Notice of Intent to Certify Sole Source

To: Interested Parties

From: Stacy Baldwin
Agency Procurement Officer

Date: November 28, 2016

Re: Sole Source Certification Number **SS5064** for **Denver Shunt and Accessories**

Contact Email Address: solesource@umc.edu

Sole Source Certification Award Details

Regarding UMMC Sole Source Certification Number **SS5064** for **Denver Shunt and Accessories**, please be advised that UMMC intends to award the purchase of the **Denver Shunt and Accessories** to **CareFusion, a division of Becton, Dickinson, and Company (BD),** as the sole source provider of the **Denver Shunt and Accessories**.

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	November 28, 2016
Second Advertisement Date	December 5, 2016

Response Deadline from Objectors	December 12, 2016, at 3:00 p.m. Central Time
Notice of Award/No Award Posted	Not before December 13, 2016

Project Details

1. **Describe the commodity that the agency is seeking to procure:**
   The University of Mississippi Medical Center (UMMC) seeks to purchase Denver Shunts and accessories. The primary function of these peritoneovenous shunts and accessories is the management of malignant and non-malignant ascites. The Denver Shunt transfers fluid from the peritoneal space to the circulatory system. This allows the patient to maintain critical protein and nutrients in the peritoneal fluid as well as normal flow through vital organs. The Denver Shunt is intended for patients that are undergoing repeat paracentesis procedures. This alternative will allow the patient to manage their symptoms of ascites from home versus multiple hospital visits for a paracentesis.

2. **Explain why the commodity is the only one (1) that can meet the needs of the agency:**
   The Denver Shunt is the only device available in the United States for the treatment of refractory ascites in which the Transjugular Intrahepatic Portosystemic Shunt (TIPS) procedure is not an option. The TIPS procedure is contraindicated in patients with elevated MELD (Model For End-Stage Liver Disease) scores, history of encephalopathy, or who have malignant ascites. This is the only FDA approved option to treat these patients that are not candidates for TIPS.

3. **Explain why the source is the only person or entity that can provide the required commodity:**
   CareFusion, a division of BD, is the only manufacturer of the Denver Shunt and proprietary accessories. They are not available from any other distributor. See supporting letter from **CareFusion, a division of BD**, Attachment A.

4. **Explain why the amount to be expended for the commodity is reasonable:**
   The estimated amount to be expended for the purchase of the **Denver Shunts and Accessories** is $20,000. 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 **Denver Shunt and Accessories** (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 **CareFusion, a division of BD**. 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 Monday, December 12, 2016, 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

75 North Fairway Drive
Vernon Hills, IL 60061

BD.com

August 12, 2016

Subject: Peritoneovenous shunt products

Dear Customer:

We recently received an inquiry about the competitive products in the peritoneovenous shunt market. Our market research has demonstrated that we are the only manufacturer and seller of a peritoneovenous shunt in the United States. Our product is the Denver Ascites shunt.
We hope this confirmation is helpful in your evaluation of this product and therapy option.

Sincerely,

Reem Groark
Senior Marketing Manager
Interventional Specialties

Attachment B

SUBMITTED IN RESPONSE TO
Sole Source Certification No. SS5064
Accepted until December 12, 2016, 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