



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

October 15, 2024

Emily Cromer
emily.cromer@unchealth.unc.edu

No Review

Record #: 4610
Date of Request: October 8, 2024
Facility Name: University of North Carolina Medical Center
FID #: 923517
Business Name: UNC Health Care System
Business #: 2991
Project Description: Relocate CT simulator from UNC Hospitals main campus in Chapel Hill to UNC Health Rockingham
County: Orange

Dear Ms. Cromer:

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 representation in your request and 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.

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. As a reminder, it is unlawful to offer or develop a new institutional health service without first obtaining a certificate of need. The Department reserves the right to impose sanctions, including civil penalties and the revocation of a license, upon any entity that offers or develops a new institutional health service without first obtaining a certificate of need.

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

Sincerely,

[Handwritten signature of Cynthia Bradford]

Cynthia Bradford, Project Analyst

[Handwritten signature of Micheala Mitchell]

Micheala Mitchell, Chief

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

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

LOCATION: 809 Ruggles Drive, Edgerton Building, Raleigh, NC 27603
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October 8, 2024

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

Via E-Mail

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

Re: No Review Request for Relocating CT Simulator from UNCH's Chapel Hill Main Campus to the UNCH Rockingham Campus

Dear Ms. Mitchell:

The University of North Carolina Hospitals (“UNCH”) asks the Department of Health and Human Services, Division of Health Service Regulation, Healthcare Planning and Certificate of Need Section (the “Agency”) to make the ruling described below for a single hospital, UNCH.

This request involves two provider-based campuses of the same hospital, UNCH. It involves:

1. The UNCH Main Campus in Chapel Hill, Orange County (hereafter, the “Main Campus”);
and
2. UNCH’s provider-based campus adjacent to UNC Health Rockingham in Rockingham County (hereafter, the “UNCH Rockingham Campus”).

Specifically, this No Review Request asks the Agency to confirm that no Certificate of Need (“CON”) is required in order for UNCH to relocate a CT Simulator from UNCH’s Main Campus to its UNCH Rockingham Campus (the “Intra-Hospital Relocation”). Although separately licensed, the Main Campus and the UNCH Rockingham Campus are both part of the same hospital, UNCH, because the UNCH Rockingham Campus is a provider-based location of UNCH, under the same Medicare provider number as the Main Campus.

The CT Simulator to be relocated in this Intra-Hospital Relocation is a Philips Brilliance Big Bore, which UNCH made operational in 2017. It was acquired pursuant to the CON approval in Project ID # J-11218-16.

The UNCH Rockingham Campus was established pursuant to authority under the 2018 Rockingham Declaratory Ruling attached as Exhibit 1 (this is the official version from DHSR's Website). That Ruling recognized that then-existing cancer center space and equipment (including a linear accelerator) could be redesignated from UNCH's sister hospital, UNC Health Rockingham, to UNCH to create the UNCH Rockingham Campus. The relocated CT Simulator here would simply be placed into that same business occupancy space at the UNCH Rockingham Campus. Under the authority outlined in the 2018 Rockingham Declaratory Ruling, the CT Simulator would be operated as un-licensed provider-based space to UNCH just as the UNCH Rockingham Campus space and equipment currently is.

This Intra-Hospital Relocation of the CT Simulator will not increase UNCH's CT Scanner complement or its Simulator complement. The act of relocating the existing, operational CT Simulator does not constitute a "purchase" or "acquisition" since UNCH: (a) currently owns it, where it is located at the Main Campus; and (b) will still own it when it is made operational at the UNCH Rockingham Campus. The relocation costs will be minimal – projected to be between \$150,000 and \$200,000 – and thus will be far below the \$4 Million that would trigger CON review.

Even though the Intra-Hospital Relocation here will simply be moving the CT Simulator within the same hospital, there is precedent for the relocation of CON *per se* reviewable equipment even from one hospital to another hospital under common ownership.

1. In no review and replacement equipment exemption determinations dated March 16, 2022, the Agency approved The Charlotte-Mecklenburg Hospital Authority ("CMHA") to relocate and replace heart-lung bypass equipment from one hospital to another, from Carolinas Medical Center ("CMC") to Atrium Health Pineville. See Exhibit 2.
2. In material compliance and replacement equipment exemption determinations dated September 29, 2017, the Agency approved CMHA to relocate and replace cardiac catheterization equipment from one hospital to another, from CMC to Atrium Health Pineville. See Exhibit 3.
3. Similarly, in an August 5, 2015 determination, the Agency approved Novant Health to relocate and replace cardiac catheterization unit from Novant Health Presbyterian Medical Center ("Presbyterian") to Novant Health Matthews Medical Center ("Matthews"). See Exhibit 4). In requesting the relocation, Novant pointed out that both Presbyterian and Matthews were within the Novant Health corporate family.

All three of the examples above involve equipment governed by SMFP need determinations with associated SMFP services areas. Thus, in those situations, it was important for the requesting parties to point out that those relocations occurred within the county service area. However, neither CT Scanners nor Simulators (of which the CT Simulator is a combination) have SMFP-defined need determinations or service areas.

Thus, there is no CON Law trigger that precludes movement of a CT Simulator from one county to another so long as there is no acquisition under either N.C. Gen. Stat. § 131E-176(16)(f1) (governing acquisitions of simulators) or N.C. Gen. Stat. § 131E-176(16)(p) (governing acquisitions of major medical equipment). That is particularly true for an Intra-Hospital Relocation such as this.

Here, the Main Campus and the UNCH Rockingham Campus are both part of a single certified hospital, under the exact same ownership. Thus, both campuses are operated by the same entity under the same provider number. As with the approvals in Exhibits 2 through 4 discussed above, there is no CON-regulated acquisition because no entity is acquiring the equipment. Moreover, UNCH has already received a CON for this very equipment.

In fact, the Intra-Hospital Relocation here is simpler and clearer than the facts presented in Exhibits 2 through 4 for two reasons:

1. No equipment is being replaced in this Intra-Hospital Relocation (which was an additional, approved step in those Exhibits 2 through 4 scenarios); and
2. The Agency's approval analysis fits UNCH here even better than it fit Novant in the Exhibit 4 scenario. In the Novant situation, Presbyterian Medical Center and Matthews Medical Center were owned by two separate Novant Health subsidiaries, but were under Novant Health ownership at the parent level. In our Intra-Hospital Relocation here, UNCH owns and operates both campuses at issue.

Thus, as with the precedents cited above, UNCH's proposed Intra-Hospital Relocation here is not CON reviewable.

Conclusion

Based on the foregoing information, UNCH asks the Agency to find that relocating the CT Simulator from one UNCH campus to another (and not increasing UNCH's CT Simulator complement) does not require a CON.

We respectfully request that you expedite this request due to logistical timing considerations. We thank you for your consideration of this request.

Sincerely,

Gary S. Qualls

Exhibits

1. 2018 UNC Rockingham Declaratory Ruling
2. No Review and Exemption Approvals, Request for Such Approvals, and Exhibits Thereto for CMHA to Relocate a Heart-Lung Bypass Machine from CMC Campus to CMHA's Pineville Campus (without exhibits)
3. No Review and Exemption Approvals dated September 29, 2017, for Request of the same date for Carolinas HealthCare System to relocate a cardiac cath unit from CMC University to CMC (without exhibits)
4. No Review and Exemption Approvals dated August 5, 2015, for July 16, 2015 Request for Novant Health Presbyterian Medical Center to replace and relocate a cardiac cath unit from Presbyterian Medical Center to Novant Health Matthews Medical Center (without exhibits)

Exhibit 1

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

IN RE: REQUEST FOR DECLARATORY)	
RULING BY THE UNIVERSITY OF NORTH)	
CAROLINA HEALTH CARE SYSTEM, THE)	DECLARATORY RULING
UNIVERSITY OF NORTH CAROLINA AT)	
CHAPEL HILL d/b/a UNC HOSPITALS, AND)	
UNC ROCKINGHAM HEALTH CARE, INC.)	

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

On February 15, 2018, The University of North Carolina Health Care System (“UNC Health Care”), The University of North Carolina at Chapel Hill d/b/a UNC Hospitals (“UNC Hospitals”), and UNC Rockingham Health Care, Inc. (“UNC Rockingham”) (collectively, the “Parties”), requested a declaratory ruling as to the applicability of Chapter 131E, Article 5 (Hospital Licensure Act) and Article 9 (Certificate of Need Law) of the North Carolina General Statutes, and of the Department’s rules, to the facts described below. Specifically, the Parties request a determination that the re-designation (without relocation) of UNC Rockingham’s Cancer Center Space, and the Radiation Therapy Equipment located therein, to unlicensed, provider-based space of its sister hospital, UNC Hospitals: (1) is permitted by the Hospital Licensure Act; and (2) does not require 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 North Carolina General

Statutes § 150B-4, the Department expressly reserves the right to make a prospective change in the interpretation of the statutes and regulations at issue in this Declaratory Ruling. Gary S. Qualls, of K&L Gates, LLP, has requested this ruling on behalf of the Parties and has provided the material facts upon which this ruling is based.

STATEMENT OF THE FACTS

Pursuant to N.C. Gen. Stat. § 116-37, UNC Hospitals, located in Chapel Hill, Orange County, North Carolina, is an operating component entity of UNC Health Care. UNC Rockingham operates an acute care hospital (“UNC Rockingham Health Care”) in Eden, Rockingham County, North Carolina. UNC Health Care is the sole corporate member of UNC Rockingham. Therefore, UNC Health Care, as the parent entity, owns both UNC Hospitals and UNC Rockingham.

While UNC Health Care is the parent of both, UNC Hospitals and UNC Rockingham are each distinct entities. Thus, while UNC Health Care owns UNC Hospitals, it owns it indirectly via being the sole owner of the subsidiary that owns UNC Hospitals. Similarly, while UNC Health Care owns UNC Rockingham, it owns it indirectly via being the sole owner of the subsidiary that owns UNC Rockingham. Effective January 1, 2018, UNC Health Care, through UNC Rockingham, acquired the assets of the former Morehead Memorial Hospital.

The Parties now wish to renovate and re-designate 11,267 square feet of radiation therapy space and outpatient medical oncology space currently operated at UNC Rockingham (the “Cancer Center Space”) to unlicensed, provider-based space of its sister hospital, UNC Hospitals (the “Re-designation”). The Cancer Center Space is situated in a single building, the Rockingham Cancer Center Building, located at 516 South Van Buren Road, Eden, Rockingham County, North Carolina. The Cancer Center Space includes one (1) linear accelerator (the “Radiation Therapy

Equipment”); two (2) private chemotherapy bays and six (6) chemotherapy chairs (the “Medical Oncology Equipment”); pharmacy and lab services; and provider-based physician offices.

Pursuant to the Re-designation, the Cancer Center Space, and the Radiation Therapy Equipment therein, will remain in the precise same location in the Rockingham Cancer Center Building, located at 516 South Van Buren Road, Eden, Rockingham County, North Carolina. UNC Rockingham will continue to own the Cancer Center Space, including the Radiation Therapy and Medical Oncology Equipment, and UNC Hospitals will lease the Cancer Center Space, including the Radiation Therapy Equipment, from UNC Rockingham through operating leases.

ANALYSIS

The Re-designation entails the Parties shifting the designation of the Cancer Center Space from a provider-based licensed location of UNC Rockingham to a provider-based, unlicensed location of UNC Hospitals. No assets will be physically moved as a result of the Re-designation.

A. Licensure Discussion

Pursuant to the proposed lease, the Cancer Center Space, and the Radiation Therapy and Medical Oncology Equipment therein, will be provider-based to UNC Hospitals, and is permitted to be operated as an unlicensed outpatient location under the North Carolina Hospital Licensure Act’s Business Occupancy Exception, contained in N.C. Gen. Stat. § 131E-76(3). N.C. Gen. Stat. § 131E-76(3) defines “hospital” as follows:

“‘Hospital’ means any facility which has an organized medical staff and which is designed, used, and operated to provide health care, diagnostic and therapeutic services, and continuous nursing care primarily to inpatients where such care and services are rendered under the supervision and direction of physicians licensed under Chapter 90 of the General Statutes, Article 1, to two or more persons over a period in excess of 24 hours. The term includes facilities for the diagnosis and treatment of disorders within the scope of specific health specialties. **The term does not include...any outpatient department[,] including a portion of a hospital operated as an outpatient department, on or off of the hospital’s main campus, that**

is operated under the hospital's control or ownership and is classified as Business Occupancy by the Life Safety Code of the National Fire Protection Association as referenced under 42 C.F.R. § 482.41”

N.C. Gen. Stat. § 131E-76(3) (emphasis added).

Because outpatient Business Occupancy locations are not part of a licensed hospital under the Business Occupancy Exception, they are not restricted by the “County Line Licensure Rule” at 10A N.C.A.C. 13B .3101(f), and thus can be located in a county other than the county in which the hospital is located. Therefore, the Cancer Center Space in Rockingham County can operate as a non-licensed, provider-based outpatient department of UNC Hospitals (otherwise predominantly located in Orange County) consistently with the Hospital Licensure Act.

The North Carolina Hospital Licensure Act’s “hospital” definition in N.C. Gen. Stat. § 131E-76(3) incorporates by reference the definitions in the 2000 Life Safety Code of the National Fire Protection Association (the “Life Safety Code”). That Life Safety Code designates whether hospital space is classified as:

1. Business Occupancy (so as to meet the Business Occupancy Exception);
2. Ambulatory Care Occupancy; or
3. Health Care Occupancy.

The Life Safety Code at NFPA 101 Section 3.3.134.1 defines what functionally constitutes occupancy for Ambulatory Health Care. The Life Safety Code classifies “Ambulatory Health Care” as a “building or portion thereof used to provide services or treatment simultaneously to four or more patients that (1) provides, on an outpatient basis, treatment for patients that renders the patients incapable of taking action for self-preservation under emergency conditions without the assistance of others; or (2) provides, on an outpatient basis, anesthesia that renders the patients

incapable of taking action for self-preservation under emergency conditions without the assistance of others.” See NFPA 101 Section 3.3.134.1A.

Because Business Occupancy classification is a functional step below Ambulatory Health Care (i.e., fewer requirements), the Department’s Construction Section looks at what falls below the Ambulatory Health Care standard to determine what is classified as Business Occupancy under the Life Safety Code. Thus, a Business Occupancy classification is appropriate when a building or portion thereof is used to provide outpatient services where treatment renders three (3) or fewer patients simultaneously incapable of self-preservation under emergency conditions without the assistance of others. In the proposed UNC Hospitals Cancer Center Space, no more than three (3) patients will be simultaneously rendered incapable of self-preservation under emergency conditions without the assistance of others. Moreover, the UNC Hospitals Cancer Center Space will be dedicated to this use.

Given the foregoing features, the Department confirms that the Re-designation (without relocation) of UNC Rockingham’s Cancer Center Space to unlicensed, provider-based space of its sister hospital, UNC Hospitals, is permitted by the Business Occupancy Exception in N.C. Gen. Stat. § 131E-76(3) of the Hospital Licensure Act.

B. CON Discussion

Pursuant to N.C. Gen. Stat. § 131E-178(a), no person shall offer or develop a “new institutional health service” without first obtaining a CON. The term “new institutional health service” is defined in numerous ways in N.C. Gen. Stat. § 131E-176(16). The Re-designation does

not trigger any of the definitions of a “new institutional health service,” which would implicate CON review.

Among these definitions is N.C. Gen. Stat. § 131E-176(16)(b), which defines a “new institutional health service” to include:

“...the obligation by any person of a capital expenditure exceeding two million dollars (\$2,000,000) to develop or expand a health service or a health service facility, or which relates to the provision of a health service”

N.C. Gen. Stat. § 131E-176(16)(b). However, the Re-designation does not constitute a “new institutional health service” under N.C. Gen. Stat. § 131E-176(16)(b) because the capital expenditures being incurred as part of this Re-designation are less than \$2,000,000. UNC Hospitals projects expenditures of \$1,918,840 in non-exempt capital costs for the Re-designation. In addition, the operating leases for the Cancer Center Space and the CON-regulated Radiation Therapy Equipment is purely an intra-organizational re-designation within UNC Health Care’s two controlled affiliates, UNC Hospitals and UNC Rockingham.

In addition, the Re-designation of the Cancer Center Space does not trigger any of the “acquisition-related” new institutional health service definitions in N.C. Gen. Stat. § 131E-176(16). Pursuant to N.C. Gen. Stat. § 131E-178(b):

“No person shall make an acquisition by donation, lease, transfer, or comparable arrangement without first obtaining a certificate of need from the Department, if the acquisition would have been a new institutional health service if it had been made by purchase....”

N.C. Gen. Stat. § 131E-178(b). Here, the Cancer Center Space and the CON-regulated Radiation Therapy Equipment are not being acquired because no legal entity outside of the UNC Health Care controlled affiliates is acquiring anything. Rather, the Re-designation is an intra-organizational re-designation within UNC Health Care controlled affiliates.

Further, pursuant to 10A N.C.A.C. 14C. 0502(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.”

10A N.C.A.C. 14C .0502(b). Because the existing Cancer Center Space is simply transitioning from being designated as outpatient space at one existing hospital to outpatient space at its existing, sister hospital, both of which entities are owned by UNC Health Care, the Re-designation does not constitute the transfer of ownership of the CON.

Moreover, because no beds are involved, the Re-designation does not constitute a “change in bed capacity” under N.C. Gen. Stat. § 131E-176(16)(c). Because no operating rooms are involved, the Re-designation does not implicate N.C. Gen. Stat. § 131E-176(16)(u). And, finally, the Re-designation does not constitute a “new institutional health service” under any other definition in N.C. Gen. Stat. § 131E-176(16).

This proposal is similar to other UNC Health Care proposals that the Department determined to be non-reviewable. On March 12, 2015, the Department determined that no CON review was necessary for the re-designation (without relocation) of Caldwell Memorial Hospital, Inc.’s (“CMHI”) Cancer Center Space, and the Radiation and Medical Oncology Equipment located therein, to unlicensed space of its sister hospital, UNC Hospitals. Similarly, on March 24, 2016, the Department determined that no CON review was necessary for UNC Health Care to re-designate (without relocation) of High Point Regional Health’s (“HPRH”) Cancer Center Space,

and the Radiation and Medical Oncology Equipment located therein, to unlicensed space of its sister hospital, UNC Hospitals.

CONCLUSION

For the foregoing reasons, assuming the statements of fact in the request to be true, I conclude that the Re-designation (without relocation) of UNC Rockingham’s Cancer Center Space, and the Radiation Therapy Equipment located therein, to unlicensed, provider-based space of its sister hospital, UNC Hospitals: (1) is permitted by the Hospital Licensure Act; and (2) does not require a Certificate of Need.

This the _____ day of April, 2018.

S. Mark Payne, Director
Division of Health Service Regulation
N.C. Department of Health and Human Services

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that I have this day served the foregoing Declaratory Ruling upon the PETITIONER by certified mail, return receipt requested, by causing a copy of same to be placed in the United States Mail, first-class, postage pre-paid envelope addressed as follows:

CERTIFIED MAIL

Gary S. Qualls
K&L GATES, LLP
430 Davis Drive, Suite 400
Morrisville, North Carolina 27560
ATTORNEY FOR THE UNC HEALTH CARE SYSTEM,
THE UNIVERSITY OF NORTH CAROLINA d/b/a UNC
HOSPITALS, and UNC ROCKINGHAM HEALTH CARE,
INC.

This the _____ day of April, 2018.

Diana Barbry
Executive Assistant to the Director
Division of Health Service Regulation

Exhibit 2



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

March 24, 2022

Gary S. Qualls
gary.qualls@klgates.com

No Review

Record #: 3848
Date of Request: March 16, 2022
Facility Name: Atrium Health Pineville
FID #: 110878
Business Name: The Charlotte-Mecklenburg Hospital Authority
Business #: 1770
Project Description: Relocate a replacement heart/lung bypass machine from Carolinas Medical Center to Atrium Health Pineville
County: Mecklenburg

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. Please see the Agency's Exempt from Review determination (Record #3847) regarding the replacement of the heart/lung bypass machine being relocated from Carolinas Medical Center to Atrium Health Pineville.

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

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

Sincerely,

Julie M. Faenza

Julie M. Faenza, Project Analyst

Micheala Mitchell

Micheala Mitchell, Chief

cc. Acute and Home Care Licensure and Certification

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

HEALTHCARE PLANNING AND CERTIFICATE OF NEED SECTION

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AN EQUAL OPPORTUNITY / AFFIRMATIVE ACTION EMPLOYER



**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

March 24, 2022

Gary S. Qualls
gary.qualls@kigates.com

Exempt from Review – Replacement Equipment

Record #: 3847
Date of Request: March 16, 2022
Facility Name: Carolinas Medical Center
FID #: 943070
Business Name: The Charlotte-Mecklenburg Hospital Authority
Business #: 1770
Project Description: Replace existing heart/lung bypass machine
County: Mecklenburg

Dear Mr. Qualls:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency), determined that the above referenced project is exempt from certificate of need review in accordance with G.S. 131E-184(a)(7). Therefore, you may proceed to acquire without a certificate of need the newer model LivaNova SRD S5 Heart Lung Perfusion System to replace the LivaNova SRD S5 Heart Lung Perfusion System (ID #48E01770). This determination is based on your representations that the existing unit will be sold or otherwise disposed of and will not be used again in the State without first obtaining a certificate of need if one is required. Please see the Agency's No Review determination (Record #3848) regarding the change of site of the replacement heart/lung bypass machine from Carolinas Medical Center to Atrium Health Pineville.

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 M. Faenza
Project Analyst

Micheala Mitchell
Chief

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

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

HEALTHCARE PLANNING AND CERTIFICATE OF NEED SECTION

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AN EQUAL OPPORTUNITY / AFFIRMATIVE ACTION EMPLOYER

March 16, 2022

Gary S. Qualls
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Via E-Mail

Micheala Mitchell, Chief
Julie Faenza, 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: Replacement Equipment Exemption and Material Compliance / No Review Request for Replacing and Relocating Heart-Lung Bypass Machine from CMHA's CMC Campus to CMHA's Pineville Campus

Dear Ms. Mitchell and Ms. Faenza:

The Charlotte-Mecklenburg Hospital Authority d/b/a Atrium Health ("CMHA") asks the Department of Health and Human Services, Division of Health Service Regulation, Healthcare Planning and Certificate of Need Section (the "Agency") to make the two rulings described below for its wholly owned facilities and operating divisions, Carolinas Medical Center ("CMC") and Atrium Health Pineville ("AH Pineville").

The Exemption Notice in Part I describes how CMHA will replace one CMHA-owned and operated Heart-Lung Bypass Unit ("Bypass Unit") at CMC with another existing, comparable Bypass Unit at CMC.

The Material Compliance / No Review Request in Part II asks the Agency to confirm that no Certificate of Need ("CON") is required in order for CMHA to relocate that replaced Bypass Unit from one existing CMHA wholly owned facility and operating division to another (i.e., from CMC to AH Pineville). The relocation of this Bypass Unit will not increase CMHA's Bypass Unit complement or the Bypass Unit complement in Mecklenburg County.¹

¹ We characterize Step 2 as, alternatively, a Material Compliance / No Review Request for the following reasons. Step 2 is most accurately called a Material Compliance Request if the "Old Bypass Unit" being replaced (or its predecessors units) were obtained pursuant to a CON, as opposed to being grandfathered under the CON Law. Because CMHA has owned the Old Bypass Unit (or its predecessors units) so long, CMHA's records do not reflect whether this particular unit originated from a CON or predated CON

A summary of each step is described immediately below. A more detailed description of each step is then provided in Parts I and II below.

Summary of Step #1

1. In Step #1, CMHA seeks a replacement equipment exemption to replace the “Old Bypass Unit” at CMC with a new Bypass Unit (the “Replacement Bypass Unit” or “Replacement Equipment”) for under \$2 Million. See N.C. Gen. Stat. § 131E-184(a)(7) and 131E-176(22a).

Summary of Step #2

2. CMHA next seeks a material compliance or (in the alternative) a no review determination to relocate the Replacement Bypass Unit to the AH Pineville Campus. The act of relocating the Replacement Bypass Unit does not constitute a “purchase” or “acquisition” since CMHA: (a) owns it when it is located at CMC; and (b) will still own it when it is made operational at AH Pineville.

I. Step #1 -- The Replacement Equipment Exemption.

CMHA first seeks a replacement equipment exemption to replace CMC’s “Old Bypass Unit” with the Replacement Bypass Unit. The Old Bypass Unit is a LivaNova S5 Heart Lung Perfusion System. The Replacement Bypass Unit is also the same make and model of LivaNova S5 Heart Lung Perfusion System, just newer. See Exhibit B (cost quote for Replacement Bypass Unit); Exhibit C (brochure for Replacement Bypass Unit); Exhibit D (CON Equipment Comparison Form). CMHA’s acquisition of this Replacement Bypass Unit is exempt as described below.

A. Section 184(a)(7) Exemption

The General Assembly has chosen to exempt certain, otherwise reviewable events from CON review. Among those exemptions is the acquisition of “replacement equipment,” as provided in N.C. Gen. Stat. § 131E-184(a)(7), set forth below:

- (a) Except as provided in subsection (b), the Department shall exempt from certificate of need review a new institutional health service if it receives prior written notice from the entity proposing the new institutional health service, which notice includes an explanation of why the new institutional health service is required, for any of the following: .

* * *

- (7) To provide replacement equipment.

requirements for heart-lung bypass machines. For example, 1996 SMFP excerpts show that CMHA already owned and operated seven (7) bypass units at CMC in that reporting year. See Exhibit A.

The CON Law then defines “replacement equipment,” as follows:

“Replacement equipment” means equipment that costs less than two million dollars (\$2,000,000) and is purchased for the sole purpose of replacing comparable medical equipment currently in use which will be sold or otherwise disposed of when replaced.

See N.C. Gen. Stat. § 131E-176(22a).

Therefore, to qualify for this exemption, the replacement equipment must cost less than \$2 Million and be “comparable” to the equipment it replaces and must be “sold or otherwise disposed of when replaced.” As described below, CMHA’s proposal qualifies for this exemption.

B. Comparable Equipment

The CON rule codified as 10A N.C.A.C. 14C.0303 (the “Regulation”) reads as follows:

10A NCAC 14C.0303 REPLACEMENT EQUIPMENT

- (a) This Rule defines the terms used in the definition of “replacement equipment” set forth in G.S. 131E-176(22a).
- (b) “Currently in use” means that the equipment to be replaced has been used by the person requesting the exemption at least 10 times to provide a health service during the 12 months prior to the date the written notice required by G.S. 131E-184(a) is submitted to the CON Section.
- (c) Replacement equipment is not “comparable” if:
 - (1) the replacement equipment to be acquired is capable of providing a health service that the equipment to be replaced cannot provide; or
 - (2) the equipment to be replaced was acquired less than 12 months prior to the date the written notice required by G.S. 131E-184(a) is submitted to the CON Section and it was refurbished or reconditioned when it was acquired by the person requesting the exemption.

10A N.C.A.C. 14C.0303(c).

CMHA used the Old Bypass Unit at CMC to perform over 30 procedures in FY 2021, thus satisfying Subsection (b). CMHA intends to use the Replacement Bypass Unit for the same health service as the Old Bypass Unit, open heart surgery, thus satisfying Subsection (c)(1). Moreover, the Old Bypass Unit was acquired in 2011, thus satisfying Subsection (c)(2). See Exhibit D. For further equipment comparison points, please refer to Exhibit D (CON Equipment Comparison Chart).

C. Cost of the Replacement Equipment

CMHA will incur \$193,380.56 in total capital costs to acquire and make operational the Replacement Bypass Unit. See Exhibits B and D. As the brochure in Exhibit C illustrates, this Bypass Unit is relatively small, moveable equipment, which does not require “installation” as would a larger piece of equipment (e.g., MRI scanner). Thus, the capital costs associated with the replacement are far less than the \$2 Million threshold in N.C. Gen. Stat. § 131E-176(22a).

D. Disposal of the Old Bypass Unit

CMHA commits to dispose of the Old Bypass Unit and not operate it again in North Carolina. See N.C. Gen. Stat. § 131E-176(22a).

II. Step #2 -- The Material Compliance / No Review Request.

This Material Compliance / No Review Request in Part II asks the Agency to confirm that no CON is required in order for CMHA to relocate the CMHA-owned and operated Replacement Bypass Unit from the CMC Campus to the AH Pineville Campus. As underscored in Part I(C) above, the Replacement Bypass Unit is a relatively small, moveable equipment unit, which does not require “installation” as would a larger piece of equipment. See Exhibits C. Thus, there are no additional relocation costs involved in the relocation from the CMC Campus to the AH Pineville Campus.

Upon relocation, the Replacement Bypass Unit will then be operated as a full-time heart-lung bypass unit at AH Pineville. After the relocation: (a) CMC will have six (6) heart-lung bypass units (five full-time units and one backup unit); and (b) AH Pineville will have three (3) heart-lung bypass units (two full-time units and one backup unit).

There is precedent for the relocation of CON *per se* reviewable equipment from one wholly owned hospital to another wholly owned hospital in the same county (and thus the same service area).

In two September 29, 2017 material compliance and replacement equipment exemption determinations, the Agency approved CMHA to relocate and replace cardiac catheterization equipment from CMHA’s University Campus to its CMC Campus. See Exhibit E.

Relatedly, in an August 5, 2015 determination, the Agency approved Novant Health to relocate and replace cardiac catheterization unit from Novant Health Presbyterian Medical Center (“Presbyterian”) to Novant Health Matthews Medical Center (“Matthews”). See Exhibit 3 to Exhibit E (Ex. E-3, Bates Nos. 17-18). In requesting the relocation, Novant pointed out that both Presbyterian and Matthews were within the Novant Health corporate family and were both located in Mecklenburg County (and thus the same cardiac cath service area). See Ex. E-4, Bates Nos. 19-24. That Agency analysis fits CMHA here even better than it fit Novant in the foregoing scenario. In the Novant situation, Presby and Matthews were owned by two separate Novant Health subsidiaries, but were under Novant Health ownership at the parent level. Here, CMC and AH Pineville are both operating units of CMHA, with both located in Mecklenburg County. Thus, CMC and AH Pineville are operated within the same entity.

Ms. Micheala Mitchell, Chief
Ms. Julie Faenza, Project Analyst
March 16, 2022
Page 5

Thus, as with the requests approved in Exhibit E (and discussed above), CMHA's proposed Bypass Relocation Project here is not CON reviewable.

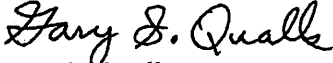
Conclusion

Based on the foregoing information, CMHA asks the Agency to make the following two conclusions:

1. Find that the replacement equipment transaction described in Part I above is exempt from CON review under N.C. Gen. Stat. § 131E-184(a)(7); and
2. Find that relocating the Replacement Bypass Unit from one existing CMHA Mecklenburg County hospital campus to another (not increasing CMHA's Bypass Unit complement) materially complies with the CON for CMC's Old Bypass Unit or is otherwise not reviewable.

We thank you for your consideration of this notice.

Sincerely,


Gary S. Qualls

Ms. Micheala Mitchell, Chief
Ms. Julie Faenza, Project Analyst
March 16, 2022
Page 6

Exhibits

- A. Excerpts from the 1996 SMFP
- B. Cost Quote for Replacement Bypass Unit
- C. Brochure for Replacement Bypass Unit
- D. CON Comparison Form
- E. Material Compliance and Exemption Approvals, Request for Such Approvals, and Exhibits There to for CMHA to Relocate Cardia Cath Equipment from CMHA's CMC Campus to CMHA's University Campus (Bates Nos. 1 – 29)

Exhibit 3



EXHIBIT
3

DEPARTMENT OF HEALTH AND HUMAN SERVICES
DIVISION OF HEALTH SERVICE REGULATION

ROY COOPER
GOVERNOR

MANDY COHEN, MD, MPH
SECRETARY

MARK PAYNE
DIRECTOR

September 29, 2017

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

Material Compliance Approval

Project ID #: F-6384-01
Facility: Carolinas HealthCare System (CHS) University
Project Description: Change site of one unit of cardiac catheterization equipment from CHS University to Carolinas Medical Center (CMC)
County: Mecklenburg
FID #: 923516

Dear Mr. Qualls:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency) has determined that the change proposed in your letter of September 7, 2017 is in material compliance with representations made in the application. This change includes changing the site of one unit of cardiac catheterization equipment from CHS University to CMC where it will be located in Cardiology Room 8. The EP unit located in that room will become a cardiac catheterization unit. Upon completion, CHS University will have zero cardiac catheterization units and CMC will have nine cardiac catheterization units on its license. However, you should contact the Agency's Construction Section to determine if they have any requirements pertinent to the proposed change.

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

Sincerely,

Gloria C. Hale
Gloria C. Hale
Project Analyst

Martha J. Frisone
Martha J. Frisone
Chief, Healthcare Planning and
Certificate of Need Section

cc: Construction Section, DHSR
Acute and Home Care, Licensure and Certification Section, DHSR
Sharetha Blackwell, Program Assistant, 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



**DEPARTMENT OF HEALTH AND HUMAN SERVICES
DIVISION OF HEALTH SERVICE REGULATION**

ROY COOPER
GOVERNOR

MANDY COHEN, MD, MPH
SECRETARY

MARK PAYNE
DIRECTOR

September 29, 2017

**Gary S. Qualls
K&L Gates
430 Davis Drive, Suite 400
Morrisville, North Carolina 27560**

Exempt from Review – Replacement Equipment

**Record #: 2387
Facility Name: Carolinas Medical Center (CMC)
FID #: 949070
Business Name: The Charlotte-Mecklenburg Hospital Authority
Business #: 1770
Project Description: Replace the existing unit of equipment at Carolinas Healthcare System (CHS) University that had been used to provide cardiac catheterization services by having a vendor remove it, rebuild it and install it in Room 1 at CMC to be used to provide EP services.
County: Mecklenburg**

Dear Mr. Qualls:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency), determined that based on your letter of September 7, 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 replace the existing unit of equipment at CHS University that had been used to provide cardiac catheterization services by having a vendor remove it, rebuild it and install it in Room 1 at CMC to be used to provide EP services. Please see the Agency's Material Compliance Approval letter dated September 29, 2017 regarding the change of site of one unit of cardiac catheterization equipment from CHS University to CMC.

Moreover, you need to contact the Agency's Construction and Acute and Home Care Licensure and Certification Sections 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

**HEALTHCARE PLANNING AND CERTIFICATE OF NEED SECTION
WWW.NCDHHS.GOV
TELEPHONE 919-855-3873**

**LOCATION: EDGERTON BUILDING • 809 RUGGLES DRIVE • RALEIGH, NC 27603
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Mr. Gary Qualls
September 29, 2017
Page 2

separate determination. If you have any questions concerning this matter, please feel free to contact this office.

Sincerely,

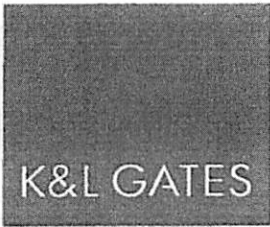
Gloria C. Hale

Gloria C. Hale
Project Analyst

Martha J. Frisone

Martha J. Frisone
Chief, Healthcare Planning and
Certificate of Need

cc: Construction Section, DHR
Acute and Home Care Licensure and Certification Section, DHR
Sharetta Blackwell, Program Assistant, Healthcare Planning, DHR



September 7, 2017



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

Via Hand Delivery

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



Dear Martha:

The Charlotte-Mecklenburg Hospital Authority (“CMHA”) d/b/a Carolinas Medical Center (“CMC”) and d/b/a CHS University seeks the two rulings described below. The Material Compliance Request in Part I merely asks to assign the Cardiac Catheterization (“Cardiac Cath”) CON Rights from one existing CMHA Equipment Unit to another (not increasing CMHA’s Cardiac Cath Unit complement). The Exemption Notice in Part II then describes how CMHA will take one of its existing electrophysiology (“EP”) Equipment Units and physically replace it with another existing, comparable CMHA EP Equipment Unit. A summary of each step is described immediately below. A more detailed description of each step is provided in Parts I and II below.

Summary of Step #1

1. CMHA seeks a material compliance determination to relocate the Cardiac Catheterization Equipment Unit CON Rights CMHA currently has for the University Campus Cardiac Cath Unit to an existing EP Unit currently housed in Cardiology Room 8 (“Room 8”) at CMC. That existing EP Unit in CMC Room 8 will become CMHA’s New Cardiac Cath Unit to supplant the old University Campus Cardiac Cath Unit. This will effectively be the substitution of the Cardiac Cath CON rights from one of CMHA’s current equipment units to another of CMHA’s current equipment units. This is couched as a material compliance request instead of a replacement equipment exemption because the equipment to be used as Cardiac Cath Equipment in CMC Room 8 is not being “purchased.” See N.C. Gen. Stat. 131E-176(22a).

Summary of Step #2

2. In Step #2, CMHA seeks a replacement equipment exemption to replace the Old University Campus Cardiac Cath Unit (which -- after Step #1 -- will no longer be a Cardiac Cath Unit with Cardiac Cath CON Rights) and replace it with an EP Unit at CMC in Cardiology Room 1 ("Room 1") for under \$2 Million (CMC Room 1 currently houses no medical equipment).

I. Step #1 -- The Material Compliance Request.

As described above, CMHA first seeks a material compliance determination to relocate the Cardiac Cath CON Rights currently assigned to the University Campus Cardiac Cath Unit to an existing EP Unit in CMC Room 8. That existing EP Unit in CMC Room 8 will become CMHA's New Cardiac Cath Unit to supplant the old University Campus Cardiac Cath Unit.¹ Since CMHA already owns the EP Unit in CMC Room 8 (to which the Cardiac Cath CON Rights are being assigned), this is a substitution of CON rights as opposed to a replacement equipment exemption. The equipment to be used as Cardiac Cath Equipment in CMC Room 8 is not being purchased, and thus does not trigger the replacement equipment definition under N.C. Gen. Stat. 131E-176(22a).

We have included floor plans showing the following:

- Exhibits 1A and 1B show macro and micro views of where the University Campus Cardiac Cath Unit is situated.
- Exhibits 2A, 2B, and 2C show macro and micro views of CMC Room 8, which will now house CMHA's New Cardiac Cath Unit.

There is precedent for the relocation of Cardiac Cath Equipment and associated CON Rights from one wholly owned hospital to another wholly owned hospital in the same county (and thus the same Cardiac Cath Service Area). In an August 5, 2015 material compliance determination, the Agency approved Novant Health to relocate and replace a Cardiac Cath Unit from Novant Health Presbyterian Medical Center ("Presbyterian") to Novant Health Matthews Medical Center ("Matthews"). See Exhibit 3.

¹ This New Cardiac Cath Unit will be the 8th Cardiac Cath Unit on the CMC Campus and will be the 9th Cardiac Cath Unit under CMC's license (given that one Cardiac Cath Unit on the CMC license is housed on the Mercy Campus). After this transaction is effectuated, the University Campus will no longer house any Cardiac Cath Units.

Martha J. Frisone, Chief
September 7, 2017
Page 3

In requesting the relocation, Novant pointed out that both Presbyterian and Matthews were within the Novant Health corporate family and were both located in Mecklenburg County (and thus the same Cardiac Cath Service Area). See Exhibit 4.

That analysis fits CMHA here even better than it fit Novant in the foregoing scenario. In the Novant situation, Presby and Matthews were owned by two separate Novant Health subsidiaries, but were under Novant Health ownership at the parent level. Here, CMC and CHS University are both operating units of CMHA and are both located in Mecklenburg County. Thus, CMC and CHS University are operated within the same entity.

Thus, neither the substitution component nor the relocation component of this material compliance project is CON reviewable.

II. Step #2 – The Replacement Equipment Exemption.

As also described above, CMHA next seeks (in Step #2) a replacement equipment exemption to replace the physical piece of equipment that was formerly used as the University Campus Cardiac Cath Unit (the “Old University Cath Unit” or the “Existing Equipment”). CMHA will replace the Existing Equipment with an EP Unit at CMC in Room 1 for under \$2 Million (CMC Room 1 currently houses no medical equipment).

After Step #1 above, the Old University Cath Unit loses its status as “Cardiac Catheterization Equipment” under N.C. Gen. Stat. 131E-176(2f) and thus no longer has CON Rights to perform “Cardiac Catheterization Services under N.C. Gen. Stat. 131E-176(2g). Thus, after Step #1, the Old University Cath Unit will be stripped of its Cardiac Cath CON Rights and will now be comparable to the New EP Equipment in CMC Room 1 because the remaining capabilities of the Old University Cath Unit are now limited to EP (and other angiographic capabilities) as opposed to Cardiac Cath Services capabilities pursuant to Cardiac Cath CON Rights. Exhibits 5A and 5B show macro and micro views, respectively, of CMC Room 1, which will now house CMHA’s Replacement EP Unit.

A. Section 184(a)(7) Exemption

The General Assembly has chosen to exempt certain, otherwise reviewable events from CON review. Among those exemptions is the acquisition of "replacement equipment," as provided in N.C. Gen. Stat. § 131E-184(a)(7), set forth below:

- (a) Except as provided in subsection (b), the Department shall exempt from certificate of need review a new institutional health service if it receives prior written notice from the entity proposing the new institutional health service, which notice includes an explanation of why the new institutional health service is required, for any of the following:

* * *

- (7) To provide replacement equipment.

The CON Law then defines "replacement equipment," as follows:

"Replacement equipment" means equipment that costs less than two million dollars (\$2,000,000) and is purchased for the sole purpose of replacing comparable medical equipment currently in use which will be sold or otherwise disposed of when replaced.

See N.C. Gen. Stat. § 131E-176(22a).

Therefore, to qualify for this exemption, the replacement equipment must cost less than \$2 Million and be "comparable" to the equipment it replaces and must be "sold or otherwise disposed of when replaced." As described below, CMHA's proposal qualifies for this exemption.

B. Comparable Equipment

The CON rule codified as 10A N.C.A.C. 14C.0303 (the "Regulation") defines "comparable medical equipment" in Subsection (c) as follows:

"Comparable medical equipment" means equipment which is functionally similar and which is used for the same diagnostic or treatment purposes.

10A N.C.A.C. 14C.0303(c).

Martha J. Frisone, Chief
September 7, 2017
Page 5

CMHA intends to use the Replacement Equipment for substantially the same types of treatments for which the Existing Equipment will be capable after Step #1 is consummated. As described above, after Step #1, the Old University Cath Unit will be comparable to the New EP Equipment in CMC Room 1 because the remaining capabilities of the Old University Cath Unit are now limited to EP (and other angiographic capabilities) as opposed to Cardiac Cath Services capabilities pursuant to Cardiac Cath CON Rights. The Replacement Equipment is therefore "comparable medical equipment" as defined in Subsection (c) of the Regulation.

Furthermore, CMHA does not intend to increase patient charges or per procedure operating expenses within the first 12 months after its acquisition. For further equipment comparison, please refer to Exhibit 9, the Equipment Comparison Chart.

Subsection (d) of the Regulation further provides that the Replacement Equipment is comparable to the Existing Equipment if:

- (1) the Replacement Equipment has the same technology as the Existing Equipment, although it may possess expanded capabilities due to technological improvements;
- (2) the Replacement Equipment is functionally similar and is used for the same diagnostic or treatment purposes as the Existing Equipment and is not used to provide a new health service; and
- (3) acquisition of the Replacement Equipment does 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.

10A N.C.A.C. 14C.0303(d).

The Replacement Equipment will meet all three of the tests set out in Subsection (d). The Replacement Equipment satisfies the technology and functionality tests in Subsection (1) and (2) as discussed above and identified in the Comparison Chart. See Exhibit 9. Moreover, CMHA represents that use of the Replacement Equipment will not result in the types of expense or charge increase described in Subsection (d)(3).

Martha J. Frisone, Chief
September 7, 2017
Page 6

C. Cost of the Replacement Equipment

The total costs are \$1,962,116.59 to acquire, install, and make operational the Replacement EP Unit (the "Replacement Equipment") and all items to be placed in CMC Room #1. The line item component costs are set forth in Exhibit 6 (Proposed Total Capital Cost Sheet). The Quote for the Replacement Equipment by itself is attached as Exhibit 7. The Quotes for other equipment items to be placed in Room #1 are included in Exhibit 8.

Thus, the costs are less than the \$2 Million threshold in N.C. Gen. Stat. § 131E-176(22a), even if one counts all items to be placed in CMC Room #1 and the related construction costs.

D. Equipment Being Replaced is Currently in Use

The Existing Equipment is currently in use at CHS University, identified as the University Campus Cardiac Cath Unit described in detail in Part I above.

CONCLUSION

Based on the foregoing information, CMHA asks the Agency to make the following two rulings:

1. Find that assigning the Cardiac Cath CON Rights from one existing CMHA Equipment Unit to another (not increasing CMHA's Cardiac Cath Unit complement) materially complies with the CON for the CHS University Cardiac Cath Unit.
2. Find that the replacement equipment transaction described in Part II above is exempt from CON review under N.C. Gen. Stat. § 131E-184(a)(7).

We thank you for your consideration of this notice.

Sincerely,


Gary S. Qualls

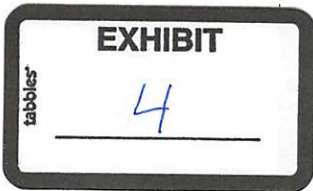
Exhibits

- 1A. Macro view of University Campus Cardiac Cath Unit
- 1B. Micro view of University Campus Cardiac Cath Unit
- 2A. Macro view of CMC Room 8, which will now house CMHA's New Cardiac Cath Unit.
- 2B. Micro view of CMC Room 8, which will now house CMHA's New Cardiac Cath Unit.
- 2C. Enlarged micro view of CMC Room 8, which will now house CMHA's New Cardiac Cath Unit.
3. August 5, 2015 Material Compliance Letter approving Novant Health to relocate and replace a Cardiac Cath Unit from Novant Health Presbyterian Medical Center to Novant Health Matthews Medical Center.
4. July 16, 2015 Request by Novant Health to relocate and replace a Cardiac Cath Unit from Novant Health Presbyterian Medical Center to Novant Health Matthews Medical Center.
- 5A. Macro views of CMC Room 1, which will now house CMHA's Replacement EP Unit.
- 5B. Micro views of CMC Room 1, which will now house CMHA's Replacement EP Unit.
6. Proposed Total Capital Cost Sheet for CMC Room 1
- 7A. EP Replacement Equipment Quote
- 7B. EP Replacement Equipment Brochure
- 7C. EP Replacement Equipment Brochure

Martha J. Frisone, Chief
September 7, 2017
Page 8

- 8. Other Equipment Quotes for Items to be placed in CMC Room 1**
 - 8A. Omnicell Items**
 - 8B. Accriva Item**
 - 8C. Surgical Light**
 - 8D. Stryker Items**
- 9. Equipment Comparison Chart**

Exhibit 4



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

Pat McCrory
Governor

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

Drexdal Pratt
Division Director

August 5, 2015

Barbara L. Freedy
Certificate of Need
Novant Health, Inc.
2085 Frontis Plaza Drive
Winston-Salem, North Carolina 27103

Material Compliance Approval

Project ID #: F-001810-83
Facility: Novant Health Presbyterian Medical Center (NHPMC)
Project Description: Locate replacement cardiac catheterization equipment at Novant Health Matthews Medical Center (NHMMC)
County: Mecklenburg
FID #: 943501

Dear Ms. Freedy:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency) has determined that the change proposed in your letter of July 9, 2015 is in material compliance with representations made in the application. This change includes relocating a cardiac catheterization lab from NHPMC's cardiac catheterization lab #1 to NHMMC. Both facilities are in the Mecklenburg County service area. However, you should contact the Agency's Construction Section to determine if they have any requirements pertinent to the proposed change.

It should be noted that the Agency's position is based solely on the facts represented by you, including supplemental information provided to the Agency in an additional letter, dated July 9, 2015, regarding NHMMC's ability to safely perform interventional cardiac catheterization procedures, 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. Please refer to the Project ID # and Facility ID # (FID) in all correspondence.



Healthcare Planning and Certificate of Need Section
www.ncdhhs.gov

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Mailing Address: 2704 Mail Service Center • Raleigh, NC 27699-2704
An Equal Opportunity/ Affirmative Action Employer



Barbara L. Freedy
August 5, 2015
Page 2

Sincerely,

Gloria C. Hale

Gloria C. Hale
Project Analyst

Martha J. Frisone

Martha J. Frisone,
Assistant Chief, Certificate of Need

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

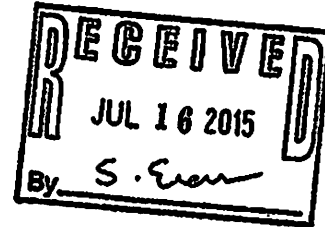


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 denise.gunter@nelsonmullins.com



July 16, 2015



Hand Delivered

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

Re: **No Review Request for Novant Health, Inc., The Presbyterian Hospital d/b/a Novant Health Presbyterian Medical Center and Presbyterian Medical Care Corp. d/b/a Novant Health Matthews Medical Center Mecklenburg County Health Service Area III**

Dear Ms. Frisone:

On behalf Novant Health, Inc. ("Novant"), The Presbyterian Hospital d/b/a Novant Health Presbyterian Medical Center ("NHPMC") and Presbyterian Medical Care Corp. d/b/a Novant Health Matthews Medical Center ("NHMMC"), I am writing to request written confirmation that the CON Law does not apply to the following transaction (the "Transaction").

Factual Background

Novant is a nonprofit health care system that owns fourteen hospitals. Two of these hospitals are NHPMC and NHMMC. NHPMC and NHMMC are acute care hospitals located in Mecklenburg County, North Carolina. NHPMC and NHMMC are wholly-owned subsidiaries of Novant Health Southern Piedmont Region, LLC, a member-managed limited liability company whose sole member is Novant. See Exhibit A. Novant is therefore the ultimate parent entity of both NHPMC and NHMMC. NHPMC and NHMMC are affiliates within the Novant corporate family. See Exhibit B, 2014 audited financials for Novant, p. 6, note 1.

Ex were disposed of

Martha J. Frisone
July 16, 2015
Page 2

NHPMC owns four units of fixed cardiac catheterization equipment. NHMMC presently provides both diagnostic and interventional cardiac catheterization services using equipment owned by a third party. See Tables 9S, 9V and 9W of the 2015 SMFP, attached hereto as Exhibit C.

The Transaction

The contract with the third party ends in December 2015. Rather than continue to incur the cost of the contract, NHPMC proposes to move one of its four existing and operational cardiac catheterization units ("Cath Lab #1") to NHMMC. In separate correspondence to the CON Section, NHPMC and NHMMC request that the CON Section determine that the replacement of Cath Lab #1 qualifies for the replacement equipment exemption under N.C. Gen. Stat. § 131E-184(a)(7) (the "Replacement Cath Lab"). NHMMC has also submitted separate correspondence to the CON Section demonstrating that NHMMC can safely perform interventional cardiac catheterization procedures without open heart surgery services on site.¹ If the Transaction is approved, the Replacement Cath Lab would then be reported on NHMMC's annual Hospital License Renewal Application.

Analysis

The CON Law applies to "new institutional health services." N.C. Gen. Stat. § 131E-178(a). N.C. Gen. Stat. § 131-176(16)f1. defines "new institutional health service" to include "the acquisition by purchase, donation, lease, transfer, or comparable arrangement" of certain types of medical equipment, including cardiac catheterization equipment. See N.C. Gen. Stat. § 131E-176(16)f1.3. For the reasons set forth below, this provision of the CON Law should not apply to the Transaction.

The Transaction involves a move between and among entities that are entirely within the Novant corporate family. Novant ultimately controls both NHPMC and NHMMC. No one outside of Novant is acquiring anything in this Transaction. Ultimately, all assets at NHPMC (including Cath Lab #1) and NHMMC are owned by Novant. As has been demonstrated through dozens of CONs applications filed throughout the years, the financials for these hospitals and all other Novant-controlled facilities are consolidated, and only one set of audited financials is produced for the entire Novant family, including NHPMC and NHMMC. See, e.g., Exhibit B, which are Novant's 2014 audited financials. As stated on page 6, note 2 of the 2014 audited financials: "[t]he consolidated financial statements include the accounts of all affiliates controlled by Novant Health." These affiliates include NHPMC and NHMMC. See *id.*, note 1. Further, when Novant issues bonds through the North Carolina Medical Care Commission, the proceeds are used to pay for projects at various

¹ These additional letters are incorporated by reference in this letter.

Martha J. Frisone
July 16, 2015
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Novant-owned facilities, including NHPMC and NHMMC. Regarding bonds issued in 2013, page 32 of the 2014 audited financials reports:

[t]he remaining proceeds [of the 2013 issue] were used to finance and reimburse Novant Health for expenditures primarily related to the construction of the following. . . . the vertical expansion of Novant Health Matthews Medical Center; . . . and the G-wing renovation at Novant Health Presbyterian Medical Center.

Exhibit B, p. 32

There will be no increase in the inventory of cardiac catheterization equipment in Mecklenburg County beyond those units which have already been approved. No new health service facilities or services are being added beyond those already approved. Rather, the Transaction should be regarded merely as a reorganization similar to those which the CON Section and the Department have previously determined are not subject to CON review.

For example, in 2011, CSA Medical Services, LLC ("CSA") proposed to transfer its interest in eight existing heart lung bypass machines to two wholly-owned subsidiary limited liability companies, CSAMS New Bern Avenue, LLC and CSAMS Lake Boone Trail, LLC. See Exhibit D. Five of the machines were located at WakeMed, and three of the machines were located at Rex.

In its no review request, CSA pointed out that 10A NCAC 14C.0502(b) allows for the transfer of *undeveloped* CONs in cases of corporate reorganizations. See Exhibit D, page 4. CSA further stated that ". . . [i]f the CON law permits the transfer of a CON for an undeveloped project to a subsidiary of the applicant without a new CON or other sanction, then it would make no sense to interpret the law to prevent an existing provider from transferring a service to a wholly-owned subsidiary after the project has been developed." *Id.* CSA also relied upon N.C. Gen. Stat. § 131E-189(c):

[m]oreover, N.C. Gen. Stat. § 131E-189(c) acknowledges that completed projects may be transferred without CON review. It states that '[a]ny transfer after [the project is completed or becomes operational] will be subject to the requirement that the service be provided consistent with the representations made in the application and any applicable conditions.' That statute does not require that a CON first be acquired before such a transfer takes place. Clearly, the reorganization of CSA's assets and CON exemption into two wholly owned subsidiaries would not constitute the 'offering or development of a new institutional

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health service' within the definition of N.C. Gen. Stat. § 131E-178(a).

Id., p. 4. The CON Section determined that the CON Law did not govern CSA's proposal. See Exhibit E.²

The CSA decision applies here. Cath Lab #1 is an existing and operational cath lab. While NHMMC is not a subsidiary of NHPMC, these two hospitals are corporate affiliates within the Novant corporate family, and are subsidiaries of the same entity (Novant Health Southern Piedmont Region) which is in turn wholly owed by Novant. Ultimately, Novant owns and controls Cath Lab #1, and that will not change as a result of this Transaction. It would not serve the purposes of the CON Law to require regulatory review of an existing cath lab that is being moved from one corporate affiliate to another in Mecklenburg County. Further, both diagnostic and interventional cardiac catheterization services have been provided for years at NHMMC; thus, the need for the service has already been established. It would not make sense for NHMMC to have to reprove the need for a service it already offers.

The CSA no review also included the 2011 Radiation Oncology Centers of the Carolinas, Inc. ("ROCC") declaratory ruling (included in Exhibit D), which permitted ROCC to transfer its interests in two radiation oncology facilities owning linear accelerators to two wholly-owned subsidiaries of ROCC. In a more recent, analogous declaratory ruling, the Department permitted Caldwell Memorial Hospital, a subsidiary of UNC Health Care, to "redesignate" its cancer center space, including a linear accelerator, to unlicensed space of its sister hospital, UNC Hospitals. See Exhibit G, a March 12, 2015 declaratory ruling issued to UNC Healthcare System, UNC Hospitals and Caldwell Memorial. In the UNC/Caldwell declaratory ruling, the Department stated:

Nor does the Redesignation of the Cancer Center Space trigger any of the 'acquisition-related' new institutional health service definitions in N.C. Gen. Stat. § 131E-176(16). The Cancer Center Space, the Radiation Oncology Equipment, and the Medical Oncology Equipment are not being acquired, because no legal entity outside of the UNC Health Care controlled affiliates is acquiring anything. Rather, this Redesignation is purely an intra-organizational Redesignation within UNC Health Care controlled affiliates. See 10A NCAC 14C.0502.

² Subsequently, Rex was permitted to acquire the membership interests in CSAMS Lake Boone Trail, and WakeMed was permitted to acquire the membership interests in CSAMS New Bern Avenue. See Exhibit F. No third party outside the Novant corporate family is involved in the Transaction.

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This Redesignation does not involve the offering or expansion of any new facility, service or equipment, and the inventory of linear accelerators and CT scanners in Caldwell County and the State overall will not change. No new radiation oncology equipment or services will be placed in operation in Caldwell County or the State as a result of this Project.

Exhibit G, p. 7.

The UNC/Caldwell ruling applies here. No legal entity outside of Novant will be acquiring anything in the Transaction. The Transaction is purely intra-organizational. The Transaction does not involve the offering or expansion of any new facility, service or equipment, and neither the inventory of cardiac catheterization labs in Mecklenburg County nor the State overall will change as a result of the Transaction. No new cardiac catheterization equipment or services will be placed in operation in Mecklenburg County or the State as a result of this Transaction.³

As the UNC/Caldwell ruling aptly recognized,

[i]t is a well-established principle of statutory construction that the intent of the Legislature controls the interpretation of the statute. *See State v. Fulcher*, 294 N.C. 503, 520, 2432 S.E.2d 338, 350 (1978). Prohibiting this simple intra-organizational Redesignation of existing services would not advance the goal of avoiding costly duplication because the Radiation Oncology Equipment and the Cancer Center Space already exist and are used to provide the same services they will provide after the Redesignation. Construing the statute otherwise would lead to absurd results that the General Assembly could not have intended. *King v. Baldwin*, 276 N.C. 316, 325, 172 S.E.2d 12, 18 (1970)('It is presumed that the legislature acted in accordance with reason and common sense and that it did not intend an unjust or absurd result.').

Exhibit G, p. 7.

³ As discussed in separate correspondence filed with the CON Section, NHMMC intends to replace the nineteen-year old Cath Lab #1 with the Replacement Cath Lab. The proposed replacement, which is exempt under N.C. Gen. Stat. § 131E-184(a)(7), does not increase the inventory of cath labs in Mecklenburg County or the State overall.

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The same is true here. The Transaction is not the sort of acquisition the CON Law seeks to regulate. Cath Lab #1 is existing equipment owned by a common parent. It will be used to provide the same services at NHMMC that it provides at NHPMC. Under these circumstances, the Transaction should not be deemed subject to CON review under N.C. Gen. Stat. § 131E-176(16)f1.3. *See also Cape Fear Memorial Hospital v. N.C. Dep't of Human Resources*, 121 N.C. App. 492, 494, 466 S.E.2d 299, 301 (1996) (holding that the legislature clearly did not intend to impose unreasonable limitations on maintaining, or expanding, presently offered health services).

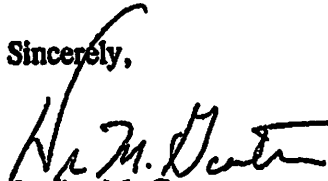
Similarly, the Transaction does not implicate N.C. Gen. Stat. § 131E-176(16)b., requiring CON review for a capital expenditure greater than \$2 million "to develop or expand a health service or a health service facility, or which relates to the provision of a health service." As discussed in the companion Replacement Equipment Exemption Request, the total cost to replace Cath Lab #1, including disposal of Cath Lab #1, is \$922,524.

Finally, the relocation of Cath Lab #1 from Charlotte to Matthews is not reviewable under the CON Law. Both hospitals are in Mecklenburg County. They are approximately 11 miles and 16 minutes apart from each other. *See Exhibit H*, a Mapquest map. The Department has previously approved relocations of equipment within Mecklenburg County that involved similar or greater distances. *See, e.g., Exhibit I* (November 13, 2006 ruling allowing Presbyterian to transfer an MRI scanner from Charlotte to Huntersville, a distance of approximately 15.44 miles); *Exhibit J* (March 3, 2008 ruling allowing Carolinas Imaging Services, LLC to relocate an MRI scanner from Huntersville to the Ballantyne area of Charlotte, a distance of approximately 31 miles); and *Exhibit K* (February 7, 2014 ruling allowing Presbyterian to change the location of an undeveloped linear accelerator from Matthews to Huntersville, a distance of approximately 25 miles).

Accordingly, Novant, NHPMC and NHMMC respectfully request that the CON Section determine that the Transaction described in this letter does not require CON review.

Thank you for your time and consideration.

Sincerely,


Denise M. Gunter

Enclosures

From: [Mitchell, Micheala L](#)
To: [Stancil, Tiffany C](#)
Subject: FW: [External] No Review for UNCH
Date: Tuesday, October 8, 2024 5:09:24 PM
Attachments: [10082024_K&L_GATES_001.pdf](#)

Tiffany would you mind logging this no review and assigning to Cindy?

Thanks,

Micheala

Micheala Mitchell, JD
[NC Department of Health and Human Services](#)
[Division of Health Service Regulation](#)
Section Chief, Healthcare Planning and CON Section
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2704 Mail Service Center
Raleigh, NC 27699-2704
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Micheala.Mitchell@dhhs.nc.gov

From: Qualls, Gary <Gary.Qualls@klgates.com>
Sent: Tuesday, October 8, 2024 5:01 PM
To: Mitchell, Micheala L <Micheala.Mitchell@dhhs.nc.gov>
Subject: [External] No Review for UNCH

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.

Micheala:

Attached is a No Review Request for filing on behalf of UNC Hospitals. Please confirm receipt for my records.

Thanks

Gary



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