

## DRUG & PHARMACY ALERT

5/11/15

### **Compounded Drugs Marketed to TRICARE Beneficiaries Undergoing Close Examination by Federal Investigators**

Ongoing investigations by both the Department of Defense (DOD) and a major U.S. media organization allege that suspicious marketing and prescribing activities have led to astronomical increases in TRICARE costs for compounded medications. According to the *Military Times*, TRICARE paid \$769 million for compound prescriptions between January and March 2015, and April's total may approach nearly \$1 billion. Costs for compound medications in August 2014 were a mere \$54 million in comparison. Major General Rich Thomas, who oversees TRICARE, stated in a CBS news investigation that virtually all of the spending is for products that the DOD believes are of dubious clinical benefit. The prescriptions have been actively marketed to service members through "cold-calls," websites, and even through direct solicitation inside military hospital pharmacies. The marketers seek personal health information and offer TRICARE beneficiaries items that are described as "free," when in fact some of the professed pain creams, scar creams and supplements have cost taxpayers up to \$15,000 for a one-month supply. The Defense Health Agency (DHA) has advised all beneficiaries never to share their information with such callers and to file a Fraud-Line report should they receive solicitations that request their personal information and offers to submit prescription claims on their behalf.

It is alleged that pharmacies have either directly or indirectly engaged marketing companies to contact TRICARE beneficiaries through direct marketing and / or proposed "clinical studies," and in some cases utilized telemedicine physicians to generate prescriptions for compounded drugs. The issues with regard to the above tactics concern who is paying for the direct marketing efforts, the telemedicine consults and the proposed clinical studies. As with the DOD's ongoing investigations from the past two years regarding waiver of co-pays, pharmacies within the compounding marketplace must insure that any marketing activities being conducted on their behalf comply with the Anti-Kickback statute, that no improper payments are being made to any consultants or patients, that copays are being collected, and that there are no breaches of patient health information in violation of HIPAA.

Pharmacies and any affiliated marketing organizations that have engaged in the activities described above need to prepare to be approached by FBI and Department of Defense investigators, as agents have already begun conducting interviews and investigations into these potentially fraudulent practices. According to the *Military Times*, some compounding pharmacies have been issued a hold on payments from DHA due to investigations into alleged fraud or illegal sales. Pharmacies engaged in compounding for TRICARE beneficiaries should take immediate steps to review their current marketing models to determine if they should continue.

Further, and in light of the activities described above and the attendant increases in both the cost of compounded drugs and the rate at which they were being prescribed, military officials overseeing the TRICARE prescription program have implemented changes to protect both the recipients of the drugs from scam remedies and the taxpayers from potentially fraudulent claims against the TRICARE prescription program. Starting on May 1, 2015, TRICARE began a new screening process for the review of compounded medications prescribed to American troops and veterans and paid for via TRICARE's prescription drug program. TRICARE had previously screened drugs to ensure they were safe and effective. The policy change will now include the review of the more than 1,000 individual ingredients commonly used in compounded medications to ensure that each ingredient is one that has been approved by the Food and Drug Administration. The DOD expects that the change will have an effect on the

aggressive direct marketing campaign methods that are having such a deleterious impact on TRICARE's prescription drug budget.

For further information or assistance, please contact any of the following lawyers at Roetzel & Andress:

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