

JUSTICE NEWS

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Nearly 500 Hospitals Pay United States More Than \$250 Million to Resolve False Claims Act Allegations Related to Implantation of Cardiac Devices

The Department of Justice has reached 70 settlements involving 457 hospitals in 43 states for more than \$250 million related to cardiac devices that were implanted in Medicare patients in violation of Medicare coverage requirements, the Department of Justice announced today.

“While recognizing and respecting physician judgment, the department will hold accountable hospitals and health systems for procedures performed by physicians at their facilities that fail to comply with Medicare billing rules,” said Principal Deputy Assistant Attorney General Benjamin C. Mizer, head of the Justice Department’s Civil Division. “We are confident that the settlements announced today will lead to increased compliance and result in significant savings to the Medicare program while protecting patient health.”

An implantable cardioverter defibrillator, or ICD, is an electronic device that is implanted near and connected to the heart. It detects and treats chaotic, extremely fast, life-threatening heart rhythms, called fibrillations, by delivering a shock to the heart, restoring the heart’s normal rhythm. It is similar in function to an external defibrillator (often found in offices and other buildings) except that it is small enough to be implanted in a patient’s chest. Only patients with certain clinical characteristics and risk factors qualify for an ICD covered by Medicare.

Medicare coverage for the device, which costs approximately \$25,000, is governed by a National Coverage Determination (NCD). The Centers for Medicare and Medicaid Services implemented the NCD based on clinical trials and the guidance and testimony of cardiologists and other health care providers, professional cardiology societies, cardiac device manufacturers and patient advocates. The NCD provides that ICDs generally should not be implanted in patients who have recently suffered a heart attack or recently had heart bypass surgery or angioplasty. The medical purpose of a waiting period -40 days for a heart attack and 90 days for bypass/angioplasty - is to give the heart an opportunity to improve function on its own to the point that an ICD may not be necessary. The NCD expressly prohibits implantation of ICDs during these waiting periods, with certain exceptions. The Department of Justice alleged that from 2003 to 2010, each of the settling hospitals implanted ICDs during the periods prohibited by the NCD.

“The settlements announced today demonstrate the Department of Justice’s commitment to protect Medicare dollars and federal health benefits,” said U.S. Attorney Wifredo A. Ferrer of the Southern District of Florida. “Guided by a panel of leading cardiologists and the review of thousands of patients’ charts, the extensive investigation behind the settlements was heavily influenced by evidence-based medicine. In terms of the number of defendants, this is one of the largest whistleblower lawsuits in the United States and represents one of this office’s most significant recoveries to date. Our office will continue to vigilantly protect the Medicare program from potential false billing claims.”

“Working as a team with the Department of Justice to investigate and settle false billing claims of this magnitude has resulted in substantial recoveries to Medicare and the successful enforcement of Medicare’s coverage requirements for these procedures,” said Inspector General Daniel Levinson of the Department of Health and Human Services’ Office of Inspector General (HHS-OIG).

The 70 settlements, representing nearly 500 hospitals, are listed on the attached chart. Most of the settling defendants were named in a qui tam, or whistleblower, lawsuit brought under the False Claims Act, which permits private citizens to bring lawsuits on behalf of the United States and receive a portion of the proceeds of any settlement or judgment awarded against a defendant. The lawsuit was filed in federal district court in the Southern District of Florida by Leatrice Ford Richards, a cardiac nurse, and Thomas Schuhmann, a health care reimbursement consultant. The whistleblowers have received more than \$38 million from the settlements. The Department of Justice is continuing to investigate additional hospitals and health systems.

The settlements were the result of a coordinated effort among the U.S. Attorney’s Office of the Southern District of Florida, the Civil Division’s Commercial Litigation Branch and HHS-OIG, Office of Investigations and Office of Counsel to the Inspector General.

This settlement illustrates the government’s emphasis on combating health care fraud and marks another achievement for the Health Care Fraud Prevention and Enforcement Action Team (HEAT) initiative, which was announced in May 2009 by the Attorney General and the Secretary of Health and Human Services. The partnership between the two departments has focused efforts to reduce and prevent Medicare and Medicaid financial fraud through enhanced cooperation. One of the most powerful tools in this effort is the False Claims Act. Since January 2009, the Justice Department has recovered a total of more than \$26.2 billion through False Claims Act cases, with more than \$16.4 billion of that amount recovered in cases involving fraud against federal health care programs.

The claims resolved by these settlements are allegations only and there has been no determination of liability.

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Civil Division

Topic:

Healthcare Fraud

[Download List of Settled Hospitals](#)

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