



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

February 21, 2014

Molly D. Jordan  
Director of Strategic Planning  
High Point Regional UNC Health Care  
P.O. Box HP-5  
High Point, NC 27261

**No Review**

Facility: High Point Regional UNC Health Care  
Project Description: Acquire Software Modules for Existing EP Equipment  
County: Guilford  
FID #: 943251

Dear Ms. Jordan:

The Certificate of Need Section (CON Section) received your letter of February 18, 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.

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](http://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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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.

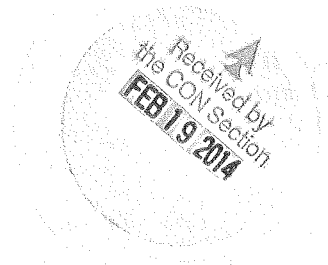
Sincerely,



Celia C. Inman  
Project Analyst



Martha J. Frisone, Interim Chief  
Certificate of Need Section



February 18, 2014

**Via Hand Delivery**

Ms. Martha Frisone, Chief  
Ms. Celia Inman, Project Analyst  
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 Software Acquisition

Dear Ms. Frisone and Ms. Inman:

High Point Regional Health ("HPR UNC") is requesting a "No Review" determination that its acquisition of three software modules is not reviewable as a new institutional health service under the North Carolina Certificate of Need ("CON") law, or otherwise triggers CON review. The software modules ("Software Acquisition") will be used in conjunction with the BioSense Webster's Carto Unit ("EP Equipment"), which provides electrophysiology services to patients at HPR UNC.

The EP Equipment was installed in 2000 and was replaced in 2010. Since that time, significant technological and delivery of care advancements have been made. As a result, the EP Equipment does not afford patients the advanced capabilities that are now available. Several important capabilities are lacking, including the ability to integrate and transmit 3-D images in real time, and enhanced mapping and diagnostic capabilities. The Software Acquisition will allow for advanced integration of mapping with fluoroscopy, improving operational capabilities and shortening procedure times.

The total cost of the proposed Software Acquisition is \$185,000.00. See Exhibit 1, Price Quotation. There are no additional costs associated with the Software Acquisition as listed in N.C. Gen. Stat. § 131E-176(16)b, including the "cost of any studies, surveys, designs, plans, working drawings, specifications, and other activities, including staff effort and consulting and other services, essential to the" Software Acquisition.

The proposed Software Acquisition does not trigger any of the definitions of a "new institutional health service," which implicates CON review. N.C. Gen. Stat. § 131E-178 provides that no person shall offer or develop a "new institutional health service" without

Ms. Martha Frisone  
Ms. Celia Inman  
February 18, 2014  
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first obtaining a CON. The term “new institutional health service” is defined in over fifteen different ways at 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. The cost of any studies, surveys, designs, plans, working drawings, specifications, and other activities, including staff effort and consulting and other services, essential to the acquisition, improvement, expansion, or replacement of any plant or equipment with respect to which an expenditure is made shall be included in determining if the expenditure exceeds two million dollars (\$2,000,000).

See N.C. Gen. Stat. § 131E-176(16)b.

The proposed Software Acquisition does not constitute a “new institutional health service” under N.C. Gen. Stat. § 131E-176(16)b because the proposal does not exceed the \$2,000,000 threshold. Moreover, the equipment to be acquired is not *per se* reviewable pursuant to the CON statutory scheme, does not result in the development of a “diagnostic center” under N.C. Gen. Stat. § 131E-176(7a), and is not “major medical equipment” under N.C. Gen. Stat. § 131E-176(14o). Because a CON was not required for the acquisition of the EP Equipment and because the EP Equipment was installed more than a year ago, the acquisition is not “a change in a project” under N.C. Gen. Stat. § 131E-176(16)e. Accordingly, the proposed software upgrade does not require HPR UNC to obtain a CON pursuant to N.C. Gen. Stat. § 131E-176(16)b, or any other provision of the CON statutes.

Based upon the foregoing information and the attached document, HPR UNC hereby requests that the Agency provide a written response confirming that the Software Acquisition described herein does not require a CON pursuant to N.C. Gen. Stat. § 131E-176(16)b, or any other provision of the CON statutes. In addition, we respectfully request that this request be considered on an **expedited basis** because HPR UNC wishes to proceed with the Software Acquisition as soon as possible.

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Ms. Celia Inman  
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If you find that you need additional information, please do not hesitate to contact me at (336) 878-6095. Thank you in advance for your consideration of this submission.

Sincerely,

A handwritten signature in cursive script that reads "Molly D. Jordan".

Molly D. Jordan  
Director of Strategic Planning





**Biosense Webster**  
a Johnson & Johnson company

Biosense Webster, Inc.  
3333 Diamond Canyon Rd  
Diamond Bar, CA 91765

**CARTO® 3 System**  
**Summary of Proposed Pricing**  
**For: High Point Regional**  
**Prepared: February 13, 2014**  
*(Expires 90 Days from Prepared Date.)*

Qty.	Cat No.	Description	Proposed Pricing*
1	C3SOUND	CARTOSOUND® <b>Image Integration Software Module</b> is a modular software package to be used with the CARTO® 3 System, Serial Number _____ that allows for the integration of real time Intracardiac echo in an integrated and a side by side manner on the CARTO® 3 System screen. This CARTOSOUND® software is compatible with the Biosense Webster SOUNDSTAR® 10F and Siemens 10F and 8F ACUNAV™ Catheters. This software module includes a Dell 390 or higher workstation. On-site training for technicians included. If needed, includes two 24" wide screen monitors. (List Price: \$75,000.00)	\$35,000.00
<b>TOTAL</b>			<b>\$35,000.00</b>

\* The information in this Summary of Proposed Pricing is not complete and may be changed. A legally binding obligation between the parties will exist only upon the execution of a definitive agreement. This document is being delivered for discussion purposes only. This is not an offer to sell the products or a solicitation of an offer to buy the products. No party shall have any obligation or liability arising from this document. Either party may cease negotiations regarding the purchase of the products at any time without further obligation or liability. The pricing for the products in this Summary of Proposed Pricing may include discounts. If a definitive agreement is executed by the parties, the document will include additional disclosure related to the discounts. The information in this document is confidential and may not be discussed with any other party without Biosense Webster's prior written consent. To request an Agreement or for any questions, please contact your Biosense Webster Representative, Kevin Corcoran at [kcorcora@its.inj.com](mailto:kcorcora@its.inj.com) or 336-210-9280.



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**CARTO® 3 System**  
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**For: High Point Regional**  
**Prepared: February 13, 2014**  
*(Expires 90 Days from Prepared Date.)*

Qty.	Cat No.	Description	Proposed Pricing*
1	KT5400124	CartoUnivu™ Module is a modular software package to be used with the CARTO® 3 System. Software allows user to visualize CARTO® 3 System Maps and fluoroscopy images in one integrated view. <i>(List Price: \$150,000.00)</i>	\$140,000.00
<b>TOTAL</b>			<b>\$140,000.00</b>

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Diamond Bar, CA 91765

## VISITAG™ MODULE

### Summary of Proposed Pricing

For: High Point Regional

Prepared on: February 13, 2014

*(Expires 90 Days from Prepared Date.)*

Qty.	Cat No.	Description	Proposed Pricing*
1	Visi	VISITAG™ Module is a modular software package to be used with the CARTO® 3 System. Software allows user to consistently tag and evaluate ablation points based on a variety of parameters	\$10,000.00
<b>TOTAL</b>			<b>\$10,000.00</b>

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