

## ABA Questions and Responses

1. When does TMA expect to provide final notice on the requests for waiver?

*TMA is in the process of reviewing submitted waiver/compromise requests, At this time; we anticipate this process to be complete by early 2010.*

2. If a manufacturer disputes products that are subject to a request for a waiver, and the request is denied, will the manufacturer only be subject to making the payment due on those products or will TMA seek interest as well?

*Manufacturers will be notified in writing of the date on which interest, penalties, and fees will begin to accrue.*

- 3a. If TMA submits invoices for products that are not covered under a Pricing Agreement, how should the manufacturer dispute those products?

*To address their question, we would not ask them to submit a waiver, but they would utilize the dispute process, with the dispute code of "J."*

- 3b. Will TMA hold off on any final resolution of the dispute until the court case is settled?

*That has not yet been determined.*

- 4a. If TMA has submitted invoices for products that are not on a manufacturer's Pricing Agreement, what is the use of a pricing agreement?

*The signing of a pricing agreement is a condition for inclusion of the drug on the uniform formulary and the availability of that drug through retail network pharmacies without a preauthorization. See section 199.21(q)(2).*

*A drug must still be considered by the P&T Committee for clinical and cost effectiveness as part of the determination of which tier of the uniform formulary the drug will be placed.*

- 4b. TMA has explained to manufacturer's having a Pricing Agreement in effect does not give any benefit to the products covered under the

## ABA Questions and Responses

Pricing Agreement with regards to P&T Committee review, so please explain the benefit of signing a Pricing Agreement with TMA.

*See 4a.*

- 5a. As listed on page 3 of TMA's Process and Procedures Guide, "TRICARE Retail Utilization Refunds are based solely on utilization of pharmaceutical agents dispensed through the TRICARE Retail Pharmacy Network to DoD beneficiaries." In reviewing the detail data received from TMA, there were long term care facilities that submitted utilization through TRICARE. Is TMA allowing long term care facilities to be considered a Retail Pharmacy?

*If the claim is entered from a pharmacy, either on-site of the long term care facility or another retail pharmacy and the pharmacy is part of the TRICARE Retail Network the claim is eligible for a refund.*

- 5b. If not, why were they not scrubbed out of the data prior to submission to the manufacturer? We can we expect this resolution?

*To date, we have not received any disputes for this reason. If a manufacturer wishes to dispute a claim they believe was filled at a long-term care facility erroneously they may do so. We will validate the claim and process accordingly.*

*To dispute, please use Dispute Code – E: Invalid pharmacy identification number/NCPDP Provider ID.*

level for authorized generic products, as such would be the only generic product available. Why, then, should manufacturers be required to pay refunds for authorized generics when they are effectively generic products, and not brand products, could not be subject to prior authorization nor moved to Tier 3?

*TMA will only request refunds for a covered drug as defined under 38 U.S.C. 8126.*

6. Also on page 1, in the 3<sup>rd</sup> note, it states over-the-counter-drugs are exempt from refunds. However, TMA has submitted in its utilization data request for refunds for drugs that are over-the-counter, do not have a non-FAMP or FCP associated with them and are not on an FSS contract. Why are these products included in the submission data and

## ABA Questions and Responses

how is TMA scrubbing the data to ensure products like this do not get passed through to the manufacturer?

*To date, we have not received any disputes for drugs that are considered over-the-counter drugs. TMA has done due diligence to ensure these products have been excluded from all utilization data. However, in the event that a product does slip through, the manufacturer should dispute the claim with the Dispute Code – J: Product not eligible for a refund.*

- 7a. TMA has stated that they will not include 340B pharmacies in their utilization data. What process is TMA using to identify 340B entities?

*TMA works with Health Resources and Services Administration (HRSA) to ensure we have an up-to-date listing of all 340B entities.*

*If a manufacturer believes they have received utilization from a 340B pharmacy, they may dispute the claims with Dispute Code – K: PHS/340B entity not extracted from utilization data.*

- 7b. Does TMA understand that 340B grant holders change quarterly and this data must be validated every quarter?

*Yes.*

8. TMA has submitted data files for 2Q2009 that include submissions from prior quarters, however, the reason this claim is being submitted late is not communicated to the manufacturer. It is stated in the Process and Procedures Guide on page 7 that prior period adjustments will be processed within 10 days, but this relates to reversals. Why are there claims for prior quarters in 2Q2009 data with no explanation?

*In communicating with manufacturers, the Retail Refunds Team realized the need to add a new dispute code for claims from prior quarters. The team does not know why a claim from a previous quarter is included in the data until they contact the pharmacy to obtain dispensing information.*

9. If a manufacturer pays a claim and then performs more analysis on that claim and determines it should not have been paid because it's a 340B account or any other reason, can the manufacturer go back to TMA and dispute that claim and ask for a credit from TMA?

## ABA Questions and Responses

*A manufacturer may dispute a claim up to one (1) year after the utilization data has been released. If the claim is accepted, TMA will credit the amount on the next quarter's utilization summary.*

10. If the manufacturer's dispute is accepted, can the manufacturer collect interest on the overpayment?

*No, TMA would credit or refund the amount due without any interest.*

11. If a manufacturer has to re-calculate their non-FAMP or FCP for prior quarters, what does this do to the TMA calculation? Does the manufacturer have to re-calculate all quarters affected by this change, whether it ends up to be a credit or a debit, and apply it to the next quarter's payment?

*TMA utilizes the annual NFAMP and FCP.*