

MEDICAL DEVICE BUSINESS SERVICES, INC. TO PAY \$10 MILLION TO SETTLE ALLEGATIONS INVOLVING OFF-LABEL PROMOTION OF TISSUE-REJECTION THERAPY

The National Association of Medicaid Fraud Control Units (NAMFCU) announced on February 24, 2021 that 28 states have the federal government to settle allegations of fraud against Medical Device Business Services, Inc. ("MDBS"), an Indiana corporation, in relation to its involvement in the off-label promotion and marketing of the UVAR XTS® and Cellex®, anti-tissue rejection systems. The total value of the settlement is \$10 million.

The settlement resolves allegations that from January 1, 2006, through December 31, 2012, MDBS promoted, marketed, and sold UVAR XTS® and Cellex® systems for uses not approved by the Food and Drug Administration. The government alleges that MDBS's conduct resulted in the submission of false reimbursement claims to government health care programs.

This settlement results from a whistleblower lawsuit originally filed in the United States District Court for the Eastern District of Pennsylvania (*United States ex rel. Johnson, et al. v. Therakos, Inc., et al.,* [Civil Action No. 12-cv-1454]). A NAMFCU Team participated in the settlement negotiations on behalf of the states. The Team included representatives from the Offices of the Attorneys General for the states of California, Florida, New Mexico, New York, Oregon, and Pennsylvania.