

ROY COOPER • Governor

KODY H. KINSLEY • Secretary

MARK PAYNE • Director, Division of Health Service Regulation

VIA EMAIL ONLY

September 29, 2023

Kenneth Burgess

kburgess@bakerdonelson.com

No Review

Record #: 4271

Date of Request: September 13, 2023

Facility Name: Carolina Spine and Neurosurgery Center

FID #: 970332

Business Name: Carolina Spine and Neurosurgery Center, P.A.

Business #: 2615

Project Description: Develop a limited liability company to be named Vanderbilt Park Associates, LLC,

and retain 100% members' interests. Transfer all existing assets, including an

existing fixed MRI scanner, to Vanderbilt Park Associates, LLC

County: Buncombe

Dear Mr. Burgess:

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,

Ena Lightbourne, Project Analyst

Micheala Mitchell, Chief

Micheala Mitchell

cc: Carolyn Coward, Esq.

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



2235 GATEWAY ACCESS POINT SUITE 220 RALEIGH, NORTH CAROLINA 27607

www.bakerdonelson.com

KENNETH LEE BURGESS, SHAREHOLDER

Direct Dial: 919-294-0802 **Direct Fax**: 919-338-7696

E-Mail Address: kburgess@bakerdonelson.com

September 13, 2023

VIA EMAIL

Micheala Mitchell, Chief

N.C. Department of Health and Human Services

N.C. Division of Health Service Regulation

Healthcare Planning and Certificate of Need Section

809 Ruggles Drive, Raleigh, N.C. 27603

Via email to: micheala.mitchell@dhhs.nc.gov

Ena Lightbourne Project Analyst

N.C. Department of Health and Human Services

N.C. Division of Health Service Regulation

Healthcare Planning and Certificate of Need Section

809 Ruggles Drive, Raleigh, N.C. 27603

Via email to: ena.lightbourne@dhhs.nc.gov

RE: No Review Determination Request Regarding Carolina Spine & Neurosurgery Center, P.A. and MH Mission Imaging, LLLP

Dear Micheala and Ena:

This correspondence is being provided to the N.C. Department of Health and Human Services, Division of Health Service Regulation, Healthcare Planning and Certificate of Need Section (the "Agency") on behalf of MH Mission Imaging, LLLP ("Mission Imaging") and Carolina Spine & Neurosurgery Center, P.A. ("Carolina Spine") (collectively the "Parties") to describe a series of related business activities (the "Transaction") between the Parties and to request that the Agency

Micheala Mitchell, Chief September 13, 2023 Page 2

confirm in writing that the Transaction is not subject to review by the Agency and the Parties are not required to obtain a certificate of need ("CON") before proceeding with the Transaction.

I represent MH Mission Imaging LLLP. Carolina Spine is represented by Carolyn Coward of the Van Wrinkle law firm in Asheville. Ms. Coward has acknowledged by her signature below that she has reviewed and joins in this No Review Determination Request.

Background

Carolina Spine holds a CON for acquisition of an MRI scanner (the "MRI Scanner"). *See* Exhibit 1 (CON authorizing acquisition of the MRI Scanner). The Carolina Spine MRI Scanner was initially issued to Mountain Neurological Center, P.A., effective May 29, 1998 to acquire an MRI Scanner, Project I.D. #B-5583-97. Mountain Neurological Center, P.A. later changed its name to Mountain Neurological and Spine Center, P.A. and then later to Carolina Spine and Neurosurgery Center, P.A. ("Carolina Spine"). The owners of Carolina Spine engaged in a series of transactions that first relocated the MRI Scanner to a new limited liability company ("LLC") which they created, called Mountain Spine and Neurological Imaging, LLC, then moved the MRI Scanner to that new LLC, and subsequently returned the MRI Scanner to Carolina Spine. Currently, the MRI Scanner remains an asset of Carolina Spine. *See* Exhibit 2, (May 9, 2013 correspondence between the Agency and counsel for Carolina Spine describing the history of the MRI Scanner CON and subsequent transactions, summarized in this paragraph). In 2017, Carolina Spine obtained an Exemption Approval from the Agency authorizing replacement of the original MRI Scanner. *See* Exhibit 3, (Agency Exemption Approval Notice for Replacement of the MRI Scanner).

The Proposed Transaction

The proposed Transaction which is the subject of this No Review Determination Request involves several steps, as described below. They are:

- The owners of Carolina Spine will create a new limited liability company ("LLC"), Vanderbilt Park Associates, LLC ("VPA")¹.
- Carolina Spine will own 100% of the members interests in VPA.
- Carolina Spine will then transfer its existing assets, including the MRI Scanner and the associated CON rights, to VPA.
- Thereafter, MH Mission Imaging, LLLP will acquire from Carolina Spine 100% of the member interests in VPA.

¹ The Parties have agreed upon the name "Vanderbilt Park Associates, LLC" for the new LLC. In the event this name subsequently is determined to not be available for registration, the Parties will agree upon a corporate name that is available.

- The ownership of the MRI Scanner and its associated CON rights will remain with VPA.
- MH Mission Imaging, LLLP will then enter into a services agreement with VPA whereby Mission Imaging will have access to the MRI Scanner.

The Transaction Is Not Subject To Agency Review And No CON Is Required For The Transaction

We do not believe that the Transaction qualifies as a "new institutional health service" under any provision of the CON Statute, specifically including N.C. Gen. Stat. § 131E1-17(16). The Transaction does not involve a change in bed capacity, the construction or other development of a new health service or health service facility, the acquisition of major medical equipment or any other item or service which qualifies as a new institutional health service and there are no other "new institutional health service" definitional elements that apply to the Transaction.

Our opinion that no CON is required for the Transaction is based upon the following:

- 1. The Agency's historical position authorizing the owners of CON-regulated equipment and/or facilities to change the underlying corporate structure of the entity holding the CON rights to such equipment and/or facilities. *See*, *e.g.*, *Exhibit 4*, (2013 Declaratory Ruling allowing physician owners of a Professional Association that owned an LLC that owned operating rooms to restructure and transfer ownership of the LLC owning the operating rooms directly to themselves, as opposed to owning the operating rooms via LLC member interests).
- 2. The Agency's historical position that the acquisition of member interests in an LLC which owns CON-regulated assets does not constitute a "new institutional health service" and thus does not require that a CON be sought or obtained prior to purchase of the LLC member interests. *Id.*
- 3. The Agency's historical position that Services Agreements of the type being entered into between Mission Imaging and VPA do not constitute "the acquisition by purchase, donation, lease, transfer or comparable arrangement" of MRI Scanners within the meaning of N.C. Gen. Stat. § 131E-176(16)fl and do not otherwise require a CON. *See* Exhibit 5, (No Review Approval by the Agency authorizing a Services Agreement arrangement between Carolina Spine and UNC Physicians Group Practice, II, LLC). *See* Exhibit 6, (correspondence between counsel for Mission Imaging and Agency counsel Derek Hunter). A draft of the Mission Imaging / VPA Services Agreement is attached hereto as Exhibit 7.

Through a series of telephone calls and emails with Deputy Attorney General, Derek Hunter, counsel for the Agency, the undersigned counsel for Mission Imaging has described the Transaction (as described herein) and obtained confirmation that the Transaction does not

Micheala Mitchell, Chief September 13, 2023 Page 4

constitute a "new institutional health service" and thus does not require that the Parties obtain a CON before proceeding with the Transaction. **See Exhibit 6.** For the reasons recited herein, we request that the CON Section acknowledge in writing at its earliest opportunity that the Transaction, as described herein, is not subject to CON Section Review and that the Parties to the Transaction may proceed with the Transaction without first obtaining a CON.

Please let me know if you have questions or need further information regarding this notice.

Very truly yours,

Kenneth Lee Burgess, Shareholder

Ken Burgess

KLB:jdm Encls.

cc: Carolyn Coward, Esq.

Rachel Coleman, Esq.

Exhibits

Acknowledgement and Approval of No

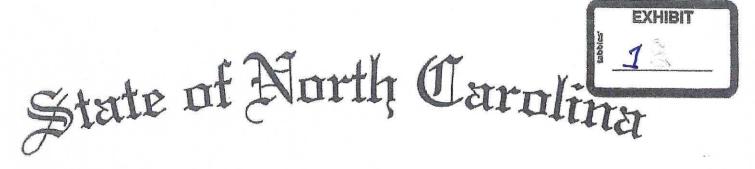
Review Determination Request

arolp L. Com

Carolyn Coward, Esq.

Counsel for Carolina Spine and Neurosugery Center, P.A.

Exhibit 1



Effective Date

Department Of Health and Human Serlices Dilision Of Hacility Serlices Certificate Of Need

B-5583-07/070332

CHECOVE DATE TO THE TABLE
Issued to: Mountain Neurological Center, P.A.
7 McDayall Character
Asheville, NG 28801 THE OC
10001
1 NY 20 173
The North Carolina Department of Health and Human Services, pursuant to the North Carolina Health Planning
and Resource Development Adr of 1978 G.S. § 131-175, et seq., as amended and recodified, G.S. § 131E-175, et
seq., hereby finds and pertitles that the rewinstitutional health service proposed by the person listed above is consis-
tent with, or as conditioned is consisted with the plans, standards, and criteria prescribed by the Act and the rules
and regulations provide the Act and the fulls.
and regulations promulgated thereunder ine lindings of the Department are attached hereto and incorporated by
reference.
This Certificate affords the person listed above the opportunity to proceed with development of the proposed
new institutional fealth service in a manner consistent with the plans, so indeeds, and criteria prescribed by the Act
and the rules and regulations promulgated thereunder. This Certificate includes and is limited to
The state of the s
SCOPE: Mountain Mountain
SCOPE: Mountain Neurological Center, P.A. shall acroire to more than one magnetic resonance imaking (MRI) scanner/Buncombe County
resonance imaging (MRI) scanner Buncombe County
CONDITIONS: See Reverse Side
PHYSICAL LOCATION WANTED NOT A 1776
PHYSICAL LOCATION: Mountain Neurological Centerio
Achove Street, Asheville, NC 20801
COSE ON MOER IS
MAXIMUM CAPITAL EXPENDITURE \$56,280 UAM VIV
MAXIMUM CAPITAL EXPENDITURE \$56,280 UAM VIDER TIMETABLE: See Reverse Side
TIMETABLE: See Reverse Side

FIRST PROGRESS REPORT DUE: August 31, 1998

Project Identification Number

This Certificate is limited to the person listed above and is not transferable or assignable. This Certificate may be withdrawn as provided in G.S. § 131E-189, and the rules and regulations promulgated thereunder.

Issuance of this Certificate does not supplant provisions or requirements embodied in codes, ordinances, statutes other than G.S. § 131E-175, et seq., rules regulations or guidelines administered or enforced by municipal, state or federal agencies or the agent thereof.

10. .. VACXI. AA

Exhibit 2





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

Pat McCrory Governor

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

> Drexdal Pratt Division Director

May 9, 2013

Frank Kirschbaum 4141 Parklake Avenue, Suite 200 Raleigh, NC 27612

Raleigh, NC 27612

RE: Inquiry / Carolina Spine and Neurosurgery Center, P.A. / Transfers of ownership of an MRI scanner relating to Project ID #B-5583-97 / Buncombe County
FID #: 970332

Dear Mr. Kirschbaum:

In response to your correspondence of April 3, 2013, the Certificate of Need Section has determined that:

 A certificate of need was issued to Mountain Neurological Center, P.A. offective May 29, 1998 to acquire an MRI scanner (Project ID #B-5583-97).

Mountain Neurological Center, P.A. changed its name to Mountain Neurological and Spine Center, P.A., and then
changed its name again to Carolina Spine and Neurosurgery Center, P.A. (Carolina Spine).

 According to the April 3, 2013 letter, "On February 1, 2006, an LLC formed by the owners of Carolina Spine, Mountain Spine and Neurological Imaging, LLC ("IASNI"), wrote to the CON Section to provide notice that it intended to acquire the Carolina Spine facility, including the MRI scanner. ... Carolina Spine does not have a record of the CON Section's response to this letter."

 Despite an extensive search of the CON Section files, the CON Section was unable to locate the February 2006 letter or any other evidence that an exemption from review was granted.

According to the April 3, 2013 letter, "MSNI owned and operated the MRI Scanner until December 2009, at which
point the facility, including the scanner, was returned to Carolina Spine. ... The CON Section was not provided
with written notice of this transaction."

Pursuant to GS 131E-184(a)(8), prior written notice is required from the buyer in order for the acquisition of an
existing health service facility, such as Carolina Spine, including the MRI scanner, to be exempt from review under
the CON law.

 The Certificate of Need Section does not issue new certificates of need whenever the name of an applicant or a facility changes.

 No penalty or any other sanction will be assessed against either MSNI or Carolina Spine for failure to provide prior written notice of the acquisitions in 2006 and 2009, respectively.

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,

CC:

Julie Halatek Project Analyst

Craig R. Smith, Chief Certificate of Need Section

Medical Facilities Planning Section, DHSR

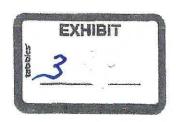


Certificate of Need Section

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/ Atfirmative Action Employer

Exhibit 3





DEPARTMENT OF HEALTH AND HUMAN SERVICES DIVISION OF HEALTH SERVICE REGULATION

ROY COOPER GOVERNOR

MANDY COHEN, MD, MPH SECRETARY

> MARK PAYNE DIRECTOR

April 19, 2017

Carolyn Coward PO Box 7376 Asheville, NC 28802

Exempt from Review - Replacement Equipment

Record #:

2237

Facility Name:

Carolina Spine and Neurosurgery Center

FID#:

970332

Business Name:

Carolina Spine and Neurosurgery Center, P.A.

Business #:

2615

Project Description:

Replace existing fixed MRI seanner

County:

Buncombe

Dear Ms. Coward:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency), determined that based on your letter of April 11, 2017, the above referenced proposal is exempt from certificate of need review in accordance with N.C. Gen. Stat. §131E-184(a)(7). Therefore, you may proceed to acquire without a certificate of need the Optima MR450w 1.5T GEM MRI system to replace the Signa Hispeed LX K4 1.5T MRI system. This determination is based on your representations that the existing unit will be disposed of and will not be used again in the State without first obtaining a certificate of need if one is required.

Moreover, you need to contact the Agency's Construction Section to determine if they have any requirements for development of the proposed project.

It should be noted that the 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.

Sincerely,

Julie Halatek Project Analyst

Clubic Halatele

Martha I Frisone

Assistant Chief, Certificate of Need

cc:

Construction Section, DHSR

Paige Bennett, Assistant Chief, Healthcare Planning, DHSR

HEALTHCARE PLANNING AND CERTIFICATE OF NEED SECTION

WWW.NCDHHS.GOV TELEPHONE 919-855-3873

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



Writer's Direct Dial: (828) 771-2506 Writer's Facsimile: (828) 255-0255 Writer's E-Mail: ccoward@ywlawfirm.com

April 11, 2017

Martha J. Frisone, Assistant Chief
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



Re: Request for Exemption to CON Review for Replacement MRI at Carolina Spine and Neurosurgery, P.A. / Buncombe County

Dear Ms. Frisone:

On behalf of Carolina Spine and Neurosurgery Center, P.A. ("Carolina Spine") and in accordance with N.C. gen Stat. § 131E-184(a)(7), I am writing to notify the Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation ("Agency") of Carolina Spine's intention to replace an existing MRI scanner currently located at 7 Vanderbilt Park Drive, Asheville, NC 28803.

Carolina Spine currently operates a fixed MRI scanner which is a Signa Hispeed LX K4 1.5T MR, PDC Cassette Building, and MR Coil and Software Upgrade, with Upgrade of 16 Channel HDx MRI ("Signa") that was acquired in 1998. The existing equipment was obtained pursuant to a certificate of need for Project ID No. B-5583-97/970332. Carolina Spine plans to replace the existing equipment with a Optima MR450w 1.5T GEM 25.0 MR System ES Platform ("Optima"). See Exhibit A, attached replacement equipment comparison form.

The estimated construction costs, including architect's fees and project contingency, for the replacement equipment is \$412,218.00. The purchase price of the Optima is \$1,386,597.04. See Exhibit B, attached equipment quote. The total capital expenditure for the proposed replacement equipment project is \$1,798,814.04. See Exhibit C, attached capital cost form.

This proposal meets the definition of "replacement equipment" as set forth in N.C. Gen. Stat. § 131E-176(22a) because:

 The cost of the equipment and the cost of all activities essential to acquiring and making operational the replacement equipment are less than \$2 million; and The sole purpose of this proposal is to replace comparable medical equipment currently in use. The Signa will be returned to GE Healthcare and moved out of North Carolina.

This proposal meets the requirements of 10A NCAC 14C .0303(d) because:

- The Optima has the same technology as the Signa although it may possess expanded capabilities due to technological improvements;
- The Optima is functionally similar and is used for the same diagnostic or treatment purposes as the Signa and is not used to provide a new health service; and
- The acquisition of the Optima will not result in more than a 10% increase in patient charges or per procedure operating expenses within the first twelve months after the replacement equipment is acquired.

The exclusions in 10A NCAC 14C .0303(e) are not applicable.

Based on the foregoing, Carolina Spine respectfully requests that the Agency confirms in writing that the above referenced proposal is exempt from CON review pursuant to N.C. Gen. Stat. § 131E-184(a)(7).

Please let me know if you need any further information.

Sincerely,

Carolyn Coward

Van Winkle, Buck, Wall, Davis and Starnes. P.A.

Attachments: Exhibit A - Equipment Comparison Chart

Exhibit B - Equipment Quote Exhibit C - Capital Cost Form

cc: Jeff Pigg, CFO

From:

Lightbourne, Ena

To:

Waller, Martha K

Subject:

Fwd: [External] No Review Request by UNC Physicians Group Practice II, LLC and Carolina Spine

Date:

Tuesday, December 28, 2021 9:56:08 PM

Attachments:

20211223120534143.PDF

Martha can you log this. Thanks.

Get Outlook for Android

From: Qualls, Gary <Gary.Qualls@klgates.com> Sent: Thursday, December 23, 2021 12:19:57 PM

To: Lightbourne, Ena <ena.lightbourne@dhhs.nc.gov>; Mitchell, Micheala L

<Micheala.Mitchell@dhhs.nc.gov>

Cc: 'Carolyn L. Coward' <ccoward@vwlawfirm.com>

Subject: [External] No Review Request by UNC Physicians Group Practice II, LLC and Carolina Spine

CAUTION: External email. Do not click links or open attachments unless you verify. Send all suspicious email as an attachment to Report Spam.

Ena:

I have attached for filing the Asheville area No Review Request we recently discussed by phone. Please confirm your receipt for my records.

As I referenced in our phone call, the parties plan to make this services agreement effective January 1.

Let me know if you have any questions.

Thanks

Gary



Gary S. Qualis
Partner
K&L Gates LLP
430 Davis Drive, Suite 400
Morrisville, NC 27560
Phone: 919-466-1182
Fax: 919-516-2072
gary.qualis@klgates.com
www.klgates.com





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

February 25, 2013

CERTIFIED MAIL

Mr. Charles Wilson Triangle Orthopaedic Associates, P.A. 120 William Penn Plaza Durham, North Carolina 27704

RE: Declaratory Ruling for Triangle Orthopedics Surgery Center, LLC

Project I.D. No. J-8616-10

Dear Mr. Wilson:

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

Sincerely,

Drexdal Pratt

DP:CO:peb

Enclosure

Cheryl Ouimet, Chief Operating Officer, DHSR cc:

Craig Smith, Chief, Certificate of Need Section Steven Lewis, Chief, Construction Section

Azzie Conley, Chief, Acute and Home Care Licensure and Certification Section

Nadine Pfeiffer, Branch Manager, 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	í
TRIANGLE ORTHOPEDICS) DECLARATORY RULING
SURGERY CENTER, LLC) DECEMBITORY ROLLING
Project I.D. No. J-8616-10	í

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.

Triangle Orthopaedics Surgery Center, LLC ("TOSC") has requested a declaratory ruling for Project I.D. No. J-8616-10 to confirm that the current shareholders of Triangle Orthopaedics Associates, P.A. (TOA) may acquire all of TOA's membership interests in TOSC 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. Charles Wilson, Chief Executive Officer of TOA, has requested this ruling on TOA's behalf and has provided the material facts upon which this ruling is based.

STATEMENT OF THE FACTS

On June 1, 2011, TOSC received a CON to develop a single-specialty ambulatory surgery center with two operating rooms in Wake County. The legal name of the approved

applicant is TOSC. TOA is the sole member of TOSC. TOA has a 100% interest in TOSC. As such, the shareholders of TOA are currently the indirect owners of TOSC. The shareholders of TOA would now prefer to have the TOSC membership interests owned directly rather than as a subsidiary of TOA for organizational administrative reasons. Acquisition of the membership interests in TOSC by the shareholders of TOA means the shareholders will become the direct owners of TOSC.

ANALYSIS

N.C. Gen. Stat. § 131E-181 provides:

- (a) A certificate of need shall be valid only for the defined scope, Physical location, and person named in the application. A Certificate of need shall not be transferred or assigned except as provided in G.S. 131E-189(c).
- (b) A recipient of a certificate of need, or any person who may subsequently acquire, in any manner whatsoever permitted by law, the service for which the certificate of need was issued, is required to materially comply with the representations made in its application for that certificate of need.

N.C. Gen. Stat. § 131E-189(c) provides:

The Department may immediately withdraw any certificate of Need if the holder of the certificate, before completion of the project or operation of the facility, transfers ownership or control of the facility, the project, or the certificate of need. Any transfer after that time will be subject to the requirement that the service be provided consistent with the presentations made in the application and any applicable conditions the Department placed on the certificate of need. Transfers resulting from death or personal illness or other good cause, as determined by the Department, shall not result in withdrawal if the Department receives prior written notice of the transfer and finds good cause. Transfers resulting from death shall not result in withdrawal.

The Department has previously determined that the acquisition of membership interests in a limited liability company does not require a CON. See, e.g., Declaratory Ruling issued to

Same Day Surgery Center New Hanover, LLC et al.; Declaratory Ruling issued to Wake PET Services, LLC, et al.; Declaratory Ruling issued to Wake Radiology Oncology Services, PLLC; Declaratory Ruling issued to Alliance Oncology; Declaratory Rulings issued to the Charlotte Mecklenburg Hospital Authority; Declaratory Ruling issued to JRH Ventures, LLC.

In this case, the TOA shareholders will be acquiring all of the membership interests in TOSC, and there is no change in entity. The planned surgery center in Wake County will remain intact as the same LLC with the membership interest now being owned directly by the TOA shareholders. The planned surgery center in Wake County will remain intact as the same LLC, but with a different membership composition. The entity to which the CON was issued (TOSC) does not change as a result of this transaction. TOSC will be the entity that develops the surgery center. The current shareholders of TOA will hold all of the membership interests in TOSC and the transfer of membership interests will not cause there to be any new owners of any membership other than the current TOA shareholders.

The scope or scale of services of the project will not change as a result of this transaction. TOSC will serve the same population, with the same charges, staffing, and operating expense structure as described in the November 2010 CON application. TOSC plans to develop the facility within the timeframe, and will adhere to the annual reposting requirements, included in the CON conditions. TOSC will continue to have 100% physician ownership after the membership acquisition. The transaction will not change the number of operating rooms for the surgery center. The membership change will have no impact on the project capital cost. The proposed physical location will not change from the original approved site identified in the CON application. TOSC agrees to materially comply with all of the requirements and representations made in its original CON application.

10A NCAC 14C .0502(b) provides:

(b) Ownership of a certificate of need is transferred when any person acquires a certificate from the holder by purchase, donation, lease, trade, or any comparable arrangement, except that ownership of a certificate of need is not transferred when:

(1) the holder of the certificate is a corporation and the identity of the holder changes because of a corporate

reorganization; or

(2) the holder of the certificate is a partnership and the identity of the holder changes because the same partners reorganize as a new partnership.

The holder of the CON for Project I.D. No. J-8616-10 is TOSC, LLC which is registered as a corporation. The identity of the holder, TOSC, is reorganizing such that the shareholders of TOA will become the direct, rather than the indirect, owners of TOSC. Therefore, the ownership by TOSC of the CON will not be transferred because of the reorganization of the corporation. The acquisition of the membership interests in TOSC by the shareholders of TOA will not violate N.C. Gen. Stat. § 131E-189(c)because ownership of the CON is not being transferred.

CONCLUSION

For the foregoing reasons, assuming the statements of fact in the request to be true, I conclude that the TOA shareholders do not require a certificate of need in order to proceed with the purchase of TOA's membership interests in TOSC. This proposed change does not constitute a change in the scope of the project, would not violate N.C. Gen. Stat. § 131E-181, or N.C. Gen. Stat. § 131E-189, or any of the rules of the Department.

This the $2.5^{-1/4}$ day of February, 2013.

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 a first-class, postage pre-paid envelope addressed as follows:

CERTIFIED MAIL

Charles Wilson Triangle Orthopaedic Associates, P.A. 120 William Penn Plaza Durham, North Carolina 27704

This the 25th day of February, 2013.

Cheryl Owimet, Chief Operating Officer

Exhibit 5



ROY COOPER . Governor KODY H. KINSLEY . Secretary MARK PAYNE • Director, Division of Health Service Regulation

VIA EMAIL ONLY

January 4, 2022

Carolyn Coward

ccoward@vwlawfirm.com

No Review

Record #:

3770

Date of Request:

December 30, 2021

Facility Name:

Carolina Spine and Neurosurgery Center

FID#:

970332

Business Name:

Carolina Spine and Neurosurgery Center, P.A.

Business #:

2615

Project Description:

Provide MRI services to UNC Physicians Group Practice II, LLC on its existing fixed MRI scanner located at the facility, pursuant to a service agreement between

UNC Physicians Group Practice II, LLC and Carolina Spine and Neurosurgery

Center P.A.

County:

Buncombe

Dear Ms. Coward:

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,

Ena Lightbourne, Project Analyst

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

AN EQUAL OPPORTUNITY / AFFIRMATIVE ACTION EMPLOYER



December 23, 2021

Gary S. Qualls D 919.466.1182 F 919.516.2182 gary.qualls@klgates.com

Via E-Mail

Micheala Mitchell, Chief
Ena Lightbourne, Project Analyst
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 Regarding Use of Carolina Spine & Neurosurgery Center, P.A.'s Fixed MRI Scanner (Project I.D. No. No. B-5583-97) by UNC Physicians Group Practice II Pursuant to Service Agreement

Dear Ms. Mitchell and Ms. Lightbourne:

This letter is a No Review Request to the North Carolina Department of Health and Human Services, Division of Health Service Regulation, Healthcare Planning and Certificate of Need ("CON") Section (the "Agency"). The requesting parties (the "Parties") are:

- 1. UNC Physicians Group Practice II, LLC ("UNC GP II"); and
- 2. Carolina Spine & Neurosurgery Center, P.A. ("Carolina Spine").

I represent UNC GP II. Carolina Spine is represented by Carolyn Coward from the Van Winkle Firm.

The Parties request confirmation that UNC GP II's use of Carolina Spine's fixed MRI Scanner (the "Carolina Spine MRI Scanner"), pursuant to a services agreement, does not require CON review. A draft proposed service agreement between UNC GP II and Carolina Spine for the MRI Scanner (the "Proposed Services Agreement") is attached as Exhibit 1.

Micheala Mitchell Ena Lightbourne December 23, 2021 Page 2

Exhibit 2 is the CON authorizing acquisition of the Carolina Spine MRI Scanner and development of the associated diagnostic center. Exhibit 3 is a May 9, 2013 Letter from the Agency explaining the name change between the original CON recipient and Carolina Spine. Exhibit 4 is an April 19, 2017 letter from the Agency confirming that the current Carolina Spine MRI Scanner is an exempt replacement of the predecessor MRI scanner.

The parties plan to engage in an underlying physician practice transaction (the "Consolidation Transaction") that does not itself require CON scrutiny, but is helpful to explain as background. On or about January 1, 2022, Carolina Spine's physician practice operations will consolidate into UNC GP II. Thus, current Carolina Spine employees will become UNC GP II employees after the Consolidation Transaction. However, Carolina Spine will remain as an ongoing concern and will continue to own certain assets, including the Carolina Spine MRI Scanner and associated diagnostic center CON rights.

UNC GP II plans to operate the Carolina Spine MRI Scanner at its existing site (7 Vanderbilt Park Drive, Asheville), pursuant to the Proposed Service Agreement. See Exhibit 1. For a number of years, Carolina Spine and Mission Health have operated under a services agreement, pursuant to which Mission had access to the Caroline Spine MRI and procedures performed by Mission on that MRI were reported on Mission Hospital's license. Our Proposed Services Agreement will supplant the services agreement between Mission and Carolina Spine.

UNC GP II will bill for the Carolina Spine MRI Scanner's services, again pursuant to the Proposed Services Agreement. However, at all times, Carolina Spine will retain the CON rights to the Carolina Spine MRI Scanner and associated diagnostic center. Thus, no CON ownership rights in the Carolina Spine MRI Scanner or associated diagnostic center will change.

Since ownership of the Carolina Spine MRI Scanner and associated diagnostic center will not change, the statutory change of ownership provisions -- N.C. Gen. Stat. §§ 131E-181(a), 131E-184, and 131E-189 -- are not implicated. Moreover, because UNC GP II will operate the Carolina Spine MRI Scanner pursuant to the Proposed Services Agreement -- rather than a lease -- that aspect of the parties' relationship will likewise not constitute a new institutional health service, and thus will not need to qualify as an exempt transfer of the diagnostic center rights under N.C. Gen. Stat. § 131E-184(a)(8).

¹ Because no lease is involved, N.C. Gen. Stat. § 131E-176(16)(f1) is not triggered in the first instance.

Micheala Mitchell Ena Lightbourne December 23, 2021 Page 3

We therefore ask the Agency to verify that the Proposed Services Agreement discussed above and attached hereto is not subject to CON review. Thank you for your assistance in regard to this matter. If you have any questions or need further information, please feel free to contact me at the number above.

Sincerely,

Bary S. Qualle Gary S. Qualls

ce: Carolyn Coward (The Van Winkle Firm)

Micheala Mitchell Ena Lightbourne December 23, 2021 Page 4

Exhibits

- 1. Draft Proposed Services Agreement
- The CON for the Carolina Spine MRI Scanner
- 3. May 9, 2013 Letter from Agency
- April 19, 2017 Agency Letter Confirming Replacement Equipment Exemption and Corresponding April 11, 2017 Request (without exhibits)



Burgess, Ken

From: Sent: Hunter, Derek < Dhunter@ncdoj.gov> Friday, February 17, 2023 12:49 PM

To:

Burgess, Ken

Subject:

RE: Follow Up To Our Call of Last Week

Ken,

I hope you're doing well. The Agency agrees with your interpretation as detailed below.

Have a great weekend!

Derek



Derek L. Hunter
Special Deputy Attorney General
Section Head/Health Service Section
(919) 716-6886
dhunter@ncdoj.gov
114 W. Edenton St., Raleigh, NC 27603
ncdoj.gov

Please note messages to or from this address may be public records.

From: Burgess, Ken <kburgess@bakerdonelson.com>

Sent: Wednesday, January 11, 2023 3:11 PM To: Hunter, Derek < Dhunter@ncdoj.gov>

Subject: FW: Follow Up To Our Call of Last Week

I wanted to provide one clarifying point to the email below and our discussion today. On the call and below, I described that the doctors who currently own the P.A. would "change the corporate structure of the P.A." to an LLC. That's not entirely precise. Rather, the doctors who own the P.A. would create a new LLC. That's designed to ensure that the new LLC doesn't somehow inherit any trailing liability of the old P.A. I think it's just a nuance but I wanted to be clear about that. Regardless, the doctors who currently own the P.A. would also entirely own the new LLC unless and until their new hospital employer purchased the LLC member interests which we know, based on prior Agency precedent, doesn't require a CON. Just wanted to be sure I was being precise in my description. Thanks Derek. Ken

From: Burgess, Ken

Sent: Monday, December 12, 2022 1:01 PM
To: Hunter, Derek < Dhunter@ncdoj.gov>
Subject: Follow Up To Our Call of Last Week

Hi Derek, this is the email I promised you when we spoke early last week. I did a bit more research and digging in the hopes of making this straightforward and of finding some applicable Agency precedent. I believe I did, with Bethany's

help. She had recall of a situation akin to what I'm about to ask you about and was able to send me a Declaratory Ruling, which is attached.

In my current situation, a group of physicians are organized as a P.A., or Professional Association which is, for all intents and purposes, a professional corporation or PC in North Carolina. The doctors' P.A. holds a CON for an MRI and they've had this CON for at least 10 years. They now want to change the corporate structure of their entity to an LLC. They are about to become employees of a local hospital rather than being in a separate P.A. as they are now. Subsequent to that reorganization, the local hospital which will employ them will acquire the member interests in that new LLC. In my experience, the Agency has permitted both of these steps in the past: 1) changing the corporate structure of a CON holder where the underlying individuals who made up the original corporate entity remain involved and 2) allowing the acquisition of the LLC member interests of an LLC holding a CON and not treating that as requiring a CON.

The 2013 Declaratory Ruling Bethany was able to send me also addresses both of these steps, with only slightly different facts. In that Declaratory Ruling allowed, certain doctors who were formed in a P.A. which owned the stock of an LLC that held a CON for ORs. The Agency allowed the doctors who owned the PA which owned the LLC holding the OR CONs to acquire those LLC member interests directly and not through the P.A. That Declaratory Ruling also reaffirmed the Agency's historical position that the acquisition of member interests in an LLC which holds a CON does not require a CON.

Not that you need any additional precedent or authority, but I also know from my own experience that even in the case of <u>undeveloped</u> CONs (which this is not of course) the Agency has allowed the transfer of such undeveloped CONs for "good cause" under G.S. 131E-189(c) where the holder of a CON is essentially selling their entire business to a new provider. I view the doctors' transition of their entity from a P.A. to an LLC much like that. That is, these doctors are creating a new corporate entity which they still control – the LLC – and placing all their assets there, including the MRI. So, that's a transfer of a CON-covered asset from Drs. X and Y to themselves, just organized into a different corporate format.

Please review this information and the attached Declaratory Ruling when you can and let me know if you agree with my interpretation. If so, then I need to work with the physicians' counsel to make this happen but I didn't want to initiate that without clear guidance from the Agency. Assuming that your client agrees with my interpretation, I'd file a No Review so we both have a paper trail. Please let me know if this prompts any questions. Thanks, Ken Burgess

Kenneth (Ken) L. Burgess Shareholder Baker, Donelson, Bearman, Caldwell & Berkowitz, PC 2530 Meridian Parkway, Suite 300 Durham, NC 27713

Phone: 919-294-0802 Cell: 919-449-4754

Email address: kburgess@bakerdonelson.com

www.bakerdonelson.com

Baker, Donelson, Bearman, Caldwell & Berkowitz, PC represents clients across the U.S. and abroad from offices in Alabama, Florida, Georgia, Louisiana, Maryland, Mississippi, North Carolina, South Carolina, Tennessee, Texas, Virginia and Washington, D.C.

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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

February 25, 2013

CERTIFIED MAIL

Mr. Charles Wilson Triangle Orthopaedic Associates, P.A. 120 William Penn Plaza Durham, North Carolina 27704

RE:

Declaratory Ruling for Triangle Orthopedics Surgery Center, LLC

Project I.D. No. J-8616-10

Dear Mr. Wilson:

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

Sincerely,

Drexdal Pratt

DP:CO:peb

Enclosure

cc: Cheryl Ouimet, 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

Nadine Pfeiffer, Branch Manager, Medical Facilities Planning Section

Marc Lodge, Special Deputy Attorney General, DOJ



Office of the Director

http://www.ncdhhs.gov/dhsr/ Phone: 919-855-3750 / Fax: 919-733-2757

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	í	DECLARATORY RULING
TRIANGLE ORTHOPEDICS	Ś	
SURGERY CENTER, LLC	í	
Project I.D. No. J-8616-10)	

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.

Triangle Orthopaedics Surgery Center, LLC ("TOSC") has requested a declaratory ruling for Project I.D. No. J-8616-10 to confirm that the current shareholders of Triangle Orthopaedics Associates, P.A. (TOA) may acquire all of TOA's membership interests in TOSC 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. Charles Wilson, Chief Executive Officer of TOA, has requested this ruling on TOA's behalf and has provided the material facts upon which this ruling is based.

STATEMENT OF THE FACTS

On June 1, 2011, TOSC received a CON to develop a single-specialty ambulatory surgery center with two operating rooms in Wake County. The legal name of the approved

applicant is TOSC. TOA is the sole member of TOSC. TOA has a 100% interest in TOSC. As such, the shareholders of TOA are currently the indirect owners of TOSC. The shareholders of TOA would now prefer to have the TOSC membership interests owned directly rather than as a subsidiary of TOA for organizational administrative reasons. Acquisition of the membership interests in TOSC by the shareholders of TOA means the shareholders will become the direct owners of TOSC.

ANALYSIS

N.C. Gen. Stat. § 131E-181 provides:

- (a) A certificate of need shall be valid only for the defined scope, Physical location, and person named in the application. A Certificate of need shall not be transferred or assigned except as provided in G.S. 131E-189(c).
- (b) A recipient of a certificate of need, or any person who may subsequently acquire, in any manner whatsoever permitted by law, the service for which the certificate of need was issued, is required to materially comply with the representations made in its application for that certificate of need.

N.C. Gen. Stat. § 131E-189(c) provides:

The Department may immediately withdraw any certificate of Need if the holder of the certificate, before completion of the project or operation of the facility, transfers ownership or control of the facility, the project, or the certificate of need. Any transfer after that time will be subject to the requirement that the service be provided consistent with the presentations made in the application and any applicable conditions the Department placed on the certificate of need. Transfers resulting from death or personal illness or other good cause, as determined by the Department, shall not result in withdrawal if the Department receives prior written notice of the transfer and finds good cause. Transfers resulting from death shall not result in withdrawal.

The Department has previously determined that the acquisition of membership interests in a limited liability company does not require a CON. See, e.g., Declaratory Ruling issued to

Same Day Surgery Center New Hanover, LLC et al.; Declaratory Ruling issued to Wake PET Services, LLC, et al.; Declaratory Ruling issued to Wake Radiology Oncology Services, PLLC; Declaratory Ruling issued to Alliance Oncology; Declaratory Rulings issued to the Charlotte Mecklenburg Hospital Authority; Declaratory Ruling issued to JRH Ventures, LLC.

In this case, the TOA shareholders will be acquiring all of the membership interests in TOSC, and there is no change in entity. The planned surgery center in Wake County will remain intact as the same LLC with the membership interest now being owned directly by the TOA shareholders. The planned surgery center in Wake County will remain intact as the same LLC, but with a different membership composition. The entity to which the CON was issued (TOSC) does not change as a result of this transaction. TOSC will be the entity that develops the surgery center. The current shareholders of TOA will hold all of the membership interests in TOSC and the transfer of membership interests will not cause there to be any new owners of any membership other than the current TOA shareholders.

The scope or scale of services of the project will not change as a result of this transaction. TOSC will serve the same population, with the same charges, staffing, and operating expense structure as described in the November 2010 CON application. TOSC plans to develop the facility within the timeframe, and will adhere to the annual reposting requirements, included in the CON conditions. TOSC will continue to have 100% physician ownership after the membership acquisition. The transaction will not change the number of operating rooms for the surgery center. The membership change will have no impact on the project capital cost. The proposed physical location will not change from the original approved site identified in the CON application. TOSC agrees to materially comply with all of the requirements and representations made in its original CON application.

10A NCAC 14C .0502(b) provides:

- (b) Ownership of a certificate of need is transferred when any person acquires a certificate from the holder by purchase, donation, lease, trade, or any comparable arrangement, except that ownership of a certificate of need is not transferred when:
 - (1) the holder of the certificate is a corporation and the identity of the holder changes because of a corporate reorganization; or
 - (2) the holder of the certificate is a partnership and the identity of the holder changes because the same partners reorganize as a new partnership.

The holder of the CON for Project I.D. No. J-8616-10 is TOSC, LLC which is registered as a corporation. The identity of the holder, TOSC, is reorganizing such that the shareholders of TOA will become the direct, rather than the indirect, owners of TOSC. Therefore, the ownership by TOSC of the CON will not be transferred because of the reorganization of the corporation. The acquisition of the membership interests in TOSC by the shareholders of TOA will not violate N.C. Gen. Stat. § 131E-189(c)because ownership of the CON is not being transferred.

CONCLUSION

For the foregoing reasons, assuming the statements of fact in the request to be true, I conclude that the TOA shareholders do not require a certificate of need in order to proceed with the purchase of TOA's membership interests in TOSC. This proposed change does not constitute a change in the scope of the project, would not violate N.C. Gen. Stat. § 131E-181, or N.C. Gen. Stat. § 131E-189, or any of the rules of the Department.

This the $2.5^{4/4}$ day of February, 2013.

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 a first-class, postage pre-paid envelope addressed as follows:

CERTIFIED MAIL

Charles Wilson Triangle Orthopaedic Associates, P.A. 120 William Penn Plaza Durham, North Carolina 27704

This the 25th day of February, 2013.

Cheryl Oumet
Cheryl Ownet, Chief Operating Officer

Exhibit 7

MRI SERVICES AGREEMENT

THIS MRI SERVICES AGREEMENT (this "Agreement") is entered into this 1st day of October, 2023 (the "Effective Date") and is by and between Vanderbilt Park Associates, LLC ("VPA") and MH Mission Imaging, LLLP ("MHI").

RECITALS:

WHEREAS, MHI is in the business of providing imaging services to its patients, for some of whom it is advisable to have MRI services.

WHEREAS, VPA owns and operates certain magnetic resonance imaging equipment and has the required North Carolina certificate of need ("CON") necessary to provide and perform services.

WHEREAS, the parties hereto desire to enter into an Agreement whereby VPA shall provide both Equipment and MRI Services as those terms are defined below to MHI on an independent contractor basis.

NOW, THEREFORE, in consideration of the premises and promises herein made, the parties agree as follows:

1. <u>VPA Duties.</u>

1.1. Equipment.

- 1.1.1. Provide MRI scanning operations in accordance with the terms and conditions of this Agreement.
- 1.1.2. Be responsible for overall operation of the MRI scanner subject to the supervision of and in coordination with MHI.
- 1.1.3. MRI Equipment. VPA shall provide a Magnetic Resonance Imaging ("MRI") system and other ancillary equipment as further described in Exhibit A of this Agreement ("Equipment). VPA shall make the Equipment available to MHI on a full-time basis at a location to be designated by MHI for the exclusive use by MHI and its employees and agents for MHI patients. Additionally, both prior to the Effective Date and during the Term of this Agreement, VPA shall take all steps required to maintain the CON necessary for the provision of this equipment.

- 1.1.3 <u>Medical Supplies</u>. It is acknowledged that MHI is generally responsible to provide Medical Supplies pursuant to Section 2.3; provided that VPA may from time to time provide medical supplies customarily required for the provision of MRI scans.
- 1.2. MRI Services. VPA shall provide to MHI either directly or through a third party contract the following services necessary for the provision of MRI scans for MHI patients.
 - 1.2.1. <u>Unit Maintenance</u>. At its sole expense, VPA shall select the vendor and arrange for all required maintenance, upkeep, and repair of the Equipment in accordance with Equipment manufacturer's specifications. Such specifications shall be provided to MHI upon request. VPA shall provide to MHI all service records on the Equipment and any service and maintenance rebates it receives resulting from extended downtime of the Equipment. VPA shall arrange for any service provider to coordinate with MHI such that if service or maintenance is necessary during non-business hours when VPA staff may not be available the necessary maintenance or service can be completed in a timely manner and to the satisfaction of MHI.
- 1.3. <u>Compliance with Standards.</u> VPA shall ensure that the services it provides to MHI either directly or through third party agreements meet or exceed any rules, regulations or standards of the Department of Health and Human Services, the Center for Medicare and Medicaid Services, the Joint Commission, the Department of Nuclear Safety, the Nuclear Regulatory Commission, or any other reasonable entity exercising authority over the Equipment or MRI Services.
- 1.4. Third Party Service Providers. If VPA contracts with one or more third parties for the provision of any services required under this Agreement, all such contracts shall be subject to MHI review and approval and upon execution by VPA (collectively, the "Approved Services Agreements"). VPA shall ensure that all Third Party Service Agreements are drafted so as to comply with the terms and requirements of this Agreement including but not limited to all relevant standards described in Section 1.3 above and any insurance coverage as further described under Section 5 below. VPA shall throughout the term of this Agreement materially comply with the material terms of all Approved Service Agreements.

2. MHI Duties.

- 2.1. Site. MHI shall secure and maintain a safe and suitable site for the Equipment in accordance with all applicable laws and regulations and Equipment specifications as provided by VPA. Any site costs (for example, power site preparation, unit installation, and necessary tenant improvements) shall be MHI's sole responsibility.
- 2.2. <u>Utilities.</u> MHI shall be responsible for providing all utilities necessary for the provision of MRI Services including but not limited to suitable electrical power for the Equipment and all required telephone and network connections.

- 2.3. <u>Medical Supplies and Consumables</u>. MHI shall provide all necessary medical supplies and consumables as may from time to time be required for the provision of MRI scans. MHI shall also be responsible for providing film and contrast media and any other nonclinical equipment necessary for the operation of the Equipment such as positioning pads, couch pads and head phones
- 2.4. <u>Patient Care</u>. During the provision of MRI Services, MHI shall be solely responsible for all medical care and management of MHI patients receiving MRI scans including availability of all medical supplies, facilities, and personnel necessary to provide patients with any required emergency care.
- 2.5. <u>Technical Staff</u>. MHI shall be solely responsible for providing directly or arranging for the provision of fully trained technologist(s) to operate the Equipment. MHI shall ensure that all personnel providing MRI Services under this Agreement will hold and maintain continuously all licenses and certifications that may be required under federal, State, and local laws or licensure requirement to enable the personnel to render MRI Services under this Agreement. Such technologists shall provide MRI Services to MHI's patients only pursuant to a written physician order and under the guidance of a Medical Director, appointed by MHI.
- 2.6. <u>Administrative/ Support Staff</u>. MHI shall provide all staff necessary for the provision of MRI Services to its patients including a medical director, a receptionist/scheduler and any other necessary support staff.
- 2.7. Exclusive Use. Only MHI, its employees, or its agents may use or operate the MRI without VPA's express written consent. As such, access to the MRI is limited to MHI Technical Staff, MHI patients receiving MRI Services, and any accompanying MHI staff, MHI emergency personnel previously educated and instructed in MRI safety procedures, and other person authorized by VPA and approved in advance by MHI.
- 2.8. <u>Policies.</u> MHI shall ensure that all of its personnel involved with the provision of MRI Services shall adhere to those VPA policies and procedures governing the use of the Equipment as provided to MHI.

3. Term.

- 3.1. <u>Term.</u> The initial term of this Agreement (the "Initial Term") shall commence as of the Effective Date and shall continue for a term of _____ years.
- 3.2. <u>Termination.</u> Notwithstanding any other provisions, this Agreement may be sooner terminated on the first to occur of any of the following:
 - 3.2.1. <u>Loss of CON.</u> The loss for any reason of the CON necessary to own and operate the Equipment.

- 3.2.2. Agreement. Written agreement by both parties to terminate this Agreement.
- 3.2.3. Breach. Excluding actions or events which may lead to termination of this Agreement pursuant to Section 3.2.4 and 3.2.5; in the event of the breach of any of the terms or conditions of this Agreement by either party and the failure of the breaching party to correct such breach within thirty (30) days after receipt of written notice of such breach by the breaching party, such other party may terminate the Agreement immediately with written notice of such termination to the breaching party,
- 3.2.4. <u>Force Majeure.</u> If either party is prevented from performing its obligations under this Agreement, by strikes or other labor disputes, official or unofficial, fire, war, flood, or any other reason beyond the party's reasonable control, each party's rights and obligations hereunder shall cease with notice of such cessation *to* the other party:
- 3.2.5. Triggering Event. In the event of the triggering event set forth below, either party may give the other party notice of intent to amend this Agreement in order to: (i) accommodate the terms and intent of this Agreement to the greatest extent possible consistent with the requirements of law; (ii) achieve the least burdensome alternative for the parties which brings this Agreement into compliance with law; and (iii) render this Agreement in compliance with law and alleviate a material adverse legal or financial consequence. If this Agreement is not so amended in writing within thirty (30) business days after such notice is given, this Agreement shall terminate as of midnight on the thirtieth (30th) business day after such notice is given. The triggering event is a written opinion of a reputable attorney, who is demonstrably familiar with healthcare law and is otherwise qualified, that any federal, state or local government or agency has passed, issued or promulgated any law, rule, regulation, standard or interpretation that would render this Agreement illegal, or that could cause significant and material adverse legal and/or financial consequences for either party hereto, including without limitation, any such action that would adversely affect the taxexempt status or the present or future tax-exempt financings of any of MHI's affiliated or related entities, or VPA's CON for the Equipment.
- 3.3. <u>Effects of Termination</u>. Upon termination of this Agreement, as hereinabove provided, no party shall have any further obligation hereunder except for (i) obligations accluing prior to the date of termination and (ii) obligations; promises or covenants contained herein which are expressly made to extend beyond the term of this Agreement.

4. <u>Compensation and Billing.</u>

4.1. <u>Compensation.</u> In exchange for the provision of the Equipment and MRI Services; MHI shall compensate VPA in the amount of _____ per month, prorated for any partial months.

Although MHI is responsible to provide all medical supplies for the provision of services to MHI patients pursuant to Section 2.3, if VPA does provide medical or other supplies from time to time, MHI will reimburse VPA for its actual out of pocket costs for such supplies within thirty (30) days from receipt of an itemized detailed invoice. The foregoing amounts shall collectively be referred to as the "Service Fee". VPA shall invoice MHI on a monthly basis with such invoice including a detailed listing of all services rendered. Payment to VPA shall be due within thirty (30) days following the submission of the invoice and shall not be dependent upon the MHI billing its patients for services or the collection thereof.

- 4.2. <u>System Upgrades.</u> VPA shall obtain approval from MHI if during the term of this Agreement the Equipment or any related software needs to be upgraded substantially to remain competitive with other MRI systems, with such approval not to be unreasonably withheld. In the event any approved system upgrade will result in additional cost to VPA, or in the event there is a new or amended Approved Service Agreement that result in additional costs to VPA, the parties will negotiate in good faith a fair market value prospective adjustment to the Service Fee, to be reflected in a written amendment to this Agreement.
- 4.3. <u>Billing and Collection.</u> MHI shall perform appropriate billing and collection functions for all technical services herein. VPA shall take or cause any third party contractor to take all steps reasonably requested by MHI to assist in the billing and collection of funds due for all services rendered hereunder. Further, VPA agrees that it will not bill independently and shall cause any third party provider to not bill independently for any services rendered pursuant to this Agreement.

5. <u>Insurance</u>,

- 5.1. <u>VPA</u>. VPA, shall, at its sole cost and expense, maintain during the term hereof such general liability and professional liability (including VPA employees who may provide services hereunder) and product liability insurance coverage with respect to the operation of the unit. VPA shall have insurance coverage with minimum limits of One Million Dollars (\$1,000,000.00) per occurrence and Three Million Dollars (\$3,000,000.00) aggregate. Upon the request of MHI, VPA shall provide MHI with certificates which evidence such insurance coverage upon request. VPA shall cause any third-party service provider to maintain the same level of relevant coverages as those listed above.
- 5.2. MHI. MHI shall, at its own expense, maintain during the term hereof, such general liability and professional liability (including MHI employed physicians and other MHI employees) in the amount of at least One Million Dollars (\$1,000,000.00) per occurrence and Three Million Dollars (\$3,000,000.00) aggregate. MHI shall provide VPA with certificates which evidence such insurance coverage upon request.

6. <u>Indemnification.</u>

- 6.1. <u>Indemnification by VPA</u>. Except as expressly provided otherwise in this Agreement, VPA agrees to indemnify and hold ham1less MHI from any and all costs, expenses, liability and claims, including reasonable attorneys' fees, for damages or injury caused by or resulting from the negligent or intentional acts or omissions by VPA or any other person, firm, or entity acting on behalf of VPA, or from VPA's breach of this Agreement, arising out of VPA's ownership, operation, or maintenance of the Equipment or its performance of this Agreement. VPA shall cooperate with MHI in the defense of any action or proceeding which may be brought against MHI in any such action or proceeding.
- 6.2. <u>Indemnification by MHI.</u> Except as expressly provided otherwise in this Agreement, MHI agrees to indemnify and hold ham1less VPA from any and all costs, expenses, liability and claims, including reasonable attorneys' fees, for damages or injury caused by or resulting from the negligent or intentional acts or omissions by MHI or any other person, firm, or entity acting on behalf of MHI, or from MHI's breach of this Agreement, arising out of MHI's rental or operation of the Equipment or its performance of this Agreement. MHI shall cooperate with VPA in the defense of any action or proceeding which may be brought against VPA action or proceeding.

7. Miscellaneous,

- 7.1. <u>Independent Contractor.</u> VPA is and shall remain at all times an independent contractor. MHI shall not have control over the methods VPA shall use in performing its work. VPA shall not represent itself, nor shall any person employed by, associated with, or contracted by VPA represent themselves to be employees or agents of the MHI and none shall have the authority to bind MHI or incur any obligation on its behalf.
- 7.2. <u>Assignment: Benefit.</u> Either party may assign this Agreement to a wholly-owned affiliate upon 30 days' prior notice to the other party.
- 7.3. Ownership. The purpose of this Agreement is to make available to MHI the use of the Equipment and the provision of those MRI Services necessary for its effective operation and nothing more. MHI shall have no right, title or interest therein or thereto, and as such, shall have no right to make changes to the Equipment without VPA's express written consent.
- 7.4, <u>Personal Property.</u> The Equipment is, and shall at all times be and remain, personal property notwithstanding that the Equipment or any part thereof may now be, or hereafter become, in any manner affixed or attached to, or imbedded in, or permanently resting upon, any real property or any building thereon, or attached in any manner to what is permanent as by means of cement, plaster, nails, bolts, screws, connection to utilities, or otherwise.
- 7.5. <u>Waiver</u>. No term of this Agreement, and no breach of this Agreement, shall be waived, altered or modified except by written instrument signed by the party sought to be bound thereby. A waiver of any breach on any one occasion shall not constitute a waiver of any other or subsequent breach whether of like or different nature. No delay or failure by any

patty to insist upon the strict performance of any term of this Agreement, or to exercise any right or remedy available upon any breach of this Agreement, shall operate as a waiver thereof, and no single or partial exercise of any right or remedy under this Agreement shall preclude other or further exercise thereof or the exercise of any other right, power or privilege. No course of dealing between the parties shall be effective to change, modify or discharge any provision of this Agreement or to constitute a waiver of any default hereunder.

- 7.6. No Joint Venture. The parties to this Agreement intend that VPA shall perform its duties hereunder as an independent contractor. Neither this Agreement nor any agreements, instruments, documents or transactions contemplated hereby shall be interpreted or deemed to create the relationship of principal and agent or employer and employee between the patties or to make them partners or joint venturers.
- 7.7. Entire Agreement: Amendments. This Agreement contains the entire understanding of the parties with respect to the provision of Equipment and MRI Services by VPA and supersedes all prior and contemporaneous agreements and understandings between the parties with respect to such equipment and services. This Agreement may be amended only by a written instrument duly executed by all parties or their respective heirs, successors, assigns or legal representatives.
- 7.8. <u>Master List of Contracts.</u> The parties acknowledge and agree that this Agreement, and any other agreement between the parties shall be included in a master list(s) of contracts that is maintained and updated centrally by MHI.
- 7.9. Notices. All fees, notices, requests; claims, demands and other communications hereunder shall be in writing and shall be deemed to have been duly given if delivered or mailed: (i) five (5) days after deposit in the United States mails, by certified mail with return receipt requested and postage prepaid; (ii) when delivered personally; (iii) one (1) business day after delivery to any nationally recognized overnight courier; or (iv) when transmitted by facsimile transmission facilities with electronic receipt confirmed, in all cases addressed to the party to be notified as follows:

MHI: MH Mission Imaging, LLLP

[address for notice]

VPA: Vanderbilt Park Associates, LLC [address for notice]

- or to such other address as any party may have furnished to the others in writing in accordance herewith, except that notices of change of address shall only be effective upon receipt.
- 7.10. <u>Gender. Number.</u> Whenever the context of this Agreement requires, the masculine gender shall include the feminine or neuter, and the singular number shall include the plural.
- 7.11. <u>Headings.</u> The section and paragraph headings contained in this Agreement are for reference purposes only and shall not affect in any way the meaning or interpretation of this Agreement.
- 7.12. <u>Governing Law</u>. This Agreement shall be governed by the internal laws and judicial decisions of the State of North Carolina, without giving effect to the conflict of laws principles thereof.
- 7.13. Severability. If any provision contained in this Agreement shall for any reason be held invalid, illegal or unenforceable in any respect, such invalidity, illegality or unenforceability shall not affect any other provision of this Agreement, but this Agreement shall be construed as if such invalid, illegal or unenforceable provision had never been contained herein, unless the invalidity of any such provision substantially deprives either party of the practical benefits intended to be conferred by this Agreement.
- 7.14. <u>Authorization</u>. Each individual executing this Agreement on behalf of a party represents and warrants that he or she is duly authorized to execute and deliver this Agreement on behalf of said party in accordance with the bylaws or operating agreement of said party; that this Agreement is not in violation of or inconsistent with or contrary to the provisions of any other agreement to which such party is a party.
- 7.15. <u>Counterparts.</u> This Agreement, or any amendment hereto may be executed in multiple counterparts each of which taken together shall be deemed an original Agreement, and all of which shall constitute a single Agreement.
- 7.16. Privacy and Security of Medical Records. MHI and VPA are "Covered Entities" as defined in the Administrative Simplification provisions of HIPAA (42 U.S.C. §§ 1320d-1320d-8, and 45 C.F.R. Parts 160 and 164 (the "Privacy Rule")). VPA may also be deemed a "Business Associate" of MHI as defined by the Privacy Rule in that it will have access to "Protected Health Information," also defined in the Privacy Rule, in fulfilling certain responsibilities under this Agreement. VPA agrees to abide by the provisions of Section 164.504(e) of the Privacy Rule when acting in it capacity as a Business Associate, and by all provisions of the Business Associate Agreement attached hereto as Exhibit B. The obligations of the parties under this Section 8.18 and the attached Business Associate Agreement shall survive the expiration, termination, or cancellation of this Agreement and/or the business relationship of the palties, and shall continue to bind VPA, its agents, employees, corporations, successors, and assigns as set forth therein.
- 7.17. <u>Document Retention</u>. In accordance with Section 952 of the Omnibus Budget Reconciliation Act of 1989 and the regulations promulgated hereunder, VPA (and any subcontractors engaged by VPA) shall, until four (4) years after the termination of this Agreement comply with requests by the Comptroller General of the United States, the Secretary of the United States Department of Health and Human Services, and their duly authorized representatives for access to this Agreement and to VPA's books, documents, and records

necessary to verify the nature and extent of the cost of such services provided by VPA hereunder. Any such request for access must be made in accordance with the provisions of Section 952. VPA shall notify the MHI immediately of any request for access to its records whether made under Section 952 by the Comptroller General or the Secretary of the Department of Health and Human Services or made by any other federal or state government representative (including the Medicare Fiscal Intermediary and the Medicare Carrier) or any private third party payer.

7.18. Contingency. The parties acknowledge that this Agreement is contingent upon the parties being satisfied that this Agreement is permissible under the North Carolina Certificate of Need Statute ("CON Law"). The parties acknowledge that a No Review Determination has been requested from the North Carolina Department of Health and Human Services, Division of Health Service Regulation, Healthcare Planning and Certificate of Need Section ("the Agency"). In the event the Agency does not provide a final favorable No Review Determination in advance of the commencement of the Initial Term, MHI, in its sole discretion, may commence this Agreement, may delay the effective date pending a satisfactory determination from the Agency, or may terminate the Agreement.

IN WITNESS WHEREOF, the parties hereto have executed this Agreement as of the day and year set forth above.

MH N	lission Imaging, LLLP
100	
Date	
Vande	rbilt Park Associates, LLC
Date	

EXHIBIT A

MRI EQUIPEMENT AS OF THE EFFECTIVE DATE

A. **EQUIPMENT:** 2018 GE Optima MR 450w 1.5T MRI system housed in a trailer.

From: <u>Lightbourne, Ena</u>
To: <u>Stancil, Tiffany C</u>

Subject: FW: [External] No Review Determination Request **Date:** Wednesday, September 13, 2023 12:58:57 PM

Attachments: 4856-5082-8415 v.1 FILED MH Mission Imaging No Review Determination Request 9.13.23.pdf

Tiffany, can you log?. Thanks.

Ena Lightbourne

Certificate of Need, Project Analyst

<u>Division of Health Service Regulation</u>, Healthcare Planning and Certificate of Need Section (*Currently, I am in the office on Thursdays and Fridays. For the rest of the week, I can be reached by email.*)

NC Department of Health and Human Services

Office: 919-855-4610

Ena.lightbourne@dhhs.nc.gov

809 Ruggles Drive, Edgerton Building

2704 Mail Service Center

Raleigh, North Carolina 27699-2704

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From: Burgess, Ken <kburgess@bakerdonelson.com> **Sent:** Wednesday, September 13, 2023 12:25 PM

To: Mitchell, Micheala L < Micheala. Mitchell@dhhs.nc.gov>; Lightbourne, Ena

<ena.lightbourne@dhhs.nc.gov>

Cc: Carolyn L. Coward <ccoward@vwlawfirm.com> **Subject:** [External] No Review Determination Request

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.

Dear Micheala and Ena, attached please find a No Review Determination Request we are filing on behalf of our client MH Mission Imaging, LLLP and also on behalf of Carolina Spine & Neurosurgery Center, P.A., represented by Carolyn Coward who has also signed the attached Request. Please let me know if you have questions or need additional information. Thank you, Ken Burgess

Kenneth (Ken) L. Burgess Shareholder Baker, Donelson, Bearman, Caldwell & Berkowitz, PC 2235 Gateway Access Point Suite 220 Raleigh, N.C. 27607

Phone: 919-294-0802 Cell: 919-449-4754

Email address: kburgess@bakerdonelson.com

www.bakerdonelson.com

Baker, Donelson, Bearman, Caldwell & Berkowitz, PC represents clients across the U.S. and abroad from offices in Alabama, Florida, Georgia, Louisiana, Maryland, Mississippi, North Carolina, South Carolina, Tennessee, Texas, Virginia and Washington, D.C.

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