

DRUG & PHARMACY ALERT

6/17/15

Federal Government Continues Aggressive Pursuit of False Claims Act Investigations into TRICARE billing with Increasing Use of Civil Investigative Demands

The U.S. government continues to ramp up False Claims Act (FCA) investigations and enforcement actions against small and independent pharmacies, particularly those that compound drugs for persons covered under TRICARE. One of the favored tools utilized by the Department of Justice (DOJ) in pursuit of FCA investigations is the Civil Investigative Demand letter (CID)¹.

Receipt of a CID is serious matter, indicating that not only have allegations of wrongdoing already been made, but that they have been deemed sufficiently reliable such that the government is willing to expend time and resources on an investigation. Upon receipt of a CID, a company should immediately consult with counsel experienced in responding to such demands. Counsel will examine the scope of information sought and formulate an appropriate response plan. The CIDs being issued are broad and overly burdensome and have no time limitation. The federal government is seeking information related to Tricare compound medication billing, but the CID is asking for any and all documents and information. It is imperative to contest the broad requests.

Until passage of the Fraud Enforcement and Recovery Act of 2009 (FERA), the CID was a very rarely used tool in the FCA investigation toolbox, largely because the FCA required that the Attorney General personally approve the issuance of a CID. The passage of FERA changed the calculus of CID use by instead allowing the Attorney General to delegate the authority to issue CIDs to individual U.S. attorneys who were conducting FCA investigations. This change in the rules broke the dam, and CIDs are now among the most often used methods of acquiring vast amounts of information from those under FCA investigation. Tony West, former head of the DOJ's civil division, estimated in 2012 that the passage of FERA brought about a six-fold increase in the number of CIDs issued. That number has only continued to increase.

The DOJ is empowered to issue a CID to obtain any information, "relevant to a false claims law investigation." The CID can impose significant burdens on the recipient, requiring that it provide considerable numbers of documents, copies of communications, and responses to written questions, all within a very short time frame. The types of documents demanded can run the gamut from all electronically-stored information to post-it and handwritten notes, while the written questions can be intrusive of sensitive corporate information. While receipt of a CID typically means that an investigation into possible violations of the FCA has begun, the recipient will often be unaware of the nature and scope of the conduct under investigation, how to respond to the demands, and the potential costs involved in complying with the CID and defending the matter.

For further information or assistance if you have received a Civil Investigative Demand letter, please contact any of the following lawyers at Roetzel & Andress:

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¹ For an example of a recent CID letter, please click [HERE](#).