Pre-proposal Teleconference Meeting Minutes for UF BPA/VARR August 25, 2015 10:30 AM to 11:30 AM CST

Covering Quotes for November 2015 DoD P&T Committee Reviews

1. Attendance

Dr. Robert Conrad – Strategic Sourcing / Industry Liaison, DHA Pharmacy Operations Division – San Antonio, TX

Bruce Mitterer – Contracting Officer – DHA Contract Management

Matthew Halbe - Contract Analyst - DHA Contract Management

2. New Solicitation Website: (http://www.health.mil/About-MHS/Other-MHS-Organizations/DoD-Pharmacy-and-Therapeutics-Committee/Drug-Classes-New-Drugs-Under-Review/November-2015)

To access the new POD website, go to www.health.mil/POD

- 3. Drug Classes:
 - a. Attention Deficit Hyperactivity Disorder Stimulants
 - b. Antirheumatics Injectable Methotrexate
 - c. Gastrointestinal-2 Agents Miscellaneous
 - d. Acne Isotretinoids
 - e. Designated Newly Approved Drugs
 - i. Namenda XR
 - ii. Namzaric
- 4. Quote Submissions
 - a. Due date for all original quotes and email duplicates is October 2, 2015 at 1:00 PM EDT

All original quotes and email duplicates are due on October 2, 2015 at 1:00 PM EDT (11:00 AM MDT). Suppliers are encouraged to submit their quotes early. For overnight delivery, it is suggested suppliers use FedEx Priority mail.

- b. DHA Point of Contact: Matthew Halbe, matthew.r.halbe.ctr@mail.mil, Ph: (303) 676-3529
- c. Other
 - i. Documents are fillable

All solicitation documents (UF BPA Template and Appendices) are locked to prevent unnecessary editing. However, the appropriate fields allow the supplier to fill in where needed. Fill in the appropriate fields before printing out the documents for submission.

Please submit one signed BPA Template (Terms & Conditions) for every drug. For example, if a supplier is quoting on two drugs with different drugs names, they should submit a separate signed UF BPA Template for each of these drugs.

For Example: The fillable fields allow you to type in your company information while keeping the integrity of the document intact. 11. Send all submissions to: Pharmacy Contracting Officer/COD Defense Health Agency 16401 East Centretech Parkway Aurora, CO 80011-9043 it of contact for the administration and management of 12. The Col s agreement is: John Smith Phone 555-5555 Name Contract Manager Title Fax Address Email

FOR THE COMPANY

BY: (signature) _____ Date

ii. Do not print duplex for original quotes.

Submit all hard copies as single-sided pages. Avoid double-sided quotes.

5. Lessons Learned: Responsiveness

It is important that suppliers respect the process that is in place by carefully reading the UF BPA, UF VARR and all instructions that accommodate it to ensure the quoting procedure is properly followed.

Citation

Past Reasons for non-responsiveness:

Non-Responsive Reason

Company does not hold an FSS contract, or the FSS contract has expired	UF BPA Paragraph 10 "The company must have an existing FSS Contract for any pharmaceutical agent(s) quoted in this UF BPA at the time the quote is submitted, and at the time the UF BPA is executed"
Signed UF BPA terms and conditions is not submitted on time	
Ensure calculations are correct and to four decimal places	UF BPA Paragraph 10 Line 13
Price per dosage unit will be the same for all package sizes	UF BPA Paragraph 8.b

Company name on the UF BPA will be the company that receives the UF BPA, and must match the FSS. No subsidiaries, affiliates, or doing business as are allowed.

Questions During Teleconference:

- Q. Regarding the ADHD review of stimulants, how many condition sets can or will be awarded?
- A: One UF BPA and one UF VARR condition set will be awarded for the ADHD stimulant class.
- Q. Can you go over some hypothetical examples that explain the mechanics of each condition set?
- A: For the ADHD Stimulant review, there are four UF BPA and two UF VARR condition sets. Basic Core Formulary (BCF) does not apply in the Retail point of service, hence the reason for only two UF VARR

condition sets. Both Basic Core Formulary condition sets offer the option of up to two UF positions, one of these two positions being the BCF selection. In the Before Step Therapy condition set, the BCF selection would be the UF agent before the step, the second UF agent would also be before the step, but would not be BCF. All other branded agents would be non-formulary. In the UF Before Step Therapy condition set (not BCF or ECF), only one OR two branded UF agent selections are possible before the step. Finally, the UF No Step Therapy condition set, one or more branded agents, allows for multiple branded agents to achieve UF status.

Depending on the UF BPA condition set selected, the corresponding UF VARR will be selected as well, depending on whether step therapy applies or not.

- Q. What is the role of generics with the use of step therapy?
- A: Generics are traditionally ahead of the step. In other words, they occupy the same position as a branded agent before the step.
- Q. Is the expectation to have step therapy required in this category moving forward?
- A: Yes, this is a possibility; however this recommendation is subject to the P&T Committee's discussion during the meeting.
- Q. Are we to assume that the products listed below will be competing against each other regardless of differences in indications?!? If not, which product/products will Dificid be competing against for formulary position?
- A: Dificid will be competing against the other branded products within the Gastrointestinal 2 Agents Miscellaneous class. The list of branded medications can be found http://health.mil/About-MHS/Other-MHS-Organizations/DoD-Pharmacy-and-Therapeutics-Committee/Drug-Classes-New-Drugs-Under-Review/November-2015 within the BPA VARR Information link.
- Q. Are you looking for Brand, Generic or both?
- A: With respect to the condition sets, they apply to brand only. Within the ADHD Stimulant class review, prior authorization criteria may apply as well as step therapy, meaning that if a condition set is selected with step therapy, the drug selected before the step will be preferred before the other branded agents. Generics will also be before the step as well.