Government Contracts

E-ALERT

April 14, 2009

Department of Defense Releases Additional Guidance for Implementation of the New TRICARE Rule

Last week, the Department of Defense ("DoD") released further guidance concerning the implementation of its new TRICARE Retail Pharmacy Network ("TRRx") final rule promulgated on March 17, 2009 (the "Final Rule"), and Section 703 of the 2008 National Defense Authorization Act ("NDAA"). (A recent Covington & Burling LLP E-Alert describing the implications of the Final Rule is available at http://www.cov.com/publications/.) DoD has released, among other materials, an updated Process and Procedure Guide for retail utilization refunds, a draft Retail Refund Pricing Agreement ("Pricing Agreement"), and responses to key questions raised since the publication of the Final Rule.

With the issuance of these documents, it appears that DoD has provided the remainder of the guidance that will be available regarding the Final Rule in advance of its effective date of May 26, 2009. Thus, DoD has provided all the information that will be available to manufacturers in deciding whether to pay the refunds for 2008, seek a waiver of prior amounts due, and/or sign a "voluntary" pricing agreement going forward. This update analyzes the new guidance from DoD and outlines next steps for manufacturers affected by these developments.

- **Requests for Waiver or Compromise.** Under the Final Rule, manufacturers must pay refunds for prescriptions filled after January 28, 2008, the effective date of the NDAA. Payments for 2008 must be made by May 26, 2009. If a manufacturer chooses to seek a waiver or compromise of its obligation to pay a refund, it must make a request pursuant to 32 C.F.R. § 199.11(g) by May 26, 2009. All waiver requests must include a calculation of the total refund amount and the amount for which the manufacturer requests waiver or compromise. Manufacturers seeking a waiver or compromise may withhold payment of the amount at issue pending a decision, but will be required to pay interest on the unpaid refund if the request is denied in whole or in part. DoD has indicated that the submission of a waiver or compromise request does not require a manufacturer to concede the correctness of DoD's interpretation of the NDAA.
- **Standards for Granting Waivers.** The materials released last week provide limited information on the criteria that DoD will use to evaluate a waiver or compromise request. Under the Final Rule, a manufacturer's voluntary removal of a drug from TRRx coverage is a basis for waiver or compromise of the refund amount. DoD has stated that "there may be merit to some . . . concerns that in particular circumstances concerning stale utilization date, prior incentive pricing agreements . . . , and other situations, there may be a reasonable basis to waive or compromise a refund." The new guidance further indicates that a manufacturer may request a waiver or compromise "on any grounds that the manufacturer deems appropriate." Otherwise, the new guidance refers manufacturers to 32 C.F.R § 199.11(g), which sets out the various bases for the compromise

or termination of a collection action, including the inability of the debtor to pay the full amount; the cost of collection; and the inability to calculate or legally defend the amount.

- **Timing of Waivers.** The new guidance makes clear that the process for requesting waiver or compromise and the submission of a new Pricing Agreement are separate and distinct processes, and that waiver requests will not be granted prior to the June 1, 2009 due date for the submission of "voluntary" price agreements. The preamble to the Final Rule indicates that DoD may grant a waiver or compromise if a company proposes to execute a new Pricing Agreement under which it agrees to provide all covered drugs to TRRx at or below the Federal Ceiling Price ("FCP"). However, the new guidance makes clear that the two processes will proceed independently. The waiver or compromise requests are due May 26, 2009 and Pricing Agreements are due June 1, 2009. DoD will not act on a waiver or compromise request until after the due date for new Pricing Agreements has passed, and perhaps not until after the Pharmacy and Therapeutics Committee meets in August 2009. Therefore, a manufacturer will have to decide whether to agree to offer FCP pricing going forward before it knows whether DoD will waive any portion of the 2008 refund amount. According to DoD's guidance, a manufacturer's remedy in the event it signs a Pricing Agreement and is not granted the waiver is to terminate the new Pricing Agreement. A Pricing Agreement may be terminated upon 60 days notice by the manufacturer, but such termination could have legal consequences in light of DoD's position that offering FCP pricing is required by law.
- **Execution of New Pricing Agreements.** DoD has indicated that it will begin reaching out to manufacturers with new Pricing Agreements around April 15, 2009, and will require that such "voluntary" agreements be executed by June 1, 2009. As stated above, the waiver or compromise requests and the execution of new Pricing Agreements are two separate processes. DoD will not execute Pricing Agreements made contingent upon the result of a waiver or compromise request. Thus, if a manufacturer wishes to make a Pricing Agreement contingent on a waiver or compromise, its only remedy is to terminate the agreement after receiving a decision on the request. If a manufacturer wishes to pursue legal remedies with regard to DoD's enforcement of the Final Rule, the execution of a Pricing Agreement may bind the manufacturer to comply with the DoD's interpretation of the NDAA, even if that interpretation is later invalidated. Although the draft Pricing Agreement provides general assurances that nothing in the Agreement shall constitute a waiver or relinquishment of any legal rights, a manufacturer who signs an agreement may be required to comply with its terms regardless of whether the agreement is based on a valid interpretation of the NDAA. However, under the terms of the Pricing Agreement a manufacturer may terminate with 60 days notice, so in the event of a successful legal challenge to the Final Rule, a manufacturer may terminate its agreement without penalty other than a potential delay of up to a year in its ability to negotiate a new agreement at prices above the FCP.
- **Disputes Over Utilization Data.** Separate and distinct from requesting a waiver or compromise of a refund amount, a manufacturer may wish to dispute the accuracy of its utilization data for 2008. The process for the resolution of such disputes is set out in the Pricing Agreement and the updated Process and Procedures Guide. If a manufacturer disputes the data, its refund obligation with regards to the amount in dispute is deferred pending a resolution. Any refund owed upon resolution will be due with interest from the original payment date. If the manufacturer and POD do not resolve the dispute within 60 days, the Director of POD will review the matter and render a decision. The manufacturer may then request reconsideration or appeal the decision under 32 C.F.R. § 199.10.

In light of the information contained in the new guidance from DoD, manufacturers must take a number of steps before the May 26 and June 1 deadlines:

1. Obtain and review the utilization data and determine whether the calculated refund amount is accurate and dispute any discrepancies in accordance with DoD procedures by May 26, 2009.

2. Pay the refund amount, or prepare and submit a waiver or refund request for some or all of the amount by May 26, 2009.

3. Determine whether to sign a "voluntary" Pricing Agreement. The Pricing Agreement is due to DoD by June 1, 2009.

If you have any questions concerning the material discussed in this client alert, please contact the following members of our government contracts practice group:

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