DoD P&T Committee Class Evaluation Information

(hereinafter referred to as "Class" and medications in the Pharmaceutical Agents table referred to as "Agents")

NOTE: The DoD Pharmacy and Therapeutics (P&T) Committee will consider Uniform Formulary Blanket Purchase Agreement (UF BPA) price quotes and Voluntary Agreement for TRICARE Retail Pharmacy Refunds (UF VARR) quotes that are contingent upon the number of agents selected for the Uniform Formulary (UF). The government is not soliciting UF BPA or UF VARR quotes for innovator drugs. The Condition Sets and procedures for submitting UF BPA and UF VARR quotes are outlined in the UF BPA Appendix, the UF VARR Appendix, and under the "UF BPA and UF VARR Quotes" section below:

Drug Class Description / Pharmaceutical Agents:

The DoD P&T Committee intends to evaluate the following pharmaceutical agents in these classes at the upcoming meeting:

DoD Uniform Formulary Class: ORAL CONTRACEPTIVES
DoD Uniform Formulary Sub-Class: EMERGENCY CONTRACEPTIVES

ELLA
PLAN B ONE-STEP

DoD Uniform Formulary Class: ANTICONVULSANTS
DoD Uniform Formulary Sub-Class: N/A

APTIOM	LAMICTAL ODT	QUDEXY XR
BANZEL	LAMICTAL XR	SABRIL
EQUETRO ER	ONFI	STAVZOR
FYCOMPA	OXTELLAR XR	TROKENDI XR
GABITRIL	POTIGA	VIMPAT

Keppra XR (added 2/17/2016)

DoD Uniform Formulary Class: ANTIPSYCHOTIC AGENTS
DoD Uniform Formulary Sub-Class: ATYPICAL

FANAPT	SAPHRIS
INVEGA	SEROQUEL XR
LATUDA	VRAYLAR
REXULTI	

Designated Newly Approved Drugs:

ENTRESTO
VIBERZI
ZECUITY

Uniform Formulary Considerations and Evaluation Criteria

In accordance with 32 CFR 199.21, the DoD P&T Committee will consider the relative clinical effectiveness and relative cost effectiveness of each class in recommending a cost share tier classification (i.e., generic (Tier 1), formulary (Tier 2), or non-formulary (Tier 3) for each agent. There is no minimum or maximum number of agents that may be placed in a given cost share tier classification, though you may submit multiple quotes based on different condition sets (See NOTE above and UF BPA and UF VARR Quotes section below). Although all the formulations (dosage

forms and/or strengths) for a given agent would typically be recommended for the same cost share tier classification, the DoD P&T Committee reserves the right to recommend different cost share tier classifications for a particular formulation of a given agent if the DoD P&T Committee finds significant differences in the clinical effectiveness or cost effectiveness between formulations of a given agent.

Basic Core Formulary (BCF) and Extended Core Formulary (ECF) Considerations

All agents recommended for the generic (Tier 1) or formulary (Tier 2) cost share tier on the Uniform Formulary will be considered for inclusion on the BCF/ECF. The DoD P&T Committee intentions for the number of BCF/ECF agents in each class and subclass are listed in the UF BPA appendix.

UF BPA and UF VARR Quotes

At this time, DoD solicits and will consider price quotes using two different instruments: the UF BPA price quote and the UF VARR quote. Pharmaceutical companies must use the UF BPA price quote for prices that will apply to MTFs and the Mail Order Pharmacy. Pharmaceutical companies must use the UF VARR quote for refunds that will apply to pharmaceuticals dispensed by pharmacies in the Retail Pharmacy Network. While generally similar, each instrument has specific instructions and different submission details.

Price Quotes for MTFs and Mail Order Pharmacy – (Price Quote Instrument: **UF BPA**)

The item descriptions and NDC numbers for this class that are covered by Federal Supply Schedule (FSS) contracts are listed in the class utilization dataset. A UF BPA price quote for a given agent must include all the NDCs that are included on the FSS contract, **unless a request to exclude specific institutional or hospital unit dose packaged NDCs are submitted in advance and approved by the DHA Contracting Officer in writing in accordance with paragraph 8 of the UF BPA**.

The prices submitted in the UF BPA price quotes will be contingent upon the number of agents selected for the UF and BCF/ECF. Pharmaceutical companies that submit UF BPA price quotes **must submit a separate pricing appendix for each NDC**. This will ensure that a company will have a valid price quote for whatever number of agents is recommended for inclusion on the UF and/or BCF/ECF. Additionally, for each agent that is quoted, there must be a signed UF BPA (for instance, if a pharmaceutical company provides pricing on two different agents, there must be two signed UF BPAs to accommodate).

On each pricing appendix, pharmaceutical companies are required to provide a price per unit of measure (each, gram, mL, etc) as well as a price per NDC (package price) for each condition set. **In the event there is a discrepancy between the two prices, the NDC price will be considered over the per unit price. The NDC price is the agreed upon price at which DoD will purchase product. Unit of measure prices are used for evaluation and administrative purposes only.**

The DoD P&T Committee will not consider UF BPA price quotes that are contingent upon market shares.

The DoD reserves the right to exclude specific formulations of a given class or agent from a submitted UF BPA quote based on the recommendations of the DoD P&T Committee and the final decision of the Director, DHA, regarding the UF and BCF/ECF for specific formulations of a given class or agent.

The establishment of a UF BPA 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, UF BPA quotes will not be accepted for generic (multi-source) pharmaceutical agents.

Price Quotes for the TRICARE Retail Pharmacy Network - (Price Quote Instrument: **UF VARR**)

The item descriptions and NDC numbers for this class, utilized in the TRICARE Retail Pharmacy Network for the last 12 months, are listed in the class utilization dataset. A UF VARR quote for an agent is required to include all the NDCs that are included in the NDC list included in the dataset. Exclusions approved for UF BPAs do not apply to UF VARRs. The DoD will make no attempt to force participating TRICARE retail pharmacies to dispense specific NDCs.

The proposed refunds submitted in the UF VARR quotes will be contingent upon the number of agents selected for the UF. Pharmaceutical companies that submit UF VARR quotes **must submit a separate VARR pricing appendix for each NDC**. This will ensure that a company will have a valid price quote for whatever number of agents is recommended for inclusion on the UF.

The DoD P&T Committee will not consider UF VARR quotes that are contingent upon market shares.

The DoD reserves the right to exclude specific formulations of a given class or agent from a submitted UF VARR quote based on the recommendations of the DoD P&T Committee and the final decision of the Director, DHA, regarding the UF and BCF/ECF for specific formulations of a given agent. UF VARR quotes will not be accepted for generic (multi-source) pharmaceutical agents.

Prior Authorization / Step Therapy

Grandfathering: 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. 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.

No grandfathering: a prior authorization process, would require all patients, regardless of past medication history to complete an adequate trial of the step-preferred agent(s) before a non-step-preferred agent is provided to a user.

Grandfathering unstipulated: DoD reserves the right to choose the grandfathering or no-grandfathering of some or all agents based the total price/clinical evaluations after quotes have been submitted and in the best interests of the Government.

Utilization Data and Determining the Cost of the Class

The **Uniform Formulary Price Quote Information Page** outlines the general approach for determining the cost of this class. Historical utilization data including quantity dispensed and 30 day equivalents by month are provided in the utilization dataset.

The evaluation price for each agent will be:

- **For the MTF and Mail dispensing venues**
    1. A UF BPA price quote
    2. If there is no UF BPA quote, the lower of:

1. Big 4 price as listed on the first day of the month preceding the DoD P&T meeting
2. FSS price as listed on the first day of the month preceding the DoD P&T meeting

- **For the Retail dispensing venue**
  1. UF VARR total calculated retail refund
  2. Absent a UF VARR Quote, the current price as of the first day of the month preceding the DoD P&T meeting

Note: If DHA signs a UF VARR higher than the FCP, this does not waive any right of the Department of Defense under 10 U.S.C. 1074g(f).

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 (UF BPA) price quote, (Enter Company Name Here) 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 UF BPA 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 UF BPA price quote, and make recommendations consistent with the Company's UF BPA 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 UF BPA that incorporates the UF prices quoted for the pharmaceutical agents in the attached Appendices by completing Paragraph 13 below. The establishment of a UF BPA 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, UF BPA quotes 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 quoted in the attached Appendices, contingent upon the pharmaceutical agent(s) being included on the BCF or the ECF. Company agrees to hold its UF BPA 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 UF BPA 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 UF BPA 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, UF BPA quotes will not be accepted for generic (multi-source) pharmaceutical agents.

3. SCOPE: Upon execution of the UF BPA, 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, Prices and Price Changes, or Paragraph 9, Termination, stated below. If the drug class containing this pharmaceutical agent(s) is/are reevaluated, this UF BPA, and the prices contained therein, will terminate when the follow-on prices in any follow-on UF BPA become effective, but no later than 14 calendar days after the follow-on UF BPA 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, TRICARE US Family Health Plan 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 UF BPA 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 UF BPA 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 UF BPA 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 UF BPA price quotation will not be accepted, or UF BPA 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 UF BPA for at least **one calendar year** following the date of that UF BPA. However, during the time period that the UF BPA is in effect, Company may offer price decreases at any time for at least one year duration.

(b) The price per unit of measure for a given dosage form and strength (each, gram, mL, etc.) 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 unit of measure 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 unit of measure from the package size with the highest price per unit of measure. Company requests to exclude institutional or 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 institutional or Hospital Unit Dose packaged NDCs or exception(s) to the same price per unit of measure 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 UF BPA, 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 UF BPA. 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 UF BPA 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 UF BPA, the FSS or Big 4 prices, including TPRs, become lower than the UF BPA prices, DoD reserves the right to order at those prices. The Company agrees the Contracting Officer may unilaterally terminate the UF BPA if the FSS or Big 4 prices become lower than the UF BPA prices, including TPRs, unless the parties agree to decrease the UF BPA prices.

9. TERMINATION: Except as provided in Paragraph 4, Effective Date and Period of Resulting Pricing Agreement and Paragraph 8, Prices and Price Changes, above, either party may terminate this UF BPA 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 UF BPA terminates for any reason (except where new FSS Contract(s) for the same item(s) is/are negotiated), this UF BPA automatically expires.

10. GENERAL PROVISIONS: 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. 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 UF BPA. 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 UF BPA _____.

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 alpha-numeric package size information provided must be included in the drug name field. **Prices price per unit of measure must be shown to two decimal places.** Package prices must equal unit of measure 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 _____ Phone_____
Title _____ Fax _____
Address _____ Email _____
_____
_____
_____

FOR THE COMPANY

BY: (signature) _____ Date _____

Name _____

Title _____

Name of COMPANY_____

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

A UF BPA 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 TRICARE Mail Order Pharmacy (**TMOP**)	Condition Set:
Include the pharmaceutical agent(s) on the UF for the Military Treatment Facility (**MTF**)	Condition Set:
Include the pharmaceutical agent(s) on the UF for the Basic Core Formulary (**BCF**)	Condition Set:
Include the pharmaceutical agent(s) on the UF for the Extended Core Formulary (**ECF**)	Condition Set:

UF BPA Number _____

BY: _____ _____

Bruce Mitterer Date
DHA Contracting Officer

TRICARE Pharmacy Voluntary Agreement for Retail Refunds (Additional Refund) for Uniform Formulary Placement (UF VARR)

CAVEATS:

The parties acknowledge that 32 C.F.R. §199.21(q), effective May 26, 2009 provides that as a condition for placement on the Uniform Formulary (UF), manufacturers are required to agree to honor Federal Ceiling Prices (FCP) for prescriptions filled in retail network pharmacies. That regulation implements 10 U.S.C. §1074g (f) which provides:

PROCUREMENT OF PHARMACEUTICALS BY TRICARE RETAIL PHARMACY PROGRAM: With respect to any prescription filled after January 28, 2008, the TRICARE retail pharmacy program shall be treated as an element of the Department of Defense (DoD) for purposes of the procurement of drugs by Federal agencies under §8126 to title 38 to the extent necessary to ensure that pharmaceuticals paid for by the DoD that are provided by pharmacies under the program to eligible covered beneficiaries under this section are subject to the pricing standards in such §8126.

GENERAL CONCEPT: UF VARR is contingent upon pharmaceutical agents being placed on the generic (1st tier) or formulary (2nd tier) of the DoD Uniform Formulary. Refund quotes for UF VARRs may be submitted only for pharmaceutical agents that are scheduled for review by the DoD Pharmacy & Therapeutics (P&T) Committee at the next Committee meeting. The DoD P&T Committee will consider refund quotes for UF VARRs as part of its evaluation of the relative cost effectiveness of pharmaceutical agents in recommending the placement of pharmaceutical agents on the DoD Uniform Formulary.

Refund Quote for Inclusion on Uniform Formulary (UF)

1. REFUND QUOTE FOR INCLUSION ON THE UNIFORM FORMULARY: By submitting this UF VARR quote, the pharmaceutical manufacturer listed in Paragraph 13 below, henceforth the Company agrees to provide refunds to the Government based on the accrued utilization of and the refund stated for the pharmaceutical agent(s) listed on the attached UF VARR Appendix. All NDC-11 packages of the pharmaceutical agent(s) marketed during the life of this agreement are covered by this agreement.

The accrued utilization will be based on the listed pharmaceutical agents that are dispensed to eligible beneficiaries by TRICARE network pharmacies under the DoD pharmacy benefits management contract associated with the TRICARE Retail Pharmacy Program. The refund quote(s) for the pharmaceutical agent(s) listed in the UF VARR Appendix is (are) contingent upon such pharmaceutical agent(s) being included on the DoD Uniform Formulary in not worse than the formulary (2nd) cost share tier.

The DoD P&T Committee will consider the refund quote for the pharmaceutical agent(s) listed in the UF VARR Appendix in the cost to the Government portion 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 (1st), formulary 2nd), or non-formulary (3rd) cost share tier. If the DoD P&T Committee determines that a pharmaceutical agent should be recommended for inclusion on the UF, the DoD P&T Committee will also make a recommendation whether the pharmaceutical agent should be placed in the generic or formulary cost share tier in accordance with 32 C.F.R. 199.21(j).

If the Director, Defense Health Agency (DHA), makes a final decision to accept the recommendations of the P&T Committee relative to the pharmaceutical agent(s) contained in the Company's refund quote and places the pharmaceutical agent(s) on the UF in not worse than the formulary (2nd) cost share tier, the DHA Chief, Pharmacy Operations Division, on behalf of the Department of Defense, will establish a UF VARR by completing Paragraph 14, UF VARR Execution, below.

2. SCOPE: The Company's quoted refund along with quarterly TRICARE Retail Pharmacy Network utilization for the quoted pharmaceutical agent(s) will be used to calculate the amount due under this Agreement and the amount to be paid to the Government as outlined in this Agreement.

3. EFFECTIVE DATE and PERIOD OF RESULTING PRICING AGREEMENT: The Agreement effective date shall be the date the Director, DHA, makes the final decision regarding placement of the pharmaceutical agent(s) on the UF. Refund accrual and invoicing will be calculated in accordance with Paragraph 8. The Agreement will continue until the effective date of any change in the classification of the pharmaceutical agent(s) contained in the Agreement as UF agent(s), or is otherwise terminated in accordance with Paragraph 10, Termination, below.

4. ELIGIBLE TRANSACTIONS: The refund will apply to all prescription transactions where a TRICARE Retail Network Pharmacy dispenses a pharmaceutical agent listed in the UF VARR Appendix to a DoD beneficiary in accordance with terms of the DoD pharmacy benefits management contract associated with the TRICARE Retail Pharmacy Program.

The Company shall not be required to pay a refund under this Agreement with respect to utilization of a pharmaceutical agent if such agent was dispensed at a Military Treatment Facility (MTF); TRICARE Home Delivery; or non-network retail pharmacies. Additionally, the Company shall not be required to pay a refund under this Agreement for retail dispensings submitted for reimbursement by eligible beneficiaries as a Direct Member Reimbursement (DMR)(paper) claim; retail dispensings submitted for reimbursement by state Medicaid agencies; retail dispensings submitted for reimbursement by commercial payers (e.g., Coordination of Benefits (COB) claims where TRICARE is the second payer); retail dispensings submitted for reimbursement by aggregators/clearinghouses; compound prescriptions; or repackaged products.

5. FINAL APPROVAL BY THE GOVERNMENT: In submitting this UF VARR refund quote for the pharmaceutical agent(s) listed in the UF VARR Appendix hereto, the Company understands that the DoD P&T Committee will consider the quoted refund(s) in determining the cost of such pharmaceutical agent(s) to the Government as part of its relative cost effectiveness evaluation of such pharmaceutical agent(s). The incorporation of a refund quote into DoD executed UF VARR is contingent upon final decision of the Director, DHA, approving the recommendations of the DoD P&T Committee.

6. EXTENT OF GOVERNMENT OBLIGATION: The placement of the listed pharmaceutical agent(s) in the UF is not worse than the formulary (2nd) cost share tier in accordance with the final decision of the Director, DHA, is a condition of receiving refunds under this Agreement. This Agreement imposes no obligation on the DoD to purchase any product.

7. REFUND: (1) The Company agrees to hold open its UF VARR refund quote for one hundred- eighty (180) days.

(2) Refund quotes will be submitted as a percentage **(expressed to four (4) decimal places XX.XXXX%)** of the most recent annual Non-Federal Average Manufacturer Price (Non-FAMP). This

refund, the Additional Refund, will be added to the refund required by 10 U.S.C. §1074g (f) and 32 C.F.R. §199.21(q), the Standard Refund. Only one Additional Refund quote will be submitted for each pharmaceutical agent. The Additional Refund quote applies to all NDC-11 packages from which the pharmaceutical agent is dispensed. The most recent annual non-FAMP is the annual non-FAMP (reported to the Department of Veterans Affairs) from which the current annual Federal Ceiling Price calculated ceiling is derived. The most recent annual non-FAMP is applicable to all prescriptions filled during a calendar year. The quoted refund percentage will remain static during the life of the agreement but the most recent annual non-FAMP, and thus the calculated refund, may change at the beginning of each calendar year.

Defense Health Agency reserves the right to use the Wholesale Average Cost (WAC) in place of non-FAMP for some medications/devices.

During the time period that the UF VARR is in effect, the Company may offer larger refunds at any time. After UF decisions for pharmaceutical agents included in this Agreement are made and while this Agreement is in effect, the Company may submit supplementary performance-based agreements for increased refunds for consideration by the DoD but shall be under no obligation to do so.

(3) In the event that the Company transfers the right to manufacture the pharmaceutical agent(s) covered by this agreement, whether by change in the Company's corporate ownership or otherwise, this UF VARR is automatically assigned to the transferee and all terms and conditions of this UF VARR remain in effect. The Company remains liable for all refunds on pharmaceutical agents dispensed within one hundred twenty (120) days after its notification to the Pharmacy Operations Division of the transfer.

8. UTILIZATION ACCRUAL AND INVOICING: (1) For purpose of calculating the refund in excess of the current FCP, the accrual of TRICARE Retail Network utilization will begin on the date that the UF status becomes effective in the TRICARE Retail Pharmacy Network. That date is the date the Director, DHA, makes the final UF decision or the effective date specified by the Director, DHA. The Government shall provide utilization data to the Company on a quarterly basis.

The billing cycle will be calendar quarters, with billing periods of January – March, April – June, July – September, and October – December. Invoices for pharmaceutical agents on the UF VARR will be distributed by the DoD on or about the 15th day of the month following the preceding billing period with payment due seventy (70) days from the date the utilization data is made available to the manufacturers.

Failure to pay in full without following the outlined dispute resolution process by the designated payment due date, or without an approved extension may result in the termination of this UF VARR and reconsideration by the DoD P&T Committee of the listed pharmaceutical agents' placement on the UF, in addition to any other remedies available to DoD.

(2) The DoD will provide billing information for the payment of pharmaceutical agents on the UF VARR and reconciliation materials due by the Company, and obtain invoicing information for the Company's agent listed in Paragraph 13, The Company, below. Invoices will note the billing period, and provide a summary of accrued utilization by product listing (NDC-11) for that billing period by unit (tablet, capsule, inhaler, etc.) and the percent refund in this UF VARR. The Company will submit the TRICARE Retail Refunds Reconciliation of Quarterly Utilization with the payment for each invoiced product listed and the dollar total of the refund by product listing (NDC-11).

(3) The Company may also obtain reporting of the billing period's accrued utilization by transaction from DoD.

9. RESOLUTION OF DISAGREEMENTS CONCERNING DATA USED TO DETERMINE REFUNDS: If the Company disputes the accuracy of the utilization data, the refund obligation as to the amount in dispute will be deferred pending good faith efforts to resolve the dispute in accordance with procedures established by the Director, DHA. When the dispute is resolved, any refund owed relating to the amount in dispute will be subject to interest, penalties, and fees from the date payment of the amount was initially due, consistent with 199.11 See 32 C.F. R. §199.21(q)(3)(iv).

10. TERMINATION: Except as provided in Paragraph 7(1) of this Agreement, either party may terminate this UF VARR by providing written notice to the other party as identified in Paragraphs 12 and 13 respectively. Such notice shall be effective one hundred-twenty (120) days following receipt of written notice of termination by the other party. In the event the class of drugs specified herein has previously been reviewed, the government solicits quotes for new BPAs/VARRs to replace any existing BPAs/VARRs. The government will not consider existing BPA/VARR prices in the UF evaluation. Any existing BPA/VARR for this class of drugs will be terminated upon the conclusion of the UF decision.

11. GENERAL PROVISIONS: Any "covered drug" as defined in 38 USC 8126(h)(2) subject to this agreement must be on the Company's FSS contract or have been offered to the FSS but exempted by VA from placement on the 65 I B Schedule.

12. UF VARR SUBMISSIONS: Send all submissions to: Pharmacy Contracting Officer/COD
DoD Uniform Formulary BPA
Defense Health Agency
16401 East Centretech Parkway
Aurora, CO 80011-9043

See next page for UF VARR submission signature page.

13. THE COMPANY: The Company point of contact for the administration and management of this agreement is:

Name:	
Title:	
Address:	
Telephone Number:	
Email Address:	
Fax Number:	

FOR THE COMPANY

By: (Signature)	
Date:	
Name:	
Title:	
Name of Company:	

14. UF VARR Execution: A Uniform Formulary Voluntary Agreement for TRICARE Retail Pharmacy Refunds (UF VARR) is hereby established between the Company and the Department of Defense for the pharmaceutical agents and applicable refunds quoted on the attached UF VARR Appendix based on the final decision of the Director, DHA, to include the pharmaceutical agents on the Uniform Formulary.

By: (Signature)	
Signed Date:	
Effective Date:	
Name:	Bruce Mitterer Contracting Officer Defense Health Agency