Pre-proposal Conference
Meeting Minutes for UF BPA/VARR
November 10, 2015
9:30 AM to 10:30 AM MST

Covering
Quotes for February 2016
DoD P&T Committee Reviews

1. Attendance

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

   Matthew Halbe – Contract Analyst – DHA Contract Management

   Tammera Cardinal – Jr. 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/February-2016

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

3. Drug Classes:
   a. **Oral Contraceptives**
   b. **Antifungal Agents-Topical Lacquers**
   c. **Ophthalmic Anti-Inflammatory/Immunomodulatory Agents-Ophthalmic Immunomodulatory Agents**
   d. **Designated Newly Approved Drugs**
      i. **Rexulti –** solicitation cancelled
      ii. **Tivorbex**
      iii. **Pazeo**
      iv. **Afrezza**
      v. **Stiverdi Respimat**
      vi. **Entresto –** solicitation cancelled

4. Quote Submissions
   a. Due date for all original quotes and email duplicates is December 17, 2015 at 11:00 AM MST, 1:00 PM EST. Any quote submitted after that will be considered late and will not be accepted.

   All original quotes and email duplicates are due on December 17, 2015 at 11:00 AM MST. Suppliers are encouraged to submit their quotes early. For overnight delivery, it is suggested suppliers use FedEx Priority mail.

   b. New DHA Point of Contact: Tammera Cardinal, tammera.j.cardinal.ctr@mail.mil, Ph: (303) 676-3440

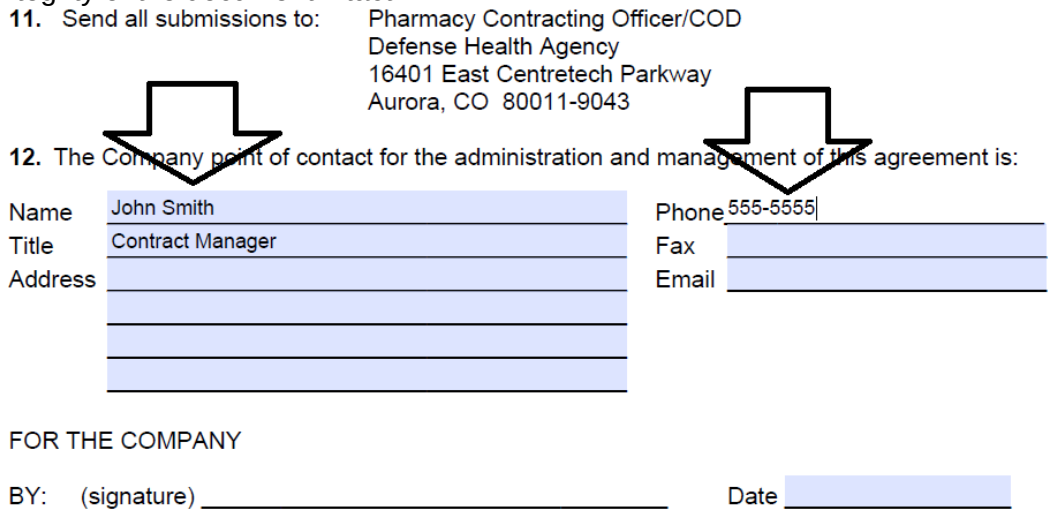
c. Other

i. Documents are fillable

ii. An original signed BPA and VARR quote submitted for each different drug. Example: if you submit a quote for Pazeo and Afreeza you cannot use just one signed quote, they must each have their own original signed quote.

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

For Example: The fillable fields allow you to type in your company information while keeping the integrity of the document intact.



iii. 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 BPA, VARR and all instructions that accommodate it to ensure the quoting procedure is properly followed.

Past Reasons for non-responsive:

Non-Responsive Reason	Citation
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 UFBPA at the time the quote is submitted, and at the time the UFBPA is executed”
Signed BPA terms and conditions is not submitted on time	http://www.health.mil/About-MHS/Other-MHS-Organizations/DoD-Pharmacy-and-Therapeutics-Committee/Drug-Classes-New-Drugs-Under-Review/February-2016
Ensure calculations are correct and to four decimal places	BPA Paragraph 10 Line 13
Price per dosage unit will be the same for all package sizes	BPA Paragraph 8.b

Company name on the BPA will be the company that receives the BPA, and must match the FSS. No subsidiaries, affiliates, or DBA's are allowed.

Questions During Teleconference:

Q: We received the following email notification regarding the upcoming review which includes the Oral Contraceptives class. While reviewing the utilization file we noticed the following products which are NOT oral, IMPLANON, NEXPLANON, and NUVARING.
Can you confirm this class is only Oral Contraceptives?
Answer: Yes, this class review is covering just the Self-Administered drugs.

Q. Is a Permanent FCP i.e First Full Quarter FCP needed to be on the FSS contract before a bid can be submitted or will any pricing on the FSS contract be suitable i.e. Provisional or Temporary? The bid documents don't seem to disclose this? Any clarification is greatly appreciated.
Answer: For a UF BPA to be executed, a permanent FSS price must be in place at the time the quote is submitted and is executed as a BPA. It must be fixed pricing and cannot be provisional or temporary because we need to ensure that the pricing will not change. See paragraph 10 of the BPA.

Q. Is this for brand products?
Answer: Yes

Q. Are generic medications being reviewed?
Answer: The uniform formulary positions within the condition sets are for brand name medications only. We do not expect bids for generic medications.

Q. Is the whole class for Pazeo being reviewed?
Answer: No, just Pazeo because the class was reviewed in the past, and Pazeo is considered a new drug in a previously reviewed class.

Q. What is the difference of the review for Afrezza now versus the review done in June?
Answer: The review done in June was for PA.

The Ophthalmic class review is just reviewing the sub class and only branded drugs within that sub-class i.e. Restasis.

Bullet points discussed.

The vendor name in paragraph 1, 10(b), 12 and the FSS contract number must match, cannot accept (example given) ABC Contractor on the Quote and the FSS Master Agreement has ABC Supplier.

The FSS contract number in paragraph 10 (b) and the FSS contract itself must match.

The unit price per dosage must be the same.
Example given; 500 mg, 30 tablet bottle, 500 mg 60 tablet bottle, 500 mg 90 table bottle must all have the same price of $0.3466 (the four decimal pricing)

If there is a discrepancy between the unit price and the NDC price, the NDC price will take precedence; however, the unit price per dose should match.

Must submit a pricing appendix for each NDC within the class unless an exception is submitted. Matt Halbe injected that the exception needs to be submitted and approved by the contracting officer prior to the cut off time and due date of the quote submittal.

If there are clerical errors on the quote submission and the quote is submitted early we may have time to fix the error, but it will be on a case by case basis.

Chris Conrad stated in regards to the innovator drug program, the clinical subject matter experts are not planning to accept clinical meetings from industry at this time due to the volume of innovator drugs and timing (some innovator drugs might receive FDA approval too close to the P&T meeting and not have a chance to get an appointment). When the innovator drug is part of a class review, an opportunity to schedule a clinical presentation as is customary will be provided. Additional information on the Innovator Drug Program as well as the Expanded MTF/Mail Pharmacy Initiative and Mail Order Requirement for Non-Formulary (Tier 3) Drugs can be found below.

1) Innovator Drug Program - Prior to review by the DoD P&T Committee, newly approved innovator drugs are considered to be in a classification pending status and will be covered by TRICARE under terms applicable to Tier 3 drugs. The requirement that NF (Tier 3) medications be filled at mail order does NOT apply to drugs in pending status. However, branded, legend medications intended for chronic use and falling into drug classes that the DoD P&T Committee has pre-defined as suitable for mail order dispensing may be automatically added to the Expanded MTF/Mail Pharmacy Initiative list (e.g., new antihypertensives).

2) The Expanded MTF/Mail Pharmacy Initiative (EMMPI) list is defined by the DoD P&T Committee, which recommends additions and removals. The program, which began 1 Oct 15, requires that non-Active Duty beneficiaries initiating treatment with drugs on the EMMPI list must fill those prescriptions at MTFs or mail order, following two courtesy fills at retail. The requirement can be waived based on individual patient needs and other appropriate circumstances. The EMMPI list contains pharmaceuticals prescribed for a chronic, long-term condition and taken on a regular recurring basis; clinically appropriate to dispense from mail; available for initial fill at retail pharmacies, for initial fill and refill at MTFs, and for refills at mail; and cost effective to dispense from mail. Currently the EMMPI list contains only branded medications, since costs for generic medications tend to be similar across pharmacy points of service.

3) Mail Order Requirement for Non-Formulary (Tier 3) Drugs - The statutory requirement for non-formulary (Tier 3) drugs presumes that non-formulary (Tier 3) medications be generally available only at mail, (although they can be made available at retail or MTFs if medically necessary for an individual patient). The P&T Committee may recommend general exceptions to the requirement based on clinical concerns and feasibility issues. Previously defined exceptions include C-IIs, antipsychotics, medications for acute use, oncology drugs, medications unavailable at mail order (e.g., limited distribution, shortages), and non-formulary (Tier 3) blood glucose test strips.