

# White Paper: Defending Cardiac Departments Against Medicare and Medicaid Audits

For Hospital Groups, ASCs and Specialty Medical Facilities

## Executive Summary

The Centers for Medicare and Medicaid services (CMS) have been taking aggressive measures to promote evidence-based healthcare, and they have been expanding their use of Recovery Audit Contractors (RACs) to recover inappropriate payments for Medicare services. Medicaid Integrity Contractor (MIC) auditors and federal regulators are also actively auditing hospitals to make sure that they are complying with the new rules and regulations. Although target audit issues vary among hospitals, the most lucrative procedures are undergoing a high level of scrutiny. This White Paper will focus on ensuring the medical necessity of interventional cardiology procedures, which has received national attention in recent months.

Hospitals are now being forced to demonstrate that cardiology procedures meet the strict medical necessity criteria and guidelines. The penalties for inappropriate reimbursement are steep, with some hospitals facing millions of dollars in fines.

CardioAudit is an external peer review program that offers a proactive approach to ensuring that a hospital's cardiovascular procedures are medically necessary, thereby helping facilities meet the challenges of the Medicare and Medicaid audits and preventing potential investigations and penalties. Developed by a group of cardiologists with the goal of ensuring adherence to evidence-based medicine and the established guidelines, CardioAudit helps hospital administrators identify and correct any potential problems before they occur.

The findings and recommendations provided by CardioAudit can result in the better assessment of coronary blockages and a reduction in the number of costly and ultimately unnecessary coronary interventions. In addition to ensuring the medical necessity of procedures, CardioAudit's board-certified cardiologists also serve to overcome potential barriers to effective peer review.

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## Introduction

The Centers for Medicare and Medicaid Services (CMS) have identified nearly \$1.03 billion in improper Medicare payments since they began their Recovery Audit Contractor (RAC) program in 2005. Of the improper payments identified by the RACs, 96% were overpayments to healthcare providers and the remaining 4% were underpayments that were repaid to healthcare providers.

According to the U.S. Department of Health and Human Services Office of Inspector General (HHS OIG), the most common Medicare reimbursement violation is the failure to comply with the medical necessity requirements, especially for certain costly diagnoses involving interventional cardiology procedures (for example, angioplasty and pacemaker implantation).

## Cardiac Procedures Under Scrutiny: Risk of Liability Increasing

The department of Justice (DOJ) has recently served a number of hospitals and health systems with subpoenas regarding Medicare billing for implantation of Implantable Cardioverter Defibrillator (ICD). The DOJ is investigating whether hospitals billed Medicare for ICDs for patients whose conditions did not satisfy the coverage criteria set forth in Section 20.4 of the Medicare National Coverage Determinations (NCDs) Manual.

The criteria state that Medicare does not cover the implantation of ICDs in patients who lack a history of arrhythmia, even if their heart function indicates that they are at elevated risk of sudden death due to arrhythmia or if the implantation occurred within 40 days of an acute myocardial infarction (MI) or within three months of bypass surgery or an angioplasty.

Estimates from a recently published study in the *Journal of the American Medical Association* indicate that more than 20% of patients who received implantable cardioverter-defibrillators (ICDs) did not meet the evidence-based criteria for implantation. These patients had a significantly higher risk of in-hospital deaths and complications following the implant. In most cases, the ICD implant was deemed “non-evidence-based,” because of improper timing.

In addition, the average length of stay for interventional cardiology procedures has gradually decreased, leading auditors to believe that they can routinely be performed in an outpatient setting. Hospitals that admit patients with these diagnoses can expect a thorough review by a variety of parties, including RACs.

There are some indications that hospitals have been increasingly shifting patient admission status for cardiac device implant cases from the inpatient to the outpatient setting. The currently available Medicare data indicate that about 50% of all ICD system placements are billed as inpatient stay with a one to two day length of stay. These are the types of cases that may be cited for performance in the wrong setting due to inaccurate and/or insufficient documentation of medical necessity or incomplete and improper coding. Regardless of the procedure setting, all cases require the appropriate assessment and documentation of the “medical necessity” for a specific level of care. Any ICD implanted in patients and billed to Medicare must include specific documentation that shows that the patient meets the determinations for coverage, including the copies of relevant diagnostic test.

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### Settlements/Fines

Penalties under the False Claims Act for performing inappropriate procedures are steep; a court may assess three times the amount of damages for each claim, plus significant civil and possible criminal penalties. These investigations also result in negative publicity for physicians and facilities can cause damage to reputations and impact revenues.

Although they did not admit any wrongdoing, one hospital in Maryland agreed to pay a \$22 million fine to settle charges that it paid illegal kickbacks to a cardiologist's practice in exchange for patient referrals. According to reports, the cardiologist may have implanted more than 500 stents that were medically unnecessary, with Medicare paying \$3.8 million of the \$6.6 million charges for those procedures.

## The Reactive Approach Can be Costly

Waiting for legal action or patient complaints can result in hefty legal costs and requires lengthy reviews. In addition,

a reactive approach to cases may not identify areas at risk for problems in the future. Uncertainties associated with healthcare reform and the increased pressure to cut costs are forcing hospitals to adopt more aggressive risk management that are methods focused on the reduction of medical errors by improving physician performance.

## CardioAudit: A Proactive Solution

CardioAudit is an external peer review program that helps hospital administrators identify and correct any potential problems before they occur. This review process is the first of its kind to systematically evaluate specific cardiac procedures (please see Table 1) to determine medical necessity in accordance with the guidelines set forth by professional medical societies and to determine compliance with Medicare NCDs, as well as necessity outside of NCD language.

# CardioAudit

**Table 1: Procedures for CardioAudit Review**

- ▶ Percutaneous coronary interventions (PCI)
- ▶ Peripheral vascular interventions
- ▶ Carotid artery interventions
- ▶ Coronary artery bypass graft (CABG) and valve surgery
- ▶ Electrophysiology procedures: ICDs, biventricular pacemakers, single and dual chamber pacemakers, radiofrequency ablation

The ongoing monitoring and identification of potential overutilization in advance of outside auditing processes allows hospitals to take remedial action, including the tightening of clinical criteria, providing additional training to physicians, and taking other corrective measures that protect all parties. Unlike internal peer review, which only looks at sentinel events, external peer review can help hospitals to efficiently discover, highlight and deal with physician performance issues before they turn into claims.

As an ongoing external peer review program, CardioAudit is a cost-effective solution to improve the quality of patient care while overcoming potential barriers to effective peer review, including conflicts of interest, uncompensated time, time limitations, sham reviews, and economic profiling. With CardioAudit, hospitals can also reduce the risk of False Claims Act liability, improve OPPE compliance, demonstrate a commitment to patient safety and improve compliance with the evidence-based guidelines.

### Building a CardioAudit Program

Implementing a CardioAudit program is a simple and straightforward process for hospitals. First, AllMed gathers information on the number of physicians and the procedures that were performed. Second, AllMed identifies an appropriate sampling size that is statistically valid. Third, AllMed determines the interval for performing case reviews in each sub-specialty area and on each practitioner. A budget and a schedule one then developed to meet the hospital's needs.

All CardioAudit cases are reviewed by leading board-certified cardiologists who are in active practice, thereby ensuring that cardiovascular procedures are medically indicated according to the latest clinical criteria, including the American College of Cardiology (ACC) and American Heart Association (AHA) guidelines. Sub-specialties include interventional cardiology, cardiothoracic surgery, electrophysiology, and peripheral vascular disease.

Reviews are conducted quarterly at three-month intervals. All physicians who the perform procedures are reviewed, and the physician is anonymous to the reviewer. On average about 10% of cases that are performed are reviewed.

The CardioAudit Report output includes an overview of the work that was done and a scored chart for all the physicians being reviewed; the scores are based on the ACC/AHA guidelines (please see Table 2). There are also an in-depth review for each physician and a clinical indications overview that includes the scoring for each case, an overall history of each case, and a short narrative from the reviewer.

**Table 2: ACC/AHA Classes of Recommendations**

<b>Class I</b>	Conditions for which there is evidence and/or general agreement that this procedure is useful and effective.
<b>Class II</b>	Conditions for which there is conflicting evidence and/or a divergence of opinion about the usefulness/efficacy of performing the procedure.
<b>Class IIa</b>	Weight of evidence/opinion is in favor of usefulness/ efficacy.
<b>Class IIb</b>	Usefulness/efficacy is less well-established by evidence/opinion.
<b>Class III</b>	Conditions for which there is evidence and/or general agreement that the procedure is not useful/effective and, in some cases, may be harmful.

## The CardioAudit Process: **Simple and Straightforward**

Implementing a CardioAudit review process is simple and straightforward, and allows for ongoing monitoring by board-certified cardiologists. For example, determining medical necessity for ICD implantation cases involves just 7 easy steps:

- ▶ The hospital sends a list of all cases from the last quarter to AllMed
- ▶ AllMed selects a random number of cases to meet the minimum requirements for statistical significance, based on biostatistical calculations
- ▶ The selected case list is returned to the Hospital
- ▶ The hospital compiles the list of cases that are called out and sends the copies of the angiograms to AllMed for review
- ▶ AllMed conducts the review and gives each case an ACC/AHA score
- ▶ The final report and case reviews are sent to the hospital
- ▶ Follow-up issues and action items are identified and discussed with board-certified cardiologists

## Conclusions

As healthcare reform becomes a national priority, insurance companies and the federal government will continue to demand that physicians and hospitals demonstrate that the invasive and expensive care they provide results in improved outcomes for patients.

AllMed's CardioAudit service, which was designed to help hospitals meet the challenges of Medicare and Medicaid audits and to prevent potential DOJ investigations, offers a proactive approach to ensure that cardiac procedures are medically indicated. Ongoing external peer review facilitates the regular assessment of high-risk procedures, which allows for risk avoidance through prevention. Rather than taking a more costly reactive approach and only reviewing sentinel events, CardioAudit focuses on promoting a proactive culture of investing in loss prevention. It is a simple and straightforward process that utilizes a proprietary system of unbiased external peer review to help administrators and medical executive committees at hospitals identify and correct any potential problems before they occur.

## Bibliography

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