

DOJ Reports \$250 Million in Settlements With 70 Hospitals Over Cardiac Device By [Richard Kusserow](#) | November 2015

The [Department of Justice \(DOJ\)](#) reported that it has settled with 457 hospitals that implanted cardiac devices in Medicare patients in violation of Medicare coverage requirements. The investigations, which included agents from the Department of Health and Human Services (HHS) Office of Inspector General (OIG), resulted in 70 settlements across 43 states amounting to over \$250 million. The report explained that the DOJ will hold hospitals and health systems accountable for procedures performed by physicians that fail to comply with Medicare billing rules. The DOJ expects this crackdown to lead to increased compliance.

The device in question, an Implantable Cardioverter Defibrillator (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, which restores the heart's normal rhythm. Only patients with certain clinical characteristics and risk factors qualify for an ICD covered by Medicare, which costs approximately \$25,000. ICDs are governed by a National Coverage Determination (NCD) implemented by the Centers for Medicare & Medicaid Services (CMS). Coverage is based on clinical trials and the guidance and testimony of cardiologists, 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 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 time to improve function on its own so that an ICD may not be necessary. The NCD expressly prohibits implantation of ICDs during these waiting periods, with certain exceptions. The DOJ stated that each of the settling hospitals implanted ICDs during the prohibited periods.

The DOJ report further noted that since 2009, it has recovered 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.

Takeaway Points

1. Most cases resulting in settlements stemmed from *qui tam* whistleblowers filing with the DOJ under the False Claims Act. The whistleblowers received more than \$38 million from the settlements.
2. The DOJ continues to investigate additional hospitals and health systems. Therefore, hospitals that have not been part of these reported settlements should review their own practices on this subject and take any needed corrective actions.
3. As part of ongoing monitoring and auditing, hospitals should review all devices they provide to ensure compliance with CMS program payment requirements.