

Upcoming P&T COMMITTEE Meeting

Pricing agreements are being reviewed by the TRICARE Management Activity (TMA) Pharmaceutical Operations Directorate (POD) and the Office of General Counsel (OGC), not the Pharmacy and Therapeutics (P&T) Committee. The POD will provide the P&T Committee with a list of non-compliant NDCs as outlined in the implementing regulation. The P&T Committee will review the list developed by the POD and will make a recommendation for placement on the 3rd tier with a paragraph (q)(2)(i)(B) pre-authorization. As with all P&T Committee recommendations, these recommendations will be reviewed by the Beneficiary Advisory Panel (BAP) and the final determination will be made by the Director, TMA. Implementation must occur within one-hundred and eighty (180) days of acceptance by the Director. The estimated implementation date for recommendations made at the August P&T meeting is early 2010.

If a prior-authorization (PA) is already in place from a previous clinical and cost effectiveness review, this PA will remain until a re-review is conducted by the P&T Committee.

Previously Posted Questions and Answers

05.20.09

Proposed Pricing Agreement Revisions

The Pricing Agreement Template TMA has provided notes that manufacturers may propose alternative language if they wish. Several questions about potential revisions have been received.

1. May manufacturers include as part of section VII(f) the clarification posted on the web site referred to as "New Clarification on Pricing Agreement"?

Yes. It is not necessary because DoD has said this is the effect of section VII (f); but if a manufacturer wishes to include that language into the text of the agreement, TMA will not object.

2. If a manufacturer wishes to submit a revised Pricing Agreement, can we have an extension of the June 1 deadline to work out the terms that both TMA and the manufacturer find acceptable?

Pricing agreements, including a completed Appendix A, are due June 1 and there are no extensions. If an agreement submitted by June 1 includes terms that TMA does not accept, but it appears a counterproposal would likely be successful in achieving an agreement, TMA will make a counterproposal,

which, if accepted by the manufacturer, will be treated as meeting the June 1 deadline.

3. The effective date section of the Pricing Agreement template (section VIII) says: "The Agreement will be effective upon signing but will in no way alter the effective date of 10 U.S.C. 1074g(f) of 28 January 2008." Based on the "New Clarification on Pricing Agreement," can we delete the reference to the statutory effective date?

The statutory effective date is January 28, 2008; that cannot be changed or disputed. With respect to manufacturer arguments regarding the effects of that fact, it has been clearly established under section VII (f) that signing the Pricing Agreement does not waive any rights. Thus, DoD sees no rationale for deleting from the Pricing Agreement references to the statute, the statutory effective date, or the regulation.

4. As a substitute for the dispute resolution procedures set forth in the Pricing Agreement Template, will TMA accept alternative procedures similar to those under the Medicaid Rebate Program?

TMA will not agree to dispute resolution procedures that are not consistent with 32 C.F.R. 199.21(q)(3)(iv). This regulation was duly promulgated and has the force of law.

5. In Section III (TMA's Responsibilities), paragraph (b) states that drugs on Tier 2 are available in retail network pharmacies without preauthorization. But it does not state that a drug covered by a pricing agreement, even if on Tier 3, will be available in retail network pharmacies without preauthorization. Will that, in fact, be the case and will TMA object if manufacturers include that in this section?

If a drug is covered by a pricing agreement, even if it is on Tier 3, it will not be subject to the preauthorization referred to in section 199.21(q)(2)(B). The primary purpose of the preauthorization referred to in section 199.21(q)(2)(B) is to make greater use of the mail order pharmacy, when appropriate. For drugs under a Pricing Agreement, this will not be the case, so TMA has no intention to require preauthorization under that paragraph. However, there are

other reasons that some drugs are subject to preauthorization under section 199.21(k), and such preauthorization requirement is possible for any drug. It is not necessary, but TMA would not object if manufacturers wish to include in Section III a provision that TMA will ensure availability of drugs listed in Appendix A through TRICARE retail network pharmacies without the preauthorization referred to in 32 C.F.R. 199.21(q)(2)(B).

6. Based on the pending legal challenge to the Final Rule, would TMA agree to a provision stating that the parties agree that if the Final Rule is invalidated by the Court, the Pricing Agreement is void as of the date signed?

No. As stated in the posted "New Clarification on Pricing Agreement," both parties reserve their claims as to the validity and enforceability of the provisions of the agreement. DoD's view is that the manufacturer would have received consideration during the term of the agreement and that it is valid. DoD acknowledges that the manufacturer may argue the opposite. Both sides reserve their rights. Obviously, a Court order, should that eventuality occur, would control. But in the meantime, TMA will not sign an agreement containing such a provision.

7. Will TMA agree to a provision that a manufacturer can add or remove a particular drug from Appendix A at any time?

Yes, subject to: a) 60 days advance notice; and b) in the case of a removal, the reinstatement restriction in paragraph IV(d).

8. Will TMA agree that whenever a drug is added to Appendix A, it will be considered by the P&T Committee for Tier 2 at the next meeting?

No. It will be considered when the drug class involved is next reviewed.

9. Will TMA agree to add to Section III, TMA's Responsibilities, a provision that TMA will maintain any drug covered by Appendix A on the Tier where listed as of the date of the Pricing Agreement?

No. TMA will initially maintain Tier 2 status for any drug currently on Tier 2 that is covered by a Pricing Agreement. But that is not a permanent guarantee. When any drug class is subsequently reviewed, a cost-effectiveness determination may result in a drug moving to Tier 3, even if it is covered by a Pricing Agreement.

Previously Posted Questions and Answers

05.20.09

Waiver/Compromise Process

Although there is no set template for submitting a waiver/compromise, below we have provided guidance to assist in completing these requests.

- A. **Debt.** *Provide the dollar amount of the debt owed under 32 CFR 199.21(q)(1), as calculated by one of the methods provided at 32 C.F.R. § 199.21(q)(3)(ii). Provide the method of calculation selected and a summary of the calculations.*

For illustrative purposes ONLY – According to 32 CFR 199.21(q)(1), Drug Maker, Inc. Owes TRICARE Management Activity (TMA) a refund in the amount of \$1 Million dollars. Drug Maker, Inc. arrived at this figure after reviewing the utilization data provided by TMA for calendar year 2008, and calculating the difference between the average non-Federal prices of the drugs it sold to wholesalers are represented by the most recent annual non-Federal average manufacture ring prices (NFAMP) reported to the Department of Veterans Affairs and the corresponding federal ceiling price (FCP). Drug Maker, Inc. reserves all defenses relating to this amount that 32 CFR 199.21(q)(1) treats as a debt.

- B. **Waiver/Compromise request.** *State whether request is for a waiver or compromise or both.*

For illustrative purposes ONLY – Drug Maker, Inc. requests a waiver of the above referenced debt. In the alternative, Drug Maker, Inc. offers \$500,000.00 in compromise of the above-referenced debt.

- C. **Legal basis for waiver/compromise.** *Specifically cite on which of the grounds provided in 32 C.F.R. § 199.11 the waiver request or compromise offer is premised.*

For illustrative purposes ONLY – Pursuant to 32 C.F.R. § 199.11(g)(3)(iv) this waiver request and alternative compromise offer is premised on Drug Maker, Inc.'s belief that there is significant doubt concerning the Government's ability to prove its case in Court for the full amount claimed.

- D. **Justification for waiver/compromise.** *Provide justification for the request.*

For illustrative purposes ONLY – Drug Maker, Inc. submits attached memorandum providing justification for the request.

COVERED PRODUCTS

1. Are biologic injectibles which are administered in a physician's office and are subject to reimbursement through current CME guidelines for Medicare B, specialty pharmacies, or "buy and bill" subject to FCP pricing for DoD beneficiaries?

Paragraph (q)(2)(iii) states, "For purposes of this paragraph (q)(2), a covered drug is a drug that is a covered drug under 38 U.S.C. 8126." If TRICARE provides utilization from the retail setting, a refund is owed.

2. Would these drugs be reimbursed through the UF TRICARE TRx system or through a medical benefit associated with TRICARE?

If the drug is covered under the prescription benefits plan, the drug is eligible for a refund. Also, if TRICARE provides utilization from the retail setting, a refund is owed.

DATA

3. The Final Rule states that for "... pharmacies that are eligible to participate in the 340B program but also fill other prescriptions, DoD will incorporate into the process appropriate procedures to identify and exclude 340B covered prescriptions." Please describe the processes that DoD will use to identify the 340B covered prescriptions to exclude the rebate eligible utilization.

Claims from Indian Health Service pharmacies, and exclusive 340B pharmacies are removed from the utilization data. If a manufacturer believes their data contains utilization from a 340B pharmacy, they may dispute the claim using reason code "K – PHS/340B entity not extracted from utilization data."

PAYMENT

4. Could you please tell me your definition of "first provisional?"

For a new drug without sales history, the first (provisional) benchmark is the initial list wholesale price, minus any discounts, and it will be the price used to begin the TRRx refund calculation.

PRICING AGREEMENTS

5. It appears from Appendix A of your mailing that you are looking for the FCP (Federal Ceiling Price: the maximum price manufacturers can charge) and the NFAMP (Non-Federal Average Manufacturer Price) for two of our products. These terms remain undefined to me. We deal with Direct Price (our price list) and AWP.

Please see pages 10 and 11 of the Process and Procedures Guide.

6. The pricing agreements refers to "refunds," the term "refund" remains unclear.

The refund is the amount owed to the Government, the formula used to calculate the refund is NFAMP – FCP. Please refer to pages 8 and 9 of the Process and Procedures Guide for additional information.

7. Are we being asked to account for each time a patient gets a prescription? As manufacturers, we assume ordering and accounting would be in bulk quantities.

Utilization data on the prescription level is provided in the .cp file that is downloaded each quarter. Refunds to the DoD are based on total quantity divided by package size, rounded DOWN to the nearest whole number. Please refer to pages 9 and 10 of the Process and Procedures Guide.

PROCESSES

8. The Process and Procedures Guide, Version 2.0 updated April 2, 2009, reviews refund calculations for new drugs and states, "for a new drug without sales history, the first (provisional) benchmark is the initial list wholesale price, minus any discounts, and it will be the price used to begin the TRRx calculation. Thereafter, the normal reporting of temporary and first annual (permanent) Non-FAMP's will be used to determine the TRRx benchmark prices." If the Non-FAMP changes mid-quarter, which Non-FAMP should be used? Most commercial contracts utilize the prevailing price.

The Non-FAMP that is reported to the VA on November 15 is the price that is to be used in calculating the rebate for the following calendar year. Please refer to page 9 of the Process and Procedures Guide.

Previously Posted Questions and Answers

05.15.09

DATA

1. We received our TRICARE claims data through the FTP site for all of 2008 and 1Q2009. We are concerned that the 2008 data is stale and the eligibility of some claims could have changed. Therefore, we are requesting refreshed claims files for 2008.

We believe the data provided is reliable and refreshing or re-running the data will not produce any significant changes. If a company believes claim data is inaccurate, please utilize the dispute resolution process.

2. Does the utilization data tell us how much a pharmacy paid for the drug dispensed?

No.

P&T COMMITTEE

3. If a drug(s) is/are being considered for the waiver/compromise process will it be included in Tier 2 or Tier 3?

The issue of Tier 2 versus Tier 3 status is independent of the waiver/compromise process.

4. The FCP final rule states, "(iv) the requirement of this paragraph (q)(2) may, upon the recommendation of the Pharmacy and Therapeutics Committee, be waived by the Director, TMA if necessary to ensure that at least one drug on the drug class is included on the Uniform Formulary." Is this the only time the P&T Committee can recommend waiving paragraph (q)(2) requirements?

That is the only regulatory provision for a waiver of the requirement of paragraph (q)(2). However, there is additional discretion in paragraph (q)(5).

5. There can be many products in the same class but there are often clear clinically superior products, which often result in those products being the market leaders. Just being in the same class does not make them all equivalent. Will the P&T Committee be allowed to do class reviews for clinical effectiveness before products are moved to the 3rd tier or all products without pricing agreements going to be automatically designated as 3rd tier (with the exception of the "only kid in town" products as stated in the rule) with no clinical review?

Please refer to the response to question #4.

6. Moving products to the 3rd tier also removes them from being generally available at the MTFs. If hundreds of products are going to move to 3rd tier based only on the lack of a pricing agreement and not clinical reviews, it appears beneficiaries who use MTFs will be left without needed medications. Are they all expected to go downtown for their prescriptions?

Paragraph (q)(5) states, that in cases in which a drug is removed from the uniform formulary or a preauthorization is required under paragraph (q)(2), the Director, TMA may for transitional time periods determined appropriate by the Director or for particular circumstances authorize the continued availability of the drug in the retail pharmacy network or in the MTF pharmacies for some or all beneficiaries as if the drug were still on the formulary.

7. How will they get those written prescriptions because most MTFs do not permit written prescriptions?

Please see the response to question #6.

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To Post_071509

8. Because the uniform formulary included all three DoD venues (MTF, mail and retail) by not signing a Retail Refunds Agreement, we jeopardize our share not only in the retail but at the mail and MTF correct? As an example, if we have a drug that is on tier 2 today and we do not sign an agreement for this drug it may be moved to tier 3 which means it would not be available in the retail or MTF (because the MTF does not stock tier 3 drugs), only at the mail. **The product would still be available through TMOP. Also review the response provided in question #6.**
9. If a drug is moved from tier 3 to tier 2, it would then be available in the MTF, correct?
Yes, it may be available in the MTF.

PAYMENT

10. Will you be sending an invoice showing the units claimed and the amount TRICARE intends to collect per quarter?
Yes, you will receive a Reconciliation of Quarterly Utilization for 1Q2009, which will show the units claimed and the amount invoiced by TRICARE for the quarter. You will then receive one each quarter going forward.

PRICING AGREEMENTS

11. Is it true that this is a one-time shot for industry and if they decided not to pay then they would not get an opportunity to play until the class is reviewed?
At any time a company may agree to place their drug onto their pricing agreement. However, this does not guarantee that their drug will move to the 2nd tier or when it will be evaluated for possible movement to the 2nd tier.
12. If they want to pay before the class comes up for review, will we accept and just the pull the prior authorization?
The drug may remain on the 3rd tier until the drug class is reviewed, however the prior authorization may be removed.
13. When completing Appendix A, are we supposed to use the NFAMP and FCP for 2008 and/or 2009?
When completing Appendix A, please use the Non-FAMP reported to the VA on November 15, 2008 and the FCP that became effective on January 1, 2009.
14. Do we return the complete agreement to you?

Please remember to select the methods of calculation on page 4 of the agreement, and to complete the three (3) bottom boxes on page 9 before returning the entire agreement to: Pharmaceutical Operations Directorate, TRICARE Retail Refund Program, Skyline 5, Suite 810, 5111 Leesburg Pike, Falls Church, VA 22041-3206.

15. We have a drug that can be dispensed by a pharmacy under 340B; does this mean we can exclude this drug from the contract?

We exclude all drugs dispensed in a known 340B pharmacy. If manufacturers suspect that a prescription was dispensed to a TRICARE beneficiary with 340B and TRICARE is displayed in their utilization data from a 340B pharmacy, the manufacturer may dispute the claim.

If the drug is excluded from the pricing agreement, the drug is subject to placement on the 3rd tier with a prior authorization.

16. Generic competition began in January 2007 for a product, considering this fact we do not expect preferred formulary status. Can we request a waiver based on this information?

A waiver may be requested. The standards for a waiver are set forth in section 199.11.

17. If a company is not satisfied with the outcome of the waiver/compromise and wishes to follow additional available remedies such as litigation, however the manufacturer does not want to terminate the existing pricing agreement, is this an option?

Yes. The Department of Defense (DoD) Retail Refund Pricing Agreement, section VI – General Provisions, paragraph (f) provides that nothing in the Pricing Agreement shall be constructed as a waiver or relinquishment of any legal rights of the Manufacturer or the DoD under the Constitution, the Act or Federal laws. Therefore, signing a pricing agreement under paragraph (q)(2), a manufacturer does not relinquish or waive the right to contest refunds under paragraph (q)(1) for prescriptions filled prior to May 26, 2009.

18. Are products still eligible for the formulary status if the company is paying prospectively?

Yes.

19. If some products on Appendix A have expired, do you want the manufacturers to leave off the NFAMP/FCP information for those products?

Yes, please advise if a product has expired or is discontinued.

20. How would you like manufacturers to handle package size discrepancies listed in Appendix A?
If there is a package size discrepancy or the package size is missing, please correct on Appendix A and submit an email to ufvarr@tma.osd.mil with the NDC and the correct package size.
21. If we have a drug on tier 3 and we do sign a pricing agreement for this drug it may move to tier 2, but that is not guaranteed.
That is correct.
22. Are the NDCs that are being submitted based on the FSS contract?
Yes.
23. If there is/are NDCs that are not on the FSS contract but were submitted, does the manufacturer still have to pay on it?
The drug must be on a FSS contract, if a drug has been submitted on Appendix A that is no longer on a FSS contract, please submit an email to ufvarr@tma.osd.mil with this information, including the date the product was removed.

Previously Posted Questions and Answers

05.08.2009

UPDATES TO PREVIOUSLY POSTED QUESTIONS & RESPONSES

1. This was originally question #5 under the Calculation heading posted on April 22, 2009: For new drugs, which of the Non-FAMP do we use, the provisional, or the 30-day?
The original response stated, "The provisional Non-FAMP should be used until the permanent Non-FAMP is issued. Once the permanent Non-FAMP is issued, the manufacture should notify TMA.

We have updated our response as follows: *The **first** provisional Non-FAMP should be used until the permanent Non-FAMP is issued. Once the permanent Non-FAMP is issued, the manufacturer should notify TMA.*
2. This was originally question #8 under the Pricing Agreements heading posted on April 22, 2009: The agreement says the manufacturer does not waive its right but will DoD consider execution of the agreement consent to pay for past transactions?
The original response stated, "Under the statute, all covered drugs in the TRICARE Retail Pharmacy network are subject to FCP."

We have updated our response as follows: *Under the statute, all covered drugs in the TRICARE Retail Pharmacy network are subject to FCP. In the Department of Defense (DoD) Retail Refund Pricing Agreement, section VII – General Provisions, paragraph (f) provides that nothing in the Pricing Agreement shall be constructed as a waiver or relinquishment of any legal rights of the Manufacturer or the DoD under the Constitution, the Act or Federal laws. Therefore, by signing a pricing agreement under paragraph (q)(2), a manufacturer does not relinquish or waive the right to contest refunds under paragraph (q)(1) for prescriptions filled prior to May 26, 2009.*

3. This was originally question #13 under the Waiver & Compromise Process heading posted on April 29, 2009: Since it is not expected that compromise decisions will be made before the due date for signing the agreement, will DoD accept an agreement as satisfying the requirement of the final rule if it agrees to honor pricing standards required by 10 USC 1074g(f) for listing pharmaceuticals provided by the network pharmacies to DoD beneficiaries prospectively but reserves the right to maintain objections to DoD's interpretation of the NDAA as applicable to transactions preceding execution of the agreement?

The original response stated, "See 32 CFR 199.21(q)(3)(iii)(B).

We have updated our response as follows: *Yes, In the Department of Defense (DoD) Retail Refund Pricing Agreement, section VII – General Provisions, paragraph (f) provides that nothing in the Pricing Agreement shall be constructed as a waiver or relinquishment of any legal rights of the Manufacturer or the DoD under the Constitution, the Act or Federal laws. Therefore, by signing a pricing agreement under paragraph(q)(2), a manufacturer does not relinquish or waive the right to contest refunds under paragraph (q)(1) for prescriptions filled prior to May 26, 2009.*

4. This was originally question #15 under the Waiver & Compromise Process heading posted on April 29, 2009: Must a company pursue a settlement of its legal position on DoD's entitlement to refunds on past transactions with DoJ before the rule requiring an agreement become effective?

The original response stated, "See 32 CFR 199.21(q)(3)(iii)(B).

We have updated our response as follows: *In the Department of Defense (DoD) Retail Refund Pricing Agreement, section VII – General Provisions, paragraph (f) provides that nothing in the Pricing Agreement shall be constructed as a waiver or relinquishment of any legal rights of the Manufacturer or the DoD under the Constitution, the Act or Federal laws. Therefore, by signing a pricing agreement under paragraph (q)(2), a manufacturer does not relinquish or waive the right to contest refunds under paragraph (q)(1) for prescriptions filled prior to May 26, 2009.*

5. This was originally question #17 under the Waiver & Compromise Process heading posted on April 29, 2009: If manufacturers have initiated the process of compromising their objections to DoD's claim for refunds on past transactions under the final rule by the effective date of May 26, must they include those transaction within the scope of the agreements due on June 1 without reservation of rights?

The original response stated, "See 32 CFR 199.21(q)(3)(iii)(B).

We have updated our response as follows: *No. In the Department of Defense (DoD) Retail Refund Pricing Agreement, section VII – General Provisions, paragraph (f) provides that nothing in the Pricing Agreement shall be constructed as a waiver or relinquishment of any legal rights of the Manufacturer or the DoD under the Constitution, the Act or Federal laws. Therefore, by signing a pricing agreement under paragraph (q)(2), a manufacturer does not relinquish or waive the right to contest refunds under paragraph (q)(1) for prescriptions filled prior to May 26, 2009.*

6. This was originally question #8 under the Pricing Agreements heading posted on April 29, 2009: When is the next time DoD will consider agreements?

The original response stated, "There is currently no scheduled general re-review of section 199.21(q)(2) agreements.

We have updated the response as follows: *While there is no scheduled general re-review of section 199.21(q)(2) agreements, if a manufacturer decides they would like to add a drug to their pricing agreement that was originally left off and placed in 3rd tier with a prior authorization, the manufacturer may propose an amendment to their current pricing agreement to do so.*

7. This was originally question #12 under the Prior Authorization Process heading posted on April 29, 2009: Will the drug be removed from coverage in the retail setting after thirty (30) days?

The original response stated, "The terms of the preauthorization will be determined through the P&T Committee process."

We have updated the response as follows: *The implementation period to move a drug to tier 3 is recommended to the Director, TMA by the P&T Committee. The P&T Committee is tasked with the responsibility of recommending the prior authorization criteria and determining the implementation period. The drug may remain on 3rd tier until the drug class is reviewed, however the prior authorization may be removed.*

Previously Posted Questions and Answers

04.29.2009

CALCULATIONS

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To Post_071509

1. Our company launched its second product in 3Q07 and as of 01.01.08 we had our "FSS Temporary Price" in place (based on the first thirty (30) days of sales). Our "Permanent FSS Price" was approved on 05.01.08. Which Non-FAMP calculation would we use to determine the 2008 rebate? Would we use the first Non-FAMP or would we use the subsequent Non-FAMP (for the launch thru the first full quarter of sales)?

Use the permanent Non-FAMP for 2008 calculations.

COVERAGE

2. We are a generic pharmaceutical supplier on the FSS/VA Programs and received the letter dated 03.18.09. We are a relatively new supplier to the Government and the letter is a bit confusing to us. I am not sure if there is any action needed to be taken by our company or if this letter is outlining new voluntary programs. Is there someone I can speak with that can help clarify this?

This program covers brand medications. Generic medications approved by the Food and Drug Administration (FDA) under 505J and over-the-counter (OTC) drugs are excluded.

3. There are supply items (syringes, diabetes supplies, etc.) that are included in the DoD pharmacy benefit, but are not pharmaceuticals. Some of these supply items have multiple products that have been reviewed by the Uniform Formulary process and assigned to tier 3 status (blood glucose test strips). Since tier 3 supply products are not pharmaceuticals and hence do not have FCPs, is it safe to assume that the proposed Prior Authorization will not apply to these products?

That is correct; this program only covered drugs which are on the Federal Supply Schedule (FSS).

PAYMENT

4. It appears under 199.21(q)(3)(iii)(B), the manufacturer may withhold payment of the amount subject to the waiver/compromise request until TMA makes a determination on the request, and this will not be considered a violation of a pricing agreement or a reason for TMA to seek a remedy. However, if the manufacturer instead pays full retroactive refunds on all of the units reported to TMA by May 26, and TMA later determines to waive or compromise those refunds, I assume TMA will refund the manufacturer the difference between the amount the manufacturer paid and the amount owed under the waiver/compromise agreement? Is this correct?

That is correct. TMA will refund the manufacturer the difference between the amount paid and the amount waived/compromised without interest.

However, if a manufacturer pays the total amount in full, there may not be any amount to establish a waiver/compromise.

PRICING AGREEMENTS

5. Why must a company terminate an agreement if it is unable to reach a settlement with respect to past transaction?
DoD is not requesting a company to terminate an agreement. DoD's position is that a contingent agreement does not satisfy the requirement of 32 CFR 199.21(q)(2)(i).
6. Is June 1 the deadline for submitting a signed agreement to DoD for consideration at the August P&T Committee meeting?
Yes, June 1 is the deadline.
7. What happens if DoD rejects the form of agreement submitted by the manufacturer?
DoD will seek a prompt resolution. The UF-VARR procedures, which provide the template for the suggested agreement, have been used successfully. A proposed agreement may be submitted prior to June 1 to give more time for a resolution. If a timely resolution is a concern, 32 CFR 199.11 provides default refund procedures, making the only required terms for an agreement by June 1 those terms specified in 32 CFR 199.21(q)(2)(i).
8. When is the next time DoD will consider agreements?
There is currently no scheduled general re-review of section 199.21(q)(2) agreements.
9. Section II c of the proposed Pricing Agreement, requires manufacturers to select whether to base the calculation on Non-FAMP or pharmacy contract price, and the selection must be made for all of the manufacturer's covered drugs for the duration of the agreement. Typically, manufacturers do not sell all of their covered drugs under contract to pharmacies all of the time. In other words, certain covered drugs not others might be sold under contract, and contracts may be with certain pharmacies but not others. To give a manufacturer the flexibility to select Non-FAMP for some drugs but contracted for others, would you propose the manufacturer proposing an agreement to the agreement specifying which covered drugs will be subject to which methodology?
The invoices will be generated based upon FCP subtracted from Non-FAMP (Non-FAMP minus (-) FCP). A manufacturer may elect to pay a NDC based upon a contracted rate. They may do so; however they will need to provide auditable documentation displaying the contracted rate and information.

PRIOR AUTHORIZATION PROCESS

11. The current regulations do not specify how a drug that is subject to prior authorization procedures will be treated if it meets the criteria. Will it be classified as a non-formulary drug subject to the higher copay?

Yes, if on tier 3, subject to Section 199.21(i)(iii).

12. Will the drug be removed from coverage in the retail setting after thirty (30) days?

The terms of preauthorization will be determined through the P&T Committee process.

WAIVER & COMPROMISE PROCESS

13. Since it is not expected that compromise decisions will be made before the due date for signing the agreement, will DoD accept an agreement as satisfying the requirement of the final rule if it agrees to honor pricing standards required by 10 USC 1074g(f) for listing pharmaceuticals provided by network pharmacies to DoD beneficiaries prospectively but reserves the right to maintain objections to DoD's interpretation of the NDAA as applicable to transactions preceding execution of the agreement?

See 32 CFR 199.21(q)(3)(iii)(B).

14. The process for seeking a waiver of DoD rights is still unclear. The preamble to the final rule indicates that DoD will entertain all requests for compromise of the amount of refunds due on past transactions through the agency's existing regulations for collections overpayments, and the preamble gives an example of how a manufacturer may agree to pay refunds based on FCP prospectively in return for a compromise on refunds for 2008 offering to pay refunds based on a date of its choosing that differs from the effective date of the statute. However, the referenced regulation provides limited criteria for settling a DoD claim of overpayment, and only DoJ has authority to settle such a claim if the amount exceeds \$100,000. How is the compromise process described in the preamble supposed to work if DoJ is handling it?

DoD intends to analyze requests for waivers or compromises and make recommendations to the Department of Justice (DoJ).

15. Must a company pursue a settlement of its legal position on DoJ's entitlement to refunds on past transactions with DoJ before the rule requiring an agreement becomes effective?

See 32 CFR 199.21(q)(3)(iii)(B).

16. Must a company waive its right to object to DoD's legal entitlement to refunds in its request for compromise?

If you are inquiring if you have to acknowledge the debt before DoD will consider a waiver or compromise, the answer is no.

17. If manufacturers have not initiated the process of compromising their objections to DoD's claim for refunds on past transactions under the final rule

by the effective date of May 26, must they include those transactions within the scope of the agreements due on June 1 without reservation of rights?

See 32 CFR 199.21(q)(3)(iii)(B).

Previously Posted Questions and Answers

04.22.2009

CALCULATIONS

1. On page 9 of the Process and Procedures Guide the instructions are: "The currently established FCP, effective January 1st thru December 31st, will be used for refund calculations and reconciliation reports relating to transactions that occurred during the same calendar year." In this case, if we are paying rebates for 2008 utilization, do we still use the CURRENT FCP which would be the 2009, or in the original rebate payment would we use the 2008 FCP since that was the FCP, "during the same calendar year?"

No, you will use the 2007 Non-FAMP and the 2008 FCP.

2. The data submitted to the manufacturer does that include prescriptions that are filled but not picked up? If not, is there a procedure to identify these units?

If a prescription is filled but not picked up, the pharmacy backs that prescription out of the system normally after ten (10) days. In the event a prescription is processed and not picked up at the end of the quarter this adjustment will show in the next quarter's data.

3. Are we to assume to subtract the negative units from the total units?

No, the negative units have already been taken out.

4. I do not have a 3Q2007 NFAMP or a 2008 FCP for a product that was released 1Q2008, according to my manager, we turned in a temporary NFAMP and FCP, do I use the temporary NFAMP and temporary FCP reported for this product in order to calculate the 3Q2008 and 4Q2008 rebates?

That is correct, use the provisional or temporary Non-FAMP and FCP.

5. For new drugs, which of the non-FAMP do we use, the provisional, or the 30-day?

The provisional Non-FAMP should be used until the permanent Non-FAMP is issued. Once the permanent Non-FAMP is issued, the manufacturer should notify TMA.

DISPUTE PROCESS

6. If there is a discrepancy, how long do manufacturers have to notify the POD? In the Process and Procedures Guide - page 14, it states that: "Such notice shall be received by the POD no later than 10 calendar days after the manufacturer's discovery of the alleged error, but in any event no later than

one year after the date of the quarterly report containing the alleged erroneous data."

The information provided in the Process and Procedures Guide is correct. Such notice shall be received by the POD no later than 10 calendar days after the manufacturer's discovery of the alleged error, but in any event no later than one year after the date of the quarterly report containing the alleged erroneous data.

7. Dispute Codes - Are these the same dispute codes that CMS uses for Medicaid?

No, the dispute resolution process is outlined on our website, and is also located as Appendix B of the proposed Pricing Agreements and in the Process and Procedures Guide.

P & T COMMITTEE

8. What criteria will DoD use to open up a drug class for P&T review earlier than what is currently posted on the website?

The schedule that is posted is subject to change as needed, our goal is to balance new drug class reviews with reviews of previously reviewed drug classes.

PAYMENT

11. Are manufacturers allowed to deduct any amount they have previously paid voluntarily from the rebate amount that is requested by the DoD?

Drugs which are on an executed UF-VARR are invoiced separately; DoD will deduct any amounts previously paid by a manufacturer.

12. I am in third tier, and may not sign a FCP agreement until the class is reviewed again by the P&T Committee. Am I correct that I will have to pay refunds on product utilization anyway from the date of enactment but not any interest?

If a Pricing Agreement is not executed, the manufacturer will still receive an invoice. If the invoice is not paid by the due date, a demand letter for payment will be sent requesting payment within thirty (30) days. If payment is not made within that thirty (30) day timeframe, interest will begin accruing back to the date of the demand for payment letter.

13. I went through the P&T process and was placed on 3rd tier, if I do not sign an agreement how long will I have before I begin to accrue interest on what I owe?

If a Pricing Agreement is not executed, the manufacturer will still receive an invoice, if the invoice is not paid by the due date, a demand letter for payment will be sent requesting payment within

thirty (30) days. If payment is not made within that thirty (30) day timeframe, interest will begin accruing back to the date of the demand for payment letter.

14. I am already in tier 3, with a prior authorization, what will happen to me if I do not agree to pay FCP?
See 32 CFR 199.21(q)(4).
15. How is interest calculated on late payments? Please provide the calculation.
Interest is calculated per 31 U.S.C. § 3717, see 32 CFR 199.11(f)(6)(x).

PRICING AGREEMENTS

16. I went through the P&T process before there was a UF-VARR form in place. I just have a BPA with a price below FCP. Do I need to do anything?
Yes, the BPA does not cover products in the retail setting. It will be necessary to place these products onto the Pricing Agreement.

PROCEDURES & PROCESSES

17. In your Process and Procedures Manual, you specify that manufacturers are to use the CMS Reconciliation of State Invoice (ROSI) and only valid adjustment/dispute codes for ROSI. However on page 13 of your Retail Refund Pricing Agreement "draft" your codes do not match those of CMS? Which are we to use?
The Process and Procedures Guide along with several processes have been updated. Please review the information regarding the Reconciliation of Quarterly Utilization (RQU).
18. Is the manufacturer suppose to send ROSI (Reconciliation of State Invoice) with their current quarter rebate? This document is what we submit to the States for Medicaid rebates.
The Process and Procedures Guide provides instructions on submitting the Reconciliation of Quarterly Utilization (RQU). This document is similar to the ROSI. We are also sending out RQUs for all quarters during the week of April 20th.
19. In addition to the ROSI, is the manufacturer suppose to send a PQAS (Prior Quarter Adjustment Statements)?
The RQU allows the manufacturers to submit prior quarter adjustments.

UF-VARRs

22. I went through the P&T process and have a UF-VARR form in place with a price below FCP; can I amend this UF-VARR with a DoD Formulary Pricing Agreement to bring the price up to FCP? Will doing this effect my formulary position?

The DoD Retail Refund Pricing Agreement does not cover drugs which are currently part of an executed UF-VARR. You may submit a proposed amendment to the current UF-VARR to bring up to FCP. Your current position on the formulary will stay in place until the P&T Committee does a class review.

Previously Posted Questions and Answers

04.20.2009

Prior to responding to the questions DoD has received in the past week, the DoD would like to thank all who have submitted the many valuable and thought provoking questions we have received. Based upon the many comments we have received, we would like to take this opportunity to clarify several items.

We have received several questions regarding how generic medications will be covered. This program only covers brand medications. Generic medications approved by the Food and Drug Administration (FDA) under 505J and over-the-counter (OTC) drugs are excluded.

We have also received several comments in regards to some not wanting to sign a Pricing Agreement until a decision is made on a manufacturer's proposed waiver/compromise. The Pricing Agreements and the waiver/compromise are two separate processes. Requests for a waiver/compromise of refunds under §199.21(q)(3)(iii) for prescriptions filled between January 28, 2008, the statutory effective date, and May 26, 2009, the Final Rule effective date, are due May 26, 2009. Pricing Agreements under §199.21(q)(2) are due June 1, 2009 for review at the August meeting of the P&T Committee. Decisions on waiver/compromise requests will not be made prior to June 1st and perhaps not prior to the August meeting. If the ultimate decision on the waiver/compromise request would change the manufacturer's willingness to have a Pricing Agreement, the manufacturer's remedy would be to terminate the Pricing Agreement.

The preamble to the Final Rule provides guidance to manufacturers in respect to the waiver/compromise process. In addition, §199.11(q) of the TRICARE Regulation provides the regulatory standards. (Note that §199.11 was revised on November 25, 2008 (73 Federal Register 71545). A copy of the revised §199.11 is posted on the website.) A manufacturer can request a waiver/compromise of an amount on any grounds that the manufacturer deems appropriate. However, in order for the DoD to consider a

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waiver/compromise requested by the manufacturer, the manufacturer must calculate and report to TMA the full amount of the refund for which the request for waiver/compromise is being made.

Clarification is also provided in the preamble to the Final Rule comments section that the provision for a waiver/compromise is available at any time. DoD intends that this process is especially available to address and resolve in a reasonable manner, issues arising from the period between the date of enactment of the statute and the effective date of the regulation.

Again, we recognize that the successful implementation of this program will be promoted through a healthy dialogue between the pharmaceutical industry and TMA.

CALCULATIONS

1. If there is a negative Non-FAMP for a product, how should we handle the calculation?
For negative annual Non-FAMP: Rebate = (Annual Non-FAMP – FCP) is negative, the resulting rebate would be zero (\$0). Guidance will be provided in the upcoming Process and Procedures Guide.
2. What guidance is there on how to calculate a refund if the annual Non-FAMP is zero and where can we locate guidance?
Please see the response above.

DISPUTE PROCESS

3. One of the major concerns is the accuracy of the Rx data which has been provided to the manufacturers to date. Our data and the TRICARE data are way off. What process has been put in place to reconcile these differences with manufacturers?
Manufacturers have the ability to dispute any claims they believe to be invalid. The dispute process has been placed on our website, along with the codes each manufacturer should use to dispute a claim. If the manufacturer wishes to dispute a claim for a reason other than those listed, the manufacturer may select the "Other" reason, and provide sufficient data and justification for the reason for the dispute.
4. How are disputes on retro-payments going to be resolved and is there a timeline for notification to TMA of disputed products?
Review and follow the directions outlined in the dispute process proposed online. We ask for all disputes for all quarters of 2008 to be submitted by May, 26th.

P & T COMMITTEE

5. Will the review schedule for the P&T Committee changes?
Yes, it will possibly be changing again.

PAYMENT

6. When will interest begin accruing on the retro-refunds if not paid by May 26, 2009?
Provisions are outlined in §199.11(F)(6)(x).
7. Will DoD proceed to collect "refunds" on all covered drugs in the future even if the drugs are not included in the pricing agreement, are in Tier 3 and are subject to prior authorization in the retail sector?
Under the statute, all covered drugs in the TRICARE Retail Pharmacy network are subject to FCP.

PRICING AGREEMENTS

8. The agreement says the manufacturer does not waive its right but will DoD consider execution of the agreement consent to pay for past transactions?
Under the statute, all covered drugs in the TRICARE Retail Pharmacy network are subject to FCP.
9. Are we going to have a single retail refund agreement for all our products or will we do separate agreements for each NDC?
A copy of the proposed Pricing Agreement is available on our website. DoD prefers that the Pricing Agreement will cover all of a manufacturer's products, except those covered by separate UF-VARRs that are at or below FCP.
10. How do we handle a refund in the new rule when a product has gone generic?
As long as the brand product is still available and being utilized by beneficiaries in the retail market, the manufacturer is responsible for refunds.
11. How long do you think it will take to establish agreements with the manufacturers of all drugs selected for the Uniform Formulary?
DoD will begin mailing proposed Pricing Agreements to the manufacturers on or about April 15th, with the due date of June 1st for manufacturers to return signed agreements to DoD. This will give manufacturers approximately forty-five (45) to review the Pricing Agreements, send through their legal departments and return to DoD for execution.
12. Is the DoD asserting entitlement to refunds on prescriptions filled by pharmacies with generic drugs that meet the definition of covered drugs?

Only generics approved by the Food and Drug Administration (FDA) as 505j generics are excluded from this program.

13. Authorized generics are treated as covered drugs for Non-FAMP and FCP purposes. Are authorized generics considered covered drugs, subject to TRRx refunds?
Please see response to question 12, above.
14. With the DoD having a generic first formulary process, there should be no need for us to refund on a branded product in this situation. We do not believe you have any control over which brand of generic is dispensed at the retail level.
Please see response to question 12, above.
15. If a manufacturer declines to include a generic drug that meets the definition of a "covered drug" in an agreement, will beneficiaries be charged the Tier 3 co-pay? How does DoD intend to subject a generic drug to prior authorization if it is the only generic version the pharmacy stocks?
Please see response to question 12, above.
16. If a company signs an agreement and DoD doesn't grant the waiver, has the company consented to pay?
If the ultimate decision on the waiver/compromise request would change the manufacturer's willingness to have a Pricing Agreement, the manufacturer's remedy would be to terminate the Pricing Agreement.
17. The pricing agreement says manufacturers' responsibilities under the agreement are limited to the drugs listed in Appendix A, but Appendix A says, "providing FCP and Non-FAMP constitutes placement of NDC-11 onto this Pricing Agreement." Does that refer to the provision of FCP and Non-FAMP information in Appendix A or does it refer to provision of the data to the VA?
It refers to Appendix A.
18. Are refunds required on products that are not part of the pharmacy benefit, based on the UF search tool on the website?
No.
19. Are OTC's included in the program?
No.
20. The Rule states that in the case of a failure of a manufacturer to make or honor an agreement to pay the refunds, the Director, TMA, in addition to other actions referred to in the Rule, may take any other action authorized by law. Please comment on the likelihood that failure to make or honor an

agreement to pay refunds would make a company ineligible for participation in all Federal programs.

TMA is unable to offer a prediction. This question involves matters outside DoD's regulatory authority.

21. In Section D, the Final Rule authorizes the Director, TMA to take legal action against any manufacturer that fails to make or honor an agreement to provide drugs at or below FCP. If participated in the program is technically voluntary, how can the Director, TMA take legal action against manufacturers' who fail to make such an agreement?

Under the statute, all covered drugs in the TRICARE Retail Pharmacy network are subject to FCP.

22. How much push-back do you anticipate from manufacturers in establishing these agreements?

We anticipate that manufacturers will comply with the statute.

PRIOR AUTHORIZATION PROCESS

23. We would also like to discuss the PA process and how it would be impacted at the retail level.

We will continue to use this website to facilitate communication with the industry.

PROCEDURES & PROCESSES

24. How much time does the DoD plan to give manufacturers to sign agreements, establish pricing at or below FCP, and if necessary, pay retroactive rebates for drugs purchased between January 28, 2008 and the Final Rule's effective date of May 26, 2009 before pursuing legal action against the manufacturer?

TMA has not established a schedule for further action.

REIMBURSEMENT

25. Does the DoD generally reimburse the retail pharmacies at the NON-FAMP prices?

No, the DoD reimburses the pharmacies at the negotiated TRICARE Retail Pharmacy (TRRx) ingredient cost and a dispensing fee.

UF-VARRs

26. What do we do where we have active UF-VARRs in classes that have been reviewed?

If the UF-VARR is at or below FCP, no action is needed. If above FCP, you should propose an amendment to make it FCP compliant and meet the requirement of §199.21(q)(2).

27. Do you plan to renegotiate UF-VARRs that have already been signed?

Please see response to question 26, above.

28. If the negotiated UF-VARR is higher, does that mean that for those NDC's, no additional payment is needed?
If you mean that the refund amount is higher under the UF-VARR, that is correct.
29. The pricing agreement does not apply to drugs covered by existing rebate agreements executed by DoD, but the Rule says manufacturers are liable for discounts on pharmacy transactions covered by those agreements that exceed the discounts on the same transaction covered by those rebate agreements. Is DoD asserting entitlement to the difference?
Under the statute, all covered drugs in the TRICARE Retail Pharmacy network are subject to FCP. If the UF-VARR is at or below FCP, no action is needed. If above FCP, the manufacturer should propose an amendment to make it FCP compliant and meet the requirement of §199.21(q)(2).
30. Will the UF-VARR amount paid count as a credit in situations where the Final Rule pricing is a greater discount?
Yes.

UNIFORM FORMULARY

31. Are you working on the fourth tier rule?
At this time, there is no proposed rule for developing a 4th tier for the TRICARE Uniform Formulary, and there are no plans for such a proposal.
32. If a drug in Tier 3 is also currently subject to PA, MN, and/or step therapy, will the PA, MN, and/or step therapy requirement be removed if the company agrees to pay the mandated refund for TRRx prescriptions?
Changes would need to be determined by the P&T Committee at the next drug class review covering the drug in question.
33. Will the PA, MN, or step therapy be removed until the next P&T review to determine if the drug should move from 3rd to 2nd tier?
Changes would need to be determined by the P&T Committee at the next drug class review covering the drug in question.
34. The Final Rule states that a drug that is on Tier 3 that is covered by a refund agreement will be subject to review at a later time to determine if it should be changed to Tier 2, what is the anticipated time frame after a company honors FCP for the P&T to review specific classes (i.e. 6 months, 1 year, 2, years, 3 years) after the company begins paying FCP? The rule only states that a review will be conducted at a later date.
Some future drug class reviews have been scheduled and are subject to change.

35. In Section D, the Final Rule states that manufacturers can request, in writing, to remove a drug from coverage in the TRRx Program, to protect them from involuntary involvement in the program. Can a drug be selected for the UF without the manufacturers consent?
Under 10 U.S.C. 1074g, the default status is Uniform Formulary status. If a company does not want to see its product to DoD and have it covered by TRICARE, the company needs to so advise TMA.
36. If a drug is selected for the UF, but the manufacturer of that drug fails to request it's exclusion in writing, is the manufacturer then obligated to provide the drug to DoD at or below FCP, even if a Manufacturer's Agreement has not been established?
Under the statute, all covered drugs in the TRICARE Retail Pharmacy network are subject to FCP.

UTILIZATION DATA

37. Can PBM (COB/OHI) claims be excluded from the VARR Utilization data?
On page 9 of the current Process and Procedures Guide, states we will exclude commercial payer claims (i.e. COB claims) if we have knowledge that these are COB claims.

WAIVER/COMPROMISE

38. The waiver or compromise provisions at new 32 C.F.R. § 199.21(q)(3)(iii) reference existing 32 C.F.R. § 199.11. That regulation authorizes waivers or compromises for "claims that do not exceed \$20,000." Given the dollar amount at issue with respect to retroactive refunds for manufacturers, we assume that TRICARE does not intend to apply that limit; can you please confirm this?
§199.11 includes procedures for larger amounts.
39. If TRICARE does intend to apply this limit in some fashion, what would constitute a single "claim" for purposes of the limit?
Please see the response to question 38 above.
40. Due to this anticipated push-back, is the DoD willing to negotiate the requirement to pay retroactive rebates on covered drugs for manufacturers who proactively and voluntarily seek to establish Manufacturers Agreements with the DoD?
§199.11 provides regulatory guidance on the waiver/compromise authority. In addition, the preamble to the Final Rule describes in detail DoD's interpretation of the statute and the availability of the waiver/compromise authority. The Government reserves judgment on waiver/compromise requests until they are received and evaluated.

41. The Final Rule, is rather vague regarding the circumstances in which TRICARE would or would not be inclined to grant a waiver or compromise? Can you offer any additional guidance on this point or give us an idea as to when such guidance will be available?
§199.11 provides regulatory guidance on the waiver/compromise authority. In addition, the preamble to the Final Rule describes in detail DoD's interpretation of the statute.
42. How can a company strengthen its' case for a waiver/compromise?
Please see the response to question 41 above.
43. How can a company justify a longer period of a waiver/compromise?
Please see the response to question 41 above.
44. What criteria will TMA use in evaluating requests for a waiver or compromise?
Please see the response to question 41 above.
45. A company is more likely to enter into a refund agreement if the company knows that it will be granted a waiver or compromise for refunds that are due on prescriptions dispensed prior to May 26, 2009. The agreements and waivers will not doubt have to get legal review in each company - a time consuming process. Can a company submit, and will the Government accept, a refund agreement that is contingent on the Government granting a waiver or compromise?
A contingent Pricing Agreement would not satisfy the requirement of §199.21(q)(2). If the ultimate decision on the waiver/compromise request would change the manufacturer's willingness to have a Pricing Agreement, the manufacturer's remedy would be to terminate the Pricing Agreement.
46. If a waiver is granted, will the product be disadvantaged in any way?
A waiver or compromise does not affect Uniform Formulary status, if that is what you mean.
47. To whom should request for a waiver or compromise be address?
Pharmaceutical Operations Directorate – Retail Refunds Team – Skyline 5, Suite 810, 5111 Leesburg Pike, Falls Church, VA 22041-3206
48. If a company applies for a waiver, is the company conceding DoD's entitlement to the money or can the company reserve the right to dispute DoD's interpretation of the NDAA as creating transactional liability without the company's consent?
Nothing in §199.21(q)(3)(iii) makes a request for a waiver/compromise conditional on a manufacturer's concession.

49. If a manufacturer applies for a waiver, must it concede DoD's entitlement to money in order to receive a waiver or can it reserve the right to dispute DoD's interpretation of the NDAA as creating transactional liability without an agreement?
Please see the response to question 48.
50. What happens if a company has applied for a waiver for some or all drugs but DoD has not granted it or reached a compromise before June 1st?
Requests for a waiver/compromise of refunds under §199.21(q)(3)(iii) for prescriptions filled between January 28, 2008, the statutory effective date, and May 26, 2009, the Final Rule effective date, are due May 26th. Pricing Agreements under §199.21(q)(2) are due June 1st for review at the August meeting of the P&T Committee. Decisions on waiver/compromise requests will not be made prior to June 1 and perhaps not prior to the August meeting. If the ultimate decision on the waiver or compromise request would change the manufacturer's willingness to have a Pricing Agreement, the manufacturer's remedy would be to terminate the Pricing Agreement.
51. Under new 32 C.F.R. § 199.21(q)(3)(iii)(C), "a request for waiver may also be premised on the voluntary removal by the manufacturer in writing of a drug from coverage in the TRICARE Pharmacy Benefit Program." Does TRICARE intend, as a general matter, to routinely grant such waiver requests in full. In other words, can a manufacturer be sure to avoid all retroactive refund liability for a drug by withdrawing the drug from the program?
The Government reserves judgment on waiver/ compromise requests until they are received and evaluated.
52. What type of information should the request for a waiver or compromise contain?
The request must include a calculation of the full amount of the refund based on the retail utilization data provided to the manufacturer. The request should also include the proposed justification based on the regulatory standards in § 199.11(g).
53. What is the specific process for submitting a request for a waiver or compromise and what justification is required?
Please see the response to question 52.
54. What supporting data should a company include in a request for a waiver/compromise?
Please see the response to question 52.

55. If DoD grants a waiver or reaches a compromise, has the company then waived its right to object to future entitlement?
The terms of the waiver/compromise would be stated.
56. If a manufacturer and DoD reach a compromise on past liability, must the manufacturer concede liability and waive its right to object to future entitlements without an agreement?
Please see the response to question 55.
57. Is the procedure of a waiver of DoD's claims for refunds only up to the effective date of the rule or can a manufacturer negotiate a compromise of entitlement to refunds on transactions going forward?
The waiver/compromise authority is not limited to prescriptions filled prior to May 26, 2009. However, a waiver/compromise request is for a specific dollar amount associated with utilization resulting from previously filled prescriptions.
58. Is DoD permitting companies to request a waiver of DoD claims for refunds only up to the effective date of the rule or can a manufacturer negotiate a compromise of entitlement of refunds on transactions going forward?
Please see the response to question 57.
59. One of our primary questions focuses on the issue of waivers for certain NDC's or product groups. We would like to discuss the issue with you around what TMA is thinking here and seek some guidance.
We have provided guidance in the regulatory materials and this website. We will continue to use this website to facilitate communication with the industry.

WEBSITE UPDATES

60. Is TMA planning to provide industry level background or should we approach this on our own behalf with TMA?
We will continue to use this website to facilitate communication with the industry.

Previously Posted Questions and Answers

03.26.2009

1. Does this exclude generics?
Yes, this program only covers branded medications. An NDC Validation was sent out in November 2008 for companies to validate their brand NDCs. If you have not had the opportunity to verify the NDCs we are providing utilization data for, please submit an email to ufvarr@tma.osd.ni to request the information we have on file for your company.

2. Is the process and procedures document going to be updated to reflect the dispute resolution process and the request for a waiver?
Yes, we have also posted the proposed dispute resolution process as a separate document on our website for review. We anticipate providing additional information on the waiver/compromise process in the near future.

3. If a company has to pay rebates beginning January 28, 2008, are the 1st quarter files only going to contain data starting with January 28th?
Yes, the 1st quarter files have been released and they contain utilization data for the period of January 28, 2008 through March 31, 2008.

4. For the first payment, will back quarter be due seventy (70) days after the final rule effective date?
The payments for all calendar quarters of 2008 are due May 26, 2009.

5. Are we getting official invoices from DoD?
At this time, you will receive the TRICARE Refunds Reconciliation of Quarterly Utilization for each quarter. This document will provide a summary of each NDC and the utilization attributed to that NDC for the respective quarter.

6. Will DoD send a final summary utilization, or are we to use the files already provided?
A summary for utilization for each NDC will be displayed on the TRICARE Refunds Reconciliation of Quarterly Utilization. For detailed utilization, you should use the files that have already been released.

7. Will there be any previous quarter's adjustment invoices once you have NFAMP and FCP?
Once Non-FAMP and FCP are available, DoD will reconcile what the manufacturer has paid and disputed; once this process is complete DoD will issue prior quarter's adjustments.

8. Please confirm the starting date for FCP-based rebate obligations for those products which are currently part of an executed UF-VARR.
If a company has a WAC-based UF-VARR, they should review it to determine if they are at or below FCP. If the executed UF-VARR is not at or below FCP, the manufacturer may submit an amended UF-

VARR to meet these standards prior to June 1, 2009 to maintain tier 2 formulary status.

If a manufacturer wishes to submit an amended UF-VARR, they should contact the UF-VARR Team at 703-681-2890 for assistance.

Previously Posted Questions and Answers

1. What is the dispute process for utilization data?
The dispute process is outlined in Appendix B of the proposed Pricing Agreement. We have also placed the proposed dispute process under OPERATIONAL DOCUMENTS on the website.

2. If a manufacturer does not sign a Pricing Agreement for a drug that is ultimately placed on the 2nd tier because it is the only drug in the drug class, what happens if the manufacturer does not pay the refunds to the Government?
See section 199.21(q)(4).

3. Are sales now considered as Federal sales and exempt from the Best Price calculation?
Yes, these are Federal sales.

4. If a manufacturer has a drug currently on the 3rd tier, and they sign a Pricing Agreement, how long after signing the Pricing Agreement will the drug move out of 3rd tier?
As discussed in the preamble to the Final Rule, for a drug previously placed in Tier 3, if the manufacturer signs an agreement to honor FCP, it will be eligible for reclassification to Tier 2 upon the next review by the P&T Committee of the drug class involved. Prior to moving a drug from Tier 3, the P&T Committee must still consider the clinical effectiveness of the drug in consideration with other drugs in that drug class.

5. If we sign a Pricing Agreement, does this mean our drugs will automatically be placed on 1st or 2nd tier?
No, along with considering cost-effectiveness, the P&T Committee must also consider the clinical effectiveness of a drug, prior to assigning formulary placement.

6. It would help to reinforce/clarify the refund due dates, even though it's been covered in the Rules and previous Q&As.
These dates are outlined in the "Dear Pharmaceutical Manufacturers" letter that was sent to manufacturers on March

18, 2009. We have also posted a copy of this letter on the website.

7. There's a lot of information covered as "several possible outcomes" on page 32, "In the case of a beneficiary presenting a prescription in a retail network pharmacy for a drug that is on Tier 3 because of the refusal of the manufacturer to honor Federal Ceiling Prices." The process outlined here may come under question by some interested parties, e.g., who decides the urgency of a product that should be filled anyway ("if the beneficiary has a valid clinical need"), how would a prescription get transferred to TMOP ("beneficiary may be advised that refills need to be obtained from TMOP") and again, "if there is no urgency, the beneficiary may be advised to submit the prescription to TMOP" – would a retail pharmacy clerk do this? So, there are some who may take this process to task on the mechanics.
No, these matters will not be decided by a retail pharmacy clerk. First, please note that drug manufacturers have an obligation under the law to honor Federal Ceiling Prices. If manufacturers comply with the law, this entire issue will be moot. If drug manufacturers do not comply with their legal obligation, it is TRICARE's policy to seek to remedy the non-compliance in a way that assures that beneficiaries receive the prescription products they need.

The prior authorization criteria will be determined by the P&T Committee for each drug. The mail order contractor will implement the criteria as part of their utilization process.

8. Regarding implications of the statement on page 29, "If there is currently in effect a UF-VARR at a price above FCP, that agreement fails to achieve the statutory requirement; DoD anticipates canceling it."
DoD will ask the manufacturer to amend the agreement to bring it into compliance with the law. If that effort fails, DoD may cancel any agreement that conflicts with the law.
9. When will the P&T Committee conduct a "fixed" cost-effectiveness review of products covered by current UF-VARRs?
We anticipate reviewing those drugs during the upcoming August P&T Committee meeting, if the current UF-VARR or an amended UF-VARR does not meet FCP.
10. Please reconcile the following interpretations of the Uniform Formulary Rule requirements that are also referenced on the top of page 32: "It requires...only that Non-Formulary drugs are available through one of the three pharmacy venues. Non-Formulary drugs are and will remain available in the TRICARE Mail Order Pharmacy (TMOP)." There is a broadly-held perception that the Uniform Formulary Rule offers coverage via

Retail, supported by the following extracted from the Uniform Formulary Final Rule:

A. Point of Clarification Concerning Availability of Non-Formulary Drugs- Public comments revealed the perception that, “non-formulary” drugs would not be available under the uniform formulary. That perception is incorrect. As stated in the proposed rule and as required by 10 U.S.C. 1074g(a)(5), we emphasize that drugs categorized as “non-formulary” must be made available through at least one of our pharmaceutical venues. DoD will make non-formulary drugs available through the TRICARE Mail Order Pharmacy and retail pharmacies at the non-formulary co-payment.

O. Availability of Non-Formulary Pharmaceutical Agents to Eligible Covered Beneficiaries – as explained in the proposed rule, non-formulary pharmaceutical agents will be available to eligible beneficiaries through the retail network pharmacies and the TMOP at the non-formulary co-payment of \$22 per prescription. Non-formulary pharmaceutical agents will be available to eligible beneficiaries through the retail non-network pharmacies at the non-formulary co-payment of 20% or \$22, whichever is greater, per prescription. Non-formulary pharmaceutical agents will be available to eligible covered beneficiaries through the MTF pharmacies only for prescriptions approved through the non-formulary special order process that validates clinical necessity for use of the non-formulary agent.

By statute, Non-Formulary drugs are required to be available in only one venue. By regulatory policy, DoD has made them available in retail pharmacies as well as TMOP. But this regulatory policy has now been revised to include preauthorization. Manufacturers can significantly advance their objective of maintaining availability through the TRICARE Retail Pharmacy Program by agreeing to comply with their legal obligation concerning FCP.

11. Is this the end of the Voluntary Agreement process?
No, DoD will continue voluntary negotiations concerning prices with an additional amount off FCP for preferred formulary placement.
12. How come I received an invoice for my UF-VARR products but not my utilization products?
Manufacturers will receive a “Reconciliation of Quarterly Utilization Data,” to complete with the units they are paying and the units they are disputing. We in turn will take this data and verify the amount submitted by the manufacturer is correct. If an incorrect amount is submitted, based upon the non-FAMP and FCP supplied, we will contact the manufacturer to work out any differences.

13. When will invoices be sent out and when will payment be due?
Utilization data for all four (4) calendar quarters of 2008 continue to be available. Data for quarter one of calendar year 2009 will be available on April 15, 2009.

We anticipate mailing the "Reconciliation of Quarterly Utilization Data" on or about April 6, 2009.

Refund payments for utilization data from January 28 through December 31, 2008 are due May 26, 2009 unless a waiver or compromise of the amount is granted in accordance with the Final Rule.

14. Do you have the agreement that is going to be used for Section 703? Is it going to be the VARR Agreement, it references Section 703.
We are currently finalizing a proposed template for the Pricing Agreement. A "draft" copy is located on our website. We anticipate mailing proposed specific Pricing Agreements to manufacturers next week.