 Mail Service Center
 Raleigh, NC 27699-2704

Re: Notification of a minor project change to Project ID #Q-8558-10 / Pitt County Memorial Hospital, Inc. / Acquire CyperKnife (linear accelerator) from Brody School of Medicine / Pitt County FID#933410

Dear Mr. Smith:

This letter serves as notification of a minor project change in approved Project ID #Q-8558-10 / Pitt County Memorial Hospital, Inc. / Acquire CyperKnife (linear accelerator) from Brody School of Medicine / Pitt County. We believe the change outlined below does not constitute a material difference in the representations made in the original CON. The change was necessary to comply with the new CMS Life Safety Code Requirements effective February, 2011.

Specifically, in the original application, Pitt County Memorial Hospital, Inc. (PCMH) stated the CyberKnife would be operated in its existing location in the existing Leo W. Jenkins Cancer Center (LWJCC) as a hospital-based service under the hospital's existing provider numbers. As a result of new CMS Life Safety Code Requirements effective February, 2011, the LWJCC does not meet the requirements for institutional space. Therefore, in its existing location, the CyberKnife cannot be operated as a hospital-based service without first incurring significant capital improvements.

To address this issue, PCMH will operate the CyberKnife in its current location, but instead of operating as a hospital-based service, PCMH will obtain an additional NPI number and new Medicare and Medicaid identification numbers to operate CyberKnife services as a freestanding radiation treatment center, doing business as "UHS CyberKnife". PCMH believes this change has not materially altered the approved CON as these changes do not require modifications to ownership, need, services to be provided, patients to be served, capital costs, staffing, time lines, or financial projections.

If you need additional information or have any questions, please do not hesitate to call me at (252) 847-3631 or email me directly at jshoveli@uhseast.com.

Sincerely,



Jeff Shovelin
 Director of Corporate Planning,
 University Health System of Eastern Carolina



North Carolina Department of Health and Human Services
Division of Health Service Regulation
Office of the Director

2701 Mail Service Center • Raleigh, North Carolina 27699-2701

Michael F. Easley, Governor
Dempsey Benton, Secretary

Robert J. Fitzgerald, Director
Phone: 919-855-3750
Fax: 919-733-2757

September 18, 2007

CERTIFIED MAIL

Susan H. Hargrove, Esquire
Smith, Anderson, Blount, Dorsett
Mitchell & Jernigan, L.L.P.
P.O. Box 2611
Raleigh, NC 27602-2611

RE: Declaratory Ruling for Radiation Therapy Services, Inc. and North Carolina Radiation
Therapy Management Services, Inc.

Dear Ms. Hargrove:

I am enclosing a Declaratory Ruling that you requested. If questions arise, do not
hesitate to let me know.

Sincerely,

Robert J. Fitzgerald

RJF:JH:peb

Enclosure

cc: Jeff Horton, Chief Operating Officer, DHSR
Lee Hoffman, Chief, Certificate of Need Section, DHSR
Azzie Conley, Chief, Acute and Home Care Licensure and Certification Section, DHSR
Marc Lodge, Special Deputy Attorney General, DOJ



Location: 701 Barbour Drive ■ Dorothea Dix Hospital Campus ■ Raleigh, N.C. 27603
An Equal Opportunity / Affirmative Action Employer



**NORTH CAROLINA DEPARTMENT OF HEALTH AND HUMAN SERVICES
DIVISION OF HEALTH SERVICE REGULATION
RALEIGH, NORTH CAROLINA**

<p>IN RE: REQUEST FOR DECLARATORY RULING BY RADIATION THERAPY SERVICES, INC. AND NORTH CAROLINA RADIATION THERAPY MANAGEMENT SERVICES, INC.</p>	<p>)))))</p>	<p>DECLARATORY RULING</p>
--	----------------------------------	----------------------------------

I, Robert J. Fitzgerald, Director of the Division of Health Service Regulation (the "Department"), hereby issue this declaratory ruling to Radiation Therapy Services, Inc. d/b/a/ 21st Century Oncology ("RTS") and North Carolina Radiation Therapy Management Services, Inc. ("NC Radiation") (collectively "Petitioners") pursuant to N.C.G.S. § 150B-4, 10A NCAC 14A.0103, and the authority delegated to me by the Secretary of the North Carolina Department of Health and Human Services. Petitioners have filed a Declaratory Ruling Request (the "Request") asking the Department to issue a declaratory ruling that they may acquire all of the stock of Carolina Radiation and Cancer Treatment Center, Inc. ("CRTC") without certificate of need ("CON") review.

This ruling is binding on the Department and the person requesting it if the material facts stated in the Request are accurate and no material facts have been omitted from the request. The ruling applies only to this request. Except as provided by N.C.G.S. § 150B-4, the Department reserves the right to change the conclusions which are contained in this ruling. Susan H. Hargrove, Sean A. Timmons, and Jennifer B. Markhan of Smith, Anderson, Blount, Dorsett, Mitchell & Jernigan, L.L.P., counsel for Petitioners, have requested this ruling on behalf of Petitioners and have provided the statement of facts upon which this ruling is based. The material facts as provided by counsel for Petitioners are set out below.

STATEMENT OF THE FACTS

Except as noted, the following statement of the facts is based on the representations of Petitioners in the Request.

Petitioner RTS is a Florida corporation. NC Radiation is a North Carolina corporation that is a wholly-owned subsidiary of RTS. Both have their principal business address in Fort Myers, Florida.

Petitioners wish to acquire 100% of the issued and outstanding stock of CRTC, which they state is a North Carolina corporation owned by Dr. Gordon Koltis that operates a radiation therapy facility for cancer patients. Petitioners describe CRTC as an oncology treatment center, that, prior to 26 August 2005, would have been a "health service facility" as defined in N.C.G.S. § 131E-176(9b). S.L. 2005-325 eliminated oncology treatment centers from the category of "health service facilities," effective 26 August 2005.

Petitioners also state that CRTC "owns and operates two linear accelerators" and "one simulator." Request, p. 3. Footnote 1 to the Request states:

CRTC has represented to Petitioners that it entered into binding obligations to acquire the second linear accelerator prior to August 26, 2005, and that the acquisition of the second linear accelerator cost less than \$750,000, including the cost of the equipment, studies, surveys, designs, plans, working drawings, specifications, construction, installation, and other activities essential to acquiring and making operational the second linear accelerator.

I note from the files of the Department that the inventory report of linear accelerator equipment submitted by Carolina Radiation Medicine, P.A., certified and dated by Gordon G. Koltis on April 6, 2007, identifies only one linear accelerator owned by CRTC. The Department files do not contain any information concerning the purported second linear accelerator.

Petitioners represent that they have executed a stock purchase agreement by which NC Radiation will acquire 100% of the issued and outstanding capital stock of CRTC from Dr. Koltis. After closing the transaction, Petitioners state that CRTC will remain a separate corporate entity that is a wholly-owned subsidiary of NC Radiation. They state that CRTC will continue to operate its freestanding radiation therapy facility at the same location in Greenville, Pitt County, North Carolina, in the same manner in which it operated prior to the transaction in all material ways. Petitioners will pay more than two million dollars to purchase the CRTC stock. The closing of the transaction is conditioned on receiving confirmation from the Department that acquisition of the stock will not require a certificate of need.

ANALYSIS

N.C.G.S. § 131E-178 provides that no person shall offer or develop "a new institutional health service" without first obtaining a CON. N.G.C.S. § 131E-176(16) defines "new institutional health service" to include: (1) "The acquisition by purchase, donation, lease, transfer, or comparable arrangement" of a linear accelerator "by or on behalf of any person," N.G.C.S. § 131E-176(16)f1.5a, and (2) "The obligation by any person of a capital expenditure exceeding two million dollars (\$2,000,000) to develop or expand a health service or a health service facility, or which relates to the provision of a health service," N.C.G.S. § 131E-176(16)b.

The transaction described by Petitioners does not constitute the acquisition of a linear accelerator or a simulator by any person because ownership of the one reported linear accelerator and one reported simulator here will not change. CRTC will continue to be the owner of these two pieces of equipment, and CRTC's legal status as a corporate entity will not change.

Similarly, the transaction is not an obligation to develop or expand a health service or a health service facility, since Petitioners represent that CRTC will continue to operate at the same

location in a manner that is the same in all material respects as it operated prior to the transaction. In addition, pursuant to S.L. 2005-325, oncology treatment centers are not "health service facilities" for purposes of the CON law.

Finally, on the specific facts of this case, the transaction proposed by Petitioners is not "a capital expenditure . . . which relates to the provision of a health service" within the meaning of N.C.G.S. § 131E-176(16)b. The definition of "health service" specifically "does not include administrative and other activities that are not integral to clinical management." Petitioners' representations indicate that stock ownership of CRTC is not integral to the clinical management of CRTC, because in all material respects the operations of CRTC will not change.

I specifically except from this Ruling any conclusions as to the status or legality of the ownership of a purported second linear accelerator by CRTC. The Department has no notice of the existence or ownership of the second linear accelerator, and I make no finding that CRTC may acquire or operate, or has properly acquired and operated, a second linear accelerator without CON review.

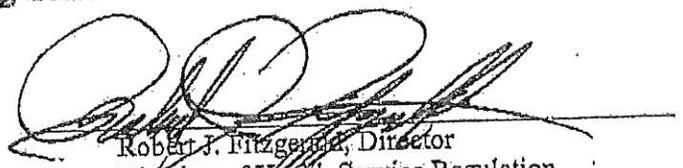
CONCLUSION

For the foregoing reasons, assuming the statements of fact in the Request to be true, I conclude that the acquisition by Petitioners of 100% of the outstanding and issued stock of CRTC, in the manner represented by Petitioners in the Request, is not subject to CON review.

This ruling is subject to the condition that, after the transaction, CRTC continues to operate its freestanding radiation therapy facility at the same location in Greenville, Pitt County, North Carolina, in the same manner in which it operated prior to the transaction in all material ways.

This ruling is not intended to address, expand or validate any activities or status of CRTC with respect to the requirements of the CON law as it relates to CRTC. The ruling is limited to the specific facts presented in the Request. It specifically does not address the status of any linear accelerator that CRTC may own or claim to own.

This 14th day of September 2007.



Robert J. Fitzgerald, Director
Division of Health Service Regulation
N.C. Department of Health and Human Services.

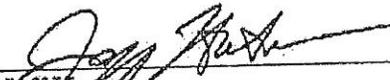
CERTIFICATE OF SERVICE

I certify that a copy of the foregoing Declaratory Ruling has been served upon the nonagency party by certified mail, return receipt requested, by depositing the copy in an official depository of the United States Postal Service in a first-class, postage pre-paid envelope addressed as follows:

CERTIFIED MAIL

Susan H. Hargrove, Esq.
Smith, Anderson, Blount, Dorsett
Mitchell & Jernigan, L.L.P.
P.O. Box 2611
Raleigh, NC 27602-2611

This the 6th day of September, 2007.



Jeff Horton
Chief Operating Officer



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

Beverly Eaves Perdue, Governor
 Lanier M. Cansler, Secretary

www.ncdhhs.gov/dhsr

Lee Hoffman, Section Chief
 Phone: 919-855-3873
 Fax: 919-733-8139

June 29, 2009

Renee J. Montgomery, Partner
 Parker Poe Adams and Bernstein LLP
 Post Office Box 389
 Raleigh, NC 27602-0389

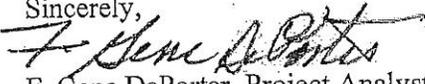
RE: Exempt from Review - Replacement Equipment/ Radiation Therapy Services, Inc. d/b/a 21st Century Oncology, North Carolina Radiation Therapy Management Services, Inc. and Carolina Radiation and Cancer Treatment Center, Inc./ Acquire a replacement linear accelerator for the second linear accelerator located at CRCTC in Greenville/ Pitt County

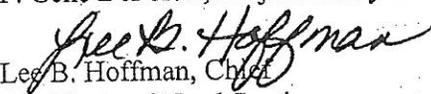
Dear Ms. Montgomery:

In response to your letters of June 23, 2009, November 18, 2008, and July 29, 2008, the above referenced proposal is exempt from certificate of need review in accordance with N.C.G.S 131E-184(a)(7). Therefore, you may proceed to acquire, without a certificate of need, the Varian 2100C, s/n 1167, to replace the existing Varian 2100C, s/n 527. This determination is based on your representations that the existing unit will be removed from North Carolina and will not be used again in the State without first obtaining a certificate of need.

It should be noted that this Agency's position is based solely on the facts represented by you and that any change in facts as represented would require further consideration by this Agency and a separate determination. If you have any questions concerning this matter, please feel free to contact this office.

Sincerely,


 F. Gene DePorter, Project Analyst


 Lee B. Hoffman, Chief
 Certificate of Need Section

cc: Medical Facilities Planning Section, DHSR



Location: 701 Barbour Drive ■ Dorothea Dix Hospital Campus ■ Raleigh, N.C. 27603
 An Equal Opportunity / Affirmative Action Employer





North Carolina Department of Health and Human Services
Division of Health Service Regulation
Office of the Director
2701 Mail Service Center • Raleigh, North Carolina 27699-2701
<http://www.ncdhhs.gov/dhsr>

Beverly Eaves Perdue, Governor
Lanier M. Cansler, Secretary

Drexdal Pratt, Director
Phone: 919-855-3750
Fax: 919-733-2757

November 4, 2011

CERTIFIED MAIL & FACSIMILE

William W. Stewart, Esq.
K&L Gates LLP
430 Davis Drive, Suite 400
Morrisville, NC 27560

RE: Declaratory Ruling for The Charlotte-Mecklenburg Hospital Authority
d/b/a Carolinas Healthcare System

Dear Mr. Stewart:

I am enclosing a Declaratory Ruling that you requested. If questions arise, do not hesitate to let me know.

Sincerely,

Drexdal Pratt

DP:JH:peb

Enclosure

- cc: Jeff Horton, Chief Operating Officer, DHSR
- Craig Smith, Chief, Certificate of Need Section
- Steven Lewis, Chief, Construction Section
- Azzie Conley, Chief, Acute and Home Care Licensure and Certification Section
- DHSR Medical Facilities Planning Section
- Marc Lodge, Special Deputy Attorney General, DOJ



**NORTH CAROLINA DEPARTMENT OF HEALTH AND HUMAN SERVICES
DIVISION OF HEALTH SERVICE REGULATION
RALEIGH, NORTH CAROLINA**

IN RE: REQUEST FOR)	
DECLARATORY RULING BY)	
THE CHARLOTTE-MECKLENBURG)	DECLARATORY RULING
HOSPITAL AUTHORITY D/B/A)	
CAROLINAS HEALTHCARE SYSTEM)	

I, Drexdal Pratt, as Director of the Division of Health Service Regulation, North Carolina Department of Health and Human Services (“Department” or “Agency”), do hereby issue this Declaratory Ruling pursuant to North Carolina General Statute § 150B-4 and 10A NCAC 14A .0103 under the authority granted me by the Secretary of the Department of Health and Human Services.

The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas Healthcare System (“CMHA”) has requested a declaratory ruling to confirm that its acquisition of the membership interests of University Radiation Oncology Center, LLC (“UROC”) and its continued operation of that facility may proceed without first obtaining a Certificate of Need (“CON”). This ruling will be binding upon the Department and the entities requesting it, as long as the material facts stated herein are accurate. This ruling pertains only to the matters referenced herein. Except as provided by N.C.G.S. § 150B-4, the Department expressly reserves the right to make a prospective change in the interpretation of the statutes and regulations at issue in this Declaratory Ruling. William W. Stewart of K&L Gates LLP has requested this ruling on CMHA’s behalf and has provided the material facts upon which this ruling is based.

STATEMENT OF THE FACTS

UROC, which is located at 8310 University Executive Park, Suite 500, Charlotte, NC 28262, is a limited liability company which provides radiation therapy treatment. UROC was

acquired by Radiation Oncology Centers of the Carolinas, Inc. ("ROCC") pursuant to an exemption in August 1997. Currently, UROC operates a Varian 2100C linear accelerator and a GE Highspeed Advantage CT simulator, which the CON Section previously approved.

On August 18, 2011, the Department issued a Declaratory Ruling determining that ROCC could transfer, without a CON, its interest in UROC and Matthews Radiation Oncology Center ("MROC") to two wholly owned subsidiaries of ROCC. Once that transaction is consummated, ROCC will be the sole member of UROC. ROCC will then transfer its entire membership interest in UROC to CMHA and CMHA will become UROC's sole member. Thus, UROC will remain intact as the same LLC, but with a different membership composition.

ANALYSIS

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. The list of new institutional health services includes "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, and "the obligation by any person of a capital expenditure exceeding two million dollars (\$2,000,000) to develop or expand a health service or a health service facility, or which relates to the provision of a health service," N.C. Gen. Stat. § 131E-176(16)(b).

Prior declaratory rulings show that the Department has already determined that these definitions do not require an entity to obtain a CON to acquire membership interests in an existing legal entity like UROC which owns and operates a linear accelerator or simulator. The declaratory ruling requested by CMHA is consistent with the Department's prior rulings that

have interpreted the applicability of the CON Law to the purchase of ownership interests in health care organizations, for the following reasons:

CMHA's acquisition of the membership interests in UROC does not constitute the acquisition of a linear accelerator or a simulator because the ownership of the equipment will not change, and the same equipment will be used to provide the same radiation oncology services, in the same location. UROC will continue to own the two pieces of equipment and UROC's legal status as a corporate entity will not change.

The purchase of ROCC's membership interests in UROC does not involve the offering or expansion of any new facility, service or equipment, and the state's inventory of linear accelerators and simulators will not change. No new or additional equipment will be acquired or placed in operation in the State.

CONCLUSION

For the foregoing reasons, assuming the statements of fact in the request to be true, I conclude that CMHA does not require a certificate of need in order to proceed with the purchase of ROCC's membership interests in UROC.

This the 4th day of November, 2011.


Drexdal Pratt, Director
Division of Health Service Regulation
N.C. Department of Health and Human Services

CERTIFICATE OF SERVICE

I certify that a copy of the foregoing Declaratory Ruling has been served upon the nonagency party by facsimile and certified mail, return receipt requested, by depositing the copy in an official depository of the United States Postal Service in a first-class, postage pre-paid envelope addressed as follows:

CERTIFIED MAIL

William W. Stewart
K&L Gates LLP
430 Davis Drive, Suite 400
Morrisville, NC 27560

This the 4th day of November, 2011.



Jeff Horton
Chief Operating Officer

**NORTH CAROLINA DEPARTMENT OF HEALTH AND HUMAN SERVICES
DIVISION OF HEALTH SERVICE REGULATION
RALEIGH, NORTH CAROLINA**

IN RE: REQUEST FOR DECLARATORY)	
RULING BY WAKE RADIOLOGY)	
ONCOLOGY SERVICES, PLLC, CANCER)	DECLARATORY RULING
CENTERS OF NORTH CAROLINA, P.C.,)	
US ONCOLOGY, INC., AOR)	
MANAGEMENT COMPANY OF VIRGINIA,)	
LLC AND WAKEMED)	

I, Drexdal Pratt, as Director of the Division of Health Service Regulation, North Carolina Department of Health and Human Services (“Department” or “Agency”), do hereby issue this Declaratory Ruling pursuant to North Carolina General Statute § 150B-4 and 10A NCAC 14A .0103 under the authority granted me by the Secretary of the Department of Health and Human Services.

Wake Radiology Oncology Services, PLLC (hereinafter “WROS”); Cancer Centers of North Carolina, P.C. (“CCNC”); US Oncology, Inc. (“USON”) and its subsidiary AOR Management Company of Virginia, LLC (“AOR”); and WakeMed have requested a declaratory ruling to confirm that the acquisition of the membership interests in WROS and the continued operation of the oncology treatment center may proceed without first obtaining a certificate of need. This ruling will be binding upon the Department and the entities requesting it, as long as the material facts stated herein are accurate. This ruling pertains only to the matters referenced herein. Except as provided by N.C.G.S. § 150B-4, the Department expressly reserves the right to make a prospective change in the interpretation of the statutes and regulations at issue in this Declaratory Ruling. Attorneys for the Petitioners have requested this ruling on their behalf and have provided the material facts upon which this ruling is based.

STATEMENT OF THE FACTS

WROS is a North Carolina professional limited liability company presently owned by certain physician-members, each of whom owns a specific percentage of the total membership interests in WROS. WROS provides radiation oncology treatment services at 300 Ashville Avenue, Suite 110, Cary, North Carolina, based on a certificate of need that was issued in 1997 to own an oncology treatment center and to operate a linear accelerator and simulator and other equipment used in furnishing radiation oncology services.

CCNC is a professional corporation organized under the laws of the State of North Carolina. CCNC employs physicians licensed to practice medicine in the State of North Carolina, who provide oncology treatment services, including radiation oncology services through the use of a linear accelerator.

USON is a business corporation organized under the laws of the State of Delaware. Through its subsidiaries, US Oncology provides administrative support for, and furnishes medical equipment used by, oncology practices throughout the United States.

AOR is a limited liability company, a subsidiary of USON and was organized under the laws of the State of Delaware and authorized to do business in North Carolina. AOR provides administrative and other support services to CCNC under a Management Services Agreement with CCNC.

WakeMed is a North Carolina nonprofit corporation engaged in the provision of acute care services and other health care services in Wake County.

WROS established its oncology treatment center on or about July 17, 1998. Since the establishment of its oncology treatment center, WROS has continuously operated the oncology treatment center established pursuant to the CON it received in 1997.

When the CON Law was amended in 2005, WROS already was operating an existing oncology treatment center pursuant to the CON that it had obtained in 1997 and using a linear accelerator and simulator that had been recognized in the SMFP inventory for seven years. Since it already owned the equipment, it was not required to obtain a second CON to be able to continue to operate its linear accelerator and simulator.

Recently, WROS physician owners approved a conversion of WROS from a professional limited liability company to a limited liability company, to occur simultaneously with the sale of ownership interests to CCNC. It is likely that WROS will change its name after the sale. Subsequently, in a separate transaction, WakeMed anticipates purchasing a minority membership interest in the renamed WROS ("the LLC").

This change in the business form of WROS that has been approved by its physician owners will not constitute a change in or dissolution of WROS, the legal entity that received the CON in 1997 and has continuously operated the oncology treatment center and the linear accelerator and simulator since they became operational.

After these two transactions, the LLC will continue to exist as a legal and business entity, and will continue to own the oncology treatment center and the equipment that was authorized under the 1997 CON, including the linear accelerator and simulator. The oncology treatment center and its equipment will remain at the same location at 300 Ashville Avenue in Cary.

The LLC will not offer any medical services. Oncology treatment services will be furnished by physicians associated with CCNC.

ANALYSIS

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. The list of new

institutional health services includes “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, and “the obligation by any person of a capital expenditure exceeding two million dollars (\$2,000,000) to develop or expand a health service or a health service facility, or which relates to the provision of a health service,” N.C. Gen. Stat. § 131E-176(16)(b).

Prior declaratory rulings show that the Department has already determined that these definitions do not require an entity to obtain a CON to acquire membership interests in an existing legal entity like WROS which owns and operates a linear accelerator or simulator. The declaratory ruling requested by Petitioners is consistent with the Department’s prior rulings that have interpreted the applicability of the CON Law to the purchase of ownership interests in health care organizations, for the following reasons:

The entity that owns the linear accelerator and simulator will not change, and the same equipment will be used to provide the same radiation oncology services, in the same location. The LLC will continue to own the linear accelerator, the simulator, and all the oncology treatment center assets that were authorized under the 1997 CON and have been used to furnish oncology treatments to patients. Its membership composition initially will change from the present physician members to a single member, CCNC, with the subsequent purchase of a minority interest by WakeMed.

The Proposed Transaction will involve expenditures by CCNC, and later by WakeMed, but these will be purchases of ownership interests in an existing limited liability company that owns the oncology treatment center. There will be no 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.

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 and simulators will not change. No new, or additional equipment will be acquired or placed in operation in the State.

CONCLUSION

For the foregoing reasons, assuming the statements of fact in the request to be true, I conclude that the Petitioners do not require a certificate of need in order to proceed with the Proposed Transaction.

This the _____ day of September, 2010.

Drexdal Pratt, Director
Division of Health Service Regulation
N.C. Department of Health and Human Services

CERTIFICATE OF SERVICE

I certify that a copy of the foregoing Declaratory Ruling has been served upon the nonagency party by certified mail, return receipt requested, by depositing the copy in an official depository of the United States Postal Service in first-class, postage pre-paid envelope addressed as follows:

CERTIFIED MAIL

Ronald I. Kirschbaum
KIRSCHBAUM, NANNEY, KEENAN & GRIFFIN, P.A.
P.O. Box 19766
Raleigh, North Carolina 27607
Attorneys for Wake Radiology Oncology, PLLC

William R. Shenton
POYNER SPRUILL LLP
301 Fayetteville Street, Suite 1900
Raleigh, North Carolina 27601
Attorneys for U.S. Oncology, Inc. and AOR Management
Company of Virginia, LLC

Larry E. Robbins
WYRICK ROBBINS YATES & PONTON, LLP
P.O. Drawer 17803
Raleigh, North Carolina 27607
Attorneys for Cancer Centers of North Carolina, P.C.

Maureen Demarest Murray
SMITH MOORE LEATHERWOOD LLP
P.O. Box 21927
Greensboro, North Carolina 27420
Attorneys for WakeMed

This the _____ day of September, 2010.

Jeff Horton
Chief Operating Officer

**NORTH CAROLINA DEPARTMENT OF HEALTH AND HUMAN SERVICES
DIVISION OF HEALTH SERVICE REGULATION
RALEIGH, NORTH CAROLINA**

IN RE: REQUEST FOR DECLARATORY RULING BY RADIATION THERAPY SERVICES, INC. AND NORTH CAROLINA RADIATION THERAPY MANAGEMENT SERVICES, INC.))))))	DECLARATORY RULING
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I, Robert J. Fitzgerald, Director of the Division of Health Service Regulation (the "Department"), hereby issue this declaratory ruling to Radiation Therapy Services, Inc. d/b/a/ 21st Century Oncology ("RTS") and North Carolina Radiation Therapy Management Services, Inc. ("NC Radiation") (collectively "Petitioners") pursuant to N.C.G.S. § 150B-4, 10A NCAC 14A.0103, and the authority delegated to me by the Secretary of the North Carolina Department of Health and Human Services. Petitioners have filed a Declaratory Ruling Request (the "Request") asking the Department to issue a declaratory ruling that they may acquire all of the stock of Carolina Radiation and Cancer Treatment Center, Inc. ("CRTC") without certificate of need ("CON") review.

This ruling is binding on the Department and the person requesting it if the material facts stated in the Request are accurate and no material facts have been omitted from the request. The ruling applies only to this request. Except as provided by N.C.G.S. § 150B-4, the Department reserves the right to change the conclusions which are contained in this ruling. Susan H. Hargrove, Sean A. Timmons, and Jennifer B. Markhan of Smith, Anderson, Blount, Dorsett, Mitchell & Jernigan, L.L.P., counsel for Petitioners, have requested this ruling on behalf of Petitioners and have provided the statement of facts upon which this ruling is based. The material facts as provided by counsel for Petitioners are set out below.

STATEMENT OF THE FACTS

Except as noted, the following statement of the facts is based on the representations of Petitioners in the Request.

Petitioner RTS is a Florida corporation. NC Radiation is a North Carolina corporation that is a wholly-owned subsidiary of RTS. Both have their principal business address in Fort Myers, Florida.

Petitioners wish to acquire 100% of the issued and outstanding stock of CRTC, which they state is a North Carolina corporation owned by Dr. Gordon Koltis that operates a radiation therapy facility for cancer patients. Petitioners describe CRTC as an oncology treatment center that, prior to 26 August 2005, would have been a "health service facility" as defined in N.C.G.S. § 131E-176(9b). S.L. 2005-325 eliminated oncology treatment centers from the category of "health service facilities," effective 26 August 2005.

Petitioners also state that CRTC "owns and operates two linear accelerators" and "one simulator." Request, p. 3. Footnote 1 to the Request states:

CRTC has represented to Petitioners that it entered into binding obligations to acquire the second linear accelerator prior to August 26, 2005, and that the acquisition of the second linear accelerator cost less than \$750,000, including the cost of the equipment, studies, surveys, designs, plans, working drawings, specifications, construction, installation, and other activities essential to acquiring and making operational the second linear accelerator.

I note from the files of the Department that the inventory report of linear accelerator equipment submitted by Carolina Radiation Medicine, P.A., certified and dated by Gordon G. Koltis on April 6, 2007, identifies only one linear accelerator owned by CRTC. The Department files do not contain any information concerning the purported second linear accelerator.

Petitioners represent that they have executed a stock purchase agreement by which NC Radiation will acquire 100% of the issued and outstanding capital stock of CRTC from Dr. Koltis. After closing the transaction, Petitioners state that CRTC will remain a separate corporate entity that is a wholly-owned subsidiary of NC Radiation. They state that CRTC will continue to operate its freestanding radiation therapy facility at the same location in Greenville, Pitt County, North Carolina, in the same manner in which it operated prior to the transaction in all material ways. Petitioners will pay more than two million dollars to purchase the CRTC stock. The closing of the transaction is conditioned on receiving confirmation from the Department that acquisition of the stock will not require a certificate of need.

ANALYSIS

N.C.G.S. § 131E-178 provides that no person shall offer or develop “a new institutional health service” without first obtaining a CON. N.G.C.S. § 131E-176(16) defines “new institutional health service” to include: (1) “The acquisition by purchase, donation, lease, transfer, or comparable arrangement” of a linear accelerator “by or on behalf of any person,” N.G.C.S. § 131E-176(16)f1.5a, and (2) “The obligation by any person of a capital expenditure exceeding two million dollars (\$2,000,000) to develop or expand a health service or a health service facility, or which relates to the provision of a health service,” N.C.G.S. § 131E-176(16)b.

The transaction described by Petitioners does not constitute the acquisition of a linear accelerator or a simulator by any person because ownership of the one reported linear accelerator and one reported simulator here will not change. CRTC will continue to be the owner of these two pieces of equipment, and CRTC’s legal status as a corporate entity will not change.

Similarly, the transaction is not an obligation to develop or expand a health service or a health service facility, since Petitioners represent that CRTC will continue to operate at the same

location in a manner that is the same in all material respects as it operated prior to the transaction. In addition, pursuant to S.L. 2005-325, oncology treatment centers are not “health service facilities” for purposes of the CON law.

Finally, on the specific facts of this case, the transaction proposed by Petitioners is not “a capital expenditure . . . which relates to the provision of a health service” within the meaning of N.C.G.S. § 131E-176(16)b. The definition of “health service” specifically “does not include administrative and other activities that are not integral to clinical management.” Petitioners’ representations indicate that stock ownership of CRTC is not integral to the clinical management of CRTC, because in all material respects the operations of CRTC will not change.

I specifically except from this Ruling any conclusions as to the status or legality of the ownership of a purported second linear accelerator by CRTC. The Department has no notice of the existence or ownership of the second linear accelerator, and I make no finding that CRTC may acquire or operate, or has properly acquired and operated, a second linear accelerator without CON review.

CONCLUSION

For the foregoing reasons, assuming the statements of fact in the Request to be true, I conclude that the acquisition by Petitioners of 100% of the outstanding and issued stock of CRTC, in the manner represented by Petitioners in the Request, is not subject to CON review.

This ruling is subject to the condition that, after the transaction, CRTC continues to operate its freestanding radiation therapy facility at the same location in Greenville, Pitt County, North Carolina, in the same manner in which it operated prior to the transaction in all material ways.

This ruling is not intended to address, expand or validate any activities or status of CRTC with respect to the requirements of the CON law as it relates to CRTC. The ruling is limited to the specific facts presented in the Request. It specifically does not address the status of any linear accelerator that CRTC may own or claim to own.

This ____ day of _____, 2007.

Robert J. Fitzgerald, Director
Division of Health Service Regulation
N.C. Department of Health and Human Services

CERTIFICATE OF SERVICE

I certify that a copy of the foregoing Declaratory Ruling has been served upon the nonagency party by certified mail, return receipt requested, by depositing the copy in an official depository of the United States postal service in a first class, postage prepaid envelope addressed as follows:

CERTIFIED MAIL

Susan H. Hargrove
Smith, Anderson, Blount, Dorsett,
Mitchell & Jernigan, L.L. P
P.O. Box 2611
Raleigh, NC 27602-2611

This ____ day of _____, 2007.

Jeff Horton
Chief Operating Officer



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/>

Drexdal Pratt, Director

Beverly Eaves Perdue, Governor
Albert A. Delia, Acting Secretary

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

February 27, 2012

Maureen Demarest Murray
Smith, Moore, Leatherwood
300 N. Greene Street, Suite 1400
Greensboro, NC 27401

RE: No Review / WakeMed / Acquisition of ownership interests of CSA-1, owners of five heart-lung bypass machines located at WakeMed / Wake County
FID #: 943528

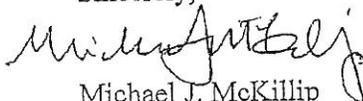
Dear Ms. Murray:

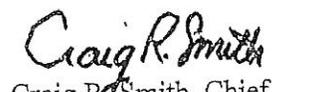
The Certificate of Need (CON) Section received your letter of February 8, 2012 regarding the above referenced proposal. Based on the CON law **in effect on the date of this response to your request**, the proposal described in your correspondence is not governed by, and therefore, does not currently 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.

Please contact the CON Section if you have any questions.

Sincerely,


Michael J. McKillip
Project Analyst

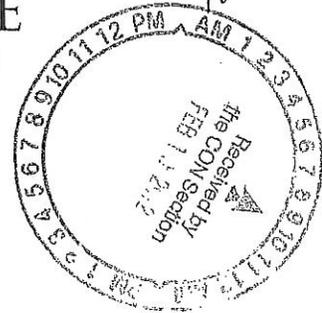

Craig R. Smith, Chief
Certificate of Need Section





SMITH MOORE LEATHERWOOD

February 8, 2012



Via E-Mail and U.S. Mail

Mr. Craig R. Smith, Chief
 Ms. Martha Frisone, Assistant Chief
 North Carolina Department of Health
 Service Regulation
 Certificate of Need Section
 2704 Mail Service Center
 Raleigh, North Carolina 27696-2704

Re: WakeMed Acquisition of Ownership Interests in CSA-1

Dear Mr. Smith and Ms. Frisone:

We represent WakeMed. The purpose of this letter is to provide notice to the North Carolina Department of Health and Human Services, Division of Health Service Regulation, Certificate of Need Section (the "Agency") and confirm that WakeMed's acquisition of the ownership interests of CSA-1 is not reviewable as a new institutional health service under the North Carolina Certificate of Need ("CON") law. CSA-1 is a wholly owned sub of CSA Medical, LLC ("CSA") and owns five (5) heart lung bypass ("HLB") machines that have been and are operated at WakeMed. WakeMed would acquire the membership interests in CSA-1, which would continue to exist as a legal entity and to own the five (5) HLB machines that would remain located and operated at WakeMed.

The Agency has issued numerous declaratory rulings and no review letters that acknowledge that acquisition of ownership interests in a legal entity does not constitute a reviewable acquisition of the medical equipment owned by that legal entity. For example, in a declaratory ruling issued to New Hanover Perfusionists, Inc., the Agency determined that the purchase of stock did not constitute the acquisition of a heart-lung bypass machine because ownership of the regulated heart-lung bypass equipment would not change. The Agency also determined that the transaction was not an obligation to develop or expand a health service or health service facility because the equipment company was not a health service facility. The stock purchase transaction proposed also was 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). The definition of "health service" specifically "does not include administrative and other activities that are not integral to clinical management." Stock or membership interest ownership is not integral to clinical management. *In re: Request for Declaratory Ruling by New Hanover Perfusionists, Inc., January 24, 2008.*

Mr. Craig R. Smith, Chief
Ms. Martha Frisone, Assistant Chief
February 8, 2012
Page 2

Similarly, the Department approved the sale of 100% of the issued and outstanding stock of a company that owned a linear accelerator to another entity. Linear accelerators are regulated in the same manner as heart-lung bypass equipment. The Department held that certificate of need review was not required for the stock purchase transaction. *See Declaratory Ruling, In re: Request for Declaratory Ruling by Radiation Therapy Services, Inc. and North Carolina Radiation Therapy Management Services, Inc.*, September 14, 2007.

We would appreciate written confirmation from you that the anticipated transaction does not require CON review. If you require additional information to consider this request, please contact us. We appreciate your consideration.

Sincerely yours,

SMITH MOORE LEATHERWOOD LLP



Maureen Demarest Murray

cc: Stan Taylor, WakeMed



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/>

Drexdal Pratt, Director

Beverly Eaves Perdue, Governor
Albert A. Delia, Acting Secretary

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

February 27, 2012

Gary S. Qualls
K & L Gates, LLP
P.O. Box 14210
Research Triangle Park NC 27709-4210

RE: No Review / Rex Hospital, Inc. / Acquisition of ownership interests of CSAMS Lake Boone, LLC, owners of three heart-lung bypass machines located at Rex Hospital / Wake County
FID #: 953429

Dear Mr. Qualls:

The Certificate of Need (CON) Section received your letter of February 9, 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.

Please contact the CON Section if you have any questions.

Sincerely,

Michael J. McKillop
Project Analyst

Craig R. Smith, Chief
Certificate of Need Section



K&L|GATES



K&L Gates LLP
 Post Office Box 14210
 Research Triangle Park, NC 27709-4210

430 Davis Drive, Suite 400
 Morrisville, NC 27560

T 919.466.1190 www.klgates.com

Gary S. Qualls
 D 919.466.1182
 F 919.516.2072
 gary.qualls@klgates.com

February 9, 2012

Mr. Craig R. Smith, Chief
 Ms. Martha Frisone, Assistant Chief
 North Carolina Department of Health
 Service Regulation
 Certificate of Need Section
 2704 Mail Service Center
 Raleigh, North Carolina 27696-2704

Re: Rex Acquisition of Ownership Interests in CSAMS Lake Boone Trail, LLC

Dear Mr. Smith and Ms. Frisone:

We represent Rex Hospital, Inc. ("Rex"). The purpose of this letter is to provide notice to the North Carolina Department of Health and Human Services, Division of Health Service Regulation, Certificate of Need Section (the "Agency") and confirm that Rex's acquisition of the ownership interests of CSAMS Lake Boone Trail, LLC ("CSA Lake Boone") is not reviewable as a new institutional health service under the North Carolina Certificate of Need ("CON") law. CSA Lake Boone is a wholly owned sub of CSA Medical, LLC ("CSA") and owns three (3) heart-lung bypass ("HLB") machines that have been and are operated at Rex. Rex would acquire the membership interests in CSA Lake Boone, which would continue to exist as a legal entity and to own the three (3) HLB machines that would remain located and operated at Rex.

The Agency has issued numerous declaratory rulings and no review letters that acknowledge that acquisition of ownership interest in a legal entity does not constitute a reviewable acquisition of the medical equipment owned by that legal entity. For example, in a declaratory ruling issued to New Hanover Perfusionists, Inc., the Agency determined that the purchase of stock did not constitute the acquisition of a heart-lung bypass machine because ownership of the regulated heart-lung bypass equipment would not change. The Agency also determined that the transaction was not an obligation to develop or expand a health service or health service facility because the equipment company was not a health service facility. The stock purchase transaction proposed also was 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). The

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Mr. Craig R. Smith, Chief
Martha Frisone, Assistant Chief
February 9, 2012
Page 2

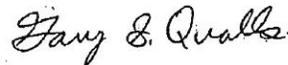
definition of "health service" specifically "does not include administrative and other activities that are not integral to clinical management." Stock or membership interest ownership is not integral to clinical management. *In re: Request for Declaratory Ruling by New Hanover Perfusionists, Inc., January 24, 2008.*

Similarly, the Department has recently approved the sale of 100% of the membership interests in a company that owned a linear accelerator to another entity. Linear accelerators are regulated in the same manner as heart-lung bypass equipment. The Department held that certificate of need review was not required for the LLC membership purchase transaction. *See Declaratory Ruling, In re: Request for Declaratory Ruling by The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas Healthcare, November 4, 2011 (attached as Exhibit 1).*

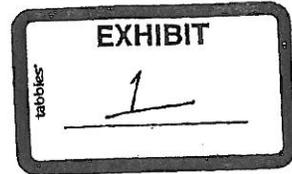
We would appreciate written confirmation from you that the anticipated transaction does not require CON review. If you require additional information to consider this request, please contact us. We appreciate your consideration.

Sincerely yours,

K&L GATES LLP



Gary S. Qualls



North Carolina Department of Health and Human Services
Division of Health Service Regulation
Office of the Director
2701 Mail Service Center • Raleigh, North Carolina 27699-2701
<http://www.ncdhhs.gov/dhsr>

Beverly Eaves Perdue, Governor
Lanier M. Cansler, Secretary

Drexdal Pratt, Director
Phone: 919-855-3750
Fax: 919-733-2757

November 4, 2011

CERTIFIED MAIL & FACSIMILE

William W. Stewart, Esq.
K&L Gates LLP
430 Davis Drive, Suite 400
Morrisville, NC 27560

RE: Declaratory Ruling for The Charlotte-Mecklenburg Hospital Authority
d/b/a Carolinas Healthcare System

Dear Mr. Stewart:

I am enclosing a Declaratory Ruling that you requested. If questions arise, do not hesitate to let me know.

Sincerely,

Drexdal Pratt

DP:JH:peb

Enclosure

- cc: Jeff Horton, Chief Operating Officer, DHSR
- Craig Smith, Chief, Certificate of Need Section
- Steven Lewis, Chief, Construction Section
- Azzie Conley, Chief, Acute and Home Care Licensure and Certification Section
- DHSR Medical Facilities Planning Section
- Marc Lodge, Special Deputy Attorney General, DOJ



Location: 809 Ruggles Drive ■ Dorothea Dix Hospital Campus ■ Raleigh, N.C. 27603
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**NORTH CAROLINA DEPARTMENT OF HEALTH AND HUMAN SERVICES
DIVISION OF HEALTH SERVICE REGULATION
RALEIGH, NORTH CAROLINA**

IN RE: REQUEST FOR)	
DECLARATORY RULING BY)	
THE CHARLOTTE-MECKLENBURG)	DECLARATORY RULING
HOSPITAL AUTHORITY D/B/A)	
CAROLINAS HEALTHCARE SYSTEM)	

I, Drexdal Pratt, as Director of the Division of Health Service Regulation, North Carolina Department of Health and Human Services ("Department" or "Agency"), do hereby issue this Declaratory Ruling pursuant to North Carolina General Statute § 150B-4 and 10A NCAC 14A .0103 under the authority granted me by the Secretary of the Department of Health and Human Services.

The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas Healthcare System ("CMHA") has requested a declaratory ruling to confirm that its acquisition of the membership interests of University Radiation Oncology Center, LLC ("UROC") and its continued operation of that facility may proceed without first obtaining a Certificate of Need ("CON"). This ruling will be binding upon the Department and the entities requesting it, as long as the material facts stated herein are accurate. This ruling pertains only to the matters referenced herein. Except as provided by N.C.G.S. § 150B-4, the Department expressly reserves the right to make a prospective change in the interpretation of the statutes and regulations at issue in this Declaratory Ruling. William W. Stewart of K&L Gates LLP has requested this ruling on CMHA's behalf and has provided the material facts upon which this ruling is based.

STATEMENT OF THE FACTS

UROC, which is located at 8310 University Executive Park, Suite 500, Charlotte, NC 28262, is a limited liability company which provides radiation therapy treatment. UROC was

acquired by Radiation Oncology Centers of the Carolinas, Inc. ("ROCC") pursuant to an exemption in August 1997. Currently, UROC operates a Varian 2100C linear accelerator and a GE Highspeed Advantage CT simulator, which the CON Section previously approved.

On August 18, 2011, the Department issued a Declaratory Ruling determining that ROCC could transfer, without a CON, its interest in UROC and Matthews Radiation Oncology Center ("MROC") to two wholly owned subsidiaries of ROCC. Once that transaction is consummated, ROCC will be the sole member of UROC. ROCC will then transfer its entire membership interest in UROC to CMHA and CMHA will become UROC's sole member. Thus, UROC will remain intact as the same LLC, but with a different membership composition.

ANALYSIS

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. The list of new institutional health services includes "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, and "the obligation by any person of a capital expenditure exceeding two million dollars (\$2,000,000) to develop or expand a health service or a health service facility, or which relates to the provision of a health service," N.C. Gen. Stat. § 131E-176(16)(b).

Prior declaratory rulings show that the Department has already determined that these definitions do not require an entity to obtain a CON to acquire membership interests in an existing legal entity like UROC which owns and operates a linear accelerator or simulator. The declaratory ruling requested by CMHA is consistent with the Department's prior rulings that

have interpreted the applicability of the CON Law to the purchase of ownership interests in health care organizations, for the following reasons:

CMHA's acquisition of the membership interests in UROC does not constitute the acquisition of a linear accelerator or a simulator because the ownership of the equipment will not change, and the same equipment will be used to provide the same radiation oncology services, in the same location. UROC will continue to own the two pieces of equipment and UROC's legal status as a corporate entity will not change.

The purchase of ROCC's membership interests in UROC does not involve the offering or expansion of any new facility, service or equipment, and the state's inventory of linear accelerators and simulators will not change. No new or additional equipment will be acquired or placed in operation in the State.

CONCLUSION

For the foregoing reasons, assuming the statements of fact in the request to be true, I conclude that CMHA does not require a certificate of need in order to proceed with the purchase of ROCC's membership interests in UROC.

This the 4th day of November, 2011.



Drexel Pratt, Director
Division of Health Service Regulation
N.C. Department of Health and Human Services

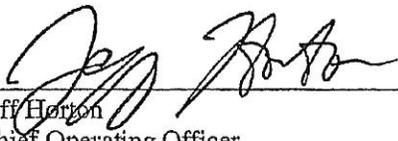
CERTIFICATE OF SERVICE

I certify that a copy of the foregoing Declaratory Ruling has been served upon the nonagency party by facsimile and certified mail, return receipt requested, by depositing the copy in an official depository of the United States Postal Service in a first-class, postage pre-paid envelope addressed as follows:

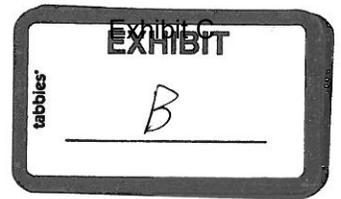
CERTIFIED MAIL

William W. Stewart
K&L Gates LLP
430 Davis Drive, Suite 400
Morrisville, NC 27560

This the 4th day of November, 2011.



Jeff Horton
Chief Operating Officer



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

April 7, 2014

Gary S. Qualls
K&L Gates, LLP
P.O. Box 14210
Research Triangle Park NC 27709-4210

No Review

Facility: Rex Hospital
Project Description: Obtain a separate license for Rex Rehabilitation and Nursing Center of Raleigh
County: Wake
FID #: 953429

Dear Mr. Qualls:

The Certificate of Need Section (CON Section) received your letter of March 24, 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.

Moreover, you need to contact the Acute and Home Care Licensure and Certification and Nursing Home 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 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.

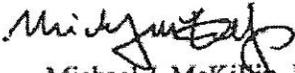


Certificate of Need Section
www.ncdhhs.gov
Telephone: 919-855-3873 • Fax: 919-733-8139
Location: Edgerton Building • 809 Ruggles Drive • Raleigh, NC 27603
Mailing Address: 2704 Mail Service Center • Raleigh, NC 27699-2704
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Mr. Qualls
April 7, 2014
Page 2

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,



Michael J. McKillip, Project Analyst



Martha J. Frisone, Interim Chief
Certificate of Need Section

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

K&L|GATES

K&L Gates LLP
Post Office Box 14210
Research Triangle Park, NC 27709-4210

430 Davis Drive, Suite 400
Morrisville, NC 27560

T 919.466.1190 www.klgates.com

Received by
the CON Section
MAR 24 2014

Gary S. Qualls
D 919.466.1182
F 919.516.2072
gary.qualls@klgates.com

March 24, 2014

VIA HAND DELIVERY

Martha Frisone,
Chief, Certificate of Need Section
Division of Health Service Regulation
North Carolina Department of Health &
Human Services
809 Ruggles Drive
Raleigh, North Carolina 27603

RE: Rex Hospital, Inc. (License No. H0065)
No Review Request To Independently License Rex Rehabilitation &
Nursing Center of Raleigh

Dear Ms. Frisone:

We are writing on behalf of our client Rex Hospital, Inc. ("Rex"). Rex owns and operates Rex Rehabilitation & Nursing Center of Raleigh (the "Nursing Center"), a nursing home with 120 nursing beds under the Rex Hospital license. Rex has decided to obtain an independent license for the Nursing Center in order to promote operational efficiencies. We are requesting confirmation from the Department of Health and Human Services, Division of Health Service Regulation, Certificate of Need Section (the "Agency") that this proposal is not subject to certificate of need review.

In this instance, the entity (Rex) that owns the Nursing Center will not change, and the same building, staff and equipment will be used to provide the same services at the same location. Rex will continue to own the CON-authorized Nursing Center assets that have been used to furnish skilled nursing care to the Nursing Center's residents. The proposed transaction does not involve the offering or expansion of any new facility, service or equipment, and the State's inventory of nursing beds will not change. No new or additional nursing home beds will be acquired or placed in operation in the State. The Nursing Center already has its own

K&L|GATES

Martha Frisone,
Chief, Certificate of Need Section
March 24, 2014
Page 2

distinct Medicare provider number (Medicare #345369), which is separate from Rex Hospital's Medicare provider number (Medicare #340114).

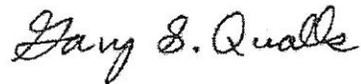
This proposal is similar to other proposals that the Agency has found to be non-reviewable. For example, the Agency recently determined that no CON review was necessary for Hugh Chatham Memorial Hospital, Inc. to independently license a nursing home that historically operated under its hospital license. See Exhibit 1.

We believe that the CON law allows the independent licensing of the Nursing Center without the requirement of a CON because such an event does not constitute the development or acquisition of a new facility or services, within the meaning of N.C. Gen. Stat. § 131E-176(16). The beds already exist in the State Medical Facilities Plan inventory and there is no new facility constructed. Thus, there has been no action which constitutes the offering or development of a new institutional health service within the meaning of N.C. Gen. Stat. § 131E-178(a), and no CON is therefore required.

We request that you provide a no review letter confirming that our interpretation of the CON law is correct and that this proposal is not subject to certificate of need review.

Please do not hesitate to contact us if you have any questions.

Sincerely,



Gary S. Qualls

K&L|GATES

Martha Frisone,
Chief, Certificate of Need Section
March 24, 2014
Page 3

Exhibits

1. Hugh Chatham Memorial Hospital, Inc. No Review Request and Response



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

March 11, 2014

S. Todd Hemphill
3105 Glenwood Avenue, Suite 300
Raleigh, North Carolina 27612

No Review

Facility: Hugh Chatham Memorial Nursing Center
Project Description: Transfer by Hugh Chatham Memorial Hospital, Inc. (HCMH) of 100% of its ownership interests in Hugh Chatham Memorial Nursing Center to Hugh Chatham Nursing Center, LLC, a wholly-owned subsidiary of HCMH and license it separately from the hospital

County: Surry
FID #: 955375

Dear Mr. Hemphill:

The Certificate of Need Section (CON Section) received your letter of February 18, 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.

Moreover, you need to contact the Acute and Home Care Licensure and Certification Section and the Nursing Home Licensure and Certification Section 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 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.

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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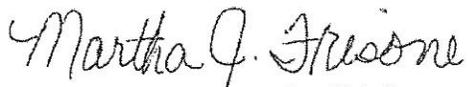


S. Todd Hemphill
March 11, 2014
Page 2

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,


Kim Randolph, Project Analyst


Martha J. Frisone, Interim Chief
Certificate of Need Section

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

JOHN T. BODE
S. TODD HEMPHILL
MATTHEW A. FISHER
DAVID R. BROYLES

*John
Kim*

BODE HEMPHILL, L.L.P.
ATTORNEYS AT LAW
3105 GLENWOOD AVENUE, SUITE 300
RALEIGH, NORTH CAROLINA 27612

TELEPHONE (919) 881-0338
FACSIMILE (919) 881-9548

WWW.BCS-LAW.COM

MAILING ADDRESS

POST OFFICE BOX 6338
RALEIGH, NORTH CAROLINA
27628-6338

Writer's E-mail: HEMPHILL@BCS-LAW.COM

February 18, 2014

Received by
the CON Section
FEB 19 2014

VIA HAND DELIVERY

Martha J. Frisone, Interim Chief
Kim Randolph, Project Analyst
Certificate of Need Section
N.C. Department of Health and Human Services
Division of Health Service Regulation
809 Ruggles Drive
Raleigh, North Carolina 27603

Re: Hugh Chatham Memorial Hospital, Inc. (License No. H0049)
No review request to transfer control of Hugh Chatham Nursing Center to wholly owned-subsiary

Dear Ms. Frisone and Ms. Randolph:

We are writing you on behalf of our client, Hugh Chatham Memorial Hospital, Inc. ("HCMH"), a North Carolina non-profit corporation. HCMH owns and operates Hugh Chatham Nursing Center (the "Nursing Center"), a combination facility with 99 nursing beds and 28 assisted living beds (20 Alzheimer's or special care unit beds and 8 general beds), under the hospital's license. HCMH has determined that it is in its best interest to transfer ownership of the Nursing Center to a wholly-owned subsidiary which it has created, Hugh Chatham Nursing Center, LLC, a North Carolina limited liability company ("HCNC"). HCMH is the sole member of HCNC. See HCNC Articles of Organization, Exhibit 1 hereto.

We also understand that as part of this transfer, the Nursing Center will need to be operated as a separately-licensed nursing facility. I have already spoken about this subject with Becky Wertz, Nurse Consultant with the Nursing Home Licensure and Certification Section, and our client is in the process of preparing the Nursing Home Licensure Application and other related documentation which she has provided. However, before that documentation can be filed, we first need to confirm with your office that this proposal is not subject to certificate of need review.

Ms. Frisone and Ms. Randolph
February 18, 2014
Page 2

The CON law provides that transfer of ownership or control of a CON would constitute grounds for withdrawal of the CON if it occurs during the course of development of a project before the project is complete. N.C.G.S. § 131E-189. There is no CON project under development at the Nursing Center. Furthermore, Agency rules provide that neither ownership nor control of a certificate of need is transferred when the holder of the certificate is a corporation and the identity of the holder changes because of a corporate reorganization, such as transferring ownership to a wholly-owned subsidiary. 10A N.C.A.C. 14C.0502(b)(1) and (c).

In this instance, the entity that owns the Nursing Center will not change, and the same building, staff and equipment will be used to provide the same services at the same location. HCMH will continue to own the Nursing Center assets that were authorized under the CON and have been used to furnish skilled nursing care to the Nursing Center's residents. The proposed transaction does not involve the offering or expansion of any new facility, service or equipment, and the State's inventory of nursing home beds will not change. No new or additional nursing home beds will be acquired or placed in operation in the State. The Nursing Center already has its own separate NPI number and Medicare number.

This proposal is similar to other proposals involving transfer of assets to wholly owned subsidiaries that the CON Section has found in the past did not require CON review. For example, the CON Section determined that a perfusion company could hold heart-lung bypass equipment in two separate wholly owned subsidiaries without undergoing CON review. See enclosed Exhibit 2 (without exhibits to original request letter).

For these reasons, we believe that the CON law allows the transfer of the Nursing Center to a wholly-owned subsidiary of HCMH, without the requirement of a CON, because such a transfer does not constitute the development or acquisition of a new facility or services by the subsidiary, within the meaning of G.S. 131E-176(16) or 10A N.C.A.C. 14C.0502. The subsidiary has no control over those services independent of its parent entity. The ultimate ownership and control of the service does not change. The beds already exist in the inventory in the State Medical Facilities Plan and there is no new facility constructed. Thus, there has been no action which constitutes the offering or development of a new institutional health service within the meaning of G.S. 131E-178(a), and no CON is required.

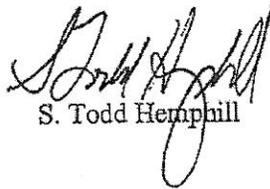
We request that you provide a letter of no review confirming that our interpretation of the CON law and applicable rules is correct and that this proposal is not subject to certificate of need review.

Ms. Frisone and Ms. Randolph
February 18, 2014
Page 3

Please let us know if you need further information or if there are questions we can answer.

Very truly yours,

BODE HEMPHILL, L.L.P.



S. Todd Hemphill

STH:sh
Enclosure
cc w/enc.:

Becky Wertz, Nurse Consultant (via hand delivery)
Paul Hammes/Don Trippel (via e-mail only)

SOSID: 1361794
Date Filed: 2/14/2014 5:00:00 PM
Elaine F. Marshall
North Carolina Secretary of State
C2014 043 00481

State of North Carolina
Department of the Secretary of State

Limited Liability Company
ARTICLES OF ORGANIZATION

Pursuant to §57D-2-20 of the General Statutes of North Carolina, the undersigned does hereby submit these Articles of Organization for the purpose of forming a limited liability company.

1. The name of the limited liability company is: Hugh Chatham Nursing Center, LLC
(See Item 1 of the Instructions for appropriate entity designation)
2. The name and address of each person executing these articles of organization is as follows: (State whether each person is executing these articles of organization in the capacity of a member, organizer or both. Note: This document must be signed by all persons listed.)
S. Todd Hemphill (Organizer)
Post Office Box 5338, Raleigh, NC 27628
3. The name of the initial registered agent is: Raymond A. Parker
4. The street address and county of the initial registered agent office of the limited liability company is:
Number and Street 131 Colony Lane
City Elkin State: NC Zip Code: 28621 County: Surry
5. The mailing address, if different from the street address, of the initial registered agent office is:
Number and Street _____
City _____ State: NC Zip Code: _____ County: _____
6. Principal office information: (Select either a or b.)
a. The limited liability company has a principal office.
The principal office telephone number: (336) 527-7000
The street address and county of the principal office of the limited liability company is:
Number and Street 180 Parkwood Drive
City Elkin State: NC Zip Code: 28621 County: Surry



The mailing address, if different from the street address, of the principal office of the company is:

Number and Street Post Office Box 580

City Elkin State: NC Zip Code: 28621 County: Surry

b. The limited liability company does not have a principal office.

7. Any other provisions which the limited liability company elects to include (e.g., the purpose of the entity) are attached.

8. (Optional): Please provide a business e-mail address Privacy Redaction
The Secretary of State's Office will e-mail the business automatically at the address provided above at no cost when a document is filed. The e-mail provided will not be viewable on the website. For more information on why this service is offered, please see the instructions for this document.



9. These articles will be effective upon filing, unless a future date is specified:

This is the 12th day of February, 2014

S. Todd Hemphill
Signature

S. Todd Hemphill, Organizer
Type or Print Name and Title

The below space to be used if more than one organizer or member is listed in item #2 above.

_____ Signature	_____ Signature
_____ Type and Print Name and Title	_____ Type and Print Name and Title
_____ Signature	_____ Signature
_____ Type and Print Name and Title	_____ Type and Print Name and Title

NOTES:

1. Filing fee is \$125. This document must be filed with the Secretary of State,

CORPORATIONS DIVISION
(Revised January 2014)

P.O. Box 29622
2

RALEIGH, NC 27626-0622
(Form L-01)

ATTACHMENT TO ARTICLES OF ORGANIZATION
HUGH CHATHAM NURSING CENTER, LLC

NAME AND ADDRESS OF INITIAL MEMBER

The sole member of Hugh Chatham Nursing Center, LLC is Hugh Chatham Memorial Hospital, Inc.

Hugh Chatham Memorial Hospital, Inc.'s address is 180 Parkwood Drive, Elkin, NC 28621



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

Beverly Eaves Perdue, Governor
 Lanier M. Causler, Secretary

www.ncdhhs.gov/dhsr

Craig R. Smith, Section Chief
 Phone: 919-855-3875
 Fax: 919-733-8139

December 9, 2011

William R. Shenton
 Poyner Spruill
 P.O. Box 1801
 Raleigh, NC 27602-1801

RE: No Review:

- o Transfer by CSA Medical Services, LLC (CSA) of 100% of its ownership interests in five (5) existing heart lung bypass machines in use at WakeMed to CSAMS New Bern Avenue, LLC, a wholly-owned subsidiary of CSA
- o Transfer by CSA Medical Services, LLC (CSA) of 100% of its ownership interests in three (3) existing heart lung bypass machines in use at Rex Hospital to CSAMS Lake Boone Trail, LLC, a wholly-owned subsidiary of CSA

Wake County

Dear Mr. Shenton:

The Certificate of Need (CON) Section received your letter of November 21, 2011 regarding the above referenced proposals. Based on the CON law in effect on the date of this response to your request, the proposals described in your correspondence are not governed by, and therefore, do not currently require a certificate of need. However, please note that if the CON law is subsequently amended such that the above referenced proposals would require a certificate of need, this determination does not authorize you to proceed to develop the above referenced proposals 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 proposals 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 proposal 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,

Martha J. Frisone
 Martha J. Frisone
 Assistant Chief

Craig R. Smith
 Craig R. Smith, Chief
 Certificate of Need Section

cc: Medical Facilities Planning Section, DHSR



Location: 809 Ruggles Drive ■ Dorothea Dix Hospital Campus ■ Raleigh, N.C. 27603
 An Equal Opportunity / Affirmative Action Employer

EXHIBIT

2



Poyner Spruill^{LLP}

November 21, 2011

Wilson Hayman
 Partner
 D: 919.783.1140
 whayman@poynerspruill.com
 William R. Shenton
 Partner
 D: 919.783.2947
 F: 919.783.1076
 wshenton@poynerspruill.com

VIA U.S. MAIL AND E-MAIL/
Craig.smith@dhhs.nc.gov
Martha.frisonc@dhhs.nc.gov

Mr. Craig R. Smith, Chief
 Ms. Martha Frisonc, Assistant Chief
 Division of Health Service Regulation
 Certificate of Need Section
 2704 Mail Service Center
 Raleigh, North Carolina 27698-2704

RE: CSA Medical Services, LLC; No Review Request regarding Transfer of Heart-Lung Bypass Machines to Wholly Owned Subsidiaries

Dear Mr. Smith and Ms. Frisonc:

This letter is submitted on behalf of CSA Medical Services, LLC ("CSA"), and two subsidiary limited liability companies to be formed and wholly owned by CSA and to be named "CSAMS New Bern Avenue, LLC" (CSA New Bern), and "CSAMS Lake Boone Trail, LLC" (CSA Lake Boone), upon receipt of your approval of this request. CSA currently owns and operates eight (8) heart-lung bypass ("HLB") machines. Five (5) of the HLB machines are operated at WakeMed and three (3) of the HLB machines are operated at Rex Hospital, Inc. ("Rex"). The purpose of this letter is to provide notice to the North Carolina Department of Health and Human Services, Division of Health Service Regulation, Certificate of Need Section (the "Agency"), and confirm that the transfer of CSA's interests in these eight (8) HLB machines and the operation of the same to two wholly owned subsidiaries of CSA is not reviewable as a new institutional health service under the North Carolina Certificate of Need ("CON") law.

The Agency has recently approved a similar transfer in an August 18, 2011 Declaratory Ruling regarding Radiation Oncology Centers of the Carolinas, Inc. ("ROCC"). That Declaratory Ruling concerned the transfer of interests in two radiation oncology facilities from ROCC to two wholly owned subsidiaries of ROCC. Attached hereto as Exhibits 1 and 2 are the ROCC Declaratory Ruling Request and the ROCC Declaratory Ruling. The ruling requested by CSA here is directly analogous to the ROCC ruling, the only difference being that ROCC involved the *per se* reviewable items of linear accelerators and simulators and CSA's request involves the *per se* reviewable items of heart-lung bypass machines.

I. BACKGROUND AND FACTS

CSA directly owns eight (8) Terumo Corporation Series 8000 HLB machines. Five (5) of these HLB machines are located and used by CSA to provide perfusion services at WakeMed, located at 3000 New Bern Avenue, Raleigh, NC 27620. Three (3) of these HLB machines are located and used by CSA to provide perfusion services at Rex, located at 4420 Lake Boone Trail, Raleigh, NC 27607. CSA also owns

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301 Fayetteville Street, Suite 1800, Raleigh, NC 27601 P.O. Box 1801, Raleigh, NC 27602-1801 P: 919.783.8400

Poyner SpruillSM

Mr. Craig R. Smith, Chief
 Ms. Martha Frisone, Assistant Chief
 November 21, 2011
 Page 2

seven (7) cell saver machines located at WakeMed in Raleigh, and two (2) located at WakeMed-Cary. These cell saver machines are Baylor Rapid Autologous Transfusion (BRAT) machines manufactured by Sorin Corporation and are not subject to CON review. CSA does not own the BRAT machines at Rex, which are owned by the hospital. CSA also provides the hospitals with the services of seven (7) licensed perfusionists, who are employed by CSA's affiliate Carolina MSO, L.L.C. (MSO) but work for CSA pursuant to its Management Services Agreement with MSO.

The five (5) HLB machines at WakeMed are labeled A, B, C, D, and E, and the three (3) at Rex are labeled 1, 2, and 3. Each HLB machine consists of the following: (a) a four (4) or five (5) pump Terumo Base; (b) three (3) or four (4) Terumo 8000 roller pump modules (8000 roller pump modules); (c) one (1) Medtronic Bio-Medicus arterial pump series 550 (Bio pump); (d) one (1) Medtronic TX 50 Flowmeter (Flowmeter); and (e) one (1) Sechrist air/oxygen mixer (Sechrist). Similarly, the seven (7) BRAT machines at WakeMed in Raleigh are labeled A, B, C, D, E, F and G, and the two at WakeMed-Cary are labeled 1 and 2. Each HLB machine (and its components) and BRAT machine is identified by its serial numbers (SN), model numbers and the hospital where it is located, as described in Exhibit 3 to this letter.

The surgeons of Carolina Cardiovascular Surgical Associates, P.A. (Practice), started performing open heart surgery and providing their own perfusion services at WakeMed in 1979 and at Rex in 1989, through either the Practice itself or a perfusion company owned by the same physicians. Each of the eight (8) HLB machines currently owned by CSA is replacement equipment for a machine owned by CSA (or a predecessor entity) prior to the year 1993, when acquisition of an HLB machine became subject to CON review regardless of its cost. W. Charles Helton, M.D., founded the Practice in 1979 and Cardinal Bio-Medical Associates, Inc. (Cardinal Bio-Medical), in 1980. Cardinal Bio-Medical was the perfusion company predecessor to CSA that like CSA was owned by the shareholders of the Practice. The two hospitals have never owned the HLB machines used at their facilities. Before 1989, Cardinal Biomedical had acquired and operated three (3) HLB machines at WakeMed and two (2) at Rex. Another cardiothoracic surgery practice in Raleigh, Atkinson & Zeok, M.D., P.A., had two (2) additional HLB machines at WakeMed and one (1) additional HLB machine at Rex. Atkinson & Zeok, M.D., P.A. merged with the Practice in 1993, and its two (2) surgeon shareholders, Alvan W. Atkinson, M.D., and John V. Zeok, M.D., joined the Practice. At the same time their three (3) HLB machines were acquired by Cardinal Bio-Medical, and they become shareholders of that perfusion company. Cardinal Bio-Medical or its successor company has continued to own and operate these eight (8) HLB machines (or their replacements) at their same respective locations at WakeMed and Rex since that time. In 1997, the shareholders of Cardinal Bio-Medical reorganized the company by forming CSA and transferring the operations and all eight (8) machines to CSA, which was owned by the same surgeons.

By 2001, CSA needed to replace all eight (8) of its HLB machines. There was a fourth HLB machine at Rex owned by surgeons Abdul G. Chaudhry, M.D. and James H. Davis, M.D. This one (1) HLB machine had been loaned to them by the manufacturer in the late 1990's to replace one they had provided for use at Rex which had become obsolete. At that time, CSA bought this fourth loaned HLB machine, which had already been used at Rex, from the manufacturer to replace one of CSA's older machines at Rex. Thereafter, Drs. Chaudhry and Davis no longer provided perfusion services or a HLB machine for use at Rex. CSA's purchase of this machine thus resulted in a net decrease in useable HLB machines at Rex from four (4) to three (3).

The same year, CSA obtained replacement equipment for its other seven (7) HLB machines at WakeMed and Rex, at a total capital cost of \$322,695. CSA's obsolete machines were subsequently removed out of North Carolina. By letter dated June 25, 2004, the Agency approved CSA's acquisition of the seven (7)

Poyner Spruill^{LLP}

Mr. Craig R. Smith, Chief
 Ms. Martha Frisone, Assistant Chief
 November 21, 2011
 Page 3

new HLB machines at WakeMed and Rex as replacement equipment. The Agency's "no review" letter of that date is attached and labeled as Exhibit 4.

CSA would like to transfer its interest in the eight (8) HLB machines into two wholly owned subsidiary limited liability companies. The first wholly owned subsidiary will be named "CSAMS New Bern Avenue, LLC" and will own the five (5) HLB machines currently operated at WakeMed. The second wholly owned subsidiary will be named "CSAMS Lake Boone Trail, LLC" and will own the three (3) HLB machines currently operated at Rex. The transfer of CSA's interests in the eight (8) HLB machines into two (2) wholly owned subsidiaries is not a CON reviewable event because it will have the following results:

- (1) No increase in the HLB machine inventory in Wake County;
- (2) No physical relocation of any HLB machines in Wake County;
- (3) No creation of any new health service facilities; and
- (4) No asset purchases of any per se reviewable equipment, consistent with the ROCC Declaratory Ruling.

This letter requests your confirmation that such a proposed transfer of interests would not trigger any of the new institutional health service provisions in the CON statute, and the transaction may proceed without first acquiring a CON.

II. ANALYSIS

The CON law provides that the "acquisition by purchase, donation, lease, transfer or comparable arrangement" of an HLB machine constitutes a "new institutional health service" that is subject to CON review. N.C. Gen. Stat. § 131E-176(16)f1; § 131E-176(a). However, we believe the creation of these two wholly owned subsidiaries is not a reviewable event because CSA, the owner of the CON rights for the eight (8) HLB machines, is not undergoing any direct change in its ownership status. Rather, this is merely a type of reorganization in the nature of those which the CON rules recognize as non-reviewable.

Until 1993, the acquisition of an HLB machine was not regulated under the CON law unless it involved the obligation of a capital expenditure exceeding two million dollars (\$2,000,000), which far exceeds the cost of this equipment. See N.C. Sess. Laws 1993, c. 7, § 2 (adding the acquisition of HLB machines and any "major medical equipment" costing more than \$750,000 as "new institutional health services" requiring a CON). However, effective March 18, 1993, the General Assembly amended the CON law to make the acquisition of HLB machines constitute a "new institutional health service" requiring a CON regardless of its cost. N.C. Gen. Stat. § 131E-176(10a), (16)f1.5, as amended by N.C. Sess. Laws 1993, c. 7, § 2.

Under the CON law, transfer of ownership or control of a CON prior to completion of a project or operation of the facility constitutes grounds for withdrawal of a CON. N.C. Gen. Stat. § 131E-189. However, the Agency's rules provide that in that situation, neither ownership nor control of a CON is transferred when the holder of the certificate is a corporation and the identity of the holder changes because of corporate reorganization, including transferring ownership to wholly owned subsidiaries. 10A N.C.A.C. 14C.0502(b)(1) and (c).

Poyner Spruill^{LLP}

Mr. Craig R. Smith, Chief
Ms. Martha Frisone, Assistant Chief
November 21, 2011
Page 5

Very truly yours,



Wilson Hayman
Partner
William R. Shenton
Partner

Attachments



**NORTH CAROLINA DEPARTMENT OF HEALTH AND HUMAN SERVICES
DIVISION OF HEALTH SERVICE REGULATION
RALEIGH, NORTH CAROLINA**

**IN RE: REQUEST FOR DECLARATORY)
RULING BY THE CHARLOTTE-)
MECKLENBURG HOSPITAL AUTHORITY) DECLARATORY RULING
D/B/A CAROLINAS HEALTHCARE)
SYSTEM AND MERCY HOSPITAL, INC.)**

I, Drexdal Pratt, as Director of the Division of Health Service Regulation, North Carolina Department of Health and Human Services (“Department” or “Agency”), do hereby issue this Declaratory Ruling pursuant to North Carolina General Statute § 150B-4 and 10A NCAC 14A .0103 under the authority granted me by the Secretary of the Department of Health and Human Services.

The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas HealthCare System (“CMHA”) and Mercy Hospital, Inc. (“Mercy”) (collectively “CHS”) has requested a declaratory ruling as to the applicability of Chapter 131E, Article 9 of the North Carolina General Statutes, and of the Department’s rules, to the facts described below. Specifically, CMHA and Mercy request a Declaratory Ruling allowing the hospital facilities situated on the “Mercy Vail Avenue Campus,” at 2001 Vail Avenue, Charlotte, NC 28207 (License # H0042), as well as some specific off-campus outpatient services, to be relicensed as part of Carolinas Medical Center’s license (License # H0071) without first obtaining a Certificate of Need (“CON”), and allowing the good cause transfer of any outstanding CONs issued to Mercy-related CON projects. This ruling will be binding upon the Department and the entity requesting it, as long as the material facts stated herein are accurate. This ruling pertains only to the matters referenced herein. Except as provided by N.C.G.S. § 150B-4, the Department expressly reserves the right to make a prospective change in the interpretation of the statutes and regulations at issue in this Declaratory

Ruling. Gary S. Qualls of K&L Gates LLP has requested this ruling on behalf of CHS and has provided the material facts upon which this ruling is based.

STATEMENT OF THE FACTS

Mercy owns and operates two separate hospital campuses which are operated under the single "Mercy/Pineville License" (License # H0042). One Mercy Hospital campus, the "Mercy Vail Avenue Campus," is located at 2001 Vail Avenue, Charlotte, NC 28207. Another Hospital campus, the "Pineville Campus," is located at 10628 Park Road, Pineville, NC 28210. CMHA owns and operates, among other hospitals, Carolinas Medical Center ("CMC") at 1000 Blythe Blvd., Charlotte, NC 28232 (License # H0071). CMHA is also the parent company for Mercy.

CMHA and its controlled affiliate Mercy have determined that operational and clinical efficiencies will be gained by shifting the Mercy Vail Avenue Campus, and some off-campus outpatient services, from the Mercy/Pineville License (License # H0042) to the CMC license (License # H0071). The off-campus outpatient services that will move from the Mercy/Pineville license are: (1) Carolinas Sleep Services-Mercy, (2) Carolinas Wound Care Center, (3) SEPC at Museum Medical Plaza.

CHS also requests a transfer of good cause of any outstanding CONs issued to Mercy. The change in outstanding Mercy/Pineville-related projects includes: (1) F-8771-12 CMC-Mercy MRI Replacement (will be licensed as part of CMC after the licensure change), (2) F-8763-11 CMC-Mercy 38 Acute Care Beds (will be licensed as part of CMC after the licensure change), (3) F-8704-11 CMC-Mercy 66 Bed Behavioral Health Hospital (will be licensed as part of CMC after the licensure change), (4) F-8640-11 and F-8764-11 Relocate LTACH beds to Pineville (will still be licensed under the Mercy/Pineville License on the Pineville campus), (5) F-8740-11 CMC-Providence Satellite ED (will still be licensed under the Mercy/Pineville

License) and (6) F-7979-07 CMC-Pineville Phase II (will still be licensed under the Mercy/Pineville License on the Pineville campus).

ANALYSIS

The CON statute sets forth the following definitions of new institutional health services:

- (16) “New institutional health services” means any of the following:
- a. The construction, development, or other establishment of a new health service facility.
 - c. Any change in bed capacity as defined in G.S. 131-176(5)

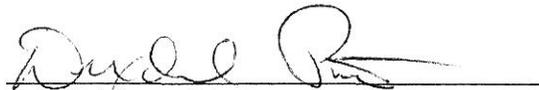
N.C. Gen. Stat. § 131E-176(16) (a) and (c).

On July 15, 2002, the Department issued a Declaratory Ruling to WakeMed to split the WakeMed Raleigh and WakeMed Cary campuses into two separately licensed hospitals, where those facilities had previously operated under a single license. Since the WakeMed transaction, which created a new license did not require a CON, it can be assumed that the Mercy relicensing transaction requested herein which does not create a new license should not require a CON. The placing of Mercy Vail Avenue Campus under the CMC license does not involve any new institutional health service definitions requiring a CON. The relicensing transaction does not constitute the construction, development, or establishment of a new health service facility. The proposed transaction does not constitute a change in bed capacity as defined by N.C. Gen. Stat. § 131E-176(16)(c) and 176(5) in that no beds are being relocated from one licensed facility or campus to another, no health service facility bed capacity is being redistributed among the categories of health service facility beds and there are no increases in the number of health service facility beds, which would require CON review.

CONCLUSION

For the foregoing reasons, assuming the statements of fact in the request to be true, I conclude that Carolinas HealthCare System and Mercy Hospital, Inc. be allowed to relicense hospital facilities situated on the Mercy Vail Avenue Campus and some specific off-campus outpatient services from the Mercy Vail Avenue Campus license (License # H0042) to the Carolinas Medical Center's license (License # H0071) including a transfer of good cause for any undeveloped CONs issued to Mercy/Pineville. The proposed licensure change has been determined to be in material compliance with representations in the respective applications.

This the 2nd day of November, 2012.



Drexel Pratt, Director
Division of Health Service Regulation
N.C. Department of Health and Human Services

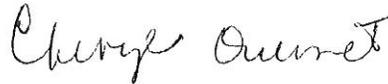
CERTIFICATE OF SERVICE

I certify that a copy of the foregoing Declaratory Ruling has been served upon the nonagency party by electronic and certified mail, return receipt requested, by depositing the copy in an official depository of the United States Postal Service in a first-class, postage pre-paid envelope addressed as follows:

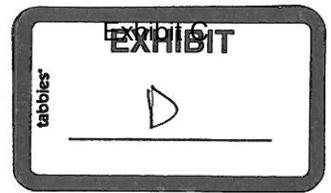
CERTIFIED MAIL

Gary S. Qualls, Esq.
K&L Gates LLP
430 Davis Drive, Suite 400
Morrisville, NC 27560

This the 2nd day of November, 2012.



Cheryl Ouimet, Chief Operating Officer



North Carolina Department of Health and Human Services
Division of Facility Services
Office of the Director
2701 Mail Service Center • Raleigh, North Carolina 27699-2701

Michael F. Easley, Governor
Carmen Hooker Odom, Secretary

Robert J. Fitzgerald, Director
Phone: 919-855-3750
Fax: 919-733-2757

July 15, 2002

Robbie Roberts, Manager
Market Planning
WakeMed
Post Office Box 14465
Raleigh, North Carolina 27620-4465

Re: Declaratory Ruling for WakeMed
Wake County

Dear Mr. Roberts:

I am enclosing a Declaratory Ruling that you requested in your letter received on May 15, 2002. If questions arise, do not hesitate to let me know.

Sincerely,

2002 for
Robert J. Fitzgerald
Robert J. Fitzgerald

RJF:JRS:cjp

Enclosure

cc: Jackie R. Sheppard, Chief Operating Officer, DFS
Steve White, Chief, Licensure and Certification Section
Lee Hoffman, Chief, Certificate of Need Section
William Warren, Chief, Construction Section
James Wellons, Attorney General's Office



NORTH CAROLINA DEPARTMENT OF HEALTH AND HUMAN SERVICES
 DIVISION OF FACILITY SERVICES
 RALEIGH, NORTH CAROLINA

IN RE: REQUEST FOR DECLARATORY)
 RULING BY WAKEMED) DECLARATORY RULING

I, Robert J. Fitzgerald, Director of the Division of Facility Services ("Agency"), do hereby issue this Declaratory Ruling pursuant to G.S. §§ 150B-4 and 10 NCAC 3B .0310, and the authority delegated to me by the Secretary of the Department of Health and Human Services. WakeMed asked the Agency to issue a ruling as to the applicability of the Certificate of Need Statute contained in G.S. §131E-176(16)(a) and G.S. §131E-178(a) to the facts described below. For the reasons given below I conclude that these portions of the Statute are not applicable with regard to WakeMed's intent to separately license its New Bern Avenue Campus ("Main Campus") and Western Wake Medical Center ("WWMC") facilities. Furthermore, I conclude that historical acute care utilization data for the last five years for the two hospitals be separately included in the *State Medical Facilities Plan* ("SMFP").

STATEMENT OF THE FACTS

- (1) WakeMed is licensed by the Department of Health and Human Services, Division of Facility Services, Licensure and Certification Section, Acute Care and Home Care Branch, as one facility with multiple sites.
- (2) WakeMed is licensed for a total of 629 acute care beds. These beds are contained on two separate locations – the Main Campus in Raleigh, with 515 acute care beds, and WWMC in Cary, with 114 acute care beds. Both facilities are located in Wake County.

Table 2 – Acute Care Utilization at WWMC Since December 1991

Fiscal Year	Patient Days	Percent Utilization
1992 (10 months)	6,078	20.8%
1993	10,511	36.0%
1994	11,508	39.4%
1995	13,352	45.7%
1996	13,030	44.6%
1997	13,640	46.7%
1998	16,492	56.5%
1999	18,161	62.2%
2000	20,432	59.6%
2001	24,945	72.7%
2002 (6 months prorated)	25,910	75.5%

(Source of FYs 1992-2001 data: Annual License Renewal Applications on file with the Agency; Source of FY 2002 data: WakeMed. Please note that WakeMed's fiscal year is October 1-September 30.)

- (11) WakeMed wishes to license the Main Campus and WWMC under separate hospital licenses for reporting and other internal administrative purposes. No changes in services, staffing, administration or other aspect of management, costs or charges would result from licensing these two hospitals separately. However, doing so might technically be interpreted as the offering of a new institutional health service, via provisions in the Certificate of Need Statute contained in G.S. §131E-178(a), as follows:

(a) No person shall offer or develop a new institutional health service without first obtaining a certificate of need from the Department; provided, however, no hospital licensed pursuant to Article 5 of this chapter that would serve a minority population that would not otherwise have been served and that continues to serve a minority population may be required to obtain a certificate of need for transferring up to 65 beds to nursing care facility beds.

G.S. §131E-176(16) defines a "new institutional health service", in part, as follows:

- a. The construction, development or other establishment of a new health service facility.*

- (12) In this request, WakeMed maintains that separate licensure of WWMC would not constitute a "change in bed capacity", as defined by G.S. §131E-176(5). No licensed beds would be relocated, nor would this proposal result in any change in the number of health service facility beds in the WakeMed system or in the Wake County Multi-Hospital Service System.

ANALYSIS

WakeMed's request that the Agency issue a Declaratory Ruling described above is based upon the following:

- (1) Neither the WakeMed Main Campus nor WWMC are new health service facilities for Certificate of Need law purposes. The Main Campus opened in 1961; WWMC opened in 1991. At the time of the opening of WWMC, it could have been separately licensed from the Main Campus without further certificate of need review.
- (2) Separate licensure of the Main Campus and WWMC would not affect government reimbursement, because both facilities currently maintain, and will continue to maintain, separate Medicare and Medicaid provider numbers.
- (3) Separate licensure of the Main Campus and WWMC would not impact medical staff organization and composition at either facility, because these facilities have, and have always had, separate medical staffs.

- (4) Separate licensure of the Main Campus and WWMC would not impact accreditation, because both facilities are separately surveyed and accredited by the JCAHO.
- (5) Separate licensure of the Main Campus and WWMC would not affect the governance of either facility, because there would be no resultant change in ownership from this proposal.
- (6) Separate licensure of the Main Campus and WWMC would not change the inventory of licensed acute care beds, either in the WakeMed system or in the Wake County Multi-Hospital Service System.
- (7) Separate licensure of the Main Campus and WWMC would not impact the reporting of acute care bed utilization data, as this data would continue to be reported to the Agency annually.
- (8) Any future capital expenditures and/or services requiring a CON pursuant to G.S. §131E-175 *et seq.*, at either the Main Campus or WWMC would continue to be obtained through the CON process.

CONCLUSION

For the reasons stated above and specific facts presented, I conclude that the separate licensure of Western Wake Medical Center from the WakeMed Main Campus does not constitute a new institutional health service or otherwise require a certificate of need under the applicable portions of the Certificate of Need Statute, specifically G.S. §131E-176(16)(a) and

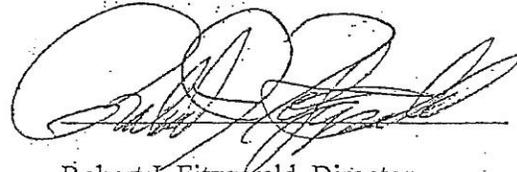
G.S. §131E-178(a). In particular, I find persuasive the facts and circumstance that, other than the common licensure, these two hospitals were organized and have historically functioned as separate facilities. Moreover, since the only change resulting from this separate licensure status is the separation of utilization data and operating statistics on the annual License Renewal Application submitted to the Agency, I have determined that requiring a certificate of need in this instance would be an overly technical interpretation of the Certificate of Need law and not in furtherance of any statutory purpose. Furthermore, I conclude that the Agency should recognize the historical utilization data for the past five years by licensed hospital in the SMFP; i.e., recognize utilization data for the Main Campus and for WWMC as separate hospitals under common ownership.

WakeMed's acute care, rehabilitation, outpatient and skilled nursing facilities shall be licensed as follows:

Table 3: Licensure of WakeMed Facilities

Licensed Under Main Campus:	Location	Licensed Under WWMC:	Location
WakeMed New Bern Avenue Campus	3000 New Bern Ave. Raleigh, NC 27610	WakeMed Western Wake Medical Center	1900 Kildaire Farm Rd. Cary, NC 27511
WakeMed Rehab	3000 New Bern Ave. Raleigh, NC 27610	WakeMed Fuquay-Varina	400 W. Ransom St. Fuquay-Varina, NC 27526
WakeMed Zebulon/Wendell	535 W. Gannon Ave. Zebulon, NC 27597		
WakeMed North	10000 Falls of Neuse Rd. Raleigh, NC 27614		

This is the 15th day of July, 2002.



Robert J. Fitzgerald, Director
Division of Facility Services

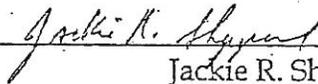
CERTIFICATE OF SERVICE

I certify that a copy of the foregoing Declaratory Ruling has been served upon the nonagency party by certified mail, return receipt requested, by depositing the copy in an official depository of the United States Postal Service in first-class, postage pre-paid envelope addressed as follows:

CERTIFIED MAIL

Robbie Roberts, Manager
Market Planning
WakeMed
P.O. Box 14465
Raleigh, NC 27620-4465

This the 15th day of July, 2002.



Jackie R. Sheppard
Chief Operating Officer

From: [Denise Gunter](#)
To: [Stancil, Tiffany C](#); [Waller, Martha K](#); [Faenza, Julie M](#)
Subject: [External] No Review Letter for Mecklenburg County (HSA III)
Date: Thursday, June 15, 2023 4:14:59 PM
Attachments: [NH Mint Hill breast center no review.pdf](#)
[Nov 28 No Review Letter.pdf](#)
[No Review Exhibit B.pdf](#)
[Exhibit C to No Review.pdf](#)

CAUTION: External email. Do not click links or open attachments unless verified. Report suspicious emails with the Report Message button located on your Outlook menu bar on the Home tab.

Good afternoon,

Attached for processing is a no review letter and exhibits for Mecklenburg County. Could you please confirm that you have received this?

Thanks.



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