126897

United States General Accounting Office

Washington, D.C.

FOR RELEASE ON DELIVERY
Expected at 9:30 AM. EDT
Friday, May 10, 1985

STATEMENT OF

MICHAEL ZIMMERMAN, ASSOCIATE DIRECTOR

HUMAN RESOURCES DIVISION

BEFORE THE

SPECIAL COMMITTEE ON AGING

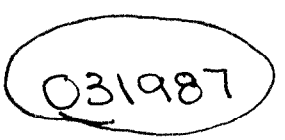
UNITED STATES SENATE

ON

MEDICARE PAYMENT RATES FOR PACEMAKER SURGERIES

Mr. Chairman and members of the Committee:

We are pleased to be here today to discuss the report we prepared for the Committee entitled Medicare's Policies and Prospective Payment Rates for Cardiac Pacemaker Surgeries Need Review and Revision (GAO/HRD-85-39, Feb. 26, 1985). In preparing the report we reviewed four major manufacturers who account for about 80 percent of domestic pacemaker sales. We also gathered data on all pacemaker surgeries performed at 12 selected hospitals and compared these data to the data used by the Department of Health and Human Services' (HHS') Health Care Financing Administration to establish Medicare's hospital prospective payment rates for pacemaker surgery.



Our review showed that the data used to compute the cardiac surgery payment rates (1) contained errors that could affect the rates' reasonableness; (2) were collected at a time when hospitals had little incentive to take full advantage of purchasing efficiencies or warranty benefits offered by pacemaker manufacturers; and (3) do not reflect the more recent shift toward the use of higher cost, more technologically advanced pacemakers.

Because of the inaccuracies in the data base, stronger hospital incentives for economical procurement of pacemakers to reduce hospital costs, and the shift to more expensive pacemakers, we believe HHS should use current data to reevaluate the reasonableness of prospective payment rates for pacemaker surgeries.

In fiscal year 1984 Medicare paid about $42 billion to the approximately 6,000 hospitals that participate in the program. We estimate that expenditures for inpatient hospital services for pacemaker surgeries under Medicare in fiscal year 1984 amounted to about $775 million, of which about $400 million represented hospital payments to manufacturers for pacemakers.

You asked that my statement concentrate on issues dealing with (1) hospital purchasing practices for pacemakers, (2) pacemaker warranties, (3) removal of working pacemakers, and (4) problems with the data used to set Medicare's prospective payment rates for pacemaker surgeries. I will address each of these issues. I have included as an enclosure to my statement a

copy of the digest of our February report which summarizes all of the issues contained in the report.

HOW HAVE INCENTIVES FOR ECONOMICAL PURCHASING BY HOSPITALS CHANGED UNDER MEDICARE'S PROSPECTIVE PAYMENT SYSTEM?

Under Medicare's former cost reimbursement system, hospitals had little incentive to seek the lowest possible prices for pacemakers because Medicare paid them their actual cost of purchasing pacemakers. However, with the introduction of Medicare's prospective payment system (PPS), hospitals now have a much stronger incentive to obtain pacemakers at as low a price as possible. This results because, under PPS, hospitals receive a flat, predetermined payment[1] for each pacemaker surgery and profit or lose depending on whether their costs are below the prospective payment rate. Therefore, hospitals should seek to hold down their costs by obtaining pacemakers as cheaply as possible. This is especially true for pacemaker surgery patients because the pacemaker itself is often the largest single cost item for such patients.

We found that before PPS, hospitals often were not using economical purchasing practices for pacemakers. Although manufacturers offered discounts ranging from 5 to 60 percent

---

[1]When fully implemented all hospitals will receive the same amount, adjusted to account for differences in wage levels among areas around the country, for urban or rural location, and for whether a hospital is a teaching facility. Currently, rates also differ by census region.

depending on the quantity and type of pacemaker purchased, only 3 of the 12 hospitals had obtained discounts during their cost reporting periods ended in fiscal year 1981, the period HHS used to compute the prospective payment rates. Seven of the other nine hospitals could have obtained, but did not obtain, discounts based on the discount availability data we obtained.

Information we obtained from the manufacturers also showed that relatively few hospitals obtained discounts. Sales where discounts were granted represented 0.5 percent of total domestic sales for one manufacturer and 0.7 percent for another, and 1.2 percent of total revenues for a third manufacturer.

Our report also discusses two ways hospitals can enhance their ability to obtain lower pacemaker prices. First, hospitals can coordinate pacemaker purchasing by getting physicians practicing at a hospital to agree to use specified types of pacemakers. This results in more units of the specified pacemakers being used and, thus, can lead to larger discounts. Only 1 of the 12 hospitals we reviewed coordinated pacemaker use.

Second, hospitals can consolidate purchasing by combining their pacemaker needs with those of other hospitals associated with them through common ownership or control or through a group purchasing arrangement. Again, consolidation increases the quantity purchased and thereby enhances the ability to obtain discounts. Only one of the six hospitals reviewed that belonged to chains obtained pacemakers through consolidated purchasing.

Also, only one hospital obtained discounts for some pacemakers by using a group purchasing organization.

Because hospitals normally were not seeking discounts, the data HHS used to compute prospective payment rates for pacemaker surgeries reflected higher than necessary costs. Introduction of PPS gave hospitals incentives to be more prudent purchasers--and they have opportunities to do so. This should result in a reduction in hospitals' cost of purchasing pacemakers compared to those reflected in the prospective payment rates. We recommended that HHS use data that reflect the improved efficiency that should result from PPS' incentives toward more prudent purchasing when it updates prospective payment rates for pacemaker surgeries.

Did Hospitals Maximize the Use of Warranties for Failed Pacemakers?

Medicare's former cost reimbursement system also gave hospitals little incentive to seek warranty credits for failed pacemakers because they were paid their costs whether or not a credit was received. In fact, obtaining a credit only resulted in a lower Medicare payment to the hospital. However, under PPS, hospitals have a strong incentive to seek warranty credits as a way of keeping costs below the flat prospective payment that is not reduced when credits are obtained.

We found that, in 53 percent of the cases reviewed, hospitals did not return explanted (surgically removed) pacemakers to

the manufacturers for testing, which was a universal condition for obtaining a warranty credit. Thus, in such cases obtaining a warranty credit was precluded.

We identified several reasons why explanted pacemakers might not be returned to the manufacturer. First, explanted pacemakers must be replaced by a model made by the same manufacturer in order to obtain a warranty credit. We found that 36 percent of the explanted pacemakers not returned to the manufacturer by the 12 hospitals were replaced by a model from a different manufacturer. Second, none of the 12 hospitals had established procedures to assure that pacemakers were returned. Third, manufacturers reduced sales representatives' or distributors' sales commissions when a warranty credit was issued, thus discouraging the salesperson from providing for the return of explanted pacemakers. Fourth, manufacturers had marketing programs that encouraged replacement of competitors' pacemakers with their own, thus precluding a warranty credit.

We believe that the lack of incentives under the cost reimbursement system to seek warranty credits combined with manufacturers' marketing policies that discouraged seeking warranty credits contributed to hospitals not taking full advantage of the benefits available under warranties. Also, two major manufacturers that did not offer warranties in 1981, the base period used to set prospective payment rates, now do. Therefore, hospitals should now be seeking and obtaining more warranty

credits, and we believe unnecessary costs are included in the data HHS used to compute prospective payment rates for pacemaker replacement surgeries.

The Deficit Reduction Act of 1984 gave HHS discretionary authority to require hospitals to return all explanted pacemakers to the manufacturers and to require the manufacturer to test all returned pacemakers and report the results. We recommended that HHS use these authorities to obtain the information necessary to assure that Medicare benefits from warranty credits when they are issued. An additional benefit from implementing our recommendation is that all explanted pacemakers would be tested, which in turn would continue to improve quality of care by better assuring that problems that cause pacemaker failure are identified and corrected.

WHAT ARE THE TYPES AND CONDITIONS OF WARRANTIES?

Manufacturers have offered two basic types of warranties. First, some manufacturers have offered a product or hardware warranty. Such a warranty provides a credit for pacemakers that fail to operate within specifications during the warranty period, usually in the amount of the original cost of the replaced unit or the cost of a functionally comparable unit. Typically, these warranties require that the pacemaker be replaced by one made by the same manufacturer and require that the explanted unit be returned to the manufacturer to verify that it has malfunctioned.

Second, some manufacturers have offered a coinsurance warranty. Such a warranty covers the unreimbursed medical expenses of the patient; that is, those expenses not covered by Medicare or other insurance. Some companies have offered both hardware and coinsurance warranties.

We compared the hardware warranty provisions provided in the United States and overseas. In most cases the warranties were comparable except that two manufacturers offered warranties overseas, but offered no warranties in the United States until 1984.

A significant difference in one manufacturer's overseas warranty provisions was that the manufacturer offered a "money-back" guarantee instead of the "replacement-in-kind" policy offered by manufacturers in the United States. Our understanding is that physician communities or paying authorities thought it unethical to require anyone to use a pacemaker manufactured by the same company whose pacemaker had failed. At the time of our visit in late 1983, a number of European countries were promulgating regulations requiring companies to provide money-back warranties. France already required that all pacemakers be warranted for 4 years and that money-back guarantees be provided.

WHAT WAS THE TESTING EXPERIENCE OF MANUFACTURERS FOR EXPLANTED PACEMAKERS AND WHAT DOES THIS IMPLY FOR MEDICARE?

We found that, because a large proportion of pacemaker replacements involve pacemakers that are later found to function within the manufacturers' specifications, Medicare may be making unnecessary expenditures. Three manufacturers provided us data on over 10,000 returned pacemakers which showed that about 70 percent of them were operating within specifications. Although changes in patients' medical condition can necessitate replacing a properly operating pacemaker, industry sources point out a number of other factors that may account for the high ratio of replaced pacemakers that are found to be within specifications. These factors, which are detailed in our report, include such things as marketing policies that provided for incentive payments for pacemaker replacement and inconsistencies between the standards used by physicians evaluating a pacemaker and the standard used by the manufacturer in factory testing.

We recommended that HHS review the situations resulting in the replacement of properly functioning pacemakers and act to minimize unnecessary replacements. The information that would be obtained by implementing our recommendation, mentioned before, to use the authorities provided by the Deficit Reduction Act of 1984, would help provide the data necessary for such a review.

HOW ACCURATE WERE THE DATA HHS USED TO COMPUTE PROSPECTIVE PAYMENT RATES FOR PACEMAKER SURGERIES?

We reviewed the 1,063 pacemaker surgeries performed at the 12 hospitals during their cost reporting years ended in 1981. Of these, 94 cases were included in the MEDPAR data file[2] HHS used to compute the prospective payment rates. Our comparison of the MEDPAR and cost data HHS used to the data we obtained showed many problems with the HHS data.

First, HHS used unaudited cost reports. We compared the unaudited and audited cost reports for 8 of the 12 hospitals, and the audited reports showed significantly lower costs. For ancillary service costs such as medical supplies and laboratory services, which represent most costs for pacemaker surgeries, the audited costs for these hospitals averaged about 5 percent lower than the unaudited costs. Thus, the use of unaudited cost reports tended to overstate the prospective payment rates.

In addition, about 10 percent of the MEDPAR pacemaker cases were classified in the wrong diagnosis related group (DRG).[3] Eight replacement cases were classified as initial implants, and one initial implant was classified as a replacement. Because

---

[2]The Medicare Provider Analysis and Review (MEDPAR) file is a 20-percent sample of Medicare hospital discharges which includes information on patients' diagnoses and the hospital charges for services provided.

[3]Each DRG contains diagnoses that are expected to be closely related in the extent of resources devoted to treating patients, and separate payments are calculated for each DRG.

initial implants are more costly than replacements, including replacements with initial implants would tend to understate the costs of initial implants, while including initial implants with replacements would tend to overstate the cost of replacements.

Another 37 pacemaker cases, or about 40 percent, were erroneously classified under DRGs other than pacemaker DRGs. Of the 37 cases, 31 were classified erroneously in lower valued DRGs, which would tend to overstate the costs for these DRGs.

Furthermore, the process used to develop costs for computing the prospective payment rates resulted in inaccuracies because of hospital billing errors and placement of charges and costs in the wrong accounts. These problems could result in either overstatement or understatement of costs depending on the specific facts in each case.

Although we could not assess the precise impact on DRG payment rates of the problems we identified, it is clear that better data are needed to update DRG payment rates. These errors affected not only the pacemaker DRGs but others as well.

This concludes my prepared statement. We will be happy to address any questions you may have.

COMPTROLLER GENERAL'S REPORT TO THE SPECIAL COMMITTEE ON AGING UNITED STATES SENATE

MEDICARE'S POLICIES AND PROSPECTIVE PAYMENT RATES FOR CARDIAC PACEMAKER SURGERIES NEED REVIEW AND REVISION

D I G E S T

Pacemaker industry sources estimate that over 100,000 pacemaker surgeries were done in 1984 and that about 85 percent of the patients receiving pacemakers were eligible for Medicare. GAO estimates that in 1984 Medicare paid about $775 million to hospitals for pacemaker surgeries, of which about $400 million represented hospital payments for pacemakers.

As a follow-up to a September 1982 hearing, the Chairman, Senate Special Committee on Aging, asked GAO to review a number of issues related to the effect on Medicare costs of certain pacemaker industry practices. In response, GAO reviewed the effect on Medicare costs of

--pacemaker manufacturers' warranty policies,

--manufacturers' marketing policies, and

--hospitals' procedures for acquiring pacemakers and charging for them.

When the Congress enacted a prospective payment system for Medicare hospital services in April 1983, GAO's work was expanded to include an analysis of the impact of manufacturers' and hospitals' policies on the reasonableness of Medicare's new payment rates for pacemaker surgeries.

The prospective payment system classifies cases into diagnosis related groups (DRGs), each of which covers a set of diagnoses expected to require similar levels of hospital resources for treatment. Each case falling under a DRG receives the same predetermined payment rate. There are four pacemaker DRGs. All DRG payment rates were calculated from 1981 cost report data provided to the government by over 5,000 hospitals and from

Tear Sheet

data on a 20-percent sample of 1981 Medicare discharges. The Department of Health and Human Services (HHS) is required to update the prospective payment rates annually and reevaluate the DRGs at least every 4 years. (See p. 3.)

GAO obtained information about warranties and marketing and pricing policies from the four pacemaker manufacturers that account for about 80 percent of sales in the United States. GAO also obtained data on 1,063 pacemaker surgeries performed at 12 hospitals during their cost reporting years ended in fiscal year 1981, the period represented by the data used by HHS' Health Care Financing Administration to compute Medicare's prospective payment rates. The hospitals were judgmentally selected to provide a mix of the types of hospitals doing pacemaker surgeries and to obtain data on the four manufacturers.

PROSPECTIVE PAYMENT SYSTEM INCENTIVES SHOULD LEAD TO MORE EFFICIENT PURCHASING AND BETTER USE OF WARRANTIES

To determine whether hospitals were efficiently purchasing pacemakers in 1981, GAO evaluated the purchasing practices of the 12 reviewed hospitals and obtained data related to this area from the four manufacturers. Although the manufacturers made discounts available to hospitals, generally ranging from 5 to 40 percent depending on the quantity and type of pacemaker purchased, only three of the hospitals had obtained discounts. Based on the discount availability data GAO obtained, at least seven other hospitals could have obtained discounts. (See p. 25.)

GAO believes they did not because:

--The manufacturers did not advertise the discounts but rather waited for hospitals to seek them.

--Medicare's cost reimbursement system in effect in 1981 provided hospitals little incentive to seek discounts because they were paid their actual purchasing cost for pacemakers.

A hospital can enhance its ability to obtain discounts by (1) agreeing with its practicing physicians on the make of pacemaker that will normally be used and coordinating pacemaker purchases or (2) consolidating pacemaker purchases with other affiliated hospitals or with a group-purchasing organization. Of the 12 hospitals in GAO's sample, 1 was coordinating its pacemaker purchases and 2 were consolidating them. (See p. 28.)

To determine if hospitals were effectively using the benefits available under pacemaker warranties offered by two manufacturers on models replaced after they failed, GAO reviewed replacement surgeries at the 12 hospitals and obtained data from the manufacturers. Replacements accounted for about 19 percent of the 1,063 pacemaker surgeries at the 12 hospitals.

In many cases, GAO could not determine whether a warranty credit could have been received because the necessary data did not exist. However, GAO did identify cases where available information indicated that credits could have been available but the hospital had not returned the removed pacemaker to the manufacturer, which is a condition of the warranty. (See p. 14.)

GAO believes that a primary reason hospitals frequently did not seek warranty credits was that Medicare's cost reimbursement system did not give the hospital an incentive to obtain credits. Obtaining a credit only reduced Medicare's payment to the hospital, and Medicare paid for the replacement pacemaker if a credit was obtained.

Introduction in fiscal year 1984 of Medicare's prospective payment system, with its predetermined payment for each pacemaker case regardless of costs, has given hospitals financial incentives to be more cost-conscious purchasers of pacemakers and to

seek warranty credits, thereby reducing their costs. Additionally, the two reviewed manufacturers that did not offer warranties in 1981 began doing so in 1984, so the availability of warranties has increased.

DATA HHS USED TO COMPUTE PROSPECTIVE PAYMENT RATES CONTAINED ERRORS

GAO compared the data it obtained at the 12 reviewed hospitals to the data HHS used to compute the prospective payment rates for pacemaker surgeries. GAO identified a number of problems, some of which indicate that the prospective payment rates may be too high and others which indicate that the rates may be too low. Specifically:

--The data HHS used were extracted from the unaudited cost reports for the 12 hospitals, as were the data for almost all of the hospitals involved in the rate computations. The eight cost reports that had been audited as of June 1984 showed lower costs than the unaudited reports. Ancillary service costs, which account for the majority of costs for pacemaker cases, averaged 5 percent lower in the audited cost reports than in the reports submitted by the hospitals. (See p. 33.)

--About 10 percent of the cases were classified in the wrong pacemaker DRG, usually a lower cost replacement being classified as an initial implant. These errors would tend to result in lower prospective rates for initial implants. (See p. 34.)

--About 40 percent of the pacemaker surgery cases were classified into nonpacemaker DRGs. Such errors tended to inflate the payment rates for the nonpacemaker DRGs because the DRGs to which the pacemaker cases were assigned covered less costly treatment. Including the pacemaker cases in the lower cost DRGs increased the average cost for those DRGs and thus increased payment rates. (See p. 35.)

--The process used to develop costs for computing the prospective payment rates resulted in inaccuracies because of hospital billing errors and placement of charges and costs in the wrong accounts. These problems could result in either overstatement or understatement of costs, depending on the specific facts in each case. (See p. 36.)

Additionally, one pacemaker DRG combined procedures involving significantly different levels of resource use, which is not supposed to be the case. DRG 117 includes procedures for replacing, removing, adjusting, or repositioning pacemakers or pacemaker leads (the wires connecting the pacemaker to the heart). Payment rates for each procedure under the DRG are the same even though, for example, replacing a lead costs substantially more than repositioning one.

PACEMAKER TECHNOLOGY AND MEDICAL PRACTICE IMPACT ON ADEQUACY OF PAYMENTS

GAO identified two issues relating to pacemaker technology and medical practice that HHS needs to address when it updates prospective payment rates. First, in 1981 only about 5 percent of the pacemakers implanted were the more sophisticated and costly dual chamber models. However, in 1984 an estimated 24 percent of pacemaker implants involved dual chamber models. (See p. 43.) Because dual chamber pacemakers and their implantation cost substantially more than single chamber models, there may be a need to establish separate DRGs for them to prevent an economic disincentive to the use of dual chamber pacemakers when such use is medically warranted.

HHS should also establish guidance on the medical conditions for which the use of the dual chamber models is appropriate to preclude the unnecessary use of this more expensive technology. HHS' current guidance on pacemaker use does not distinguish among the conditions for which single chamber versus dual chamber models are appropriate. (See p. 45.)

Another potential problem is that pacemakers are being replaced when still operating within specifications. Three manufacturers provided GAO data on the results of tests of over 10,000 returned pacemakers which showed that about 70 percent of them were operating within the manufacturers' specifications. (See p. 49.)

Physicians may replace pacemakers that are still functioning within specifications for various medical reasons, such as changes in a patient's condition. Manufacturers also cited the following nonmedical reasons: (1) marketing policies that provide for incentive payments from manufacturers to hospitals and doctors for pacemaker replacement and (2) inconsistencies between the standards used by physicians evaluating a pacemaker and the standards used by the manufacturer in factory testing pacemakers.

REMOVED PACEMAKERS SHOULD BE RETURNED TO MANUFACTURERS

Manufacturers test removed pacemakers when they are returned to determine if any problems, such as manufacturing defects or faulty parts, could adversely affect quality of patient care. GAO found that about 53 percent of the pacemakers removed at the sample hospitals were not returned to the manufacturers, precluding quality assurance testing. All four manufacturers estimated that a substantial portion of such pacemakers are not returned to them. This can inhibit the manufacturers' quality assurance programs. (See p. 22.)

Section 2304 of the Deficit Reduction Act of 1984 (Public Law 98-369) requires HHS to establish a registry of all pacemakers and leads implanted in Medicare beneficiaries and requires hospitals to report to HHS the information needed for the registry as a condition of receiving Medicare payment. The law also permits HHS to require hospitals to return all removed pacemakers to the manufacturers and to require the manufacturers to test all returned pacemakers and report the results.

HHS should use these authorities to require that all removed pacemakers be returned for testing. This would help strengthen controls over quality of care and give HHS the information necessary to know when warranty credits are issued. This information could in turn be used to assure that Medicare benefits from warranty credits. As of February 1985 HHS had not issued regulations implementing section 2304. (See pp. 20 and 24.)

RECOMMENDATIONS

GAO recommends that the Secretary of HHS:

--Require hospitals to return all removed pacemakers and leads to the manufacturers and require the manufacturers to test all returned pacemakers and leads and report the results to the hospitals. (See p. 21.)

--Direct the Administrator of the Health Care Financing Administration to revise Medicare's prospective payment rates using data reflecting current hospital pacemaker implantation costs. (See p. 31.)

--Direct the Administrator to determine (1) if the increased use of dual chamber pacemakers warrants establishment of separate DRGs for them, (2) the conditions under which the use of higher cost dual chamber pacemakers is medically appropriate, and (3) if the high percentage of functioning pacemakers that are replaced is resulting in unnecessary Medicare costs. (See p. 58.)

--Direct the Administrator to review the appropriateness of inclusion under the same prospective payment rate of both higher and lower cost pacemaker procedures. (See p. 40.)

- - - -

GAO did not obtain official comments on this report from HHS, the manufacturers, or the hospitals reviewed.