

How to report unapproved medical devices or non-FDA approved medical implants and obtain a whistleblower reward

Reporting unapproved FDA devices or medical implants billed to Medicare

This article addresses how to get a whistleblower reward for reporting fraud against Medicare or Medicaid by using medical devices or medical implants that have not been FDA approved.

One way doctors, hospitals, and medical device or implant manufacturers cheat Medicare or Medicaid is by using medical implantable devices that have not been FDA approved. You would be surprised to know that some doctors, hospitals and manufacturers of medical implants use devices that have not been FDA approved.

Generally Medicare requires that implantable medical devices (IMD) clear FDA approval before Medicare will reimburse the healthcare provider for the surgery or medical procedure using implants.

Examples of Medicare fraud by using medical devices or implants requiring FDA approval

There are many types of medical implantable devices, and there have been instances of Medicare fraud by using unapproved implants or devices for most of them. Here is a short list of the types of implantable medical devices that must be FDA approved to bill Medicare, or it is fraud: pacemakers, stents, prosthetic heart valves, cardioverter defibrillators and many other cardiac implant devices; orthopedic implants (such as artificial knees or hips); cochlear implants; spinal disks; and robotic surgery machines.

It is estimated that as much as ten percent of spending under Medicare is fraudulent, including using medical devices or medical implants that are not FDA approved. When medical device or implant manufacturers sell unapproved devices, it risks the health or safety of individual patients and increases healthcare costs for everyone.

To stamp out fraud against Medicare and Medicaid by makers of medical implants and devices, the government is offering huge whistleblower rewards. To receive a reward for reporting non-FDA approved devices or implants, you must follow a strict set of procedures. By following the reward rules is also the best way to get Medicare to open an investigation and put an end to device or implant manufacturers cheating Medicare and risking patient safety.

This rest of this article addresses how to report Medicare fraud for using non-FDA approved medical devices or implants and obtain a whistleblower reward.

Tips for reporting Medicare fraud for using non-FDA approved devices or implants

Here are just two key tips for how to report unapproved devices or implants.

First, simply calling a hotline to report Medicare fraud for using non-FDA approved devices or implants will not entitle you to a reward. In fact it may hurt your chance of getting a reward. The whistleblower reward program prohibits the government from paying rewards based on tips. In addition, only the first to follow the proper way of applying for a reward gets paid. The only way how to get a reward for reporting non-FDA approved devices unbundling fraud is using an attorney (usually on a contingency basis where they get a portion of any whistleblower reward) to file a qui tam lawsuit under the False Claims Act. Your lawyer must strictly follow all of the exact procedures for you to be eligible for a reward for reporting that a medical implant or device was not FDA approved. Therefore, you should select an attorney with experience handling Medicare reward applications for using non-FDA approved implants or devices.

In addition, you must report the unapproved FDA device or implant in sufficient detail and show why and how the FDA rules require approval. Your attorney should be able to find the appropriate regulations and present your allegations of fraudulent use of non-FDA approved devices or implants in a convincing fashion. Indeed, 75% of whistleblower applications are rejected. That is why it is key that you select a lawyer with experience with Medicare fraud cases involving unapproved FDA devices or implants.

How much reward for reporting Medicare fraud for using non-FDA approved medical devices

The size of a whistleblower reward is determined by the amount Medicare recovers based on your allegations that the device or implant was not FDA approved. The government can collect the full cost of each procedure using a device that was not approved. Because the reward amount is between 15% to 25% of what Medicare collects back from the Medicare provider or manufacturer of the device or implant, the rewards can and have been in the tens-of-millions of dollars for the right type of allegation of fraud by using a device that is not FDA approved.

How to report Medicare fraud for using a device that is not FDA approved

The Hesch Firm's website (and the books authored by Mr. Hesch) walk you step-by-step through the entire process of reporting Medicare or Medicaid fraud by using a FDA unapproved device and how to get a whistleblower reward.

Mr. Hesch is experienced investigating allegations that a medical device was not approved by the FDA but was fraudulently billed to Medicare. He handled allegations of unapproved medical devices during his 15 years as an attorney the Civil Fraud Section of the U.S. Department of Justice in Washington, D.C. handling Medicare fraud cases. Since forming the Hesch Firm, Mr.

Hesch also has represented whistleblowers obtain rewards for reporting Medicare fraud because the device or implant was not approved by the FDA.

Visit his website at www.HowToReportFraud.com to find out if Mr. Hesch can help you answer the question of how to report unapproved medical devices or implants and apply for a whistleblower reward.