

AUTHORIZED GENERICS AND TRICARE

by Lisa C. McNair, CIS Senior Manager, TRICARE Consulting

The Office of Generic Drugs states that a generic drug must have the identical active ingredient as the brand drug. An *authorized generic* is defined as a prescription drug that is produced by the pharmaceutical manufacturer of the brand drug, but is marketed and dispensed under another label at generic pricing.

In April 2009, the Pharmaceutical Operations Directorate (POD) published questions and answers to assist pharmaceutical manufacturers with their understanding of the TRICARE Retail Refunds Program. In those Q&A's the POD advised, "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." The following question regarding authorized generics was also presented and answered in those same Q&A's, "Authorized generics are treated as covered drugs for Non-FAMP and FCP purposes. Are authorized generics considered covered drugs, subject to TRRx refunds?" the following response was provided, "Only generics approved by the Food and Drug Administration (FDA) as 505J generics are excluded from this program."

In response to a recent inquiry regarding excluding authorized generics from the TRICARE Retail Refunds Program, TRICARE stipulated that the determination of which drugs are covered under the program falls under the purview of the regulation not the pricing agreement. (The inquiry pointed to a note in the Department of Defense (DoD)/TRICARE Pricing Agreement that stated, "This agreement only covers brand medications.") 38 U.S.C. 8126 identifies authorized generics as covered drugs, thus they are subject to the pricing standards of 10 U.S.C. 1074g(f). TRICARE goes on to state, "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"

What does this mean to pharmaceutical manufacturers of authorized generics or generic manufacturers who distribute an authorized generic? First and foremost, these products are subject to the TRICARE Retail Refunds Program. If these products have not been placed on an executed DoD/TRICARE Pricing Agreement, the manufacturer should amend their executed agreement to add these products. For manufacturers who market these products and who have not entered into an executed pricing agreement with TRICARE, the manufacturer needs to enter into an executed agreement and make any necessary payments to TRICARE to become compliant with the regulation.

If you have questions or need additional information regarding the TRICARE Retail Refunds Program and authorized generics, please contact me at lisamcnair@cis-partners.com.

About the Author

Lisa McNair is Senior Manager of TRICARE Consulting with CIS. A certified pharmacy technician with more than 18 years of pharmaceutical industry experience, Lisa assists CIS' pharmaceutical manufacturing clients by offering insight into the mandatory task of recalculating and submitting payment for retro-active TRICARE liabilities. During her time as a pharmacy analyst working with the Department of Defense (DoD), McNair was instrumental in assisting with the development and implementation of the DoD/TRICARE Retail Refunds Program and the TRICARE Pharmacy Benefit Program. She possesses a diverse portfolio featuring excellent key relationship management, project management, and pharmacy program implementation. She has served as a compliance manager, quality assurance specialist, and business training manager.