*In 1994, the HHS Office of the Inspector General began an investigation of 132 hospitals suspected of billing for experimental medical devices and associated procedures not covered by Medicare. Medicare is now seeking to recover millions of dollars paid to these facilities. We solicited this article from the Health Care Financing Administration, which responded by describing the investigation and new regulations designed to redefine and clarify reimbursement policies for medical devices.—Editors*

# Encouraging Medical Device Innovation: Reimbursement Problems and New Policies

*CHESTER A. ROBINSON, DPA*
*THOMAS E. HOYER, MA MBA*
*THOMAS A. AULT, MS*

The established legal guidelines that govern the approval of medical products are designed to ensure safety and efficacy. The laws regarding the development and use of medical devices—prosthetics and implants—are no exception.

There is a widely accepted insurance principle prohibiting coverage for unapproved technologies. Under Medicare law, the Health Care Financing Administration (HCFA), which administers the Medicare program, can pay only for medical services that are considered "reasonable and necessary." Like most other insurers, Medicare has maintained a longstanding policy of regarding as experimental (and therefore not covered) all medical devices being studied in clinical trials. The reasoning behind this policy has always been that a device characterized as experimental by the Food and Drug Administration (FDA) cannot, by definition, be covered because its safety and efficacy are still under scrutiny and providing insurance coverage for these unapproved devices would present broad public health and safety concerns.

The FDA premarket approval requirements for medical devices did not distinguish between devices that were genuinely new and devices that were modifications of existing products. The FDA requires that revised devices—second- or third-generation pacemakers and defibrillators, for example—be studied in premarket clinical trials when they are redesigned, use new materials, are labeled for a new use, are produced by a new manufacturer, or are otherwise changed from previously approved versions. Despite the fact that the effectiveness of many such devices has been well documented and their use is based on a well-developed foundation of technical and clinical knowledge, enhanced devices require another round of premarket clinical trials.

The aim of clinical studies of many modified devices, therefore, is to demonstrate that a particular device is at least as effective and safe as the existing standard treatment, confirming and documenting a device's safety and effectiveness rather than establishing it. The important implication is that the risks are generally low for patients involved in clinical studies of such devices.

## Hospital Billing Scandal

Hospitals do have legitimate scientific and marketing motives for using investigational medical devices. Unfortunately, these motives can also provide them with the financial incentives for illegally billing for their use. Many hospitals are interested in being on the "cutting edge" of medical progress and so participate in studies of new and innovative medical device technologies. However, even if hospitals are willing to absorb the cost of the device itself—a small portion of the patient's total medical bill—hospitals are left in the position of absorbing the unreimbursed medical expenses associated with implanting or applying such devices. This financial pressure made it hard for some hospitals to resist, erroneously or intentionally, billing the Medicare program for these services.

In mid-1994, the HHS Office of the Inspector General (OIG) began an investigation of Medicare payments over the last decade for procedures in which an investigational (new or revised) device was used. The OIG commenced an investigation of this problem by issuing 132 subpoenas to teaching and research hospitals throughout the country. The OIG found that the number of improper billings on a per-hospital basis ranged from fewer than 10 to more than 400 procedures.[1]

One of the experimental devices consistently billed to Medicare was the Automatic Implantable Cardiac Defibrillator. Implantable defibrillators are designed to sense an arrhythmia and send an electrical shock to return the heart to a normal rhythm. These are expensive devices and medical procedures, averaging $40,000 to $60,000 per patient.

A key informant in the medical industry who assisted the OIG in its investigational has alleged that bills for experimental atherectomies using lasers are often submitted improperly. These experimental devices are intended to cut or remove plaque from

the arteries. Hospitals using these devices claimed they were performing angioplasty balloon procedures, an accepted therapy billable under Medicare. The informant provided first-hand knowledge of these improper billings practices. According to his testimony:

> Whenever the hospitals truthfully disclosed to Medicare that these devices were experimental, their claim for payment was denied. As a result, some hospitals and "clinical investigators" came up with the idea of re-invading the patient with an angioplasty balloon after the experimental procedure. They would run the balloon up into the patient's artery, expand it and take an x-ray for the patient file in the event of a Medicare audit. A bill would then be submitted to Medicare, hiding the experimental device procedure and instead claiming reimbursement for an FDA-approved angioplasty. Physician training sessions sponsored by the medical industry promoted this falsification as the "reimbursement balloon."[2]

The OIG's report to the Senate Committee on Governmental Affairs indicated that virtually all of the subpoenaed hospitals had billed Medicare for investigational devices. Some hospitals, in explaining their actions to the Committee, stated that HCFA's policy was unclear, and others claimed that they did not know about it. Yet, according to Senator William V. Roth, about half of the hospitals under investigation had already provided evidence to the OIG that they knew such billing was improper. A smaller number provided evidence that there was an attempt to cover up their actions.[3] In at least one hospital, patient consent forms were removed from files in order to conceal the investigative nature of certain implant surgeries. Certain hospitals continued to bill Medicare for these investigational procedures even after receiving subpoenas from the OIG.[3]

Officials at HCFA, however, maintain that the policy was spelled out in Medicare program manuals, including the Hospital Provider Manual. The hospital manual explains and interprets the Medicare statute and billing rules, and hospitals know that these rules are binding. The Medicare Hospital Provider Manual stated clearly that:

> Medical devices which have not been approved for marketing by the Food and Drug Administration are considered investigational by Medicare.... Program payment, therefore, may not be made for medical procedures or services performed using devices which have not been approved for marketing by the FDA.

FDA premarket approval requirements for medical devices did not distinguish between devices that were genuinely new and devices that were modifications of existing products.

Medicare officials, testifying before the Senate committee, emphasized that if hospitals felt that the policy was unclear, they should have made attempts to discuss it with HCFA. If the policy was clear but providers disagreed with it, the proper course of action would be the same—to contact HCFA. Finally, in almost every instance in which hospitals billed for an investigational device, they could instead have furnished an approved device, legally billed Medicare for it, and received payment.

Efforts have been initiated to recover significant Medicare overpayments. HCFA is currently working with the OIG to determine the extent to which any overpayments may have been made to hospitals. If Medicare paid claims that were billed inappropriately—in this case for medical devices that had not been approved by the FDA—those payments constitute overpayments that are subject to recovery by HCFA. The agency is already at work identifying overpayments and expects to seek recoveries in accordance with the Federal Claims Collection Act and the Medicare Act. Potential criminal violations related to the submission of fraudulent claims have been referred to the Department of Justice for investigation.

### Reevaluation of Medicare's Coverage

Beginning in the spring of 1994 (about the same time as the OIG started its investigations), and in part due to the impetus of Vice President Gore's National Performance Review, HCFA and the FDA reevaluated their respective coverage and classification policies for investigational medical devices.

The review showed that not all of the devices undergoing clinical trials—devices that had received an Investigational Device Exemption—were truly experimental. An opportunity existed to make a distinction between devices that are genuinely new and experimental and those devices that are generational improvements of existing products. The two agencies considered how Medicare beneficiaries could be given greater access to those devices that represented advances in proven

medical technology while continuing to be protected from the potential hazards of unproven devices.

The FDA agreed with the need to further refinement its classification system and worked with HCFA to develop two new categories:

Category A consists of novel, first-of-a-kind technologies. These are innovative devices for which risk has not been established and initial questions of safety and effectiveness have not been resolved. Category A devices, which are still considered experimental, would not be covered by Medicare.

Category B devices are newer generations of proven technologies for which initial questions of safety and effectiveness have been resolved. Devices placed in this category would be eligible for Medicare coverage if they met Medicare's other coverage requirements. For example, an experimental automatic defibrillator could be considered for coverage under this policy since the Medicare program already covers such devices. However, a hearing aid could not be covered since the Medicare law excludes coverage of hearing aids.

## New Policy for Medicare

In a widely applauded policy shift, beginning November 1, 1995, Medicare began to pay for certain Category B medical devices undergoing clinical trials. Approximately 94% of the 1200 devices currently being studied in FDA-approved clinical trials have been assigned to Category B. If these devices meet Medicare's other coverage requirements, they can qualify for Medicare payment while they are being studied in clinical trials. Any device manufacturer who disagrees with the categorization of a device can request a reevaluation by the FDA and HCFA.

Medicare coverage of devices will be limited to patients in FDA-approved studies, in which each device is available at a certain number of sites, for a specified number of patients, and is subject to a specified protocol. In any such study, informed patient consent is essential, and the patient consent form will include all of the information needed for well-informed patient participation.

Each FDA-approved investigational device will be assigned an identification code to enable Medicare's fiscal intermediaries and carriers to establish special claims processing procedures associated with the study. Reimbursement for a device will be limited to what Medicare would have paid for a comparable approved device.

Financial pressures made it hard for some hospitals to resist, erroneously or intentionally, billing the Medicare program for these services.

The vast majority of Medicare coverage and payment decisions are made as part of claims processing by Medicare fiscal intermediaries and carriers. These are private insurance companies that contract with HCFA to process and pay Medicare claims. Intermediaries process hospital claims and carriers process claims from physicians, clinical laboratories, and medical suppliers.

The benefits of this new policy are substantial. It extends coverage to Medicare beneficiaries participating in FDA-approved clinical trials, enabling them to have access to the latest medical technology. At the same time, it facilitates the collection of information about these devices to determine whether they can be approved for unrestricted marketing. Because Medicare is a major payor for health services—total spending for 1995 was approximately $176 billion, and nearly 40 million people are eligible—this change in policy has the potential to significantly affect the development and more rapid adoption of new medical device technologies, as well as likely encourage similar changes in the private insurance sector.

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All authors are with the Bureau of Policy Development, Health Care Financing Administration, Department of Health and Human Services, Baltimore, MD. Dr. Robinson is the Director of the Division of Durable Medical Equipment and Devices, Mr. Hoyer is the Director of the Office of Chronic Care and Insurance Policy, and Mr. Ault is the Director of the Bureau.

*Address correspondence to Dr. Robinson, Health Care Financing Administration, Room C4-03-25, 7500 Security Blvd., Baltimore, MD 21244-1850; tel. 410-786-0291; fax 410-786-0169; e-mail <crobinson3@hcfa.gov>.*

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