



DEPARTMENT OF HEALTH AND HUMAN SERVICES
DIVISION OF HEALTH SERVICE REGULATION

ROY COOPER
GOVERNOR

MANDY COHEN, MD, MPH
SECRETARY

MARK PAYNE
DIRECTOR

August 21, 2017

Lisa Griffin
Novant Health, Inc.
2085 Frontis Plaza Boulevard
Winston-Salem, NC 27103

Exempt from Review – Replacement Equipment

Record #: 2367
Facility Name: Novant Health Forsyth Medical Center
FID #: 923174
Business Name: Novant Health, Inc.
Business #: 1341
Project Description: Replace existing nuclear medicine equipment
County: Forsyth

Dear Ms. Griffin:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency), determined that based on your letter of August 16, 2017 and supplemental information, 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 Siemens Symbia Intevo 6 nuclear medicine equipment to replace the ADAC Forte nuclear medicine equipment, Serial # 9911023. 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.

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

Sincerely,

Handwritten signature of Celia C. Inman in black ink.

Celia C. Inman
Project Analyst

Handwritten signature of Martha J. Frisone in black ink.

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

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



August 16, 2017



Via Email

Ms. Celia Inman, Project Analyst, Certificate of Need
N.C. Department of Health Service Regulation
809 Ruggles Drive
Raleigh, North Carolina 27603

2085 Frontis Plaza Boulevard
Winston-Salem, NC 27103

Re: Novant Health, Inc. – Novant Health Forsyth Medical Center;
Replacement of Nuclear Medicine Equipment;
Winston-Salem, NC (Forsyth County)



Dear Ms. Inman:

Novant Health, Inc. and Novant Health Forsyth Medical Center (“NHFMC”) intend to replace an existing nuclear medicine unit currently located at the main campus of NHFMC in Winston-Salem, North Carolina. NHFMC will acquire a new Siemens Symbia Intevo nuclear medicine unit. See **Attachment A** for the Equipment Quote. As part of the equipment cost, the vendor will provide onsite clinical training for the equipment. The total capital cost for the proposed replacement equipment project is estimated to be \$1,313,015.68¹. See **Attachment B** – Project Capital Cost.

The proposed project meets the definition of “replacement equipment” found in G.S. 131E-176(22a) and 10A N.C.A.C 14C.0303 for the following reasons:

- (1) NHFMC will replace the existing nuclear medicine unit with the proposed nuclear medicine unit that is functionally similar and will be used for the same diagnostic purposes, although it possesses expanded capabilities due to technological improvements.
- (2) The proposed nuclear medicine unit will not be used to provide a new health service.
- (3) The acquisition of the proposed nuclear medicine unit 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.
- (4) NHFMC seeks to replace comparable medical equipment currently in use at project cost less than \$2 million.
- (5) The existing equipment was not purchased second-hand nor was the existing equipment leased.

In support of our request, please find attached:

- Attachment A** – Vendor Equipment Quote
- Attachment B** – Project Capital Cost
- Attachment C** – NC CON Equipment Comparison chart

¹ The project cost does not include sales, property or excise taxes as NHFMC is not subject to these taxes as a non-profit, tax-exempt organization.

Ms. Celia Inman
NHFCM Replacement Equipment – Nuclear Medicine
August 16, 2017

NHFCM's acquisition of the replacement nuclear medicine unit does not require a certificate of need because none of the definitions of "new institutional health services" set forth in N.C.G.S. Section 131E-176(16) apply to the proposed project. As outlined above, the total cost for the project is \$1,313,015.68. The proposed capital cost includes equipment, as well as studies, surveys, designs, plans, working drawings, specifications, construction installation and other activities essential to making the equipment operational.

Note on Page 6 of the equipment quote included in Attachment A that the existing nuclear medicine camera is to be deinstalled and removed by Siemens. The camera has no residual value except to be used for salvage parts.

Based on the information provided, please confirm that NHFCM's replacement equipment request does not constitute a new institutional health service and is exempt from certificate of need review.

If you need additional information, please do not hesitate to contact me.

Sincerely,



Lisa Griffin
Manager, Certificate of Need
Novant Health, Inc.

Enclosures

Cc: Barbara Freedy, Director, CON, Novant Health



Siemens Medical Solutions USA, Inc.
40 Liberty Boulevard, Malvern, PA 19355
Fax: (866) 309-6967

SIEMENS REPRESENTATIVE
Stuart Waddey - (919) 605-9227

Customer Number: 0000006208

Date: 7/24/2017

FORSYTH MEDICAL CENTER
3333 SILAS GREEK PARKWAY
WINSTON-SALEM, NC 27103

Siemens Medical Solutions USA, Inc. is pleased to submit the following quotation for the products and services described herein at the stated prices and terms, subject to your acceptance of the terms and conditions on the face and back hereof, and on any attachment hereto.

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Contract Total: \$785,000

Proposal valid until 1/24/2018

Estimated Delivery Date: 9/2017

Estimated delivery date is subject to change based upon factory lead times, acceptance date of this quote, customer site readiness, and other factors. A Siemens representative will contact you regarding the final delivery date.

This proposal includes the trade-in of equipment referenced in Trade Sheet Project # 2017-1345.

The Pricing of this Quotation includes the Service Parts as detailed on the attached Service Proposal 1-KTOOIJ. Customer acknowledges that the Service Parts shall be invoiced upon shipment.

This Quotation is specific to FORSYTH MEDICAL CENTER and contains information which is confidential and proprietary to Siemens, including but not limited to discounts and pricing. The Customer may not distribute or disclose this quotation or any portion hereof to, or discuss any of the information (including pricing) contained herein with, any other customer or consultant, buying group, or other third party.

Pricing in this Quotation is contingent on Customer purchasing multiple units concurrently.

Quotation is contingent on Customer receiving State CON approval.

Accepted and Agreed to by:

Siemens Medical Solutions USA, Inc.

FORSYTH MEDICAL CENTER

By (sign): _____
Name: Stuart Waddey
Title: Account Executive

By (sign): _____
Name: _____
Title: _____

**ATTACHMENT A –
Equipment Quote**



Siemens Medical Solutions USA, Inc.
40 Liberty Boulevard, Malvern, PA 19355
Fax: (866) 309-6967

SIEMENS REPRESENTATIVE
Stuart Wadley - (919) 605-9227

Date: _____

Date: _____

***By signing below, signor certifies that no modifications or additions have been made to the Quotation.
Any such modifications or additions will be void.***

By (sign): _____

Siemens Medical Solutions USA, Inc.
 40 Liberty Boulevard, Malvern, PA 19355
 Fax: (866) 309-6967

SIEMENS REPRESENTATIVE
 Stuart Waddey - (919) 605-9227

Quote Nr: 1-JIB0ZF Rev. 1

Terms of Payment: 00% Down, 80% Delivery, 20% Installation
 Free On Board: Destination

Purchasing Agreement: VIZIENT SUPPLY LLC

VIZIENT SUPPLY LLC terms and conditions apply to Quote Nr 1-JIB0ZF

Symbia Intevo 6

All items listed below are included for this system:

Qty	Part No.	Item Description
1	14421229	Symbia Intevo 6 The Symbia Intevo 6 is built on SPECT/CT technology, providing seamless integration of two equal modalities. The integration of state-of-the-art SPECT and high quality six slice CT gives this system full functionality for all SPECT-only, SPECT/CT, or stand-alone CT diagnostic applications in Oncology, Neurology, General Nuclear Medicine, and Cardiology.
2	14421231	Low Profile 3/8" Detectors The low profile high resolution, digital detector assembly includes a .95 cm (3/8 in.) thick NaI (TI) crystal.
1	14421234	Caudal Tilt Caudal tilt on Detector 2 allows for precise positioning of static and dynamic acquisitions.
2	07835494	Low_Energy_Hi_Res Collimator Symbia Low energy (140 keV), high resolution, parallel hole collimator
2	07835452	Medium Energy Collimator Symbia Medium energy (300 keV), parallel hole collimator
1	14414929	IQ-SPECT IQ-SPECT is a unique ultra-fast cardiac solution option for general purpose SPECT systems that enables a selection of optimized protocols: - 4 minutes using standard dose - 8 minutes using half dose - 16 minutes using only a quarter of the dose
1	14421323	Symbia Productivity Package The productivity package automates collimator exchange and quality control, increasing the productivity of the Symbia Intevo and Evo camera systems.
1	08717873	Symbia Collimator Cart The collimator cart is designed to hold extra collimators and allows collimator exchange without pivoting the bed.
1	10413528	AQC Web Based Training AutoQC web based training is available on the Siemens training website.
1	10273914	AutoQC source kit This source kit contains includes 1 - Gd-153 line and 1 - Co-57 point source required for the automatic quality control option.

Note: The site Radioactive Material License may need to be updated to receive this source.

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Qty	Part No.	Item Description
1	10273917	<p>AutoQC Source Registration Kit</p> <p>Source registration kit for Symbia Automatic Quality Control option. This kit contains information on updating site radioactive materials license, contact information for source vendor, and user instructions.</p>
1	14421689	<p>xSPECT Bone</p> <p>Advanced bone imaging reconstruction software that uses the CT as the frame-of-reference for the image reconstruction enabling CT-like anatomical clarity and resolution.</p>
1	10183566	<p>Internal ECG for Symbia</p> <p>The internal ECG gating system provides ECG triggering for the nuclear subsystem for nuclear cardiology examinations. In addition, for Symbia Intevo Excel, 2, 6 and 16, and T2, T6, and T16 cameras, the internal ECG gate provides ECG triggering to the CT subsystem for CT applications that require ECG gating.</p> <p>The ECG gate is built into the Symbia patient bed and is controlled by the Symbia acquisition workplace. The leads are AHA (American standard) color coded. They connect near the head of the patient bed and travel with patient, thus never interfering with scanning.</p> <p>The ECG waveform is displayed on the touch-screen Patient Positioning Monitor.</p>
1	08418407	<p>Extra Hand Controller</p> <p>This option provides an extra hand controller for the Symbia Intevo and T series scanners.</p>
1	10119031	<p>UPS for Symbia Camera Systems</p> <p>Uninterruptible power supply option that provides 10 minutes of back up power to the SPECT gantry enabling the proper shut down in the event of a power loss. Also provides noise filtering and transient suppression.</p> <p>Specifications:5.0 KVA Input configuration: 200-240 VAC, 50/60 Hz, L6-30P Output configuration: 208 VAC, L6-30R</p>
1	05245316	<p>UPS for e.soft/c.cam (60 Hz)</p> <p>Uninterruptible power supply option that provides 10 minutes of back up power enabling the proper shut down of the system in the event of a power loss.</p>
1	10413526	<p>PHS Extended Pivot</p> <p>The PHS extended pivot option extends the range of pivot for the patient bed in gurney mode.</p>
1	14421816	<p>SPECT.CT Dual Monitor Software</p> <p>The option enables your Hybrid Acquisition Console to utilize 2 LCD or DICOM monitors.</p>
1	14415058	<p>Monitor, 19" LCD DICOM</p> <p>The 19" DICOM Calibrated LCD monitor is designed to meet the demanding requirements of medical imaging. The display features high contrast even under high ambient light conditions that can be encountered in nuclear medicine viewing environments. The gamma curve is exactly matched to CIE/DICOM recommendation, enhancing the ability to display both color and gray scale images. Light output stability is ensured by continuous backlight control throughout the display's lifetime.</p>
1	08717758	<p>e.media option</p> <p>The e.media patient comfort and education package integrates high quality video and sound through the color touch screen patient positioning monitor.</p>
1	14415788	<p>e.media DVD Player</p> <p>The e.media patient education and comfort package plays high quality video and sound through the color patient positioning monitor via a built-in commercial DVD player. The small size and compact shape of the e.media DVD player allows convenient storage and easy access for changing media.</p>
1	14415195	<p>4 Quadrant Phantom</p> <p>A 4 quadrant 2.0-2.5.30.3.5 mm standard pattern slightly modified for use with Symbia Imaging Systems</p>
1	14415101	<p>ACR SPECT Phantom Kit</p> <p>The ACR Phantom Kit includes a flangeless Jaszczak SPECT phantom, instructions for performing all acquisition and processing steps, and, if necessary, software licenses that allow an e.cam Cardiac camera system to acquire and process phantom data for accreditation and acceptance testing purposes.</p>

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Qty	Part No.	Item Description
1	14421368	Organ Processing for Symbia This upgrade will add organ processing capabilities to your acquisition workplace.
1	14415033	Planar 1/2 Time Imaging Planar 1/2 Time Imaging provides shortened Planar acquisition times.
1	14415736	Advanced 3D Features The Advanced 3D FeaturesImage Fusion package includes the 3D package, the Image Fusion package, and Automatic Image Fusion functionality.
1	14421332	Cardiology Engine Cedars The Cardiology Engine Cedars assists in the diagnosis and quantitative assessment of coronary artery disease by enabling the visualization of SPECT studies as well as quantified perfusion assessment.
1	07830909	Remote Diagnostic Services Siemens Remote Services. A broadband VPN connection is required for full remote service functionality and optimal system uptime.
1	10521454	Under Floor PHS Cable Kit for routing the cable between patient bed and the Symbia Intevo or T series gantry under the floor.
1	10412858	Symbia Hybrid US Installation This option includes the mechanical installation of the Symbia Intevo or T series scanner system.
1	14421240	Dedicated Reconstruction System This high performance workstation is a state of-the-art 64-bit computer architecture capable of handling high resolution data without impeding workflow. This workstation is seamlessly connected to the acquisition console by allowing the user to perform advanced reconstructions from the acquisition console.
1	MI_SPECT_PM	MI SPECT Project Management A Siemens Project Manager (PM) will be the single point of contact for the implementation of your Siemen's equipment. The assigned PM will work with the customer's facilities management, architect or building contractor to assist you in ensuring that your site is ready for installation. Your PM will provide initial and final drawings and will coordinate the scheduling of the equipment, installation, and rigging, as well as the initiation of on-site clinical education.
1	MI_SPEC_IQ_1 2	IQ SPECT Onsite Training Up to (12) hours of on-site clinical education training, scheduled consecutively (Monday - Friday) during standard business hours for a maximum of (4) imaging professionals. Training will cover agenda items on the ASRT approved checklist. Uptime Clinical Education phone support is provided during the warranty period for specified posted hours. This educational offering must be completed (12) months from install end date. If training is not completed within the applicable time period, Siemens obligation to provide the training will expire without refund.
1	MI_SPEC_ADD _32	Additional onsite training 32 hours Up to (32) hours of on-site clinical education training, scheduled consecutively (Monday - Friday) during standard business hours for a maximum of (4) imaging professionals. Training will cover agenda items on the ASRT approved checklist if applicable. This educational offering must be completed (12) months from date of purchase order. If training is not completed within the applicable time period, Siemens obligation to provide the training will expire without refund.
1	MI_SP_NEMA_ XR_29	NEMA_XR-29 Standard This system is in compliance with NEMA XR-29 Standard Attributes on CT Equipment Related To Dose Optimization and Management, also know as Smart Dose
1	4SPAS014	Low Contrast CT Phantom & Holder
1	MI_SP_P_CON VRSNPRG	Conversion Training Assurance Program This conversion assurance program is designed to help customers successfully transition to Siemens imaging systems. The program consists of (1) on-site consultation of up to 12 hours conducted by a Siemens Clinical Education Specialist and a specialized bundle of 5 web based e-learning modules up to support and optimize turnover training for up to 8 users. Up to 50 CE's may be available for users via the WBT e-learning modules. The consultation session will focus on the evaluation of your current procedures, clinical workflows and protocols and will also provide an overview of how your new Siemens system's features will benefit your overall workflow. Your

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40 Liberty Boulevard, Malvern, PA 19355
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SIEMENS REPRESENTATIVE
Stuart Waddey - (919) 605-9227

Qty	Part No.	Item Description
		Siemens specialist will also review the schedule and focus of other affiliated training that may have been acquired with your system purchase. This educational offering must be completed by the later of (12) months from install end date or purchase date. If training is not completed within the applicable time period, Siemens obligation to provide the training will expire without refund.
1	MI_PR_CCOFF_OBSERV	Comp Conv Offset Clinical Education
1	MI_SPEC_ELR_NOFFSET	E.Learn Conversion Offset
1	MI_PR_CCOFF_DEINST	Comp Conv Offset Deinstallation
1	MI_PR_CCOFF_VALUE	Comp Conv Offset Competitive Sys
1	MI_CTSPEC_A_DD_32	Additional CT onsite training 32 hours 32 Up to (32) hours of on-site clinical education training, scheduled consecutively (Monday - Friday) during standard business hours for a maximum of (4) imaging professionals. Training will cover agenda items on the ASRT approved checklist if applicable. This educational offering must be completed (12) months from install end date. If training is not completed within the applicable time period, Siemens obligation to provide the training will expire without refund.
1	NUSYS_TRAD_E_IN_ALL	NU-Sys Trade-in-Allowance Project# 2017-1345 Serial# 9911027 Deinstall date 12/2017 \$0
1	MIS_DEINSTA_LL_EQP	MI SPECT Deinstallation Equipment for Project# 2017-1345 \$9,950
1	NMSYS_ADDL_RIGGING	Additional Rigging NMSYS \$4,200
2	MI_S_XSPECT_ONS12	xSPECT Onsite Training-12hrs Up to (12) hours of on-site clinical education training, scheduled consecutively (Monday - Friday) during standard business hours for a maximum of (4) imaging professionals. This training will provide you with the knowledge required to unlock the potential of the excellent image quality and quantification capabilities provided by xSPECT technology. Training will cover agenda items on the ASRT approved checklist. This educational offering must be completed (12) months from install end date. If training is not completed within the applicable time period, Siemens obligation to provide the training will expire without refund.
3	MI_S_GENERA_LSRT	SPECT General syngo Remote Trainer This offering is for one (1) syngo Remote Trainer(sRT) session of up to 120 minutes and allows up to (4) imaging professionals to participate.. This virtual personalized follow-up training covers topics determined by your current needs. Powered by a secure broadband Virtual Private Network (VPN) connection, syngo Remote Trainer connects to your Siemens imaging console and provides you with real-time support and training. An SRS connection must be activated to utilize syngo Remote Assist. This educational offering must be completed by the later of (12) months from purchase or install end date. If training is not completed within the applicable time period, Siemens obligation to provide the training will expire without refund.
1	MI_SPEC_INIT_AL_32	Initial onsite training 32 hrs Up to (32) hours of on-site clinical education training, scheduled consecutively (Monday - Friday) during standard business hours for a maximum of (4) imaging professionals. Training will cover agenda items on the ASRT approved checklist. Uptime Clinical Education phone support is provided during the warranty period for specified posted hours. This educational offering must be completed (12) months from install end date. If training is not completed within the applicable time period, Siemens obligation to provide the training will expire without refund.
1	MI_SPEC_ELEARN	e.learning cont.edu subscription-12 mths This (12) month multi-modality e.learning subscription will provide access for (10) imaging professionals at the customer site to utilize up to (50 CEUs). This educational offering must be completed (12) months from date of purchase order. If training is not completed within the applicable time period, Siemens obligation to provide the training will expire without refund.

System Total: \$785,000

**ATTACHMENT B –
Project Capital Cost Form**

PROJECT CAPITAL COST

A. Site Costs		
	(1) Full purchase price of land	
	(2) Closing Costs	
	(3) Site Inspection & Survey	
	(4) Legal Fees & subsoil investigation	
	(5) Site Preparation Costs	
	(6) Other:	
	(7) Sub-Total Site Costs	
B. Construction Contract		
	(8) Cost of Materials*	\$396,892.38
	(9) Cost of Labor	
	(10) Other: <i>Construction Contingency</i>	\$33,295
	(11) Sub-Total Construction Contract	\$430,187.38
C. Miscellaneous Project Costs		
	(12) Building Purchase	
	(13) & (14) Fixed Equipment Purchase/Lease + Movable Equipment Purchase/Lease	\$831,146
	(14a) Information Technology	\$7,500
	(15) Furniture	
	(16) Landscaping	
	(17) Consultant Fees (CON Consultant)	
	Other: Signage	\$2,500
	<i>Sub-Total Consultant Fees</i>	
	(18) Financing Costs (Bond, Loan, etc.)/Imputed Interest	
	(19) Interest During Construction	
	(20) Other (Specify): <i>Project Contingency</i>	\$41,682.30
	(21) Sub-Total Miscellaneous	\$882,828.30
D. Total Capital Cost of Project	(22) Total Capital Cost of Project -<i>Sum above Subtotals for Rows (11) & (21)</i>	\$1,313,015.68

*Construction contract includes labor and materials

**ATTACHMENT C –
NC Equipment Comparison Form**

Equipment Comparison Form

	Existing Equipment	Replacement Equipment
Type of Equipment (List Each Component)	Dual Head SPECT Camera	SPECT/CT
Manufacturer of Equipment	ADAC	Siemens
Tesla Rating for MRIs	N/A	N/A
Model Number	Forte	Symbia Intevo 6
Serial Number	9911023	TBD
Provider's Method of Identifying Equipment	Internal Asset Numbering System	Internal Asset Numbering System
Specify if Mobile or Fixed	Fixed	Fixed
Mobile Trailer Serial Number /VIN#	N/A	N/A
Mobile Tractor Serial Number /VIN#	N/A	N/A
Date of Acquisition of Each Component	December 1999	TBD
Does Provider Hold Title to Equipment or Have a Capital Lease?	Title	Title to be held by Forsyth Medical Center upon purchase
Specify if Equipment Was/Is New or Used When Acquired	New	New
Total Capital Cost of Project	\$645,000	\$1,313,015.68
Total Cost of Equipment	\$570,000	\$785,000
Fair Market Value of Equipment	\$0	\$785,000
Net Purchase Price of Equipment	\$570,000	\$785,000
Locations Where Operated	Forsyth Medical Center – Nuclear Medicine Dept.	Forsyth Medical Center – Nuclear Medicine Dept.
Number of Days in Use/To be Used in NC per Year	365	365
Percent of Change in Patient Charges by Procedure	N/A	No increase
Percent of Change in Per Procedure Operating Expenses by Procedure	N/A	No increase
Type of Procedures Currently Performed on Existing Equipment	Nuclear Medicine Studies	N/A
Type of Procedures New Equipment is Capable of Performing	N/A	Nuclear Medicine Studies

Inman, Celia C

From: Griffin, Lisa L (CON) <lgriffin@novanthealth.org>
Sent: Thursday, August 17, 2017 3:34 PM
To: Inman, Celia C
Subject: RE: Replacement Equipment Notice - NH Forsyth Medical Center - Nuc Med Camera

Hi Celia –

The replacement of the nuc med camera with an upgraded nuc med SPECT camera involves reinforcing the floors and adding additional shielding to the room. Also, an existing storage room is being renovated to provide for a larger, renovated control room area. The new control room requires new wiring, electrical, & mechanical work along with the ductwork in the rooms is being brought to current codes.

Let me know if you need more information on this replacement.

Thank you,

Lisa Griffin
Manager, Certificate-of-Need/Business Planning
Novant Health
(704) 384 - 3462
