

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

November 1, 2024

Daina DiMarco and Robbie Roberts ddimarco@wakemed.org and <u>RRoberts@wakemed.org</u>

Exempt from Review – Replacement Equipment

Record #:	4636
Date of Request:	October 29, 2024
Facility Name:	WakeMed Briar Creek Healthplex
FID #:	070833
Business Name:	WakeMed
Business #:	2018
Project Description:	Replace CT scanner
County:	Wake

Dear Daina DiMarco and Robbie Roberts:

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 Siemens Somatom CT scanner to replace the Philips Brilliance CT scanner. 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.

It should be noted that the Agency's position is based solely on the facts represented by you and that any change in the facts 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,

Crystal Kearney

Crystal Kearney Project Analyst

Micheala Mitra 00

Micheala Mitchell Chief

cc: Acute and Home Care Licensure and Certification Section, DHSR Radiation Protection Section, DHSR Construction 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 MAILING ADDRESS: 809 Ruggles Drive, 2704 Mail Service Center, Raleigh, NC 27699-2704 https://info.ncdhhs.gov/dhsr/ • TEL: 919-855-3873

AN EQUAL OPPORTUNITY / AFFIRMATIVE ACTION EMPLOYER



WakeMed Health & Hospitals 3000 New Bern Avenue Raleigh, North Carolina 27610 919-350-8000

Sent via electronic mail to: crystal.kearney@dhhs.nc.gov

October 23, 2024

Ms. Crystal Kearney, Project Analyst Healthcare Planning and Certificate of Need Section Division of Health Service Regulation 2704 Mail Service Center Raleigh, NC 27699-2704

Re: Request for Exemption from Review to Replace One Unit of Fixed CT Equipment at WakeMed Brier Creek Healthplex

Dear Ms. Kearney:

This letter is to inform you of WakeMed's intent to replace one unit of fixed computed tomography (CT) equipment at WakeMed Brier Creek Healthplex. WakeMed will purchase a new Seimens SOMATOM go.Top dual CT scanner, allowing for faster scanning times, improved patient throughput, reduced patient exposure to radiation, enhanced image quality, and reduced maintenance costs.

The estimated total cost of the CT replacement project is \$1,449,888, including \$733,757.27 for the new scanner. Please see Attachment 1 for the equipment quote from the vendor and Attachment 2 for the Equipment Comparison Chart.

Because the project does not constitute a new institutional health service as defined in §131E-176(16)b, and does not exceed the cost threshold for major medical equipment as defined in §131E-176(14o), WakeMed believes this project is not subject to certificate of need review and is requesting that the Agency confirm that WakeMed may proceed without first obtaining a CON.

Thank you for your attention to this matter. If you have questions or require additional information, please contact Daina DiMarco at 919-350-1221 or <u>ddimarco@wakemed.org</u>.

Sincerely,

Robbie Roberts Director, Market Planning

Attachments



SIEMENS REPRESENTATIVE Andrew Pampu - 1 (910) 964-1962 andrew.pampu@siemens-healthineers.com

PRELIMINARY PROPOSAL

Customer Number: 0000011224

Date: 22-03-2024

WAKEMED HEALTH AND HOSPITALS

3000 NEW BERN AVE RALEIGH, NC 27610

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.

Table of Contents

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Contract Total: 698,045 USD

(total does not include any Optional or Alternate components which may be selected)

Proposal valid until 06-05-2024



SIEMENS REPRESENTATIVE Andrew Pampu - 1 (910) 964-1962 andrew.pampu@siemens-healthineers.com

PRELIMINARY PROPOSAL

Quote Nr:	CPQ-1106644 Rev. 0
Terms of Payment:	00% Down, 80% Delivery, 20% Installation Free On Board: Destination
Purchasing Agreement:	PREMIER PURCHASING PARTNERS LP
	PREMIER PURCHASING PARTNERS LP terms and conditions apply to Quote Nr CPQ-1106644
	Customer certifies, and Siemens relies upon such certification, that : (a) PREMIER PP-IM-273 CT is the sole GPO for the purchases described in this Quotation, and (b) the person signing this Quotation is fully authorized under the Customer's policies to choose and indicate for Customer such appropriate GPO.

SOMATOM go.Top (VA30/VA40)

All items listed below are included for this system:

Qty	Part No.	Item Description	Extended Price
1	14460603	SOMATOM go.Top As a member of the SOMATOM go. platform, the SOMATOM go.Top supports all users to provide the best scan for every type of patient – no matter the clinical demands and challenges. The scanner features a unique tablet-based mobile workflow, user guidance with our GO technologies, and exclusive innovations such as Tin Filter low-dose technology. SOMATOM go.Top is built for personalization of processes and care, allowing every operator to optimally adapt to the individual patient and indication while interacting with patients in a more personalized way than ever before. Produce excellent results for the full clinical spectrum including Dual Energy imaging, and offer what others cannot – for a successful CT business.	507,000 USD
1	14460600	Identifier SRS Smart Remote Service (SRS) is a secured data link that connects your medical system to Siemens service experts. Via SRS, the performance and condition of your equipment can be monitored in real time. SRS makes a broad range of proactive and interactive services available. A VPN connection is to be provided by Customer. The Customer agrees to allow connection to Siemens' remote service diagnostic equipment to the secured telecommunications link at his own expenses. The Customer bears the cost of any technical requirements for any such connection over and beyond the actual product (e.g. establish a broadband connection).	0 USD
1	14460605	 SW Base Package SW Base Package Scan&GO mobile workflow, including tablet, remote control, camera, and a new workplace design Check&GO flags problems with scan coverage or contrast distribution as they occur Recon&GO reduces post-processing to just one click, with: Inline Anatomical Ranges, Inline Table and Bone Removal, Inline Vessel Ranges and Multi Reconperforming multiple reconstructions in one step CT View&GO provides a variety of clinical applications and tools for smooth reading in just one workflow 	0 USD
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Qty	Part No.	Item Description	Extended Price
		SAFIRE SOMATOM go. scanners achieve higher efficiency with in dose reduction with Sinogram Affirmed Iterative Reconstruction while maintaining excellent image quality	
		Interleaved Volume Reconstruction Enhances spatial sampling in z-direction, independent of pitch	
		CARE Dose4D, CARE kV, 10 kV Steps, CARE Child Personalized dose control tools that allow you to increase consistency of low dose CT scanning techniques across all technologists	
		Endoscopic View Simulated views of e.g. the inside of bronchi, colon and any other hollow structures Twin Spiral Dual Energy and Dual Energy ROI syngo Single Source Dual Energy Scan mode option offers the possibility to acquire two spiral data sets in sequence at different energies HD FoV** Enables a field of view up to 70 cm, which is optimal for visualization of obese patients and those that are positioned outside the CT isocenter	
		*In clinical practice, the use of SAFIRE may reduce CT patient dose depending on the clinical task, patient size, anatomical location, and clinical practice. A consultation with a radiologist and a physicist should be made to determine the appropriate dose to obtain diagnostic image quality for the particular clinical task	
		** The image quality for the area outside the standard 50 cm scan field does not meet the image quality specifications shown in the technical data sheet and image artifacts may appear, depending on the anatomy scanned	
1	14472863	SW Base Extension VA40 Check&GO Metal Detection Check&GO Metal Detection helps to prevent mistakes and rescans by alerting the user when metallic objects such as belts, chains, keys, earrings or other are not removed and present on the scan area after the topogram is done. It informs the user both on the tablet and the console for their presence before the spiral or the sequential scan.	0 USD
		Flex Dose Profile For long scan ranges, Flex Dose Profile works in combination with CARE Dose4D and FAST Planning to allow a more optimal modulation of the dose. In longer scans, some organs require more dose than the rest of the scan, i.e. there are different target dose levels needed for different anatomical regions, e.g. in regular thoracoabdominal examinations or in chest pain or TAVI procedures. FAST Planning automatically detects individual patient landmarks and anatomies, while Flex Dose Profile adjusts the tube currents for more personalized and accurate dose handling. Flex Dose Profile is displayed on the AWP and the Scan&GO tablet with the same visual logic as any other procedure, so users of any level of experience can utilize it right away.	
		Tilted spiral Tilted spiral scan mode for additional clinical flexibility.	
1	14468565	TwinSpiral Dual Energy The TwinSpiral scan mode offers the possibility to acquire two consecutive spiral data sets at different energies used for non-contrast scans and the two different kV levels with independent mAs modulation deliver a combination of both morphological and functional information within one examination. Harnessing the power and spectral properties of the Tin Filter, TwinSpiral DE allows a better spectral separation for non-contrast examinations.	0 USD



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Qty	Part No.	Item Description	Extended Price
1	14468563	myExam Compass myExam Companion enhances consistency of CT procedures, independent of operator skills. It helps reduce the number of protocols and complexity of advanced examinations, by suggesting which settings are more appropriate for every patient. Based on the procedure and patient characteristics it guides users to find the optimal combination of acquisition and reconstruction parameters, standardized results, and always the right dose.Being a part of myExam Companion, myExam Compass is based on the condensed knowledge of thousands of scans and protocols from our installed base whichhave been recognized and aggregated into clinical decision trees provided ex-factory.	0 USD
1	14468557	High Performance Package High Performance Package Item includes: High Power 70, High-speed 0.33 s, Physiological Measurement Module, ECG cable, iMAR, Cardio Spiral, BestPhase, Cardio Quick Sequence, CARE Contrast III, Inline Spine Ranges, Inline Rib Ranges, syngo.CT CaScoring, Recon&GO CaScoring, Any kV CaScoring	65,000 USD
1	14460606	Scan&GO wireless edition Includes Scan&GO Tablet and Remote Scan Control. Built around a new mobile workflow, the SOMATOM go. platform features a line-up of innovative solutions – tablet, remote control, camera, and a new workplace design – that bring an unparalleled level of flexibility and mobility to daily CT routines. The solutions also enhance patient comfort for potentially higher levels of patient satisfaction.	0 USD
		The lightweight, high-resolution tablet gives our customers total freedom over how they work: only a few steps for the entire scan.	
1	14472322	UPS UPS. An uninterrupted power supply, for the syngo Acquisition Workplace in the event of network fluctuations and brief power failures.	0 USD
1	14460885	307 kg Patient Table Patient table with 676 lb / 300 kg weight limit designed to accommodate virtually all patients with a long scan range of 2000 mm.	20,800 USD
1	14460613	Foot Switch for Pat.Table control Additional flexibility with a foot switch that controls patient table movements only.	780 USD
1	14468564	myExam Cockpit The clinical decision trees utilized by myExam Compass are fully transparent. Users can tailor clinical decision trees to the need of their institution with myExam Cockpit, the central user interface for fast and intuitive clinical decision tree configuration.	0 USD
1	14468207	Flex 4D Spiral - Neuro Flex 4D Spiral – Neuro applies a continuously repeated bi-directional table movement, moving the patient smoothly in and out of the gantry over the desired scan range. This allows dynamic CT imaging over a larger range than the physical detector size. These dynamic procedures are handled on the AWP with the same visual logic as any other procedure, so users of any level of experience can perform them right away.	13,000 USD
		The optional tiltable head holder is recommended for optimal positioning of stroke patients.	
1	14468676	Aution Patient Restraint 400 mm 400 mm wide restraint strap for the safe positioning of even obese patients on the patient table.	260 USD
1	14460643	Table Accessories Set More table accessories for further flexibility based on the clinical needs. Includes table side rails, storage box and infusion holder.	520 USD
1	14460614	Table Extension Comfortable table accessory to extend the maximum scan range.	676 USD
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Siemens Medical Solutions USA, Inc.

40 Liberty Boulevard, Malvern, PA 19355

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Qty	Part No.	Item Description	Extended Price
1	14482574	Positioning & Fixation Set Item includes - Arm Support - Patient fixation with slider	520 USD
1	14461418	Tiltable Head Holder Tiltable Head Holder for the fixation of the patient's head. Tilt range between +30 till – 15 degree.	1,300 USD
1	E93PM100UCT	Eaton 93PM-100 kW UPS Complete system backup without interruption. One UPS per CT.	58,158 USD
		Includes the following:	
		Eaton 93PM UPS Electronics Cabinet w/integrated maintenance bypass sidecar Eaton 93PM Single Battery Cabinet System (Full load back-up time @ 100 kW of 8.2 minutes.) Network Card Eaton 24x7 start-up One year (24x7) warranty through Eaton Corp.	
		Not approved for sites that require OSHPD.	
		Optional Remote Monitoring Panel	
		Shipment is to customer's dock. Customer is responsible for logistics from the dock to inside location.	
1	BISI2_WINSTAL L	Bayer ISI2 Interface, w/ Install Bayer ISI2 Interface enables CAN III networking between Siemens CT system and Bayer Stellant injector. Requires appropriate Siemens' CT system functionality (i.e. CareContrast).	9,603 USD
		This part number includes a separate visit by a Bayer Service engineer to install the ISI interface (when a customer is using an injector already onsite).	
1	CTSDEF01	CT Slicker Thermoseal seams and flaps deflect fluids, reducing contaminant penetration into the cushion and table. Contaminants are retained on the tabletop or shunted to the floor. Cleanup is faster, more thorough, and contaminant build-up is reduced. Built using heavy, clear, micro matte vinyl, and top grade hook and loop fastening strips (Velcro) to better fit the specified table. Custom vinyl resists tears and minimizes radiologic interference. Latex free. Set includes CT Skirts. Shipped with main cover, a catheter bag holder, and 3 restraining belts unless otherwise noted.	364 USD
1	4SPAS014	Includes warranty from RADSCAN Medical. Low Contrast CT Phantom & Holder	2,704 USD
1	CT_LUNGIMAGI		2,704 03D 0 USD
	NGGO	Lung Imaging Go: For well over a decade, CT has been recognized and used as the standard of care for lung nodule visualization and sizing. This is due to CT's spatial resolution, geometric accuracy, and ability to create various reconstructions and 3D views. The high contrast environment in the chest between the lungs and the nodules makes for a relatively easy visualization task for clinicians using CT images. Recent advances in CT technology have allowed these scans to be effectively performed at lower doses, higher resolutions, and faster scan times. The SOMATOM go.Platform leverages Tin Filter Technology to further enhance the delivery of low dose lung cancer screening for high risk populations*. The SOMATOM go scanners are delivered with specific scan protocols to provide low dose lung cancer screening exams that use Siemens-exclusive Tin Filter Technology to reduce unnecessary radiation. These default protocols also utilize Siemens proprietary dose reducing features such as CARE Dose4D TM , automatic	
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Qty	Part No.	Item Description	Extended Price
		exposure control technology, that further modulates and adapts dose for every patient, for high image quality at low dose. The SOMATOM go scanners come with default low dose lung imaging protocols below 1 mSv. *As defined by professional medical societies.	
1	ACCESS_PROT ECT	Access Protection Scan Protocols are password protected allowing only authorized staff members to access and permanently change protocols	0 USD
1	CARE_DOSE4D	CARE Dose4D CARE Dose4D delivers the highest possible image quality at the lowest possible dose for patients - maximum detail, minimum dose. Adaptive dose modulation for up to 60% dose reduction	0 USD
1	CARE_DOSE_C ONFIG	CARE Dose Configurator CARE Dose Configurator: Enhancement of Siemens' renowned real-time dose modulation CARE Dose4D, introducing new reference curves for each body region and for each body habitus allowing to adjust the configuration even more precisely to the patient's anatomy.	0 USD
1	CARE_BOLUS	CARE Bolus Operating mode for CM-enhancement-triggered data acquisition.	0 USD
1	DICOM_SR	DICOM SR Dose Reports DICOM structured file allows for the extraction of dose values (CDTIvol, DLP)	0 USD
1	DOSELOGS	DoseLogs Whenever a dose limit exceeds the established reference dose levels (Dose Notification and Dose Alert) a report is automatically created on the system, enhancing your ability to track radiation dose.	0 USD
1	DOSE_ALERT	Dose Alert Dose Alert: Dose Alert automatically adds CTDIvol and DLP values depending on z-position (scan axis). The Dose Alert window appears, if either of these cumulative values exceeds a user-defined threshold.	0 USD
1	DOSE_NOTIFIC ATION	Dose Notification Dose Notification: Dose Notification provides the ability to set dose reference values (CTDIvol, DLP) for each scan range. If these reference values are exceeded the Dose Notification window informs the user.	0 USD
1	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 known as Smart Dose.	0 USD
1	SURE_VIEW	SureView Provides exceptional image quality at any pitch setting, enabling you to scan faster because you can scan at any pitch without degrading image guality	0 USD
1	UFC_DETECTO R	UFC Detector Ultra Fast Ceramics (UFC) technology is a unique type of scintillation technology material that quickly and efficiently transforms radiation from the X-ray tube into light signals. Its superb overall quantum efficiency and unique short afterglow enable time-critical X-ray detection at low doses and extremely fast data collection.	0 USD
1	CT_GO_STELL AR	Stellar Low Noise Technology Detector The Stellar detector's high-end technology includes fully integrated components. As a result, Stellar detector technology keeps electronic noise low, increases dose efficiency and improves spatial resolution. The smart configuration of the detector elements simplifies access, eases maintenance, and increases scanner uptime. For SOMATOM go scanners, the Stellar detector features a 3D anti-scatter collimator for even more efficient optimization of X-ray energy.	0 USD
1	SYNGO_VRT	syngo VRT Advanced 3D functionality as an extension to the basic 3D viewer, containing volume rendering technique (VRT) and advanced editing functions.	0 USD
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Siemens Medical Solutions USA, Inc.

40 Liberty Boulevard, Malvern, PA 19355

SIEMENS REPRESENTATIVE

Andrew Pampu - 1 (910) 964-1962 andrew.pampu@siemens-healthineers.com

PRELIMINARY PROPOSAL

Qty	Part No.	Item Description	Extended Price
1	SYNGO_BONE_ REMOVAL	syngo Bone Removal Simple, automated bone removal functionality for the syngo 3D application. Preconfigured algorithms for angiography and hip/pelvis fracture scenarios are included to facilitate fast removal of bone structure for three dimensional presentation and analysis of CT data.	0 USD
1	WORKSTREAM 4D	Workstream4D WorkStream 4D further enhances the already superb workflow of SOMATOM CT scanners by offering direct generation of sagittal, coronal, oblique or double-oblique reconstructed images directly from CT raw data as part of the CT protocol.	0 USD
1	CT_FLEX_DOS E_PROFI	Flex Dose Profile In combination with CARE Dose 4D and FAST Planning, Flex Dose Profile allows a more optimal modulation of the dose in long scans ranges where different quality references might be needed. It is displayed at the AWP and at the Scan&GO tablet.	0 USD
1	HD_FOV_70CM	HD FOV Designed to enable visualization of the human body parts and skin line located outside of the 50cm standard field of view up to the bore size.	0 USD
1	CT_TIN_FILTER	SOMATOM go. Tin Filter Tin Filters block unnecessary low energy photons for non-contrast exams optimizing the X-ray spectrum increasing dose efficiency especially for applications with high air (or bone)-to-soft tissue contrast.	0 USD
1	CT_PM	CT 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.	0 USD
1	CT_BTL_INSTA LL	CT Standard Rigging and Installation	9,360 USD
1	CT_ADDL_RIG GING	Additional Rigging CT	8,000 USD

System Total 698,045 USD



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PRELIMINARY PROPOSAL

FINANCING: The equipment listed above may be financed through one of our financing partners. Ask us about our full range of financial products that can be tailored to meet your business and cash flow requirements. For further information, please contact your local Sales Representative.

Siemens Healthineers is pleased to submit this Preliminary Pricing Proposal. A Preliminary Pricing Proposal is provided for planning purposes only; it is not contractually binding. To receive a contractually binding proposal for the Products listed above, inclusive of Terms, Conditions, and Warranty coverage, please contact your Siemens Healthineers Sales Representative.

Siemens Healthineers Andrew Pampu 1 (910) 964-1962 andrew.pampu@siemens-healthineers.com

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Type (e.g., Cardiac Catheterization, Gamma Knife®, Heart-lung bypass machine, Linear Accelerator, Lithotriptor, MRI, PET, Simulator, CT Scanner, Other Major Medical Equipment) Manufacturer	CT scanner
Philips	
	Siemens
Brilliance 16 Air	ir Somatom go.Top
209	CT room
fixed	fixed
9/2011	9/2024
Was the existing equipment new or used when acquired? / Is the replacement equipment new or used?	new
	\$1,449,888
	\$733,757.27
WakeMed Brier Creek CT	er WakeMed Brier Creek CT
Mobile lease – Philips Incisive	
	ou
	N/A
Will the replacement equipment result in any increase in the average operating expense per procedure?	ou
	N/A
Diagnostic CT	
	Diagnostic CT
	eek CT ile lease - os Incisive nostic CT

Pate of last revision: J/L/

 From:
 Kearney, Crystal

 To:
 Stancil, Tiffany C

 Subject:
 FW: [External] WakeMed Letters of No Review/Exemption

 Date:
 Tuesday, October 29, 2024 11:53:51 AM

 Attachments:
 Brier Creek CT Replacement 2024.pdf Fuquay Varina MOB 2024.pdf North LDR Rooms 2024.pdf

 Wake Forest MOB 2024.pdf

FYI

I received these request

Crystal Kearney

Project Analyst, Certificate of Need Division of Health Service Regulations, Healthcare Planning and Certificate of Need NC Department of Health and Human Services

Office: 919-855-3883 (I am in the office on Monday and Tuesday, and can best be reached by email)

Crystal.kearney@dhhs.nc.gov

809 Ruggles Drive, Edgerton Building #228 2704 Mail Service Center Raleigh, NC 27699-2704

From: DAINA DIMARCO <DDiMarco@wakemed.org>
Sent: Tuesday, October 29, 2024 11:34 AM
To: Kearney, Crystal <crystal.kearney@dhhs.nc.gov>
Subject: [External] WakeMed Letters of No Review/Exemption

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.

Hi Crystal,

Please see WakeMed's attached letters of no review for the following projects:

- Fuquay Varina Medical Office Building
- Wake Forest Medical Office Building
- Replacement of a CT Scanner at Brier Creek Healthplex
- Renovation to add 2 LDR Rooms at WakeMed North Hospital

Please let us know if you have any questions!

Thanks! Daina Daina DiMarco, MHA, MBA WakeMed Corporate Planning 919-350-1221

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