1a. On page 1 of TMA's template Pricing Agreement, in the 3rd note, it is stated that, "This agreement only covers brand medication," which suggests that generic drugs are exempt from refunds. An authorized generic is a "covered drug," in that it was approved under an NDA, but it is not a brand product. Rather, authorized generics compete as generic products, at generic product prices. At the retail pharmacy level, a pharmacist makes no distinction authorized generics and typical (505J) generics when electing which generic product to stock (pharmacies typically only stock one generic version of any product). Furthermore, neither the manufacturer nor TMA has any control over which generic – an authorized generic of a 505J generic – is dispensed. Additionally, at the time of dispense, the authorized generics are adjudicated as generic drugs by most if not all third party payors. TMA would violate its own regulatory obligation to cover generic products should it institute a prior authorization at the retail 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?

The intent of the Pricing Agreement is to satisfy the requirement of the TRICARE regulation, 32 CFR 199.21(q)(2)(i), for a manufacturer's written agreement with respect to covered drugs. It is the regulation, not the Pricing Agreement, that establishes which drugs are covered drugs. Authorized generics, being covered drugs under 38 U.S.C. 8126, are covered drugs under the regulation. 32 CFR 199.21(q)(2)(iii). They are subject to the pricing standards required by 10 U.S.C. 1074g(f) and to the requirement of a written agreement as a condition for inclusion on the uniform formulary and availability through retail network pharmacies without preauthorization. The way to ensure that authorized generics will be available to TRICARE beneficiaries at retail network pharmacies is for manufacturers to enter into written agreements to honor the same pricing standards used for those authorized generics when they are otherwise sold under depot contracting systems or under the FSS to the "Big 4".

1b. Does TMA intend to exercise its authority under the final rule and carve authorized generics out of the definition of covered drugs?

See 6a. The Director, TMA, has authority under the regulation to establish exceptions, "consistent with law," to the regulatory

designation of covered drugs. Pursuant to 38 U.S.C. 8126, authorized generics are covered drugs. DoD does not intend to disturb this legal status.