



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

January 4, 2022

Gary S. Qualls
Gary.qualls@klgates.com

No Review

Record #: 3769
Date of Request: December 30, 2021
Facility Name: Carolina Spine and Neurosurgery Center
FID #: 970332
Business Name: UNC Physicians Group Practice II, LLC
Business #: 3498
Project Description: Utilize an existing fixed MRI scanner owned by Carolina Spine and Neurosurgery Center, P.A. pursuant to a service agreement between UNC Physicians Group Practice II, LLC and Carolina Spine and Neurosurgery Center P.A.
County: Buncombe

Dear Mr. Qualls:

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.

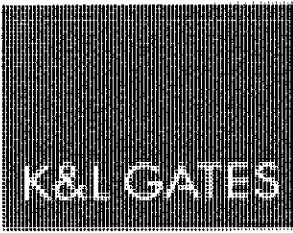
Please do not hesitate to contact this office if you have any questions.

Sincerely,
Ena Lightbourne
Project Analyst

Micheala Mitchell
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



December 23, 2021

Gary S. Qualls  
D 919.466.1182  
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gary.qualls@kligates.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.

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 Carolina 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,<sup>1</sup> 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).

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<sup>1</sup> 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,



Gary S. Qualls

cc: Carolyn Coward (The Van Winkle Firm)

**Exhibits**

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

# Exhibit 1

MRI Services Agreement

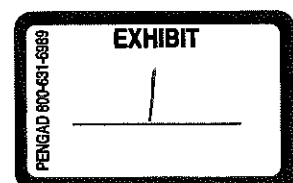
This MRI Services Agreement (the "Agreement") is made and entered into as of January 1, 2022 ("Effective Date") by and between Carolina Spine & Neurosurgery Center, PA ("CSNC") and UNC Physicians Group Practices II, LLC ("GPII").

WHEREAS, CSNC owns and operates certain magnetic resonance imaging equipment and has the certificate of need ("CON") required by North Carolina to do so; and CSNC desires to provide magnetic resonance imaging ("MRI") services to GPII; and

WHEREAS, GPII desires to receive from CSNC MRI services at GPII's designated sites;

NOW, THEREFORE, in consideration of the mutual promises contained herein and intending to be legally bound hereby, the parties agree as follows:

1. Equipment. CSNC shall provide to GPII the MRI equipment as described in **Exhibit A**, attached hereto and incorporated herein (the "MRI Unit"), except that CSNC reserves the right to substitute such equipment in the event of unavailability of the MRI Unit or equipment failure of the MRI Unit for a period of more than fourteen (14) days. In such event of unavailability or failure of the MRI Unit, CSNC shall provide to GPII a comparable unit of MRI equipment which CSNC obtains through a lease agreement or otherwise, which is acceptable to GPII in its sole discretion. CSNC shall make such MRI Unit available to GPII on a full-time basis, for GPII's exclusive use.
2. Site Selection, Preparation, Maintenance and Access. The MRI Unit shall be located on GPII's premises or designated offsite premises, as mutually agreed upon by CSNC and GPII (the "Service Location"). As of the Commencement Date, the Service Location is 7 Vanderbilt Avenue, Suite 100, Asheville, North Carolina, subject to further change as agreed upon by the parties. All costs and expenses associated with the site selection, preparation and maintenance shall be the sole responsibility of CSNC. Utilities for the MRI Unit will provided by GPII at GPII's cost (or through GPII's lease payments to the landlord of the Service Location). Access to the site and the MRI Unit shall be limited to CSNC personnel, patients, and GPII personnel, all who have been instructed in MRI safety procedures. Both parties will use reasonable efforts to maintain a safe and suitable site for the MRI Unit which complies with the MRI Unit manufacturer's specifications and applicable laws and regulations.
3. CSNC's Responsibilities. CSNC shall provide to GPII with the following:
  - (a) Provide MRI scanning operations in accordance with the terms and conditions set forth in **Exhibit A**.
  - (b) Be responsible for the operation of the MRI Unit, subject to the overall supervision of GPII or its Designated Physician(s).
  - (c) Perform or arrange for all routine maintenance of the mobile MRI Unit.



- (d) Provide certain leasehold improvements to the Service Location associated with the MRI Unit and its operations.
- (e) Use reasonable efforts to comply with the quality assurance and performance improvement initiatives as outlined by GPII from time to time with respect to the MRI services.

4. GPII's Responsibilities. GPII shall:

- (a) Provide sufficient qualified staff members to operate the MRI Unit, including a qualified technologist and patient coordinator as may be reasonably required.
- (b) Transport and escort patients to and from the MRI Unit in accordance with GPII's established operating procedures, as well as process and prepare all patients (including obtaining appropriate patient information) in accordance with GPII's pre-established procedures.
- (c) Designate one or more physicians to provide professional services with respect to the MRI scans (the "Designated Physician(s)"). Such Designated Physician shall, at all times during each Operating Day, be present or immediately available for consultation and resolution of questions which may arise concerning the need, methods or circumstances of a particular MRI scan, shall oversee the quality of the testing performed and the proper operation of the MRI Unit, shall supervise the administration of contrast media (and inject contrast media if necessary) and monitor patients for possible reactions thereto, shall oversee the monitoring and discharge of patients receiving sedation and shall provide medical care as necessary to patients receiving MRI scans on the MRI Unit. CSNC shall not, under any circumstances, be responsible for providing medical treatment to any patient or for the professional or medical care of any patient.
- (d) GPII and its Designated Physicians, without exception, shall be responsible for (i) arranging for the medical interpretation of all MRI scans performed on the MRI Unit, (ii) the preparation and delivery of reports for each MRI scan performed, and (iii) the labeling of any anatomical or pathologic structure on a diagnostic film. CSNC shall not, under any circumstances, interpret MRI scans, label films, render medical advice or perform any medical diagnosis or treatment or prepare a report related thereto, for any patient receiving a MRI scan on the MRI Unit.
- (e) Arrange for the provision of all films, electronic and digital storage media, PACS technology if appropriate, linens, general medical supplies and incidentals as necessary.
- (f) Provide a written physician order for the MRI scan, a signed patient consent, and patient information as may be necessary to perform the MRI scan for each patient scheduled to receive a MRI scan.



- (g) Prepare the MRI Unit to receive patients at the time specified for the commencement of each Operating Day as set forth in **Exhibit A**.
5. Fees and Billing. GPII will pay CSNC fees in accordance with **Exhibit A**. All fees for a billing period will be due and payable within fifteen (15) days of the last day of such period. CSNC will invoice GPII once each month. GPII shall be responsible for all billings to patients and/or third party payors for MRI exams performed on the MRI Unit. CSNC shall not bill, and CSNC shall not cause bills to be submitted to, any patient or third party payor for MRI exams provided hereunder. GPII is pursuing diagnostic modality accreditation from the American College of Radiology ("Accreditation"). The parties agree and acknowledge that such Accreditation is required in order for MRI services to be reimbursed by certain third party payors, and therefore the MRI Unit shall not be utilized for patients of such third party payors until final ACR Accreditation is obtained by GPII.
6. Insurance.
- (a) CSNC shall maintain a self-insurance trust or professional and comprehensive general liability insurance coverage, including coverage for property damage, with limits of not less than One Million Dollars (\$1,000,000) per occurrence and Three Million Dollars (\$3,000,000) annual aggregate. This insurance shall provide coverage for CSNC. Upon request, CSNC shall provide current certificates of insurance evidencing such coverage to GPII.
- (b) GPII shall maintain professional and comprehensive general liability insurance coverage with limits of not less than One Million Dollars (\$1,000,000) per occurrence and Three Million Dollars (\$3,000,000) annual aggregate. GPII shall maintain privacy and cyberliability insurance coverage in amounts no less than \$\_\_\_\_\_ per occurrence and annual aggregate, to include at a minimum coverage for claims (including but not limited to third party tort claims), civil monetary fines and other penalties insurable by law. GPII shall, upon request, use its best efforts to provide current certificates of insurance evidencing such coverage to CSNC.
- (c) If either party's policies of insurance are cancelled, terminated or altered, GPII and CSNC shall notify immediately each other and MRI scanning services will be suspended until such insurance coverage is reinstated consistent with the provisions set forth in this Agreement.
7. Taxes. CSNC shall pay and otherwise agree to indemnify and hold GPII harmless against the payment of (i) all taxes (and penalties and interest thereon) which are measured by the net income of CSNC, and (ii) all state, county and municipal property taxes measured by the value of the MRI Unit.
8. Independent Contractors. The relationship between CSNC and GPII is that of independent contractors with respect to the services to be performed hereunder. Nothing herein shall be construed to create a joint venture or partnership between the parties hereto.

9. Term and Termination. The initial term of this Agreement shall begin on the Effective Date, and shall continue for a three (3) year period, unless earlier terminated as provided herein (the "Initial Term"). Thereafter, this Agreement shall automatically renew each year anniversary for successive terms of one (1) year each, unless sooner terminated as hereinafter provided (each a "Renewal Term"), unless either party gives written notice of cancellation to the other party at least one hundred eighty (180) days prior to the expiration of the then current Renewal Term. In addition, this Agreement may be terminated as follows:
- (a) In the event of a breach of a material provision of this Agreement, the non-breaching party shall provide the breaching party with written notice setting forth the alleged breach. The breaching party shall cure said breach within thirty (30) days of receipt of the written notice, or if such breach cannot reasonably be cured within thirty (30) days, shall commence to cure said breach within thirty (30) days and thereafter diligently pursue curing of such breach. If the breaching party fails to cure said breach within the above-described time, the non-breaching party may terminate this Agreement upon at least ten (10) days prior written notice to the breaching party.
  - (b) By either party, at its sole discretion, immediately upon written notice to the other party in the event the North Carolina CON Section suspends, rescinds or modifies required CON authorization for the provision of MRI services hereunder that adversely affects CSNC's ability to fulfill its obligations under this Agreement.
  - (c) By either party immediately upon written notice to the other party in the event the other party's license is suspended, revoked or cancelled or such party becomes debarred, suspended, excluded or otherwise ineligible to participate in any Federal or state health program.
  - (d) By either party upon written notice to the other party in the event either party is the subject of any state or federal bankruptcy, insolvency, receivership or liquidation proceedings and such proceedings remain undismissed after ninety (90) days from the date of filing.
  - (e) Notwithstanding anything to the contrary contained in this Agreement, this Agreement shall automatically terminate, without the need for any further writing by any party, following an election by GPII or CSNC to unwind the Transaction as permitted in Article 7 of that certain Master Acquisition Agreement between CSNC, GP II and certain physician owners of CSNC, dated December \_\_, 2021 ("Master Agreement"). The effective date of the termination of this Agreement will be concurrent with the Unwind Date (as such term is defined in the Master Agreement).
10. Records. In compliance with Title 42 U.S.C. Section 1395x(v)(1)(I) and its implementing regulations, CSNC agrees, until the expiration of four years after the services are furnished

under this Agreement, to allow the Secretary of the Department of Health and Human Services and the Comptroller General access to this Agreement, and any books, documents, and records of CSNC necessary to verify the nature and extent of the services provided under this Agreement.

If pursuant to this Agreement, any of the CSNC's duties and obligations are to be carried out by an individual or entity subcontracting with CSNC and that subcontractor is to a significant extent, associated or affiliated with, owns, or is owned by or has control of or is controlled by CSNC, each such subcontractor shall itself be subject to the access requirement, and CSNC hereby agrees to require such subcontractors to meet the access requirement.

11. Governing Law. This Agreement shall be governed by and interpreted in accordance with the laws of the state of North Carolina.
12. Successors Bound. The provisions of this Agreement shall inure to the benefit of and be obligatory upon the parties hereto and their successors and permitted assigns.
13. Assignability. This Agreement may not be assigned by either party without the prior written consent of the other party, which consent shall not be unreasonably withheld or delayed; provided that either party may assign this Agreement to any affiliate of such party or any entity that acquires all or substantially all of such party's assets, whether by merger, acquisition or otherwise.
14. Entire Agreement; Amendments. This Agreement constitutes the entire agreement between the parties pertaining to the subject matter hereof and supersedes all prior and contemporaneous agreements, representations and understandings of the parties, oral or written. This Agreement may only be modified, altered, changed, or amended by a writing signed by the parties hereto.
15. Compliance With Laws. Each of the parties hereto covenants and warrants that it shall comply with and observe all applicable local, state and federal laws, rules and regulations in any way affecting its business and the provision of services under this Agreement, including, without limitation, the Medicare and Medicaid reimbursement rules.
16. Modification To Comply With Law. To the extent that any law, rule, or regulation of any authority (including the Joint Commission or other relevant accrediting agency) having jurisdiction over the parties to this Agreement shall raise question as to the legality, enforceability, or appropriateness of this Agreement or any provision hereof particularly as it relates to Medicare and Medicaid reimbursement, federal Stark Law, and the tax-exempt status of a party, the parties agree to negotiate promptly regarding modification as may be required to bring this Agreement into compliance with such applicable law, rule, or regulation. Should the parties be unable to agree upon such modification within a period of thirty (30) days from the date any party shall give notice to the others of such changes in law, rule, or regulation, this Agreement shall be deemed terminated. The terms of this section shall survive the termination or expiration of this Agreement.

17. Participation in Federal and State Health Programs. Each of the parties hereto warrants and represents that it is not debarred, suspended, excluded or otherwise ineligible to participate in any federal or state health program. Each party hereby agrees that it shall notify the other party in writing within two (2) days should it become debarred, suspended, excluded or otherwise ineligible to participate in any federal or state health program. In the event either party receives such notice or becomes aware that the other party has been disbarred, suspended, excluded or otherwise ineligible to participate in any federal or state health program, it may immediately terminate this Agreement pursuant to Section 9 above.
18. Waiver. The failure to insist on strict compliance with any of the terms, conditions, or covenants contained in this Agreement shall not be deemed a waiver of such terms, conditions or covenants nor shall any waiver or relinquishment of any right one or more times be deemed a waiver or relinquishment of such right at any other time.
19. Severability. If any term or provision of this Agreement shall, to any extent, be invalid or unenforceable, such term or provision shall be treated as severable, leaving the remainder of this Agreement valid and enforceable.
20. Force Majeure. Neither party shall be liable for any damages arising out of any failure to perform its obligations under this Agreement which failure is caused by or which results from, either directly or indirectly, fire, flood, earthquakes, Acts of God, civil or military authority, acts of public enemy, war, strikes or other work interruptions or any similar or dissimilar cause beyond the reasonable control of either party.
21. Notices. All notices hereunder shall be in writing and shall be deemed given only if sent by (i) United States first class mail, registered or certified, postage prepaid, return receipt requested, or (ii) overnight courier, all charges prepaid, receiving party signature requested, addressed as follows:

To GPII:                   UNC Physicians Group Practices II, LLC  
4420 Lake Boone Trail  
Raleigh, NC 27607  
Attn.: President & CEO

With a copy to:  
University of North Carolina Health Care System  
Attn.: Legal Department  
101 Manning Drive  
2nd Floor, Medical Wing E  
7600 Campus Box  
Chapel Hill, North Carolina 27514

To CSNC:                   Carolina Spine and Neurosurgery Center, P.A.  
Attn: President

7 Vanderbilt Park Drive  
Asheville, NC 28803

22. Indemnification. Each party hereto shall indemnify and hold the other party harmless from and against any and all liability, loss, damage, cause of action, cost or expense (including reasonable attorney's fees) arising out of, or in any way connected with, any negligent or intentional act or failure to act, or any other wrongful conduct by the respective party, its members, agents, employees or subcontractors in the performance of its duties under this Agreement
23. HIPAA Compliance. CSNC and GP II shall comply in all material respects with the standards for privacy and security of individually identifiable health information of the Health Insurance Portability and Accountability Act of 1996, the Health Information Technology for Economic and Clinical Health Act, and the rules and regulations promulgated thereunder, all as the same may be amended from time to time (collectively, "HIPAA"). CSNC further agrees as a requirement of this Agreement to protect such information to the same degree and in the same manner as required of a "business associate" as set forth in 45 C.F.R. § 164.504(e) and to fulfill the obligations set forth in **Exhibit B**, incorporated herein by reference.
24. Proprietary Information. The parties hereto agree that each party's proprietary information, including, but not limited to, policies and procedures, pricing and statistical data, logos, trademarks and service marks, copyrighted or other proprietary materials ("Proprietary Information") furnished or disclosed to the other party for purposes of this Agreement shall remain the property of the disclosing party and shall not be divulged, disclosed or communicated to any third party or otherwise used by the non-disclosing party without the prior written consent of the disclosing party.
25. Contingency. This Agreement is contingent upon the parties being satisfied that this Agreement is permissible under the North Carolina Certificate of Need Law ("CON Law") for any location contemplated by this Agreement.
  - (a) The parties agree and acknowledge that a No Review Determination has been requested by the NC Division of Health Service Regulation Healthcare Planning and Certificate of Need Section ("NCDHSR"). In the event NCDHSR does not provide a final, favorable determination in advance of the Effective Date, GPII has the sole discretion to determine to commence this Agreement or delay the Effective Date pending a satisfactory determination from NCDHSR. In the event GPII elects to commence this Agreement in the absence of a final determination from NCDHSR, and either (i) NCDHSR subsequently fails to provide a favorable determination for the parties, or (ii) NCDHSR subsequently denies the No Review Request, then GPII may elect to immediately either terminate this Agreement or suspend this Agreement, and the parties shall immediately cease operation of the MRI Unit until the parties are satisfied that this Agreement is permissible under CON Law. Such election shall be in GPII's sole discretion.

- (b) In the event GPII does not obtain final Accreditation prior to April 1, 2022, GPII may elect to immediately suspend or terminate this Agreement, in GPII's sole discretion, and the parties shall immediately cease operation of the MRI Unit until such time as final Accreditation has been approved.

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

**CAROLINA SPINE & NEUROSURGERY  
CENTER, P.A.**

**UNC PHYSICIANS GROUP  
PRACTICES II, LLC**

By: \_\_\_\_\_

By: \_\_\_\_\_

**EXHIBIT A**

A. MRI Equipment

The equipment to be provided under this Agreement is a 2018 GE Optima MR450w 1.5T MRI system housed in a trailer.

B. Schedule of Operations

The MRI Unit will be located at the Service Location on a full-time basis. CSNC shall provide MRI Services each weekday for an eight (8) hour day, from 8:00 am to 5:00 pm (which time period includes a one (1) hour lunch break) (each, an "Operating Day").

C. Service Fees

CSNC will charge GPII a total monthly fee of \$ \_\_\_\_\_ (the "Fees") during the first two (2) years of the Initial Term of the Agreement. Then, beginning with and during the third (3<sup>rd</sup>) year of the Initial Term, the total monthly fee will be reduced to \$ \_\_\_\_\_ due to the cost of the Leasehold Improvements ceasing due to the change in Service Location. The Fees are comprised of the following amounts:

1. Equipment: \$ \_\_\_\_\_ per month shall be allocated to the provision of the MRI Unit and the operating costs (property taxes and maintenance service contract) associated with the MRI Unit.
2. Leasehold Improvements: \$ \_\_\_\_\_ per month shall be allocated to the leasehold improvements made to the Service Location at 7 Vanderbilt Avenue, Suite 100, Asheville, North Carolina. In the event of a change to the Service Location, the total Fees amount shall decrease in order to no longer include this amount allocated to Leasehold Improvements.

The parties acknowledge and agree that the compensation and other consideration set forth in this Agreement represent a fair market value exchange, negotiated in an arm's length transaction, and not determined in a manner which takes into account the value or the volume of referrals or other business generated between the parties. Prior to the beginning of the Renewal Term, the parties will engage a valuator to determine a new fair market value rate for the Fees.

D. Downtime

Downtime is defined as the inability of the mobile MRI Unit to perform scheduled MRI scans due to malfunction, not due to GPII error or negligence. In the event of Downtime, GPII will use its best efforts to reschedule patients, and CSNC will cooperate with such rescheduling. If rescheduling is necessary beyond each Operating Day, no additional compensation shall be due.

**EXHIBIT B**

**BUSINESS ASSOCIATE AGREEMENT**

This Business Associate Agreement (the “Agreement”) is made effective January 1, 2022 by and between UNC Physicians Group Practices II, LLC, hereinafter referred to as “Covered Entity”, and Carolina Spine & Neurosurgery Center, P.A., hereinafter referred to as “Business Associate”, (individually, a “Party” and collectively, the “Parties”). This Agreement supersedes any previously executed Business Associate Agreement between the Parties.

WITNESSETH:

WHEREAS, the Parties wish to enter into or have entered into one or more arrangements whereby Business Associate will provide certain services to Covered Entity (the agreement(s) evidencing such arrangement(s) are collectively referred to herein as the “Arrangement Agreement”); and

WHEREAS, pursuant to such arrangement(s), Business Associate may have access to Protected Health Information (as defined below) and may be considered a “business associate” of Covered Entity as defined in the Health Insurance Portability and Accountability Act of 1996’s (“HIPAA”) General Administrative Requirements, Administrative Requirements, and Privacy and Security rules in 45 CFR Parts 160, 162, and 164 (the “HIPAA Rule”); and

WHEREAS, the Parties desire to enter into this Agreement in order to comply with HIPAA, the HIPAA Rule, and Title XIII of Division A and Title IV of Division B of the American Recovery and Reinvestment Act of 2009 (“HITECH”), which together require that a covered entity and its business associate enter into a business associate agreement that meets certain requirements; and

NOW, THEREFORE, in consideration of the Parties’ continuing obligations under the Arrangement Agreement, compliance with the HIPAA Rule and HITECH, and other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the Parties agree to the provisions of this Agreement in order to address the requirements of the HIPAA Rule and HITECH and to protect the interests of both Parties.

I. DEFINITIONS

Except as otherwise defined herein, any and all capitalized terms in this Agreement shall have the definitions set forth in the HIPAA Rule.

II. PERMITTED USES AND DISCLOSURES OF PROTECTED HEALTH INFORMATION



Business Associate may use or disclose Protected Health Information as necessary to carry out its duties to Covered Entity pursuant to the terms of the Arrangement Agreement or as Required By Law. Business Associate shall not, without the prior written consent of Covered Entity, disclose any Protected Health Information on the basis that such Disclosure is Required By Law without first notifying Covered Entity so that Covered Entity shall have an opportunity to object to the Disclosure and to seek appropriate relief unless immediate Disclosure is Required By Law.

### III. LIMITATIONS ON USE AND DISCLOSURE OF PROTECTED HEALTH INFORMATION

(a) Business Associate shall not use or disclose Protected Health Information other than as permitted or required by this Agreement or as Required By Law.

(b) All Uses and Disclosures of Protected Health Information by Business Associate are subject to the minimum necessary rule of the Privacy Rule and must comply with Covered Entity's policies regarding the minimum necessary Use or Disclosure of Protected Health Information.

(c) To the extent that Business Associate receives, stores, processes, or otherwise deals with any information about patients of Covered Entity's substance abuse programs ("program patients"), defined by 42 CFR Part 2 ("Part 2"), Business Associate agrees that it is fully bound by Part 2 and will resist, in judicial proceedings if necessary, any efforts to obtain access to information pertaining to program patients except as permitted by Part 2.

### IV. PRIVACY AND SECURITY REQUIREMENTS

(a) Business Associate will implement appropriate safeguards to prevent Use or Disclosure of Protected Health Information other than as permitted in this Agreement.

(b) Business Associate will implement Administrative, Physical, and Technical Safeguards that reasonably and appropriately protect the confidentiality, integrity, and availability of any Electronic Protected Health Information that it creates, receives, maintains, or transmits on behalf of Covered Entity as required by the HIPAA Rule.

(c) Business Associate shall comply with the guidance from the U.S. Department of Health and Human Services to render Unsecured Protected Health Information unusable, unreadable, or indecipherable to unauthorized individuals, with respect to Electronic Protected Health Information in motion and at rest, and destruction of Protected Health Information.

(d) To the extent Business Associate carries out obligations of Covered Entity under the HIPAA Rule, Business Associate shall comply with the applicable provisions of the HIPAA Rule as if such Use or Disclosure were made by Covered Entity.

(e) Business Associate agrees to provide HIPAA training to all of its personnel who service Covered Entity's account or who otherwise will have access to Protected Health Information.

(f) Business Associate agrees to ensure that its agents, including any Subcontractors, that create, receive, maintain or transmit Protected Health Information on behalf of Business Associate agree to the same (or greater) restrictions and conditions that apply to Business Associate with respect to such information, and agree to implement reasonable and appropriate safeguards to protect any of such information that is Electronic Protected Health Information. Business Associate agrees to enter into written agreements with any Subcontractors in accordance with the requirements of the HIPAA Rule. Before allowing any Subcontractor or agent that is not organized under the laws of any state within the United States ("Foreign Subcontractor") to use or disclose, or have access to, Protected Health Information, Business Associate shall obtain the prior written consent of Covered Entity to the use of such Foreign Subcontractor, which consent may be withheld in Covered Entity's sole discretion.

(g) Business Associate agrees to take reasonable steps to ensure that its employees' actions or omissions do not cause Business Associate to breach the terms of this Agreement.

(h) Business Associate will comply with (i) Covered Entity's Notice of Privacy Practices; (ii) any limitations to which Covered Entity has agreed in regard to an Individual's permission to use or disclose his or her Protected Health Information; and (iii) any restrictions to the Use or Disclosure of Protected Health Information to which Covered Entity has agreed or is required to agree.

V. AVAILABILITY OF PROTECTED HEALTH INFORMATION, AMENDMENTS, AND ACCOUNTING OF DISCLOSURES

(a) Access to Protected Health Information. Within five (5) calendar days of a request by Covered Entity for access to Protected Health Information about an Individual contained in a Designated Record Set, Business Associate shall make available to Covered Entity such Protected Health Information for so long as such information is maintained by Business Associate in the Designated Record Set, as required by 45 CFR § 164.524.

(b) Amendment of Protected Health Information. Within five (5) calendar days of receipt of a request from Covered Entity for the amendment of an Individual's Protected Health Information or a record regarding an Individual contained in a Designated Record Set (for so long as the Protected Health Information is maintained in the Designated Record Set), Business Associate shall provide such information to Covered Entity for amendment and incorporate any such amendments in the Protected Health Information as required by 45 CFR § 164.526.

(c) Accounting of Disclosures. Within five (5) calendar days of notice by Covered Entity to Business Associate that it has received a request for an accounting of Disclosures of Protected Health Information, Business Associate shall make available to Covered Entity information to permit Covered Entity to respond to the request for an accounting of Disclosures of

Protected Health Information, as required by 45 CFR § 164.528. Business Associate will comply with Covered Entity's policy regarding accounting of Disclosures.

(d) In the event an Individual makes a request under this Section V directly to Business Associate, Business Associate will notify Covered Entity of such request within three (3) business days and shall cooperate with, and act only at the direction of, Covered Entity in responding to such request.

#### VI. AVAILABILITY OF BOOKS AND RECORDS; AUDITS

(a) Business Associate will make its internal practices, books and records relating to the Use and Disclosure of Protected Health Information available to the Secretary of the Department of Health and Human Services for purposes of the Secretary determining Covered Entity's compliance with the terms of the HIPAA Rule, and, at the request of the Secretary, will comply with any investigations and compliance reviews, permit access to information, and cooperate with the review of any complaints, as required by law.

(b) Business Associate shall permit Covered Entity, in its discretion, to conduct an audit of Business Associate's compliance with this Agreement, HIPAA, the HIPAA Rule, and HITECH. Such audit may consist of a series of inquiries that require written responses. Business Associate shall promptly and completely respond to Covered Entity's requests for information in support of the audit, which shall not be conducted more than once annually except in cases of an actual or reasonably suspected Security Incident or reasonably suspected noncompliance with this Agreement, HIPAA, the HIPAA Rule, or HITECH. Each Party shall bear its own costs associated with the audit.

#### VII. REPORTING TO COVERED ENTITY

(a) Business Associate shall report to Covered Entity (using the contact information on Exhibit A) any Use or Disclosure of Protected Health Information that is not in compliance with the terms of this Agreement, as well as any Security Incident and any actual or suspected Breach, of which it becomes aware, without unreasonable delay, and in no event later than ten (10) calendar days of such discovery. Such notification shall contain the elements required by 45 CFR § 164.410.

(b) Unless prohibited from doing so by applicable law or by a court order, without unreasonable delay, Business Associate will notify Covered Entity in writing of any request by any governmental entity, or its designee, to review Business Associate's compliance with law or this Agreement, to pursue a complaint, or to conduct an audit or assessment of any kind, if such review, complaint, audit or assessment pertains to the Arrangement Agreement or this Agreement.

#### VIII. MITIGATION, COOPERATION, INDEMNIFICATION, AND INSURANCE

(a) Business Associate agrees to mitigate any harmful effect that is known to Business Associate of a Use or Disclosure of Protected Health Information by Business Associate in violation of the requirements of this Agreement, as well as to provide complete cooperation to Covered Entity should Covered Entity elect to review or investigate such noncompliance or Security Incident. Business Associate shall cooperate in Covered Entity's breach analysis and/or risk assessment, if requested. Furthermore, Business Associate shall cooperate with Covered Entity in the event that Covered Entity determines that any third parties must be notified of a Breach, provided that Business Associate shall not provide any such notification except at the direction of Covered Entity.

(b) Business Associate shall indemnify and hold harmless Covered Entity, its officers, directors, employees, and agents, for any injury, claims, costs (including reasonable attorneys' fees), liabilities, or damages arising from or relating to any noncompliance with this Agreement or any Security Incident attributable to the negligence of Business Associate, including the failure to execute the terms of this Agreement.

(c) Notwithstanding other provisions of this Agreement or the Arrangement Agreement, Business Associate shall be liable under this Agreement for damages caused by the negligence or misconduct of its employees, directors, Subcontractors, or agents. Damages include, but are not limited to, reasonable and actual costs that Covered Entity incurs as a result of a Breach, including but not limited to Breach notification, when the Breach is caused by the negligence or misconduct of Business Associate's employees, directors, Subcontractors, or agents.

(d) To the extent that Business Associate has limited its liability under the terms of the Arrangement Agreement, whether with a maximum recovery for direct damages or a disclaimer against any consequential, indirect or punitive damages, or other such limitations, all limitations shall exclude any damages to Covered Entity arising from Business Associate's breach of its obligations under this Agreement, the HIPAA Rule, or relating to its Use, Disclosure, or safeguarding of Protected Health Information.

(e) Business Associate agrees to obtain and maintain at all times during which it maintains Protected Health Information subject to the Arrangement Agreement and/or this Agreement, privacy and cyber liability insurance coverage in amounts no less than \$\_\_\_\_\_ million per occurrence and annual aggregate, to include at a minimum coverage for claims (including but not limited to third party tort claims), civil monetary fines, and other penalties insurable by law. Business Associate shall provide certificates of insurance to Covered Entity upon request.

## IX. TERMINATION

(a) This Agreement shall be effective as of the date first set forth above and shall terminate upon the earlier of (i) the termination of all agreements between the parties, and (ii) the termination by Covered Entity for cause as provided herein.

(b) Notwithstanding anything in this Agreement or the Arrangement Agreement to the contrary, Covered Entity shall have the right to terminate this Agreement and the Arrangement

Agreement immediately if Covered Entity determines that Business Associate has violated any material term of this Agreement.

(c) At termination of this Agreement, the Arrangement Agreement (or any similar documentation of the business relationship of the Parties), or upon request of Covered Entity, whichever occurs first, if feasible, Business Associate will return (in a manner or process approved by the Covered Entity) or destroy all Protected Health Information received from Covered Entity, or created, maintained, or received by Business Associate on behalf of Covered Entity, that Business Associate still maintains in any form and retain no copies of such information. If such return or destruction is not feasible, Business Associate will (i) retain only that Protected Health Information necessary under the circumstances; (ii) return or destroy the remaining Protected Health Information that the Business Associate still maintains in any form; (iii) extend the protections of this Agreement to the retained Protected Health Information; (iv) limit further Uses and Disclosures to those purposes that make the return or destruction of the Protected Health Information not feasible; and (v) return or destroy the retained Protected Health Information when it is no longer needed by Business Associate. This paragraph shall survive the termination of this Agreement and shall apply to Protected Health Information created, maintained, or received by Business Associate and any of its Subcontractors.

## X. MISCELLANEOUS

(a) No Third Party Rights. Except as expressly stated herein or in the HIPAA Rule, the parties to this Agreement do not intend to create any rights in any third parties. The obligations of Business Associate under this Agreement shall survive the expiration, termination, or cancellation of this Agreement, the Arrangement Agreement and/or the business relationship of the parties, and shall continue to bind Business Associate, its agents, employees, contractors, Subcontractors, successors, and assigns as set forth herein.

(b) Ownership. Under no circumstances shall Business Associate be deemed in any respect to be the owner of any Protected Health Information created or received by Business Associate on behalf of Covered Entity.

(c) Injunctions. Covered Entity and Business Associate agree that any violation of the provisions of this Agreement will cause irreparable harm to Covered Entity. Accordingly, in addition to any other remedies available to Covered Entity at law, in equity, under the Arrangement Agreement, or under this Agreement, in the event of any violation of any of the provisions of this Agreement, or any explicit threat thereof, Covered Entity shall be entitled to an injunction or other decree of specific performance with respect to such violation(s) or explicit threat thereof.

(d) Amendment, Assignment, and Severability. No Party may assign its respective rights and obligations under this Agreement without the prior written consent of the other Party. This Agreement may be amended or modified only in a writing signed by the Parties. In the event that any provision of this Agreement is held by a court of competent jurisdiction to be invalid or unenforceable, the remainder of the provisions of this Agreement will remain in full force and effect. In addition, in the event a Party believes in good faith that any provision of this Agreement fails to comply with the then-current requirements of the HIPAA Rule, such Party shall notify the other Party in writing. For a period of up to thirty (30) days, the Parties shall address in good faith

such concern and amend the terms of this Agreement, if necessary to bring it into compliance. If, after such thirty-day period, a Party believes in good faith that the Agreement fails to comply with the HIPAA Rule, then either Party has the right to terminate upon written notice to the other Party.

(e) Independent Contractor Status. None of the provisions of this Agreement are intended to create, nor will they be deemed to create any relationship between the Parties other than that of independent parties contracting with each other solely for the purposes of effecting the provisions of this Agreement and any other agreements between the Parties evidencing their business relationship. Business Associate shall not be considered an agent of Covered Entity.

(f) Governing Law; Waiver. This Agreement will be governed by the laws of the State of North Carolina. No change, waiver or discharge of any liability or obligation hereunder on any one or more occasions shall be deemed a waiver of performance of any continuing or other obligation, or shall prohibit enforcement of any obligation, on any other occasion.

(g) Conflicts. The parties agree that, in the event that any documentation of the arrangement pursuant to which Business Associate provides services to Covered Entity contains provisions relating to the Use or Disclosure of Protected Health Information that are more restrictive than the provisions of this Agreement, the more restrictive provisions will control. The provisions of this Agreement are intended to establish the minimum requirements regarding Business Associate's Use and Disclosure of Protected Health Information.

IN WITNESS WHEREOF, the Parties have executed this Agreement as of the day and year written above.

COVERED ENTITY:

BUSINESS ASSOCIATE:

By: \_\_\_\_\_

By: \_\_\_\_\_

Title: \_\_\_\_\_

Title: \_\_\_\_\_

**EXHIBIT A**

**Contact Information for UNC Health Care System Members & Affiliates:**

The UNC Health Care System Privacy Office is located at the following address:

UNC Health Care System Privacy Officer:

5221 Paramount Parkway, Suite 430

Morrisville, NC 27560

(984) 974-1069

The UNC Health Care System Privacy Office is responsible for the privacy services for UNC Physicians Group Practices II, LLC.

**Reporting Privacy Breaches and Security Incidents:**

To report to Covered Entity (1) any use or disclosure of Protected Health Information not in compliance with the terms of this Agreement that might be considered a privacy breach or (2) any Security Incident (as defined in the Agreement), Business Associate should contact the Privacy Office listed above.

# Exhibit 2



# State of North Carolina

## Department Of Health and Human Services Division Of Facility Services Certificate Of Need

Project Identification Number B-5583-97/970332 Effective Date May 29, 1998

Issued to: Mountain Neurological Center, P.A.  
7 McDowell Street  
Asheville, NC 28801

The North Carolina Department of Health and Human Services, pursuant to the North Carolina Health Planning and Resource Development Act of 1978, G.S. § 131E-175, et seq., as amended and recodified, G.S. § 131E-175, et seq., hereby finds and certifies that the new institutional health service proposed by the person listed above is consistent with, or as conditioned is consistent with, the plans, standards, and criteria prescribed by the Act and the rules and regulations promulgated thereunder. The findings 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 health service in a manner consistent with the plans, standards, and criteria prescribed by the Act and the rules and regulations promulgated thereunder. This Certificate includes and is limited to:

SCOPE: Mountain Neurological Center, P.A. shall acquire no more than one magnetic resonance imaging (MRI) scanner/Buncombe County

CONDITIONS: See Reverse Side

PHYSICAL LOCATION: Mountain Neurological Center  
7 McDowell Street, Asheville, NC 28801

MAXIMUM CAPITAL EXPENDITURE: \$56,280

TIMETABLE: See Reverse Side

FIRST PROGRESS REPORT DUE: August 31, 1998

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... 10/11/98*

# Exhibit 3





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

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:

1. A certificate of need was issued to Mountain Neurological Center, P.A. effective May 29, 1998 to acquire an MRI scanner (Project ID #B-5583-97).
2. 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).
3. 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 ("MSNI"), 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."*
4. 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.
5. 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."*
6. 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.
7. The Certificate of Need Section does not issue new certificates of need whenever the name of an applicant or a facility changes.
8. 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,

Julie Halatek  
Project Analyst

Craig R. Smith, Chief  
Certificate of Need Section

cc: 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/ Affirmative Action Employer



# Exhibit 4





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 scanner  
**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

Martha J. 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





THE  
VAN WINKLE  
LAW FIRM

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

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

11 North Market Street, Asheville, NC 28801 P.O. Box 7376, Asheville, NC 28802 (828) 258-2991  
422 South Main Street, Hendersonville, NC 28792 (828) 697-6196  
[www.vwlawfirm.com](http://www.vwlawfirm.com)

- 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:

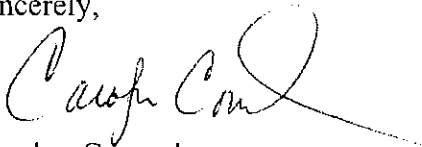
- The Optima has the same technology as the Signa although it may possess expanded capabilities due to technological improvements;
- The Optima is functionally similar and is used for the same diagnostic or treatment purposes as the Signa and is not used to provide a new health service; and
- The acquisition 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](#)

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Martha can you log this. Thanks.

Get [Outlook for Android](#)

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**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. Qualls**  
Partner  
K&L Gates LLP  
430 Davis Drive, Suite 400  
Morrisville, NC 27560  
Phone: 919-466-1182  
Fax: 919-516-2072  
[gary.qualls@klgates.com](mailto:gary.qualls@klgates.com)  
[www.klgates.com](http://www.klgates.com)

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any disclosure, copying, distribution, or use of the contents of this message is prohibited. If you have received this e-mail in error, please contact me at [Gary.Qualls@klgates.com](mailto:Gary.Qualls@klgates.com).

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