



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

Pat McCrory
Governor

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

Drexdal Pratt
Division Director

March 11, 2014

Gary Qualls
Post Office Box 14210
Research Triangle Park, NC 27709

No Review

Business: The Charlotte-Mecklenburg Hospital Authority (CMHA)
Project Description: Redesignation of a Medical Oncology Provider-Based Outpatient
Department of CMC-NorthEast and CMHA-Owned Physician Office
space to a Provider-Based Outpatient Department of CMC in Charlotte
County: Cabarrus

Dear Mr. Qualls:

The Certificate of Need Section (CON Section) received your letter(s) of February 28, 2014 regarding the above referenced proposal. Based on the CON law **in effect on the date of this response to your request**, the proposal described in your correspondence is not governed by, and therefore, does not currently require a certificate of need. However, please note that if the CON law is subsequently amended such that the above referenced proposal would require a certificate of need, this determination does not authorize you to proceed to develop the above referenced proposal when the new law becomes effective.

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

It should be noted that this determination is binding only for the facts represented by you. Consequently, if changes are made in the project or in the facts provided in your correspondence referenced above, a new determination as to whether a certificate of need is required would need to be made by the Certificate of Need Section. Changes in a project include, but are not limited to: (1) increases in the capital cost; (2) acquisition of medical equipment not included in the original cost estimate; (3) modifications in the design of the project; (4) change in location; and (5) any increase in the number of square feet to be constructed.



Certificate of Need Section

www.ncdhhs.gov

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

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

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

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Gary Qualls
March 11, 2014
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Please contact the CON Section if you have any questions. Also, in all future correspondence you should reference the Facility I.D. # (FID) if the facility is licensed.

Sincerely,


Fatimah Wilson, Project Analyst



Martha J. Frisone, Interim Chief
Certificate of Need Section

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

Journal

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

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Morrisville, NC 27560

T 919.466.1190 www.klgates.com

Received by
the CON Section
FEB 28 2014

February 28, 2014

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

Via Hand Delivery

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

Re: No Review Letter Regarding Redesignation of Medical Oncology Provider-Based Outpatient Department of CMC-NorthEast and CMHA-Owned Physician Office Space to a Provider-Based Outpatient Department of CMC in Charlotte

Dear Ms. Frisone:

Our client, The Charlotte-Mecklenburg Hospital Authority (“CMHA”), is requesting a “No Review” determination that the North Carolina Certificate of Need (“CON”) law does not require CON review of already developed and operational provider-based medical oncology and physician office space being redesignated in status as follows:

1. The space being redesignated has historically been operated as the following two distinct spaces:
 - a. One space has been operated as a provider-based location of Carolinas Medical Center-NorthEast (“CMC-NorthEast”) on the CMC-NorthEast Campus; and
 - b. The other space has been operated as freestanding, CMHA-owned physician office space on the CMC-NorthEast Campus.
2. The space described above (collectively the “Medical Oncology Space”) is being redesignated to an unlicensed provider-based location of Carolinas Medical Center (“CMC”) in Charlotte, yet physically remaining on the CMC-NorthEast Campus.

Ms. Martha Frisone
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CMHA is a North Carolina hospital authority. CMHA owns and operates several hospitals. Among those hospitals, CMHA operates CMC, a hospital in Charlotte, Mecklenburg County and CMC-NorthEast, a hospital in Concord, Cabarrus County. Both CMC and CMC-NorthEast are directly under the organizational umbrella of CMHA, as operating divisions of CMHA. Neither is a separate legal entity.

In 2005, CMC-NorthEast received a CON to develop and operate medical oncology services in a building (the "Oncology Building") on the CMC-NorthEast campus. See CON attached as Exhibit 1. That CON authorized approximately \$13 Million in capital expenditures. For many years, that Oncology Building has been operated partially as a provider-based part of CMC-NorthEast's licensed hospital and partially as CMHA-owned physician office space. There is 26,124 square feet of space on the first floor of the Oncology Building which houses the Medical Oncology Space, located at 100 Medical Park Drive, Suite 110, Concord, North Carolina. See Floor Plan for Medical Oncology Space highlighted on attached Exhibit 2.

CMHA is shifting the designation of that Medical Oncology Space from a provider-based licensed location of CMC-NorthEast and freestanding physician office space to a provider-based, unlicensed location of CMC (the "Redesignation"). No assets are physically moving as a result of the Redesignation.

The Medical Oncology Space will be provider-based to CMC, and is permitted to be operated as an unlicensed outpatient location under the Business Occupancy Exception, in accordance with N.C. Gen. Stat. § 131E-76(3).¹ Because outpatient Business Occupancy

¹ That statute defines "hospital" as follows for licensure purposes:

"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 private mental facilities licensed under Article 2 of Chapter 122C of the General Statutes, nursing homes licensed under G.S. 131E-102, adult care homes licensed under Part 1 of Article 1 of Chapter 131D of the General Statutes, and 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**

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

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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 Medical Oncology Space (in Cabarrus County) can operate as a non-licensed, provider-based outpatient department of CMC (in Mecklenburg County).

The Redesignation does not trigger any of the definitions of a “new institutional health service,” which would implicate CON review. N.C. Gen. Stat. § 131E-178 provides that 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).

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

. . . [T]he 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

See N.C. Gen. Stat. § 131E-176(16)(b).

However, the Redesignation does not constitute a “new institutional health service” under N.C. Gen. Stat. § 131E-176(16)(b) because no capital expenditures are being incurred as part of this Redesignation. Those expenditures were incurred years ago as the Oncology Building (and the Medical Oncology Space therein) was being developed. Moreover, this is purely an intra-organizational Redesignation within CMHA. No legal entity is acquiring anything from any other legal entity.

Moreover, none of the equipment in the Medical Oncology Space is either “major medical equipment” under N.C. Gen. Stat. § 131E-176(14o) or *per se* reviewable pursuant to N.C. Gen. Stat. § 131E-176(16)(f1). However, even if it were, the Medical Oncology Space (and any equipment therein) is not being acquired because no legal entity is acquiring anything from any other legal entity in this Redesignation as this is purely an intra-organizational Redesignation within CMHA.

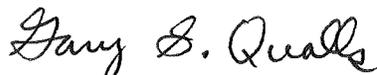
Ms. Martha Frisone
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Finally, the Redesignation does not constitute the establishment of a new health service facility under N.C. Gen. Stat. § 131E-176(16)(a) because the existing space is simply transitioning from CMHA-owned physician office space and outpatient space at one existing hospital to outpatient space at another existing hospital. Because no beds are involved, the Redesignation does not constitute a “change in bed capacity” under N.C. Gen. Stat. § 131E-176(16)(c). Because no operating rooms are involved, the Redesignation does not implicate N.C. Gen. Stat. § 131E-176(16)(u). Nor does the Redesignation constitute a “new institutional health service” under any other CON trigger in N.C. Gen. Stat. § 131E-176(16).

Accordingly, the Redesignation does not require CMHA to obtain a CON pursuant to any provision of the CON statutes. Thus, based upon the foregoing information and the attached documents, CMHA hereby requests that the Agency provide a written response confirming that the Redesignation described herein does not require a CON.

Please let us know if you need additional information. We thank you for your consideration of this submission.

Sincerely,



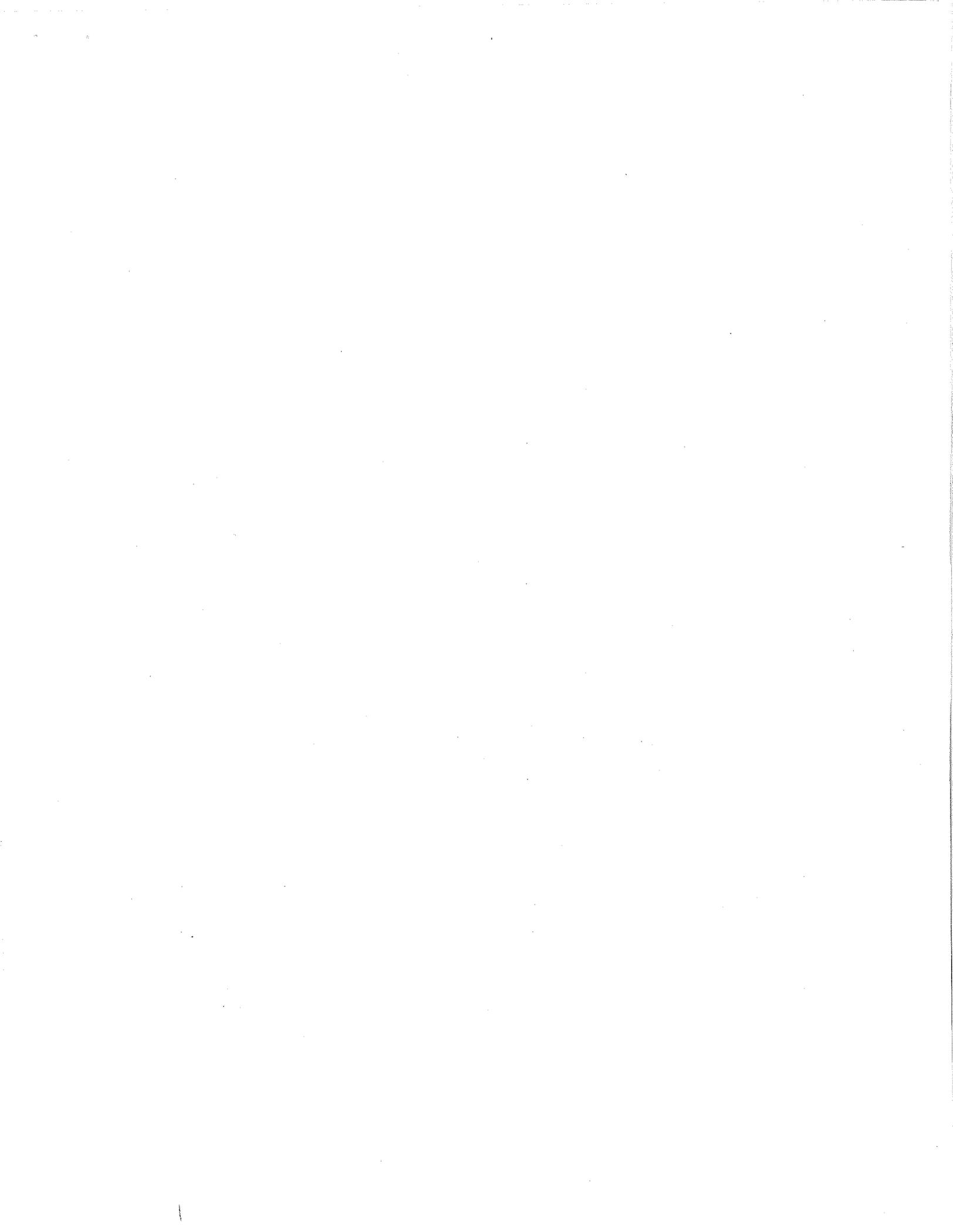
Gary S. Qualls

Enclosures

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Exhibits

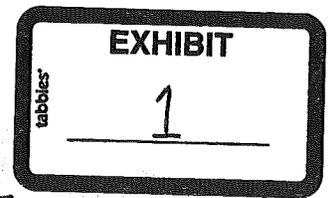
1. CON for Oncology Building
2. Floor Plan for Medical Oncology Space



STATE OF NORTH CAROLINA

Department of Health and Human Services

Division of Facility Services



CERTIFICATE OF NEED

for

**Project Identification Number F-7136-04
FID#943049**

**ISSUED TO: Cabarrus Memorial Hospital
d/b/a NorthEast Medical Center
920 Church Street
Concord, NC 28027**

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

SCOPE: NorthEast Medical Center shall expand its Cancer Center to include increased outpatient medical oncology space, pharmacy space, support space and medical office space/ Cabarrus County

CONDITIONS: See Reverse Side

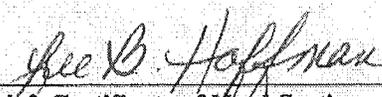
**PHYSICAL LOCATION: NorthEast Medical Center
920 Church Street
Concord, NC 28027**

MAXIMUM CAPITAL EXPENDITURE: \$12,953,429

TIMETABLE: See Reverse Side

FIRST PROGRESS REPORT DUE: July 1, 2005

This certificate is effective as of the 19th day of March, 2005.



Chief, Certificate of Need Section
Division of Facility Services

CONDITIONS

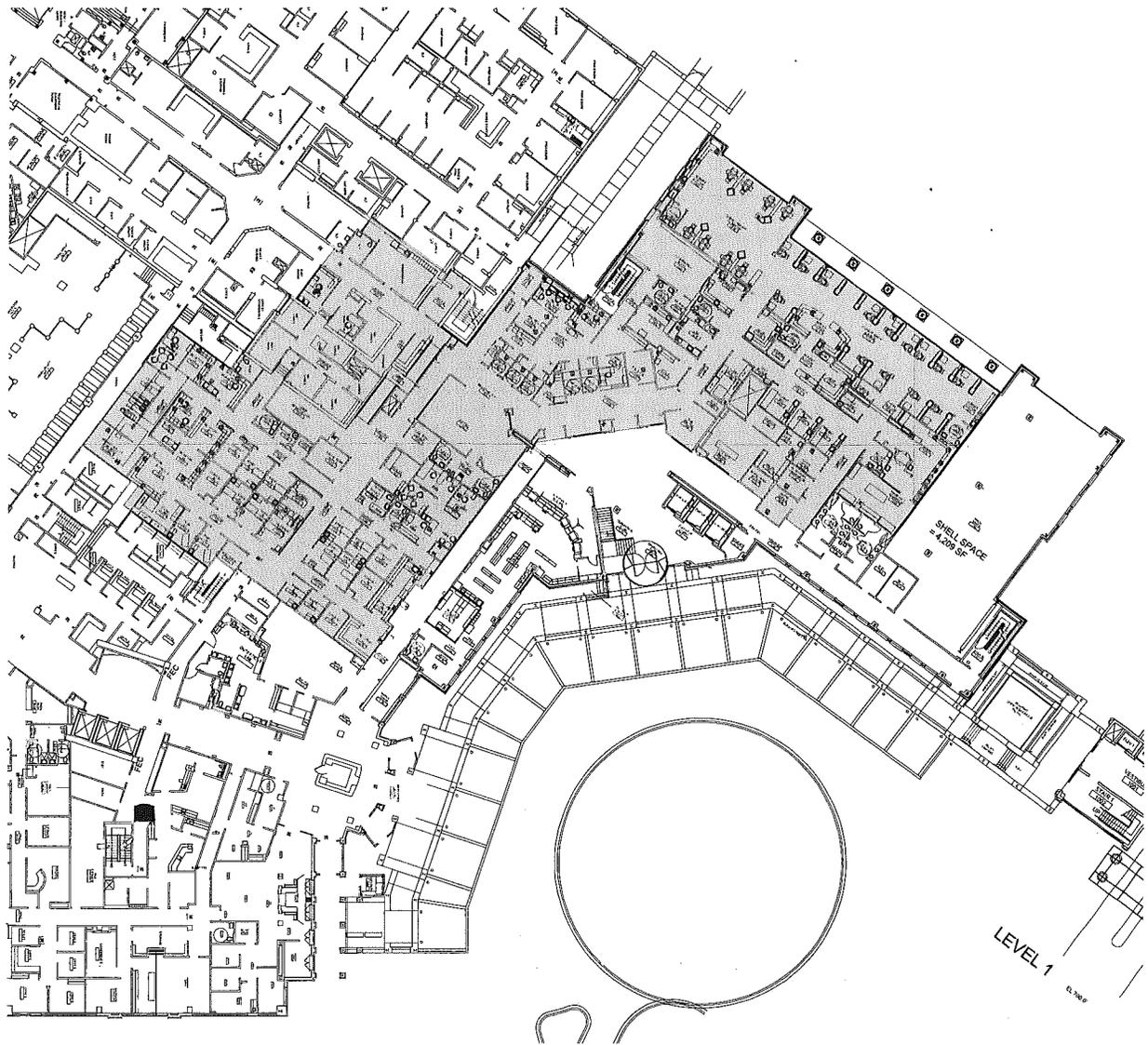
1. Cabarrus Memorial Hospital d/b/a NorthEast Medical Center shall materially comply with all representations made in its certificate of need application.
2. Cabarrus Memorial Hospital d/b/a NorthEast Medical Center shall not acquire, as part of this project, any equipment that is not included in the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

A letter acknowledging acceptance and compliance with all conditions stated in the conditional approval letter was received by the Certificate of Need Section on March 18, 2005.

TIMETABLE

Contract Award	June 13, 2005
25% completion of construction	December 15, 2005
50% completion of construction	June 15, 2006
75% completion of construction	December 15, 2006
Occupancy/offering of service(s)	July 1, 2007





LEVEL 1

SCALE: 1/8" = 1'-0"



**CAROLINA'S
HEALTHCARE SYSTEM**
FREDERICKSVILLE REGIONAL MEDICAL CENTER
4250 Robert Carter Drive
FREDERICKSVILLE, VA 22404

Base Elevation
FLOOR PLAN - LEVEL 01

Area	Area	Area
INVESTMENT GROUP 1	26,124 SF	
INVESTMENT GROUP 2	26,124 SF	
INVESTMENT GROUP 3	26,124 SF	

Room	Area	Area
101	101	101
102	102	102
103	103	103

DATE: 1/16/2014
PROJECT: INVESTMENT GROUP 1
KEY: N/A
DRAWN BY: J. BROWN
CHECKED BY: J. BROWN
DATE: 1/16/2014

Facilities Management Drawings
PROJECT NAME
FLOOR PLAN - LEVEL 01

REQ-02

1/16/2014 10:14:42 AM

Facilities Management Drawings

N/A

EXHIBIT
2
tabbics