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***U.S. ex rel. Jamison v. McKesson Corp et al., 2011 U.S. Dist.  
LEXIS 32851 (N.D. Miss. Mar. 28, 2011)***

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In a ruling on March 28, 2011, the U.S. District Court for the Northern District of Mississippi held that the United States could not sustain False Claims Act (FCA) charges that were based upon allegations that a durable medical equipment (DME) supply company was a “sham” and violated Medicare DME supplier standards (Supplier Standards). The district court granted motions for partial summary judgment by defendants Beverly Enterprises, Inc. and McKesson Corporation and denied the U.S. Department of Justice’s (DOJ’s) cross-motion because DOJ could neither prove the essential element of falsity nor carry its burden to show that defendants violated the Supplier Standards. In particular, the court’s holding was based upon its findings that the DME company’s initial and continued enrollment in Medicare had been approved by the Centers for Medicare & Medicaid Services (CMS), that the company relied in good faith on government determinations of compliance, and that all claims submitted by the company were properly paid.

In 1998, Beverly established a subsidiary called Ceres Strategies Inc. to serve as the procurement arm for its nationwide network of skilled nursing facilities. Several years later, that subsidiary formed another company, Ceres Strategies Medical Services LLC (Ceres), for the purpose of providing enteral nutrition to residents at all Beverly facilities. Ceres later contracted with McKesson for billing services. Ceres first successfully

obtained its supplier number in 2003. Palmetto GBA National Supplier Clearinghouse (Palmetto), the Medicare contractor charged with DME supplier enrollment and verification, inspected Ceres, reviewed documents, and declared the company compliant with the Supplier Standards. Ceres successfully renewed its supplier number through Palmetto in 2006.

Between 2007 and 2010, Palmetto twice revoked Ceres’ supplier billing number for non-compliance with the Supplier Standards and Ceres twice filed an administrative appeal, each time with the same result: CMS agreed that Ceres was in compliance and reinstated Ceres’ supplier number retroactive to the date of revocation. In 2008, between the first and second administrative proceedings, DOJ commenced its FCA action alleging that Ceres was never compliant and that it submitted legally false claims.

Defendants’ motions for summary judgment challenged the FCA elements of falsity and knowledge. The court granted defendants’ motion for summary judgment, and denied DOJ’s cross-motion, based upon DOJ’s inability as a matter of law to prove falsity, and the court therefore did not reach the knowledge issue. The court expressly noted four reasons for its holding:

1. Ceres was at all times entitled to payment by Medicare;

2. DOJ failed to prove an objective falsehood necessary for finding a false claim;
3. DOJ failed to prove non-compliance with any particular Supplier Standard; and
4. Defendants acted in good faith reliance on determinations of compliance by Palmetto and CMS when submitting claims under Ceres's supplier number.

In support of its first stated reason, the court extensively examined Ceres' history of review and investigation by Palmetto, culminating in the two instances of reinstatement of Ceres' supplier billing number. Despite the issuance of letters of revocation, all claims submitted from 2003 through 2009 were honored because Palmetto determined Ceres' date of compliance to be retroactive to the date of revocation. Testimony by Palmetto confirmed that suppliers are presented the opportunity (as Ceres was) to correct non-compliance (as Ceres did) prior to revocation of billing privileges. Thus, as Ceres was entitled to the reimbursements claimed, both under the regulations and pursuant to the CMS and Palmetto determinations, no false claims were made.

Aside from Ceres' entitlement to reimbursement, the court noted that DOJ's theory of liability did not rest on an objective falsehood, as required by the FCA, but rather on DOJ's subjective interpretation of defendants' regulatory duties. The court stated that if regulations are thoroughly unclear, as a matter of law, the FCA falsity and knowledge requirements cannot be met. The administrative history here proved that grounds for disagreement over the scope of the regulatory provisions existed. The record reflected that Palmetto interpreted the twenty-one Supplier Standards differently than did DOJ. On this basis alone, DOJ failed to allege an objective falsehood; further, all claims between 2003 and 2007 were based

on Palmetto's determination of compliance with the standards, which established both good faith and reasonable reliance by Ceres, and therefore, a lack of falsity.

The court also extensively reviewed—and rejected—DOJ's specific claims that Ceres violated more than half of the twenty-one Supplier Standards. As to one Supplier Standard, the court held that the conduct the government alleged to be improper was not prohibited, and as to most, the court stated that the government failed to provide sufficient evidence to support a finding of violation. The court also focused heavily upon Palmetto's role and responsibility in monitoring and verifying DME supplier compliance with the Supplier Standards. The court rejected the assertion that Ceres was never compliant by pointing to Palmetto's confirmation of compliance in 2003, 2006, 2007, and 2009. It noted that a defendant cannot be held to have submitted false claims where the governmental agency charged with compliance deemed it to be compliant, and that mere contractual or regulatory non-compliance does not establish a knowingly false claim.

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