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Introduction to the Clinical Issues for Medicare Patients

In a study published in the Journal of the American Medical Association in April of 2012, former CMS Administrator Donald M. Berwick estimated that financial waste from "overtreatment" of Medicare and Medicaid patients added as much as 87 billion dollars in government spending for 2011 alone. Berwick D, Hackbarth A, *Eliminating Waste in US Health Care,* JAMA, 307(14): 1513-1516 (April 11, 2012).

The authors defined "overtreatment" as "care rooted in outmoded habits, supply-driven behaviors, and ignoring science."

The Centers for Medicare and Medicaid Services ("CMS") has attempted to address the problem by establishing National Coverage Determinations based on scientific consensus. Such National Coverage Determinations are critical to Medicare patients receiving evidence-based medical treatment and critical to containing the escalating costs of federal healthcare programs.

One of these National Coverage Determinations specifically addresses Medicare coverage conditions for implantable cardioverter-defibrillator[1] ("ICDs").

Based on the determinations of the Medicare Coverage Advisory Committee composed of independent medical experts and based on the findings of published controlled scientific studies, CMS has established the conditions of Medicare coverage governing ICD procedures.

CMS has generally excluded Medicare coverage for ICD procedures in patients who have suffered an acute myocardial infarction (AMI) within the past 40 days and patients who

[1] Implantable cardioverter-defibrillators are electronic devices designed to detect and treat tachyarrhythmias or fast heart rates. Implanted under the skin in the upper abdomen, the defibrillator is connected with lead wires to two defibrillation electrodes placed surgically in or around the heart. The defibrillator is designed to interrupt the abnormal rhythm, allowing the normal rhythm to resume. Sensors inside the defibrillator monitor the heart. If a sensor detects an irregularity, such as fibrillation, the defibrillator is programmed to deliver a strong electric shock directly to the heart.

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have undergone coronary artery bypass graft surgery or percutaneous transluminal coronary angioplasty within the past 3 months.

The National Coverage Determination's exclusion of coverage for ICD procedures within 40 days of an acute myocardial infarction is based on numerous scientific studies demonstrating that such procedures in the days and weeks following an acute myocardial infarction are not beneficial and are potentially harmful to the heart as it heals and recovers after an AMI. Such harm includes worsening heart failure.

The 2006 Guidelines published by the American College of Cardiology and American Heart Association confirmed, "ICD implantation should be deferred until at least 40 d [days] after AMI in patients meeting the above criteria in order to allow time for ventricular function and because ICD therapy has not been demonstrated to improve survival when implanted within 40 days after myocardial infarction."[2]

Even though the National Coverage Determination specifically excluded coverage for ICD procedures under certain clinical conditions, the defendant hospitals still submitted claims for payment and certified such claims were covered procedures under Medicare rules. While the settling hospitals will argue that some of their claims for ICD procedures survived the DOJ audits, the 70 settlements for 257 million dollars represent thousands of claims for surgical procedures to implant ICDs in violation of the NCD.

In each of these surgeries, the patient was entitled to receive an advanced beneficiary notice ("ABN") but didn't. The laws and regulations addressing advance beneficiary notices to Medicare patients are based in part on the important policy of providing information to such patients so that they can make an informed decision prior to the treatment or procedure which is not covered by Medicare policy. The Medicare Claims Processing Manual Section 40.3 states, "The purpose of the ABN is to inform a Medicare beneficiary, before he or she receives specified items or services that otherwise

[2] *See* ACC/AHA/ESC 2006 Guidelines for Management of Patients with Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death: A Report of the American College of Cardiology/ American Heart Association and the European Society of Cardiology Committee for Practice Guidelines, *J. Am. Coll. Cardiol.* 2006; 48; e247-e346, p. e283.

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might be paid for, that Medicare certainly or probably will not pay for them on that particular occasion."