Uniform Formulary Solicitation, Price Quotes and Uniform Formulary Blanket Purchase Agreement

1. PRICE QUOTE FOR INCLUSION ON UNIFORM FORMULARY: By submitting this Uniform Formulary Blanket Purchase Agreement (UFBPA) price quote,

henceforth, Company, agrees to provide pharmaceutical agents to military treatment facilities (MTFs), and the TRICARE Mail Order Pharmacy (TMOP) at the prices quoted at the attached Appendices. Company agrees to hold its UFBPA price quote valid for 180 days. These prices shall be lower than, or equal to, the Federal Supply Schedule (FSS), to include Temporary Price Reductions (TPRs) and/or Big 4 prices available to the Department of Defense (DoD) for the pharmaceutical agent(s). This price quote is contingent upon the pharmaceutical agent(s) being included on the DoD Uniform Formulary (UF). If the price quote is also contingent upon the number of different pharmaceutical agents selected for the UF, that condition shall be identified in the Appendices to this document. In addition to clinical effectiveness, per 32 CFR 199.21(a)(3)(ii), the DoD Pharmacy and Therapeutics (P&T) Committee will consider the price quote as part of its evaluation of the relative cost effectiveness of pharmaceutical agents in recommending the selection of agents for the UF, and the classification of a pharmaceutical agent in the generic, formulary, or non-formulary cost share tier. Assuming the DoD P&T Committee's relative cost effectiveness analysis determines that a pharmaceutical agent should not be recommended for exclusion from the UF, the P&T Committee will apply the standards described in 32 CFR 199.21(j) to determine whether the pharmaceutical agent should be placed in the generic or formulary cost share tier. Should the DoD P&T Committee review the therapeutic class relevant to the pharmaceutical agent(s) contained in the Company's UFBPA price quote, and make recommendations consistent with the Company's UFBPA price quote, and should the Director, Defense Health Agency (DHA), make a final decision to accept that recommendation, a DHA Contracting Officer will establish a UFBPA that incorporates the UF prices guoted for the pharmaceutical agents in the attached Appendices by completing Paragraph 13 below. The establishment of a UFBPA with a pharmaceutical company for a generic (multi-source) pharmaceutical agent does not establish that pharmaceutical company as the sole source of supply for the pharmaceutical agent. However, in the event of existing Joint DoD/Veterans Administration (VA) contracts, UFBPA guotes will not be accepted for generic (multi-source) pharmaceutical agents.

2. PRICE QUOTE FOR INCLUSION ON BASIC CORE FORMULARY OR EXTENDED CORE FORMULARY: The Basic Core Formulary (BCF) and Extended Core Formulary (ECF) are subsets of the UF. The DoD P&T Committee determines whether a pharmaceutical agent is to be evaluated for the BCF or the ECF. The Company agrees to provide pharmaceutical agents to MTFs at the prices guoted in the attached Appendices, contingent upon the pharmaceutical agent(s) being included on the BCF or the ECF. Company agrees to hold its UFBPA price quote valid for 180 days. These prices shall be lower than, or equal to, the Federal Supply Schedule (FSS), to include Temporary Price Reductions (TPRs), and/or Big 4 prices available to DoD for the pharmaceutical agent(s). If the price quote is also contingent upon the number of different pharmaceutical agents selected for the BCF or the ECF, that condition shall be identified at the attached Appendices to this document. In addition to clinical effectiveness, per 32 CFR 199(a)(3)(ii), the DoD P&T Committee will consider the BCF or the ECF price quote as part of its evaluation of the relative cost effectiveness of pharmaceutical agents in recommending the selection of one or more agents for inclusion on the BCF or ECF. Should the DoD P&T Committee recommend the inclusion of the Company's pharmaceutical agent(s) on the BCF or the ECF, and should the Director, DHA, make a final decision to accept that recommendation, a DHA Contracting Officer will establish a UFBPA that incorporates the BCF or ECF prices quoted for the pharmaceutical agents in the attached Appendices by completing Paragraph 13 below. The establishment of a UFBPA with a pharmaceutical company for a generic

(multi-source) pharmaceutical agent does not establish that pharmaceutical company as the sole source of supply for the pharmaceutical agent. However, in the event of existing joint DoD/VA contracts, UFBPA quotes will not be accepted for generic (multi-source) pharmaceutical agents.

3. SCOPE: Upon execution of the UFBPA, prices will be provided to the DoD Prime Vendor via the Defense Logistics Agency (DLA) Troop Support.

4. EFFECTIVE DATE and PERIOD OF RESULTING PRICING AGREEMENT: The agreement will be effective upon signature of the Contracting Officer. However, prices will not be effective until loaded into the electronic pricing database by DLA upon receipt of the signed copy by the Contracting Officer. Prices will be loaded into the electronic pricing database by DLA on a date agreed to between the DLA and the Company; however, prices shall be effective in the DoD's Prime Vendor systems for MTFs and TMOP purchases no later than 14 calendar days after the date this agreement is signed by the DHA Contracting Officer. However, the date that the formulary status changes and any restrictions are applied is the date the Director, DHA, makes the final UF decision or the effective date specified by the Director, DHA. The agreement will continue until 1) the drug class that contains this pharmaceutical agent(s) is/are reevaluated and any resulting changes implemented; or 2) it is otherwise terminated in accordance with Paragraph 8, <u>Prices and Price Changes</u>, or Paragraph 9, <u>Termination</u>, stated below. If the drug class containing this pharmaceutical agent(s) is/are reevaluated therein, will terminate when the follow-on UFBPA is signed.

5. PARTICIPATING ENTITIES: Ordering activities are MTFs and TMOP. MTF prices specified herein will apply to all transactions for the specified pharmaceuticals made by DoD MTF pharmacies, USFHP Designated Providers, and the U.S. Coast Guard. TMOP prices will apply to all transactions for the specified pharmaceuticals made by the TMOP contractor to replenish stock used to fill prescriptions for TRICARE beneficiaries through the TMOP. "Other Government" ordering activities are excluded from utilizing these UFBPA prices. The ordering activity is not defined by the Prime Vendor utilized.

6. EXTENT OF GOVERNMENT OBLIGATION: This price quotation imposes no obligation on DoD to purchase any product. If a UFBPA is signed by both parties, DoD will be obligated only to the extent of authorized transactions actually made pursuant to that agreement, according to the pharmaceutical agent's inclusion on the UF, cost share tier classification on the UF, and inclusion on the BCF or the ECF.

7. FINAL APPROVAL BY GOVERNMENT: In submitting this UFBPA price quote, the Company understands that the DoD P&T Committee will consider these prices in determining the cost of the pharmaceutical agent to the government as part of its relative cost effectiveness evaluation. The prices in the UFBPA price quotation will not be accepted, or UFBPA executed until such time as the Director, DHA, approves the recommendation of the DoD P&T Committee. Pursuant to 10 U.S.C. 1074g and 32 CFR 199.21, the recommendations of the DoD P&T Committee and the final decisions of the Director, DHA are not limited by the condition sets for which price quotes are solicited.

8. PRICES and PRICE CHANGES:

(a) Company agrees to provide its products at prices no higher than those submitted here, in any resulting UFBPA for at least **one calendar year** following the date of that UFBPA. However, during the time period that the UFBPA is in effect, Company may offer price decreases at any time for any duration.

(b) The price per dosage form unit for a given dosage form and strength of the pharmaceutical agent will be the same for all available package sizes (e.g., 30s, 100s, 1000s) within a given dispensing

venue. Quotes must include all National Drug Codes (NDCs) available for purchase by the Government and on the Company's FSS contract for quoted form and strength. Company requests for exception to the same price per dosage form unit across package sizes must be submitted in writing to the Contracting Officer not less than 14 calendar days prior to the quote due date. It is within the Government's sole discretion to grant an exception. The Contracting Officer may be contacted using the address in Paragraph 11. If an exception is granted by the Government, the DoD P&T Committee's relative cost evaluation for that dosage form and strength will use the price per dosage form unit from the package size with the highest price per dosage form unit. Company requests to exclude Hospital Unit Dose packaged NDCs must be submitted in writing to the Contracting Officer not less than 14 calendar days prior to the quote due date. The Contracting Officer may be contacted using the address in Paragraph 11. The Government's decision on exclusion of Hospital Unit Dose packaged NDCs or exception(s) to the same price per dosage form unit across package sizes will be provided to the Company no more than seven calendar days after receipt of the request. The Government decision is final and not subject to appeal.

(c) If after one calendar year following the date of this UFBPA, and no more frequently than annually thereafter, there has been an increase in the Federal Ceiling Price reflected on Company's FSS contract, Company may request to increase its price under the UFBPA. However, in no event shall a price increase exceed the percentage increase in the Consumer Price Index (CPI) for All Urban Consumers, current series, as published by the Bureau of Labor statistics, U.S. Department of Labor, for Prescription Drugs and Medical Supplies over the time period elapsed since the UFBPA price was last set. The Company shall notify the Contracting Officer in advance if the Company desires a CPI price increase. The CPI price increase and effective date will be incorporated via a modification to this agreement by mutual agreement of the parties.

(d) If during the life of the UFBPA, the FSS or Big 4 prices, including TPRs, become lower than the UFBPA prices, DoD reserves the right to order at those prices. The Company agrees the Contracting Officer may unilaterally terminate the UFBPA if the FSS or Big 4 prices become lower than the UFBPA prices, including TPRs, unless the parties agree to decrease the UFBPA prices.

9. TERMINATION: Except as provided in Paragraph 4, <u>Effective Date and Period of Resulting</u> <u>Pricing Agreement</u> and Paragraph 8, <u>Prices and Price Changes</u>, above, either party may terminate this UFBPA by providing written notice to the other. Such notice shall be effective one hundred twenty (120) days, or earlier if all parties agree, following receipt of notice of termination by the other party. If the Company's existing FSS Contract for any pharmaceutical agent(s) quoted in this UFBPA terminates for any reason (except where new FSS Contract(s) for the same item(s) is/are negotiated), this UFBPA automatically expires.

10. GENERAL PROVISIONS: 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. All terms of Company's FSS Contract apply to this agreement. (NOTE: The VA has ruled that an "FSS Interim Agreement" is an undefinitized Letter Contract as defined by Federal Acquisition Regulation Part 16.603 and does not support the execution of a UFBPA. Quotes submitted under FSS Interim Agreements will not be considered by the DoD P&T Committee when evaluating the relative cost effectiveness of a pharmaceutical agent.)

- a. Name of Company on FSS Contract
- b. Company's current FSS Contract number
- c. DoD P&T Committee designated Drug Class quoted in this UFBPA
- d. DoD Condition Set Provisions:

- 1) All generic agents may be on the UF.
- 2) All generic agents are eligible to be used before the step therapy and are not included in Condition Set scenarios quotes.
- 3) Generic agents may be on the BCF and are not included in Condition Set scenario quotes.
- 4) Generic agents will be used in cost analysis at the lowest available price.
- 5) Brand name agents with generic equivalents are only available if medically necessary. The pharmacy benefits program mandates substitution of generic drugs listed with an "A" rating in the current Approved Drug Agents with Therapeutic Equivalence Evaluations (Orange Book) published by the Federal Drug Administration unless sufficient clinical justification from the prescriber is submitted.
- 6) If a generic formulation of a branded product becomes available, DHA reserves the right to use the generic formulation of the branded product as the step-preferred agent.
- 7) BCF agents are approved by generic name, dose and form.
- 8) DHA reserves the right to evaluate a combination agent's merit either as a single entity or relative to the component agents.
- 9) Step-preferred agent(s) are agents available prior to the step therapy criteria process.
- 10) Step therapy, a prior authorization process, would require all new patients to complete an adequate trial of the step-preferred agent(s) before a non-step-preferred agent is provided to a new user through a MTF pharmacy or TMOP. Unless otherwise noted, patients must have tried an agent in the class in the previous 180 days in order to be excluded from the prior authorization process.
- 11) DHA reserves the right to evaluate an agent's various formulations as individual brand agents or view the formulations as one brand agent.
- 12) Prior Authorizations based on clinical criteria may be placed on any agent.
- 13) All prices quoted must include applicable FSS Industrial Funding Fee (IFF). All package sizes must be expressed as whole numbers using numeric characters only. Any alphanumeric package size information provided must be included in the drug name field. **Prices per strength and dosage form must be shown to four decimal places.** Package prices must equal dosage form prices multiplied by the package size. A quote must be submitted for each strength and dosage form identified by NDC number (11 digits) on the attached Appendices. **NOTE:** The P&T Committee has excluded most NDCs for Hospital Unit Dose packaging and injectable forms covered for outpatient use by the TRICARE pharmacy benefit program.

11. Send all submissions to: Pharmacy Contracting Officer/COD Defense Health Agency 16401 East Centretech Parkway Aurora, CO 80011-9043

12. The Company point of contact for the administration and management of this agreement is:

Name Title Addre		_ Phone _ Fax _ Email	
FOR ⁻ BY:	THE COMPANY (signature)	- Date	
51.	Name		
	Name of COMPANY		

13. (To be completed by the DHA Contracting Officer)

A UFBPA is hereby established between the Company and the DoD for the pharmaceutical agents and applicable prices quoted in the attached the Appendices. Based on the final decision of the Director, DHA to [fill in the Condition Set for all that apply]:

Include the pharmaceutical agent(s) on the UF for the	Condition Set:
TRICARE Mail Order Pharmacy (TMOP)	
Include the pharmaceutical agent(s) on the UF for the	Condition Set:
Military Treatment Facility (MTF)	
Include the pharmaceutical agent(s) on the UF for the	Condition Set:
Basic Core Formulary (BCF)	
Include the pharmaceutical agent(s) on the UF for the	Condition Set:
0 (<i>i</i>)	
Extended Core Formulary (ECF)	

BY:

Name: Bruce Mitterer DHA Contracting Officer

Date