

Notice of Intent to Certify Sole Source

To: Interested Parties

From: Stacy Baldwin
Agency Procurement Officer

Date: December 22, 2016

Re: Sole Source Certification Number **SS5068** for **NxStage System One disposables and Pureflow SL Products**

Contact Email Address: solesource@umc.edu

Sole Source Certification Award Details

Regarding UMMC Sole Source Certification Number **SS5068** for **NxStage System One disposables and Pureflow SL products**, please be advised that UMMC intends to award the purchase of the **NxStage System One disposables and Pureflow SL products** to **NxStage Medical, Inc.** as the sole source provider of the **NxStage System disposables and Pureflow SL products**.

UMMC issues this notice in accordance with Mississippi state law, policy, and procedures for sole source procurements.

Sole Source Criteria

1. Where the compatibility of equipment, accessories, or replacement parts is the paramount consideration (and manufacturer is the sole supplier).
2. Where a sole supplier's item is needed for trial use or testing.
3. Where a sole supplier's item is to be required when no other item will service the needs of UMMC.

Schedule

Task	Date
First Advertisement Date	December 22, 2016

Second Advertisement Date	December 29, 2016
Response Deadline from Objectors	January 4, 2017, at 3:00 p.m. Central Time
Notice of Award/No Award Posted	Not before February 17, 2017

Project Details

1. Describe the commodity that the agency is seeking to procure:

The University of Mississippi Medical Center seeks to purchase NxStage System One disposables and Pureflow SL products for hemodialysis in home treatments. UMMC currently leases NxStage System One hemodialysis cyclers machines. The disposables used with NxStage System One hemodialysis cyclers and Pureflow SL products are proprietary to NxStage Medical, Inc. and the only disposables that may be used with NxStage's cyclers.

2. Explain why the commodity is the only one (1) that can meet the needs of the agency:

NxStage System One is the only true portable hemodialysis machine cleared for home use by the U.S. Food and Drug Administration. No other company will provide hemodialysis machines on a rental basis. The disposables used with NxStage System One hemodialysis cyclers and Pureflow SL products are proprietary to NxStage Medical, Inc. and the only disposables that may be used with NxStage's cyclers. Pursuant to the Centers for Medicaid and Medicare Services (CMS) rules, UMMC is required to ensure that home dialysis patients have their supplies delivered on a frequency that meets the physician's prescribed therapy schedule.

3. Explain why the source is the only person or entity that can provide the required commodity:

NxStage System One disposables and Pureflow SL products are solely manufactured and distributed by NxStage Medical, Inc. See supporting letter from **NxStage Medical, Inc.**, Attachment A.

4. Explain why the amount to be expended for the commodity is reasonable:

The estimated amount to be expended is for the purchase of the **NxStage System One disposables and Pureflow SL products** is \$350K. This amount is within the expected price range for these products.

5. Describe the efforts that the agency went through to obtain the best possible price for the commodity:

Through market intelligence, UMMC was able to negotiate best pricing for these products. All applicable discounts were explored and applied.

Submission Instructions and Format of Response from Objecting Parties

Interested parties who have reason to believe that the **NxStage System One disposables and Pureflow SL products** (hereafter, “Products”) should not be certified as a sole source should provide information in the Vendor Form for the State to use in determining whether or not to proceed with awarding the sole source to **NxStage Medical, Inc.** The Vendor Form may be found at

<http://www.dfa.state.ms.us/Purchasing/documents/ObjectiontoSoleSourceDetermination.pdf>.

Objections must include the certification in Attachment B.

Comments will be accepted at any time prior to Wednesday, January 4, 2017, at 3:00 p.m. (Central Time) to solesource@umc.edu. Responses may be delivered via email to solesource@umc.edu. UMMC WILL NOT BE RESPONSIBLE FOR DELAYS IN THE DELIVERY OF RESPONSES. It is solely the responsibility of the Interested Parties that responses reach UMMC on time. Responses received after the deadline and responses that lack all required information will be rejected. UMMC reserves the right to inspect Interested Party’s commodity for comparison purposes.

If you have any questions concerning the information above or if we can be of further assistance, please contact solesource@umc.edu.

Attachment A: Vendor Correspondence

Attachment B: Objection Certification



Attachment A

December 8, 2016

Annie Gates
Business Operations Manager Renal Division
University of Mississippi Medical Center
350 West Woodrow Wilson Avenue RM 235
Jackson, MS 39213

Re: Sole Source

Dear Ms. Gates:

No other company other than NxStage Medical, Inc. sells the NxStage home hemodialysis machines. In addition, no company other than NxStage Medical, Inc. sells cartridges that would be compatible and work with the NxStage hemodialysis machines that the University of Mississippi currently owns and is in its patients' homes. No company other than NxStage Medical, Inc. sells the PureFlow SL Dialysate Preparation System that is compatible and works with such NxStage hemodialysis machines. NxStage has not performed any testing to validate whether or not third party pre-mixed bagged dialysate fluids are compatible for use with such NxStage hemodialysis machines.

Thank you

Sincerely,

A handwritten signature in black ink, appearing to read 'MWT', followed by a horizontal line.

Matthew W. Towse
Senior Vice President and Chief Financial Officer
NxStage Medical, Inc.

Attachment B

**SUBMITTED IN RESPONSE TO
Sole Source Certification No. SS5068
Accepted until January 4, 2017, at 3:00 p.m.**

I certify that the information contained in this objection is true and accurate to the best of my knowledge. I understand that UMMC will investigate all statements made in this objection and that any false or misleading information provided may result in adverse action.

Objector Name
Objector's title

Date