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BY THE COMPTROLLER GENERAL
**Report To The Chairman
 Special Committee On Aging
 United States Senate**
 OF THE UNITED STATES

**Medicare's Policies And Prospective
 Payment Rates For Cardiac Pacemaker
 Surgeries Need Review And Revision**

In fiscal year 1983, the Department of Health and Human Services (HHS) implemented a Medicare prospective payment system (using data based on medical practices and costs in 1981) that pays hospitals predetermined fixed rates based on a patient's medical condition. GAO reviewed the 1981 data and how changes in medical practices and costs since that time may have affected prospective payment rates for cardiac pacemaker surgeries.

The information GAO obtained from 12 hospitals and 4 major pacemaker manufacturers showed that the data used to compute the 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; 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 bases, stronger hospital incentives for economical procurement of pacemakers to reduce hospital costs, and the shift to more expensive pacemakers, GAO believes HHS should use current data to reevaluate the reasonableness of prospective payment rates for pacemaker surgeries.

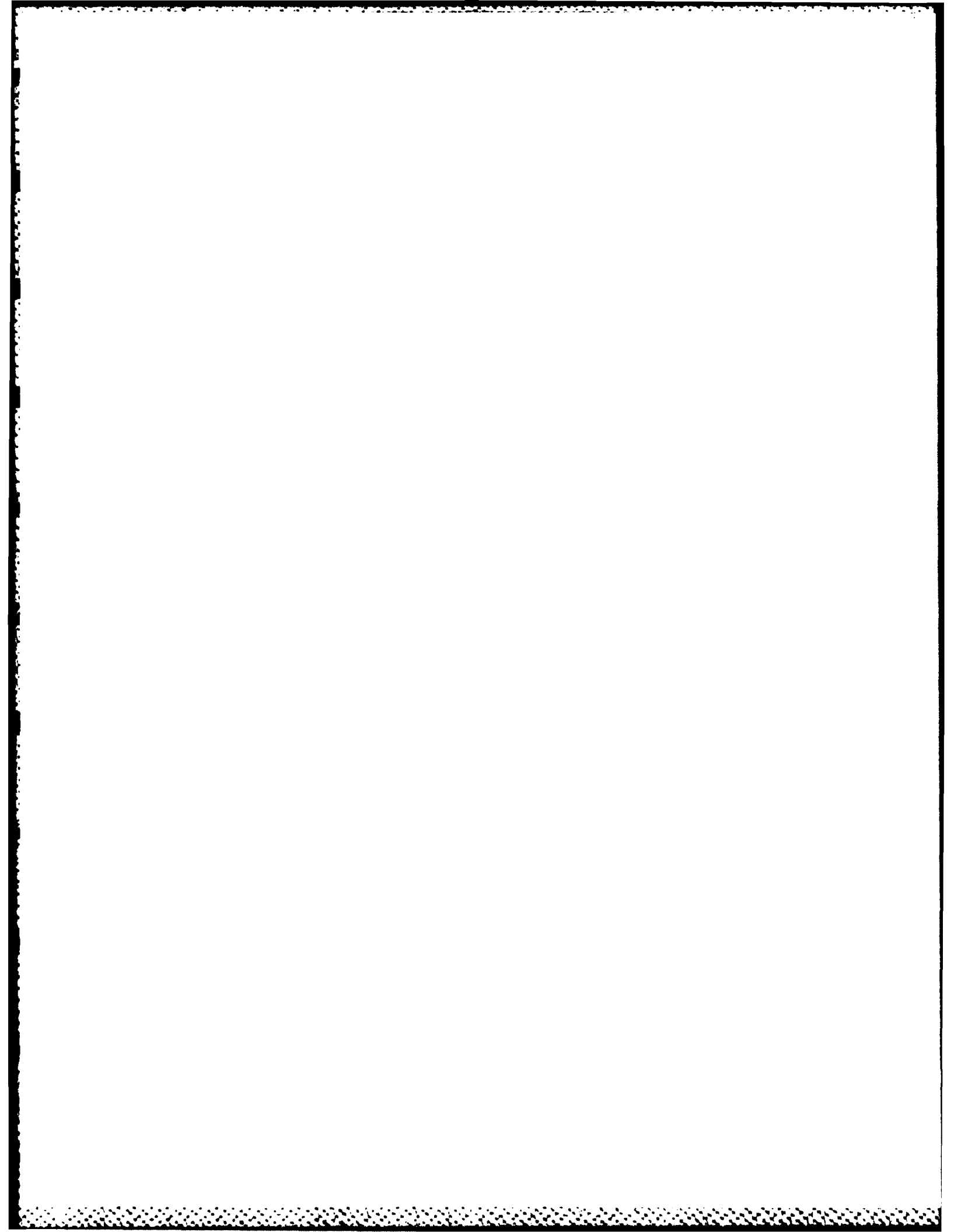
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 FEBRUARY 26, 1985

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COMPTROLLER GENERAL OF THE UNITED STATES
WASHINGTON D.C. 20548

B-214207

The Honorable John Heinz
Chairman, Special Committee on Aging
United States Senate

Dear Mr. Chairman:

This report discusses Medicare's hospital prospective payment rates for cardiac pacemaker surgeries and the changes that have occurred in the pacemaker field since the data used to compute these rates were accumulated that could affect the rates' reasonableness. We undertook this review in response to your request.

As arranged with your office, we plan no further distribution of the report until 30 days from its issue date unless you publicly announce its contents earlier. At that time, copies will be sent to the Secretary of Health and Human Services and other interested parties, and copies will be made available on request to others.

Sincerely yours,

Comptroller General
of the United States



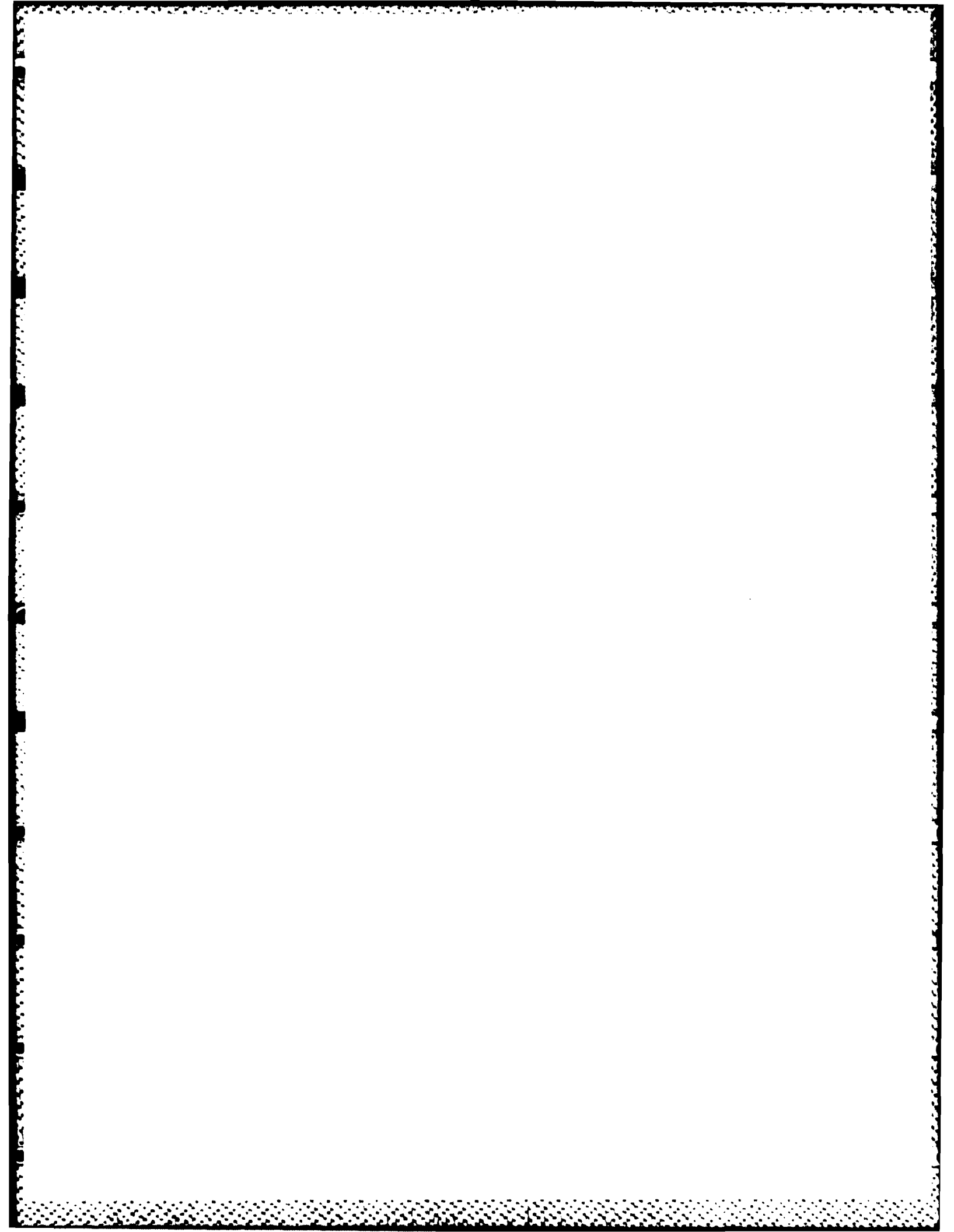
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D I G E S T

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

--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

--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.)

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.)

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

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CHAPTER 1

INTRODUCTION

In September 1982, the Senate Special Committee on Aging held a hearing related to the cardiac pacemaker industry and Medicare's costs for pacemaker implantations. The Committee's Chairman requested us to review certain issues raised at the hearing. In October 1982 we discussed the request with the Committee and agreed to look into the effect on Medicare costs of

- pacemaker manufacturers' warranty policies,
- manufacturers' marketing policies, and
- hospitals' procedures for acquiring pacemakers and charging them to Medicare.

In April 1983, the Congress enacted a prospective payment system to be phased in beginning on October 1, 1983, for hospitals participating in Medicare. This system changed the payment method for inpatient hospital services, including pacemaker-related stays. Our work was expanded to include an analysis of the effect of hospital practices related to acquiring, implanting, and replacing pacemakers on the adequacy and reasonableness of the pacemaker payment rates computed under the new prospective payment system.

PACEMAKERS

Pacemakers are small devices implanted under the skin on the patient's chest and connected to the heart by insulated wires, called leads, inserted through the blood vessels. The pacemaker electrically stimulates the heart, causing it to beat. Typically, pacemakers, which weigh less than 2 ounces, are implanted in patients to combat heart rhythm and conduction disorders, which are especially common among older people. In typical conditions, the heart may slow to a point where it does not pump enough blood. To treat this condition, the pacemaker regulates the heart by stimulating it with electric impulses. Manufacturers indicate that over 500,000 Americans currently use pacemakers and that in 1983 the average pacemaker was priced at about \$4,200. Medicare's maximum allowable physician payments for implanting a pacemaker ranged in 1984 from \$660 to \$2,063, depending on the area of the country where the surgery was performed.

The pulse generators used in the first implantable pacemakers 26 years ago were permanently preset at the time of manufacture and offered limited pacing mode selections.

The coordinated approach used by this hospital closely resembles the process used in France to procure pacemakers. In France, manufacturers are required to present their products and suggested prices to the government. The government in turn sets the price it will allow for pacemakers and publishes a list from which hospitals must select their pacemakers.

At the other 11 hospitals visited, the decision on the brands and types of pacemaker to be used is made solely by the physician. The 11 hospitals act only as the purchasing agent. By failing to coordinate their pacemaker purchases, the hospitals forego the opportunity to negotiate the most favorable discount prices for pacemakers and insure the compatibility of equipment for pacemaker monitoring without buying multiple types of this equipment.

Hospitals can reduce costs
by consolidated pacemaker purchasing

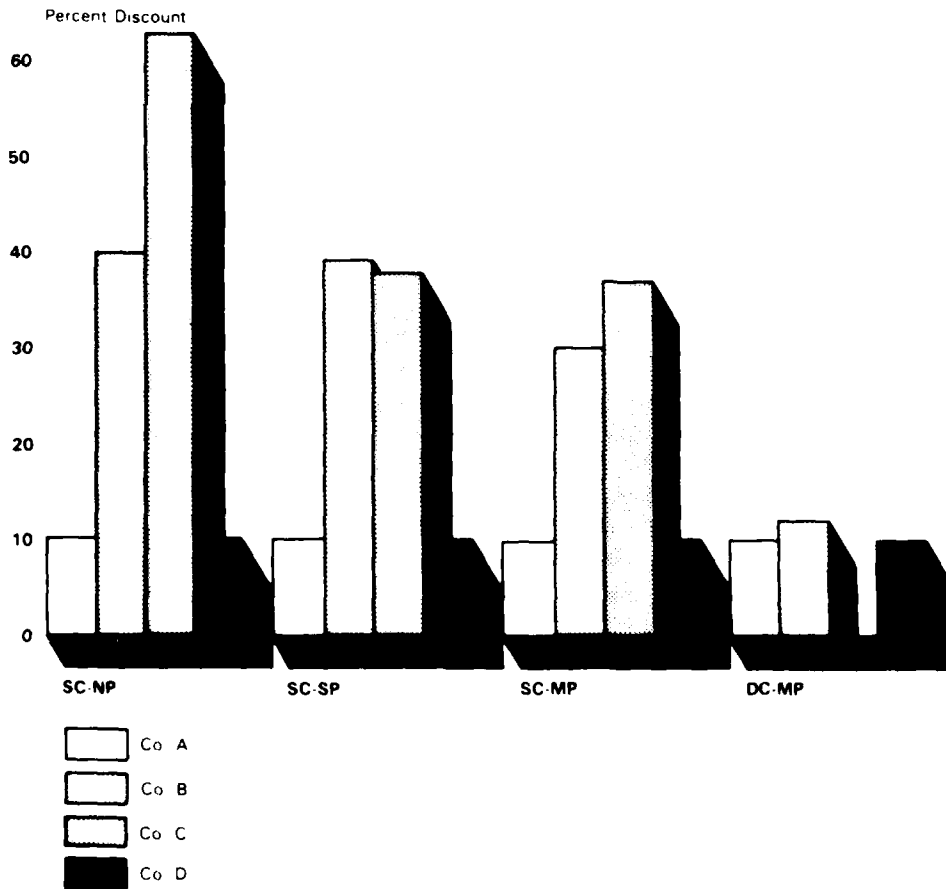
Purchase discounts generally vary in relation to the quantity of pacemakers ordered. Thus, a hospital chain operation or group-purchasing organization that combines the needs for several hospitals can obtain substantially larger discounts than could be obtained if the individual hospitals did their own purchasing.

A California hospital in our sample has benefited from its parent company obtaining discounts for the combined pacemaker purchases of its 16 hospitals. By consolidating its pacemaker purchases in this manner, the parent company was able to enter into two agreements that provided for discounts. One agreement had discounts ranging from 2 to 15 percent of catalog price for pacemaker purchases in a recent year. The discount percentage varied based on the manufacturer's share of the chain's combined pacemaker purchases. As the manufacturer's share increased, the quantity purchased from it would also increase.

However, five other hospitals in our sample that were owned by chains had not consolidated pacemaker purchases. Also, many hospitals belong to group-purchasing organizations and, thereby, are able to combine purchasing power and gain the advantage of volume discounts. However, only one of the hospitals acquired some pacemakers through a group-purchasing organization.

The following examples demonstrate how some hospitals in our review could have availed themselves of lower pacemaker prices through consolidated purchasing with other hospitals owned by the same chain.

**Quantity Discounts Available
by Manufacturer, 1981 (Note a)**



SC-NP = Single Chamber - Nonprogrammable
 SC-SP = Single Chamber - Simple programmable
 SC-MP = Single Chamber - Multiprogrammable
 DC-MP = Dual Chamber - Multiprogrammable

Note a: Discounts for companies A and D varied based on the quantity purchased. The discounts shown in the graph are for quantities between 161 and 290 for company A and between 95 and 104 for company D. Both companies allowed hospitals to combine all types of pacemakers to meet quantity requirements. Companies B and C offered the discounts shown irrespective of the quantities purchased.

CHAPTER 4

MEDICARE'S PROSPECTIVE PAYMENT SYSTEM

PROVIDES HOSPITALS INCENTIVES TO BE

MORE PRUDENT PURCHASERS OF PACEMAKERS

Because hospitals receive flat payments for treating patients under Medicare's prospective payment system and profit or lose depending on whether their costs are above or below the payment rates, they have an incentive to be more prudent purchasers than under cost reimbursement. Although manufacturers offered discounts for volume pacemaker purchases, a very low percentage of manufacturers' sales involved discounts during the base year for prospective payment rates. We believe the incentives of the prospective payment system should result in more hospitals seeking discounts and in other improvements to hospital purchasing practices. Therefore, we believe that the prospective payment rates for pacemaker DRGs overstate the costs of pacemakers compared to what an efficient hospital would now be paying for them.

MANUFACTURERS' DISCOUNTS CAN REDUCE PACEMAKER SURGERY COSTS

Prudent procurement practices and Medicare regulations require that hospitals take advantage of quantity discounts available from manufacturers. Medicare's cost reimbursement principles also state that if a hospital's costs are inflated due to its failure to take advantage of available discounts, the excess costs may be disallowed. While data obtained from manufacturers and hospitals show discounts ranging from about 5 to over 60 percent, only 3 of the 12 hospitals reviewed obtained quantity discounts. Seven other hospitals could have obtained discounts based on the discount availability data we obtained. Under the recently adopted prospective payment system, hospitals will have an incentive to obtain discounts to trim their pacemaker costs. However, DRG payment rates for pacemaker surgeries do not reflect the economies hospitals can realize by obtaining discounts.

One reason why hospitals may not have solicited discounts is the fact that Medicare traditionally operated on a cost reimbursement basis. Consequently, hospitals had little incentive to contain prices paid for pacemakers. Another reason may be that manufacturers have not advertised their discount policies, but rather have waited for the hospitals to take the initiative and solicit a discount.

4. To gather data required to be prepared and maintained by the manufacturer by the Food and Drug Administration (FDA), which regulates medical devices including pacemakers.
5. To obtain physical evidence that would be useful in possible product liability actions.
6. To gather historical data concerning pacemaker performance useful to the manufacturer in research and development of improved pacemakers.

Whenever a pacemaker is returned, the manufacturers' practices are to send the physician or hospital (1) a letter stating whether the pacemaker was functioning properly, including a brief analysis of the reason for the pacemaker failure, if any; (2) a report summarizing the numerical data obtained from their analysis of the subject pacemaker; and (3) notification when the warranty provisions are met that a credit will be issued.

FDA is required to monitor the performance of medical devices such as pacemakers.¹ To carry out its monitoring-related activities, FDA needs to have access to the results of the manufacturers' evaluations of returned pacemakers. As stated above, the manufacturers must obtain explanted pacemakers from hospitals to make this type of evaluation.

Under the Medical Device Amendments of 1976 (Public Law 94-295),² FDA is required to monitor the safety and efficacy of pacemakers. FDA is also responsible for investigating consumer complaints about products it regulates, including pacemakers. To assist FDA in carrying out these responsibilities, the 1976 amendments require manufacturers of medical devices to establish and maintain records needed to ascertain the safety and effectiveness of medical devices, including information regarding the devices' adverse effects on health. Hospitals need to return explanted pacemakers to enable FDA to carry out these responsibilities. As discussed in chapter 2, many hospitals do not return all explanted pacemakers to the manufacturers.

¹The regulations on good manufacturing practices for medical devices (21 C.F.R. Part 820) require, among other things, that manufacturers are responsible for maintaining complaint files and conducting failure investigations on products that do not perform to specifications.

²For more detail on the requirements of this act, see our report Federal Regulation of Medical Devices--Problems Still To Be Overcome (GAO/HRD-83-53, Sept. 30, 1983).

credits were obtained by the reviewed hospitals, there was little assurance that Medicare benefited from them.

Under Medicare's prospective payment system, hospitals now have incentives to seek warranty credits and thereby reduce their costs. Moreover, two additional major manufacturers now offer product warranties whereas they did not in 1981, the base year used to establish Medicare's prospective payment rates. These changes indicate to us that hospitals should be able to reduce the resources needed to perform replacement pacemaker surgeries and that the data used to establish the DRG payment rates for replacements overstate hospitals' current costs.

The Deficit Reduction Act of 1984 provides a framework under which HHS could assure that it obtains the information necessary to determine the impact of the changes related to warranties discussed in this chapter on the amount of hospital resources needed to perform pacemaker replacement surgeries. Furthermore, HHS could use the provisions of this law to gain immediate benefit from warranty credits, for example, by deducting the amount of a warranty credit from DRG payments. Because it appears that few credits were obtained during the base year used for establishing Medicare's prospective payment rates, such action should not severely affect the fairness of Medicare payments to hospitals for replacement surgeries. HHS could also wait until it obtained enough data from implementing the provisions and adjust the payment rates to reflect the changes in hospital costs that result from the increased availability of warranties and the new incentive to seek warranty credits. Of course, Medicare would not receive the benefits arising from these changes in the interim.

RECOMMENDATIONS

We recommend that the Secretary of HHS require hospitals to return all explanted pacemakers and leads to the manufacturer, require the manufacturer to test all returned pacemakers and leads, and require the manufacturers to report the results of the tests to the hospitals. This would provide the information necessary to determine the extent to which warranty credits are being issued.

We also recommend that the Secretary use the information obtained through implementation of the above recommendation to assure that Medicare benefits when warranty credits are issued.

some of the units could have been subject to replacement at no cost under the product warranty policies of the manufacturers that originally produced them.

Another company had a similar pacemaker exchange marketing program, which provided for incentive payments whenever a unit manufactured by a competitor was replaced with one of its own manufacture. The payments went to the patient for medical expenses not covered by a third party payor such as Medicare or to the hospital where the surgery was performed. About 133 pacemakers manufactured by competitors were explanted and replaced during a 17-month period ended November 15, 1983, under this marketing program. The data provided by the manufacturer failed to indicate the name of the competitor that manufactured the unit, the date the unit being replaced was originally implanted, or the disposition of the explanted unit by the hospital where the surgery was performed. Consequently, no information was available to show whether the unit that was removed would have been covered by the warranty policy of the company that manufactured the unit. To the extent that these units were covered by a warranty, the hospital and ultimately the Medicare program lost the warranty's financial benefits.

Another manufacturer with a similar marketing program sold about 250 pacemakers during an 18-month period ended October 1983 as replacements for pacemakers manufactured by competitors. No information was available to show whether the units removed would have been covered by the original manufacturers' warranties. Consequently, we were unable to ascertain whether they would have been subject to warranty credits.

HOSPITALS LACKED PROCEDURES TO ASSURE MEDICARE BENEFITED FROM PACEMAKER WARRANTY CREDITS

In addition to the problems discussed in the previous sections, there was no assurance that Medicare costs were properly adjusted by the reviewed hospitals to reflect the credits when they were obtained.

Replacement surgeries at the 12 hospitals ranged from 9 to 24 percent of total pacemaker surgeries. Replacements averaged 17 percent, and the pacemaker implantation periods for the replaced pacemakers ranged from 1 day to 6-1/2 years. Although some pacemakers outlast the warranty and are not subject to replacement under manufacturers' product warranties, many are replaced during the warranty period.

There was no uniformity in the treatment of warranty credits received from manufacturers at the 12 hospitals. We were able to verify that the hospital credited the patients'

Example 5. A pacemaker with a pacing-for-life-replacement warranty was implanted in a beneficiary on April 22, 1978, and was explanted on June 3, 1981, about 38 months later. Replacement surgery was performed because the pacemaker failed, a condition which, if verified by the manufacturer, would be covered under the warranty. The pacemaker was replaced by another one made by the same company, so that warranty condition was met. However, the explanted pacemaker was not returned to the manufacturer, so no credit was issued. The available credit was the original purchase price of the explanted pacemaker--\$2,295.

Because of the incentives under the prospective payment system for hospitals to decrease their costs, they should now be seeking to obtain warranty credits, but Medicare will not benefit from this because the DRG payment rates are based on data from a period when this incentive was not present to the extent it is today.

MANUFACTURERS' POLICIES DISCOURAGED
SALES REPRESENTATIVES FROM ARRANGING
FOR THE RETURN OF EXPLANTED PACEMAKERS

A substantial number of pacemaker surgeries involve replacing pacemakers. Many of these replacements are performed under marketing practices which provide for manufacturers deducting a part of the sales representatives' or distributors' sales commission when a warranty credit is issued for a returned pacemaker. This policy tends to discourage sales representatives from providing for the return of explanted pacemakers to the manufacturers.

For example, one manufacturer reduced the distributor's sales commission by approximately \$800 if a \$4,000 pacemaker was returned to the manufacturer and a warranty credit was issued for it. Another manufacturer reduced its own sales representative's commission by about \$100 if a similarly priced explanted pacemaker was returned to the manufacturer and a warranty credit was issued.⁴

⁴In May 1984, this company directed its sales representatives to instruct hospital operating room staff on how to return its explanted pacemakers. The company also notified its sales representatives not to accept explanted pacemakers. Instead, this manufacturer is furnishing hospitals with self-addressed mailbags to facilitate the return of explanted pacing products.

At another hospital that returned some explanted pacemakers to the manufacturer, hospital officials stated that they made the unreturned pacemakers available for teaching purposes or gave them to the physicians, who often returned them to the patient if a manufacturer's sales representative determined that they were outside the warranty period.

A representative of another hospital said that explanted pacemakers were usually returned to the various manufacturers' sales representative. However, he could not systematically account for what happened to explanted pacemakers because the hospital did not maintain records on its disposition of them. The hospital also lacked records on the manufacturers' technical evaluation of explanted pacemakers. But the hospital staff did indicate that occasionally a sales representative would volunteer a comment such as "that pacemaker you gave us was within specifications." Manufacturers' data showed that 13 of 23 explanted pacemakers had not been returned.

Another hospital had a policy to return pacemakers to the manufacturers only if they were replaced by a unit made by the same manufacturer. According to a hospital official, this policy apparently evolved because the hospital staff felt that, because the manufacturer's warranty policy was tied to the replacement of the explanted unit with one made by the same manufacturer, it would be a waste of time to send the explanted unit back for analysis if it were being replaced with a unit made by another manufacturer. However, three of the seven pacemakers not returned to the manufacturer were replaced by models from the same manufacturer. Also, not returning explanted pacemakers makes it harder for manufacturers to assure comprehensive quality control testing, which is important for assuring quality of care.

At one hospital, we found many explanted pacemakers being stored. The hospital operating room clinical director stated that the question of whether a pacemaker was returned to the manufacturer was usually resolved between the patient's physician and the manufacturer's sales representative. If they decided that the pacemaker was within warranty, the sales representative customarily took the pacemaker and returned it to the manufacturer. Pacemakers not returned were retained in storage.

Failure to return pacemakers
leads to loss of warranty benefits

Under the Medicare cost reimbursement system, hospitals had little economic incentive to seek replacement credits because Medicare would pay for the replacement pacemaker. About 53 percent of the pacemakers explanted at the 12 hospitals reviewed

Second Manufacturer's Explanted Pacemakers
That Could Have Been Covered
if Warranties Had Been Offered in the United States

Pacemaker model	Average implantation (years before replacement of unit in U.S.)	Number of observations	Warranty period (years)		
			United States		Outside the U.S. and Canada ^a
			Before 1984	1984	
A	9.07	2	None	10	5 (Rep)
B	7.70	2	None	10	5 (Rep)
C	4.29	1	None	10	LTR
D	4.98	1	None	10	LTR
E	3.39	7	None	10	5 (rep) ^b
F	3.36	1	None	10	LTR
G	2.97	2	None	10	5 (rep) ^b
H	4.89	1	None	10	LTR
I	5.41	1	None	10	LTR
J	4.76	3	None	10	LTR
K	3.20	2	None	10	LTR
L	1.92	1	None	10	LTR
M	1.92	2	None	10	LTR
N	0.36	4	None	10	LTR
O	0.17	3	None	10	LTR
P	0.20	2	None	10	LTR
Total		35			

^a"Rep" means replacement warranty, and "LTR" means lifetime replacement warranty.

^bWarranty states that for pulse generators set at rates in excess of 75 pulses per minute, the replacement agreement is valid for 4 years from date of implant.

Assuming the pacemakers failed to meet specifications and were replaced by units of the same manufacturer, 31 of the 35 replaced units would have been replaced at no charge if the company had offered U.S. customers the same warranty it made available in foreign markets. The comparison also shows that all 35 units returned would have been within the company's warranty period if the warranty policy implemented by the manufacturer in 1984 had been in effect.

significantly decrease expenditures for pacemaker replacements because payment rates are based on 1981 hospital cost data that do not reflect these two companies' warranties. Specifically, our review showed that if warranties similar to those extended to overseas customers of these two manufacturers had been made available to their U.S. customers, the warranties would likely have covered many of the two companies' pacemakers explanted in this country in 1983.

To demonstrate the potential effect of the differences in warranty policies offered by the two companies in this country and abroad, we prepared the table below for seven pacemaker models sold in the United States without warranties that were recently returned to one of the manufacturers. The table compares, for seven pacemaker models explanted in the United States, warranty periods provided for such models by the manufacturer in European nations to the periods the pacemakers were implanted before removal. It shows that 81 percent, or 169 of 209 units, could have been subject to a product warranty in Europe but not the U.S. market.

One Manufacturer's Explanted Pacemakers
That Could Have Been Covered
Under Warranties Offered in Europe

<u>Pacemaker model</u>	<u>Number of observa- tions in in U.S.</u>	<u>Warranty Period^a</u>					<u>Pacemakers replaced in the U.S. within the European warranty period</u>	
		<u>U.S.</u>	<u>Germany</u>	<u>France</u>	<u>Spain</u>	<u>U.K.</u>	<u>Number</u>	<u>Percent</u>
		----- (years) -----						
A	7	none	5(mb)	4(mb)	5(rep)	5(mb)	7	100
B	74	none	5(mb)	4(mb)	5(rep)	5(mb)	34	46
C	47	none	5(mb)	4(mb)	5(rep)	5(mb)	47	100
D	50	none	2(rep)	4(rep)	2(rep)	2(rep)	50	100
E	13	none	2(rep)	4(rep)	2(rep)	2(rep)	13	100
F	12	none	4(mb)	4(mb)	4(rep)	4(mb)	12	100
G	<u>6</u>	none	4(mb)	4(mb)	4(rep)	4(mb)	<u>6</u>	100
Total	<u>209</u>						<u>169</u>	81

^a"Mb" means money-back warranty. "Rep" means replacement warranty, i.e., the same unit or original cost toward a new unit.

the same company.¹ Second, some manufacturers have offered a coinsurance warranty. In this case, the warranty covers the unreimbursed medical expenses of the patient, but does not provide a credit for the cost of the device if the patient is a Medicare beneficiary or has other insurance that covers this expense. Some companies that offered hardware warranties also offered coinsurance warranties.

Under Medicare's cost reimbursement system, the hospital as the purchaser had little incentive to favor a product with a hardware warranty over one without such a warranty because Medicare payments were tied to costs. Hardware warranties were competitively important primarily for what they conveyed about product performance and reliability. Industry sources told us warranties covering unreimbursed medical expenses developed because of the concern that patients not be asked to bear significant expenses in the case of product failures. Also, by defraying patient expenses, physicians were encouraged to focus only on the medical appropriateness of a replacement, not the financial implications of their decision.

DIFFERENCES IN PRODUCT WARRANTIES IN THE UNITED STATES AND OVERSEAS

The pacemaker companies' warranty provisions differed significantly regarding covered time periods and types of benefits in their various geographical market areas. For 1981 through early 1984, two of the four manufacturers in our review offered product warranties in their overseas markets but not in the U.S. market. The two manufacturers instead gave customers in this country a coinsurance warranty, under which they agreed to pay certain medical expenses, such as physicians' fees and hospital expenses, which were not reimbursed by Medicare or other health insurance.

Two pacemaker companies provided product warranties in both the U.S. and overseas markets. We noted some warranties provided in the United States were more generous than those provided overseas. For example, the warranty period for one model was 8 years in the United States but only 4 years overseas. For another model, the overseas warranty was 84 months, whereas in the United States the model was warranted for the life of the patient. In both markets, the credit was limited to an amount equal to the original price of the failed unit, but not more

¹The warranty is made to the patient who receives the pacemaker and recognizes that some states do not permit manufacturers to exclude or limit their liability and that these exclusions and limitations may not apply to some patients.

to establish Medicare's prospective payment rates. We also obtained data on the hospitals' markup policies, patient billings, and policies pertaining to purchase discounts and manufacturer credits for explanted (removed from patients) pacemakers. In addition, we looked at their procedures for returning explanted pacemakers to the manufacturers. The results of our work at the 12 hospitals cannot be projected to the universe of hospitals where pacemaker surgeries were performed. However, the hospitals were not selected because of indications of problems, but rather to get a mix of the types of hospitals performing pacemaker surgeries. Therefore, we believe that the data we developed provide an insight into the accuracy of the data used to establish Medicare's DRG payment rates.

We also studied Medicare's principles for reasonable cost reimbursement as they relate to the accuracy of the data used to set the DRG rates, the law and regulations governing Medicare's hospital prospective payment system, and the methodology HCFA used to compute the DRG rates. From HCFA we obtained the MEDPAR pacemaker data for the 12 hospitals and compared those data with our data for the hospitals.

Our fieldwork was conducted from November 1982 through August 1984. As requested by the Special Committee, we did not obtain comments from HHS or the manufacturers on this report. We did discuss the report with representatives of the manufacturers, who agreed that the report did not include company-identifiable proprietary data.

Except as noted above, our review was conducted in accordance with generally accepted government auditing standards.

We reviewed the four pacemaker manufacturers whose sales account for about 80 percent of the pacemaker sales in the United States. The four manufacturers are:

- Cordis Corporation, Miami, Florida.
- Intermedics, Inc., Freeport, Texas.
- Medtronic, Inc., Minneapolis, Minnesota.
- Pacesetter Systems, Inc., Sylmar, California.

About 10 other companies sell pacemakers in the United States.

From each reviewed manufacturer, we obtained a description of the quality assurance program for pacemakers explanted and returned by hospitals, data on pacemaker product warranties issued in the domestic and overseas markets, and price lists for pacemakers sold domestically. The manufacturers each provided us with a listing of their 150 largest customers and information on sales and discount practices for their domestic and overseas operations. Data obtained from the manufacturers on the industry's marketing and quality control practices included (1) the companies' returned goods procedures, which set forth the procedures for handling returned pacemakers; (2) warranty data for pacemakers sold in the United States and overseas markets; (3) patient registration and implant data for both initial pacemaker implants and replacements; (4) bid submissions, contracts, and related correspondence with specific hospitals, including discount agreements with specific buyers; and (5) payments made to patients, physicians, and hospitals for medical expenses not covered by third party insurers.

We also visited three of the four manufacturers' European headquarters and principal manufacturing facilities. We obtained data on their warranty practices by country and on product discounting. We observed the handling of pacemakers returned for analysis, discussed the effectiveness of the pacemaker registration system, and obtained data showing pacemaker utilization by model. The fourth company produces its products for the European market under a joint venture agreement with an overseas company, and we did not visit that operation.

All four companies provided data that they consider to be proprietary. They expressed concern about its disclosure, which they felt could have an adverse effect on their marketing arrangements. The companies provided data with the understanding that we would not disclose its source. The type of data the companies considered as confidential included (1) their overseas market share by country and pacemaker model, (2) their overseas

reflect actual costs. The payment rate depends on which diagnosis related group (DRG)² the case is classified into. The prospective payment system is being phased in over 3 years beginning in fiscal year 1984, and eventually hospitals will be paid a uniform rate (adjusted to reflect variations in local wage levels, urban or rural location, and teaching status) established for each DRG.

The Social Security Act, as amended by Public Law 98-21 and the Deficit Reduction Act of 1984 (Public Law 98-369, July 18, 1984), required that Medicare payments be neither more nor less during fiscal years 1984-85 than they would have been under the former reasonable cost payment methodology and established the rules by which the DRG rates will increase as follows:

--For fiscal year 1985, the DRG payment rates are increased by the HHS-estimated percentage increase in the hospital market basket (an index designed to measure changes in the prices hospitals pay for goods and services) plus 0.25 percent.

--For fiscal year 1986, the DRG payment rates cannot be increased by more than the estimated change in the hospital market basket plus 0.25 percent.

--For fiscal year 1987 and later, the DRG payment rates will be increased by the amount HHS determines is necessary to pay for the efficient and effective delivery of medically appropriate and necessary care of high quality and to reflect changes in treatment patterns, technology, and other factors that may change the relative use of hospital resources.

To compute the DRG payment rates, HCFA used data from hospital cost reports for periods ended in fiscal year 1981 and the calendar year 1981 Medicare Provider Analysis and Review (MEDPAR) file.³ MEDPAR is a 20-percent sample of Medicare hospital discharges and includes information on the diagnoses of the patients and the hospital charges for services provided in treating the patients. MEDPAR charge data were converted to cost data by applying information from the cost reports. The

²Each DRG contains diagnoses which are expected to be closely related in the extent of resources devoted to treating patients.

³For DRGs with too few MEDPAR discharges, non-MEDPAR discharge data from Maryland and Michigan were used to compute DRG weights. The use of this additional data was not necessary for pacemaker-related DRGs.

The result of these incentives and opportunities for prudent purchasing should be a reduction in hospitals' costs of purchasing pacemakers compared to that reflected in the prospective payment rates, which are based on 1981 data.

We believe that when HHS updates prospective payment rates for pacemaker DRGs in the future, it should use current data that reflect the prices of pacemakers available through the more efficient purchasing practices.

RECOMMENDATION

We recommend that the Secretary of HHS direct the Administrator of HCFA, when updating pacemaker DRG rates, to use data that are as current as possible to reflect the improved efficiency that should result from the incentives toward prudent pacemaker purchasing under Medicare's prospective payment system.

which could distort results.² Finally, it was inflated to reflect current price levels, using changes in the hospital market basket index, which reflects changes in the prices of goods and services purchased by hospitals.

FLAWS IN HHS' DATA BASE
AFFECT DRG RATES

A comparison of our data with pacemaker MEDPAR data for the 12 hospitals disclosed numerous errors and flaws that could affect the DRG rates. Specifically, we found that

- the cost reports HHS used were unaudited;
- about 10 percent of the 94 pacemaker MEDPAR cases for the 12 hospitals were classified in the wrong pacemaker DRG;
- an additional 37 pacemaker cases, or an additional 40 percent, were erroneously classified on MEDPAR under DRGs other than the pacemaker DRGs;
- the conversion factors HHS used to convert MEDPAR charges into the costs on which the DRG weights are based were (a) unaudited, (b) affected by hospital billing errors, and (c) lacked uniform classification of costs; and
- pacemaker DRG classifications combine procedures involving significantly different levels of resource use.

Use of unaudited cost reports

A major procedural problem we noted was the use of unaudited 1981 cost reports for determining the DRG rates. For the 12 hospitals reviewed, none of the cost reports used by HHS in developing the DRG rates had been audited. Eight of the cost reports had been audited when we conducted our fieldwork, and the audited reports showed significantly lower costs than the reports HHS used to develop the DRG rates. For ancillary service costs such as medical supplies and laboratory services, which account for about half of total costs, the audited costs for these hospitals averaged about 5 percent lower than the

²Cases for which the standardized costs were outside three standard deviations from the geometric mean for a DRG were eliminated.

classified into either an initial implant (8 errors) or replacement (1 error) DRG. Because on the average initial implant patients have a longer length of stay and higher costs than replacement patients, such errors affect the costs and relative weighting factors of the respective DRGs. Including replacements with initial implants would tend to understate the cost of initial implants, while including initial implants with replacements would tend to overstate the cost of replacements.

Additional MEDPAR pacemaker classification errors

The MEDPAR file contained additional classification errors that could affect the weighting factors of the DRGs. Thirty-seven pacemaker cases that we identified as meeting criteria for inclusion in MEDPAR were not included. These 37 cases represent about a 40-percent increase over the 94 MEDPAR pacemaker cases.

To obtain the 20-percent sample for the MEDPAR file, HHS used a sampling technique whereby the file is supposed to include all cases from each hospital where the beneficiary's Medicare number ended with a "5" or "0." However, we noted that the MEDPAR file did not contain any pacemaker cases for 1 of the 12 hospitals we reviewed. Review of our data showed that at least 15 of the pacemaker cases for that hospital should have been included in the MEDPAR pacemaker file. Analysis of the MEDPAR file for these cases showed that they were classified under DRGs other than pacemaker DRGs.⁶ All of those DRGs had lower values than pacemaker DRGs.

Although we did not always record the beneficiary's Medicare number with our data, which is necessary to determine if the case should be in the MEDPAR file, we were able to identify 22 additional pacemaker cases at the remaining 11 hospitals that were also omitted from the MEDPAR file. Comparison of these cases to the MEDPAR file showed that 16 were erroneously classified in lower value DRGs, 2 were misclassified in higher value DRGs, and MEDPAR did not include 4 of the cases although it should have.

⁶Of interest in these cases is the fact that the pacemaker was implanted in a catheterization laboratory rather than an operating room and the MEDPAR file indicated no surgery was performed. As indicated in the footnote on page 47, use of a catheterization lab rather than an operating room results in lower costs. The DRGs assigned to these 15 cases had a lower relative weight than the pacemaker DRGs. Because the cost of the pacemaker represents a major element of the total costs of these cases, their misclassification would tend to increase the weights of the DRGs to which they were assigned.

Example of Differences in Cost
of Pacemaker Surgery Between
Unaudited and Audited Costs

<u>Cost center</u>	<u>Unaudited cost-to- charge ratio</u>	<u>Audited cost-to- charge ratio</u>	<u>MEDPAR charges</u>	<u>Charges converted to costs for DRG rate setting</u>	<u>Charges converted to costs based on audited report</u>
Operating room	.57770	.65155	\$ 365	\$ 210.86	\$ 237.81
Pharmacy	.37102	.35270	476	176.60	167.88
Lab	.70383	.67316	594	418.07	399.85
Radiology	.82863	.77295	288	238.64	222.61
Supplies	.56264	.36771	6,782	3,815.82	2,493.80
Other	.60751	a	248	150.66	150.66 ^a
Total ancillary			\$8,753	\$5,010.65	\$3,672.61
Room			\$1,990	1,601.70	1,601.70 ^a
Total				<u>\$6,612.35</u>	<u>\$5,274.31</u>

^aNot computed for purposes of this example. The costs shown are unaudited costs.

For this case, use of audited cost report data would have decreased ancillary service costs by over \$1,300, or about 27 percent.

Hospital billing errors

In computing charges, hospitals usually mark up the cost of services. Hospital markup policies vary considerably and are generally graduated with lower cost items having a higher markup. Hospital errors on patient bills that affect the total charges used to compute cost-to-charge ratios distort the ratios and, thus, costs based on MEDPAR charges. Data from our 12 sample hospitals showed numerous billing errors related to hospital charges to patients for pacemakers and leads.

Although hospitals captured the costs of pacemakers in their cost centers, we noted numerous cases where the hospitals did not bill appropriate charges, generally because they incorrectly applied their markup policy or they omitted a charge for a pacemaker and/or lead. We noted that 5 of the 94 MEDPAR pacemaker cases did not include a charge for the pacemaker.

PRESENT PACEMAKER DRG GROUPS CASES
WITH SIGNIFICANTLY VARYING RESOURCE USE

DRG 117 (cardiac pacemaker replacement and revision excluding pulse generator replacement only) covers procedures for replacing leads, removing leads, removing pacemaker systems, and adjusting or repositioning pacemakers or leads. These procedures entail different resources levels--for example, replacing a lead costs more than repositioning one--but each procedure receives the same payment rate. Of the 94 cases at the 12 reviewed hospitals included in MEDPAR, 4 were classified as DRG 117 cases. Of these four

- one entailed replacement of the pacemaker and lead (case 1 in chart below),
- two were incorrectly classified because they entailed replacement of the pacemaker only and should have been classified in DRG 118 (cases 2 and 3), and
- one entailed only repositioning the lead (case 4).

Because pacemaker and lead charges and costs constitute a major portion of total charges and costs, the grouping of these dissimilar cases in one DRG may be inappropriate. The following table shows the difference in charges for the four cases.

<u>Case</u>	<u>Total MEDPAR charges</u>	<u>Total MEDPAR charges converted to cost</u>	<u>Pacemaker charge</u>	<u>Percent of total charge</u>	<u>Lead charge</u>	<u>Percent of total charge</u>
1	\$8,634	\$6,671	\$3,900	45	\$700	8
2	5,686	4,517	3,834	67	-	-
3	5,136	2,930	3,025	59	-	-
4	4,965	3,491	-	-	-	-

In the pacemaker repositioning case, if a pacemaker had been required, the total charges would have been increased by about \$3,800, the average charge for a pacemaker at this hospital. MEDPAR charges converted to costs of \$3,491 for this case would have been increased by about \$3,150, or 90 percent.¹⁰

¹⁰The \$3,150 cost shown here is not the average cost of a pacemaker at this hospital. Rather, it is a computed figure based on the application of the cost-to-charge ratio to the charge--the procedure used with the MEDPAR data. The actual average cost of a pacemaker for this hospital was about \$3,340.

CHAPTER 6

EFFECTIVE REVIEW OF PACEMAKER

SURGERIES IS NEEDED UNDER

A PROSPECTIVE PAYMENT SYSTEM

Two issues have arisen related to pacemaker surgeries that we believe need attention by HHS to assure that adequate pacemaker care is available to Medicare patients and that the most economical method of such care is provided.

First, the incidence of the use of higher cost dual chamber pacemakers has increased dramatically to an estimated 23 percent in 1984 from 5 percent in 1981, the year that forms the basis for Medicare's prospective payment system. Because implantation of dual chamber pacemaker costs substantially more (about \$1,300 in 1981) than single chamber pacemakers, the prospective payment rates could provide an economic disincentive to providing dual chamber models when they are medically appropriate. This, in turn, may justify the establishment of separate DRGs for dual chamber models.

On the other hand, separate DRGs could provide an incentive for the use of these higher cost models and the medical conditions where their use is appropriate have not been firmly established. HHS should evaluate whether separate DRGs for dual chamber pacemakers are warranted and establish guidance on when the use of these models is medically appropriate. The latter would involve expanding Medicare's current guidance on the medical conditions warranting pacemaker use to distinguish among conditions where the use of single chamber and dual chamber models is appropriate.

Second, the data we obtained during our review indicate that about 70 percent of the pacemakers explanted and returned to the manufacturer were still operating within specifications. While there are medical reasons for replacing properly operating pacemakers, manufacturers we spoke with believe there are excessive replacements. HHS needs to examine this issue.

THE COST OF DUAL CHAMBER VERSUS SINGLE CHAMBER PACEMAKERS

Because of the higher cost of dual chamber pacemakers and the need to use two leads instead of one, hospital resources required to implant a dual chamber pacemaker are higher than with a single chamber pacemaker. Also, hospital costs are higher because hospital stays and operating room time for patients

USE OF DUAL CHAMBER
PACEMAKERS IS INCREASING

In the past few years, physicians have increased the use of dual chamber pacemakers. Industry sources estimated that dual chamber implants represented about 5 percent of the total pacemaker implants in the United States in 1981. However, in 1984 they estimated that about 23 percent of all pacemaker implants in the United States will be dual chamber units. The medical conditions for which the use of dual chamber pacemakers is medically appropriate have not been firmly established. A recent report stated:

"Dual chamber cardiac pacing offers obvious theoretical advantages over traditional [single chamber] pacing. Nevertheless, no widely agreed upon criteria exist for the selection of patients for [dual chamber] pacemakers compared with the simpler [single chamber] systems."¹

Estimates in the literature of the proportion of patients suitable to dual chamber pacemakers varied widely. Also, the physicians we spoke to about this issue had widely varying opinions. However, there is agreement that such factors as age, activity, the specific nature of the disorder, and the patient's general health must be considered in deciding whether to implant a single or dual chamber pacemaker. Many feel that use of dual chamber pacemakers will become more prevalent within the next 5 years.

Physicians tend to agree that use of dual chamber pacemakers can be justified for younger patients and for older patients exhibiting a poor tolerance for other pacemakers or patients who suffer from a loss of synchrony between the two chambers of the heart. Studies show that these patients can have a 15- to 35-percent increase in cardiac output when synchrony between the chambers is restored by the use of a dual chamber pacemaker. This in turn will allow these patients to lead a more normal life.

¹William J. Stewart, MD, et al, "Doppler Ultrasound Measurement of Cardiac Output in Patients with Physiologic Pacemakers," The American Journal of Cardiology, Vol. 54, Aug. 1, 1984.

The graph shows that there is an increasing trend toward the use of dual chamber pacemakers in the United States and abroad. About 5 percent of all pacemakers implanted in the United States in 1981 were of the dual chamber type. In that same year dual chamber pacemakers made up about 3.5 percent of all implants in 12 European countries and 2 percent in Japan. However, in 1983 dual chamber pacemakers made up about 20 percent of the total in the United States, 13 percent in the 12 European countries, and 12 percent in Japan.

DUAL CHAMBER PACEMAKERS MAY REQUIRE NEW DRGs AND ADDITIONAL GUIDANCE

The prospective payment system provides hospitals with an incentive to choose the most economical type of pacemaker for implantation in patients. However, this incentive could lead hospitals and physicians to reduce the implantation of dual chamber pacemakers which, in turn, could have an adverse impact on patients' care. Conversely, it has not been established under which conditions and for whom dual chamber models are appropriate. There were wide variations in the proportion of single and dual chamber pacemakers implanted in our sample hospitals.

Because of the cost differences involved in implantation, HHS should consider the desirability of establishing separate DRG classifications for dual and single chamber pacemakers. A precondition to the establishment of such classifications is a determination of what medical conditions warrant the use of dual chamber pacemakers.

Physicians' choice of pacemaker type may be influenced by DRG payment rates

The incentives of Medicare's prospective payment system to hold down costs can influence hospitals and physicians to implant less expensive pacemakers when a more expensive, more technologically advanced pacemaker would be appropriate. Two negative consequences can result from this. First, the patient will have been denied the most appropriate and effective medical care. Second, industry sources maintain that the probability that the patient will have to undergo a replacement operation is significantly increased. For example, they point to a worsening of the symptoms related to impaired synchrony between the chambers of the heart or the emergence of new symptoms which could make it necessary to upgrade to a more technologically advanced pacemaker. Depending on how long the pacemaker has been implanted, the cost of the replacement operation and pacemaker might increase overall Medicare costs for treating the patient. The replacement operation also increases patient risk because of the second operation.

in determining whether some physicians may be unnecessarily using dual chamber pacemakers.³

Need to examine utilization
of dual chamber pacemakers

As shown in the following graph, we found a wide variation in the proportion of dual chamber pacemakers implanted in the 12 hospitals in our sample.

³This chapter discusses whether hospitals receive adequate reimbursement for increasingly expensive pacemaker technology under current DRG rates. However, one intermediary official told us that hospitals could resort to a stratagem to get around the DRG rate limitations. The stratagem would involve hospitalizing a patient for several days under part A of the Medicare program for evaluation under a DRG code covering heart-related problems but not pacemaker implantation or replacement. Following the patient's discharge for this initial hospitalization, the patient would be brought back on an outpatient basis under part B of the Medicare program for the actual pacemaker implantation or replacement. Because Medicare's requirement for review of all readmissions occurring within 7 days of discharge applies only to part A admissions and not to procedures charged to part B outpatient services, the stratagem would allow hospitals to recover the full cost of hospitalization, including expensive pacemaker costs. Some hospitals already recognize the economic advantage of implanting pacemakers on an outpatient basis. Also, with the introduction of smaller pacemakers and improvements in pacemaker accessories such as leads, some hospitals have begun to reduce pacemaker implant costs by implanting pacemakers in catheterization laboratories instead of operating rooms. At one of the institutions involved with this, the catheterization room charge is 30 to 40 percent less than the operating room charge for a similar period of time. Medical research indicates that about 58 percent of pacemaker surgeries are performed in the operating room, 24 percent in the catheterization lab, 14 percent in the X-ray department, and about 5 percent in other type special procedure rooms. (See Victor Parsonnet, MD, Candice C. Crawford, MA, Alan D. Bernstein, EngScD, "The 1981 United States Survey of Cardiac Pacing Practices," Journal of the American College of Cardiology, Vol. 3, No. 5, May 1984, pp. 1321-32.)

more than for a single chamber unit; in 1984, industry sources estimate the additional cost could exceed \$2,000.

REPLACEMENT OF FUNCTIONING PACEMAKERS BY PHYSICIANS

Because a large proportion of pacemaker replacements involve pacemakers that are later found to function within the manufacturer's specifications, Medicare may be making unnecessary expenditures. Although changes in patients' medical condition can necessitate replacing a properly operating pacemaker, industry sources point out that a number of factors unrelated to the patients' condition may account for the high ratio of replaced pacemakers that are found to be within specifications upon analysis by manufacturers.

Of 1,196 pacemakers explanted in the United States and returned to one manufacturer over a 4-year period, the manufacturer found after testing the pacemakers that about 33 percent were within specifications. Another manufacturer found that of 3,667 pacemakers returned during a recent 36-month period, about 70 percent were operating within the manufacturer's specifications.⁴ A third manufacturer found that of about 5,400 pacemakers returned in the United States during a recent 36-month period, about 80 percent were functioning within specifications.

Although it is difficult to determine the exact causes for the high ratio of pacemakers removed that are still operating within specifications, industry sources told us that it appears that contributing factors may be (1) marketing policies that provide for incentive payments for pacemaker replacement, (2) inconsistencies between the standards used by physicians evaluating a pacemaker and the standards used by the manufacturer in factory testing, and (3) changes in the medical condition of the

⁴During a recent 36-month period about 64 percent of this manufacturer's units returned from the overseas market were within specifications.

one manufactured by a competitor or to trade-up to one of its technologically more advanced units.⁷

One of the four manufacturers who did not offer a product warranty offered a "freedom of choice" replacement credit program during the period May 1980 through January 1982. This program provided for a \$500 credit to either the physician, the hospital, or the patient for any patient who received one of its pacemaker models regardless of the type of pacemaker explanted.

⁷Payment of incentives raises concerns about possible violations of federal statutes intended to curtail abuses in procuring goods and services. Section 1877(b) of the Social Security Act [42 U.S.C. 1395nn(b)] prohibits manufacturers from offering inducements to buy a medical product or service reimbursable under Medicare. This section of the law states:

"Whoever knowingly and willfully offers or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person

- A) to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under this title, or
- B) to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under this title,

shall be guilty of a felony and upon conviction thereof, shall be fined not more than \$25,000 or imprisoned for not more than 5 years, or both."

(See app. XI for more detail on the applicability of this provision to pacemakers.)

replaced. An additional 17 payments of \$500 were made for surgeries that provided for the implantation of a technologically more advanced unit (trade-up) as a replacement for the company's own pacemaker.¹⁰

A third manufacturer, which requires the submission of documentation in support of claims for uninsured medical expenses, also offered a marketing program¹¹ directed at selling pacemakers to replace a competitor's or one of its own pacemakers that has expired or is otherwise in need of being replaced. At one point, the program placed no limitations on the amount of reasonable uninsured medical expenses that this manufacturer was willing to pay. However, because some of the claims submitted and paid were as high as \$8,000, the company limited the amount to \$600 per replacement. The average unreimbursed medical expense dropped noticeably after the implementation of the \$600 limitation. About 250 competitors' units were replaced under this manufacturer's program during a recent 18-month period, and the average medical expenses paid during that period amounted to \$561. The company also replaced 515 of its own pacemakers under the program during the same 18-month

¹⁰This company is the other manufacturer reviewed by us that did not offer a product warranty. In 1984 the company adopted a warranty policy which provides for a credit for a pacemaker which is found to be functioning out of specifications within the specified warranty period. The manufacturer requires, however, that the pacemaker be replaced with a product manufactured by it. Specifically, the manufacturer offers two options. Option "A" provides the hospital with a full credit of the original purchase price of the explanted pacemaker, not to exceed the price of the new unit. Option "B" provides the hospital that replaced the pacemaker with a 50-percent credit of the original purchase price of the removed pacemaker, not to exceed 50 percent of the price of the new pacemaker. Also, reimbursement of uninsured medical expenses under the two options differ in that option "A" provides for a payment of \$500 to the patient for unreimbursed medical expenses. Option "B" provides for the payment of \$2,500 to the patient for uninsured medical expenses.

¹¹This manufacturer believes that the payment of unreimbursed medical expenses for replacement of pacemakers may, under some circumstances, become an incentive payment or an inducement to the physician to replace the patient's pacemaker. However, the manufacturer believes that, if properly administered, payment to the pacemaker patient of unreimbursed medical expenses under a warranty or as part of a product advisory or recall action may be appropriate and legitimate.

noninvasive techniques (for example, electrocardiogram or telemetry), and second, the pacemaker must be analyzed once it has been removed from the patient. The analysis of pacemaker function based on noninvasive testing is the most critical step in avoiding unnecessary removal of normally functioning pacemakers. The most common cause of error in this step is physician misunderstanding of the pacemaker's normal operation.

In evaluating whether an explanted pulse generator is out of specification, manufacturers informed us that they typically rely on their own laboratory evaluation of the returned unit and on documented information showing the unit's clinical performance. The functional evaluation of the returned unit can involve several methods of nondestructive electrical testing that are designed to determine whether the product meets design specifications. These tests are performed at body temperature using standard electrical loads. Several additional evaluation techniques are used when standard test procedures do not detect or isolate a reported clinical problem. These include testing at temperature extremes, thermal cycling, and long-term monitoring. Once an anomalous condition has been verified through functional testing, the product is subjected to destructive analysis; that is, it is disassembled and analyzed.

Frequently, performance problems identified by the physician cannot be verified or duplicated in the laboratory. According to industry sources, discrepancies between the company's returned product analysis and the physician's evaluation may occur for several reasons. For example, a physician may incorrectly judge a problem with the pacing lead as being a pulse generator failure. A small break in the lead could result in cessation of pacing, which might be incorrectly interpreted as a pulse generator failure. The lead break could also result in oversensing, which might incorrectly appear to be a pulse generator problem.

Another reason is that physicians sometimes choose to replace units in response to an initial decline in the pacemaker's rate but before end-of-life is actually indicated. For example, replacement of a pulse generator is indicated when the rate drops 10 percent. If the unit is replaced when the rate has dropped less than 10 percent, perhaps for the convenience of the patient or because the patient is in the hospital for another reason, the unit will be found by a manufacturer to be operating within specifications.

Sometimes the discrepancy between the physician's analysis of an explanted pacemaker and that of the manufacturer is a result of the limited equipment available to and experience of the physician. The complete analysis of a sophisticated pacemaker

near future. The physician may also feel that the patient is in relatively good health after admission to the hospital for another reason and does not want to take a chance that the patient will not be in equally good health when the performance indicators show the pacemaker must be replaced. Physicians in these situations may note on the form returned with the explanted pacemaker that the reason for explant was pacemaker failure because the pacemaker was approaching the end of its useful life, even though the the pacemaker has not actually reached the point where it must be replaced.

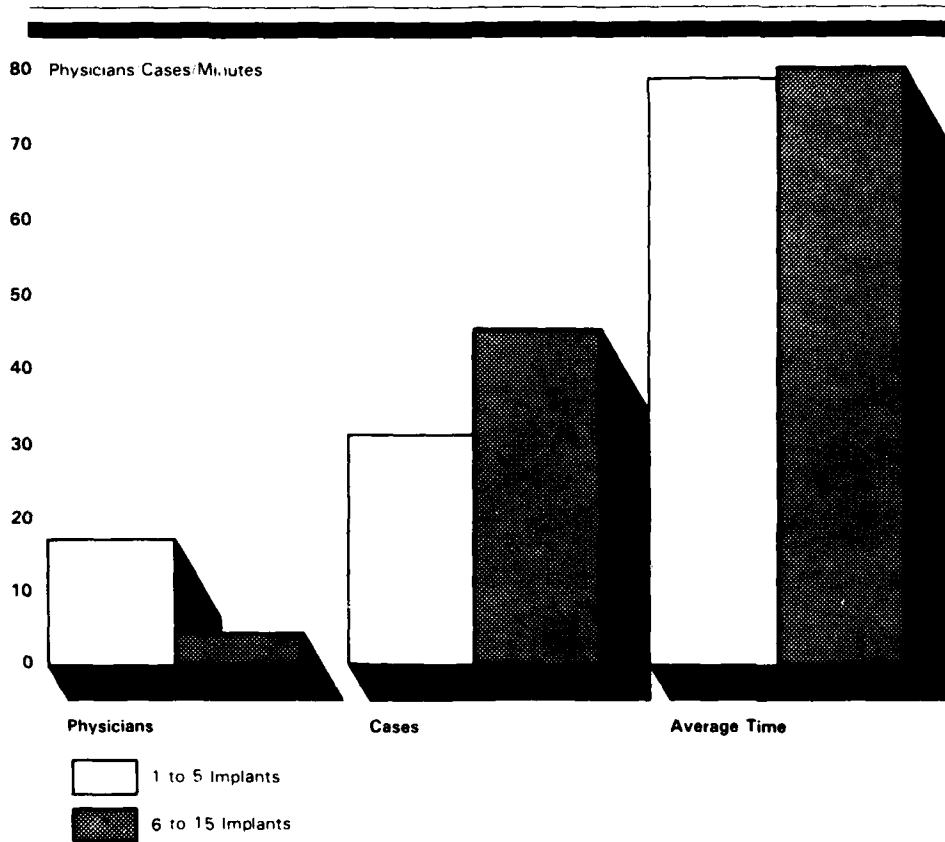
CONCLUSIONS

The choices made by physicians and hospitals in selecting pacemakers significantly affect the cost as well as the quality of care provided to patients. Because the current DRG classifications and weights do not recognize the increasing use of dual chamber units, the prospective payment system's incentives may influence hospitals and physicians to implant less expensive models when more expensive models would provide the most effective therapy.

A new DRG classification for dual chamber pacemakers would tend to decrease the possibility that payment rates unduly influence pacemaker choice. However, we are concerned that if a separate DRG is established, it could provide an incentive to implant dual chamber pacemakers in cases where they are not medically warranted. HHS should determine if the current DRG categories for pacemakers need to be revised to separate single chamber models from dual chamber models which involve significantly greater costs. To protect against the overuse of dual chamber pacemakers, HHS should also determine what medical conditions warrant the use of dual chamber pacemakers. This would involve expanding Medicare's current guidance on the medical conditions warranting pacemaker use to distinguish among conditions where the use of single chamber and dual chamber models is appropriate.

The nature and frequency of pacemaker replacements are also of concern because of their impact on patient care and Medicare program costs. A large portion of all replacements involve the removal of pacemakers that are still functioning within specifications. Physicians may replace properly functioning units for various medical reasons related to changes in patients' condition. However, marketing practices of manufacturers encourage replacements and upgrading to more advanced and more expensive units. In addition, for a variety of reasons physicians' test results do not agree with those obtained by the manufacturers, and there is inconsistent interpretation of replacement guidelines. These may also contribute to early removal of pacemakers that are functioning within specifications.

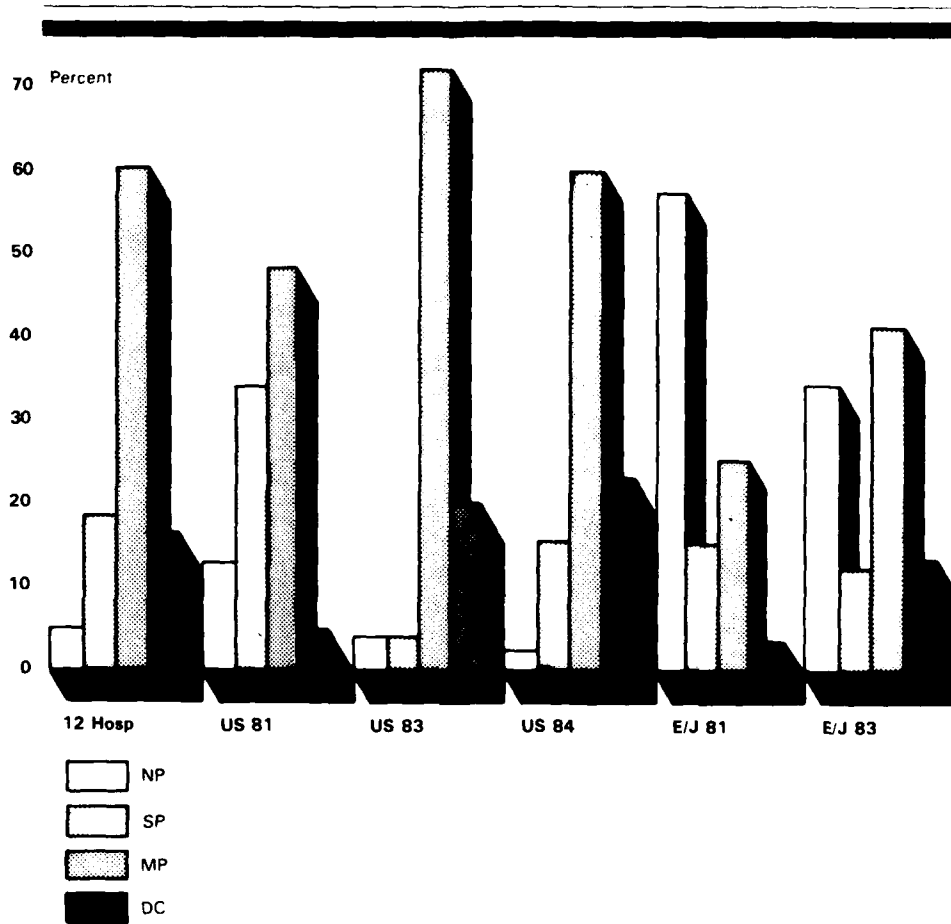
**Dual Chamber Pacemakers
Initial Implant Times for 76 Surgeries**



For 17 physicians who performed from 1 to 5 surgeries, implanting a total of 31 dual chamber pacemakers, the average time was about 79 minutes per surgery.

For 4 physicians who performed from 6 to 15 surgeries, implanting a total of 45 dual chamber pacemakers, the average time was about 80 minutes per surgery.

**Comparison of Model Implants
USA, Europe/Japan, and 12 Hospitals**



12 HOSP = Implants at the 12 hospitals included in GAO review.

US 81 = Implants in United States in 1981

US 83 = Implants in United States in 1983

US 84 = Implants in United States in 1984

E/J 81 = Implants in Europe and Japan in 1981

E/J 83 = Estimated implants in Europe and Japan in 1983

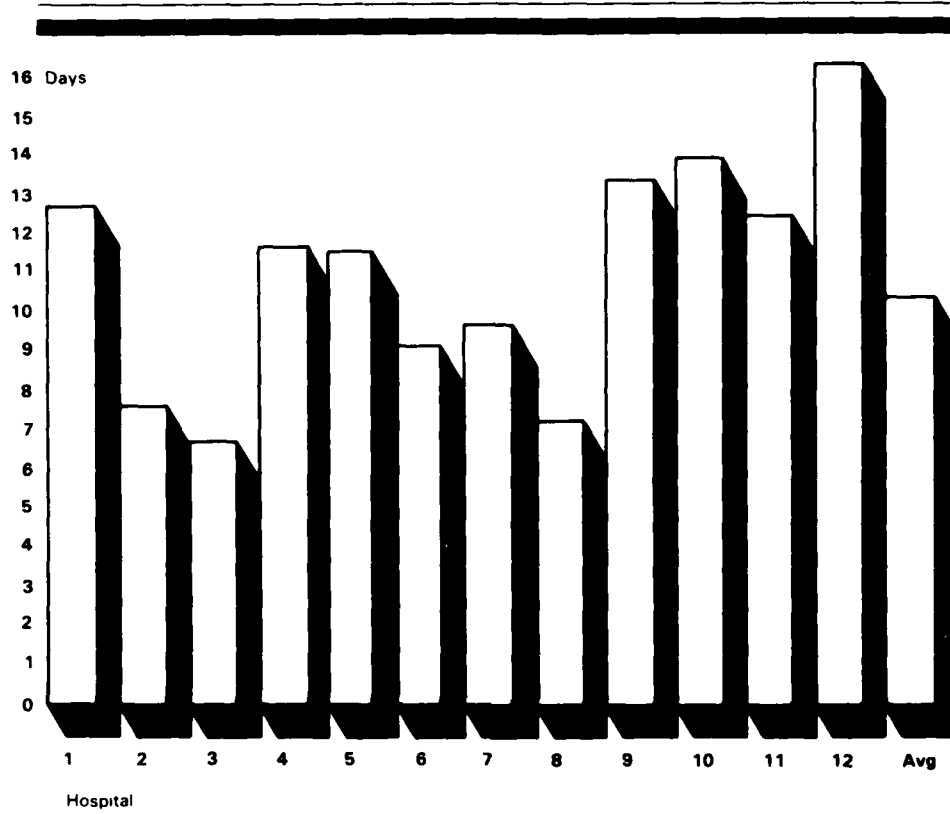
NP = Single chamber nonprogrammable

SP = Single chamber simple programmable

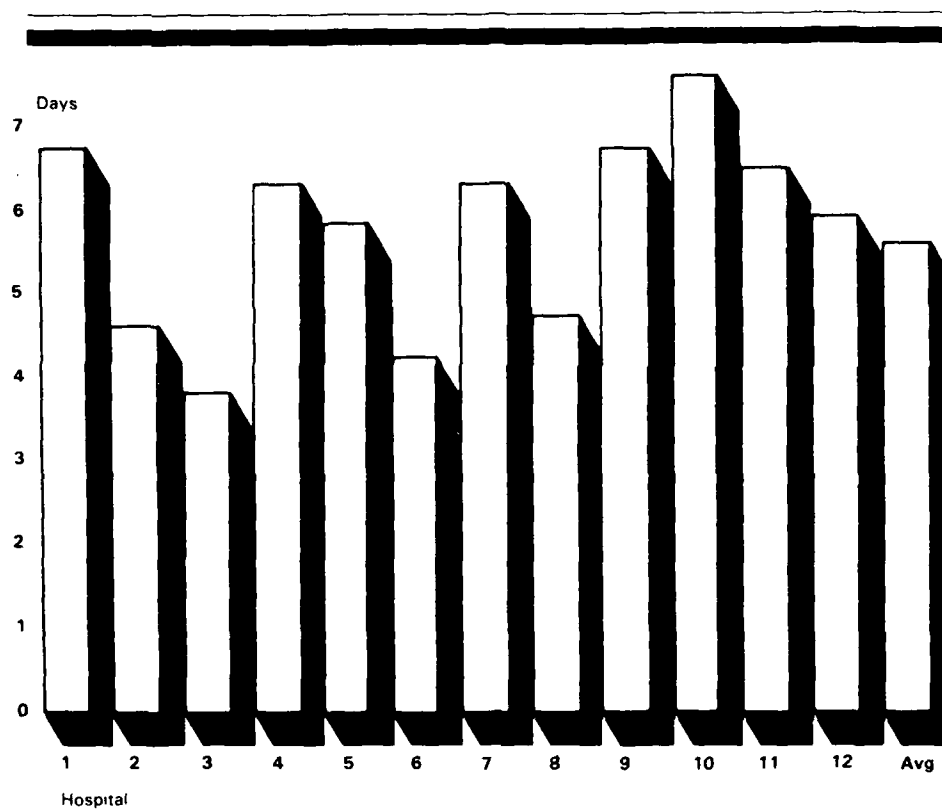
MP = Single chamber multiprogrammable

DC = Dual chamber pacemakers

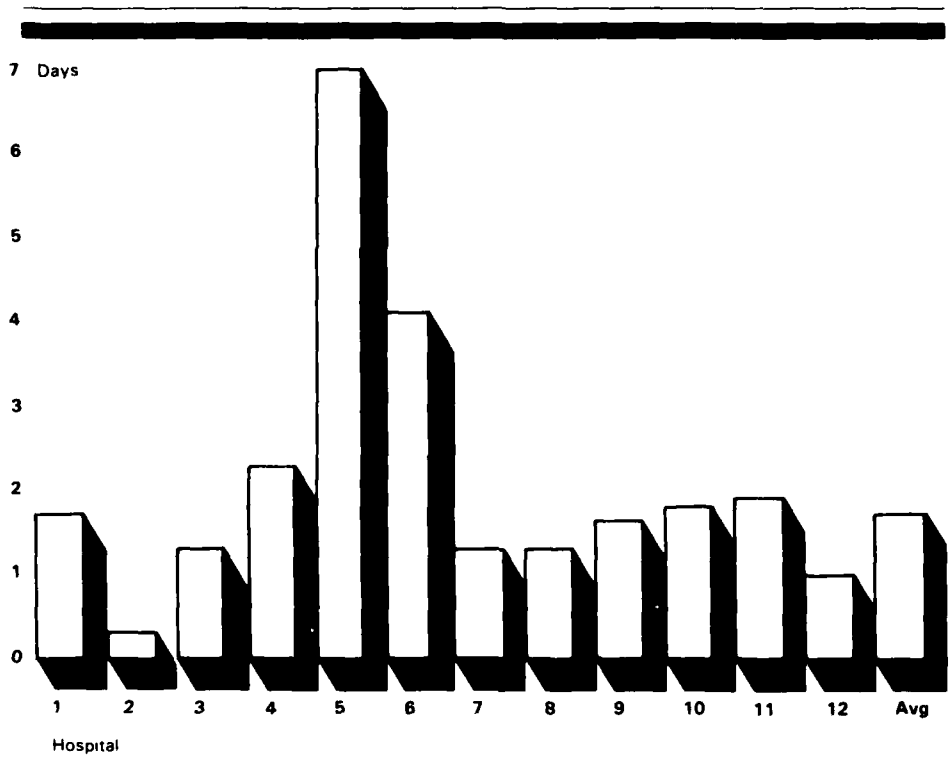
**Average Length of Stay
Initial Implants, 1981**



**Average Length of Stay
Initial Implant, Operation to Discharge**



**Average Length of Stay
Replacements, Admission to Operation**



medicare
Part A Intermediary Letter
Part B Intermediary LetterDepartment of Health
and Human ServicesHealth Care Financing
Administration

Part A No. 83-19

Part B No. 83-11

Date DECEMBER 1983

**SUBJECT: Possible Violations of Section 1877(b) of the Social Security Act
(Anti-Kickback Provision)**

It has come to our attention that some manufacturers may be offering rebates, kickbacks, and/or "free goods" in return for the purchase of pacemakers and intraocular lenses. These activities may be violations of Section 1877(b) of the Social Security Act (Anti-Kickback Provision):

I. General - Statutory Provision

Section 1877(b) of the Social Security Act provides as follows:

"(1) Whoever knowingly and willfully solicits or receives any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind--

(A) in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under this title, or

(B) in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or items for which payment may be made in whole or in part under this title,

shall be guilty of a felony and, upon conviction thereof, shall be fined not more than \$25,000 or imprisoned for not more than five years, or both.

(2) Whoever knowingly and willfully offers or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person--

(A) to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under this title, or

(B) to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under this title,

shall be guilty of a felony, and upon conviction thereof, shall be fined not more than \$25,000 or imprisoned for not more than five years, or both.

END

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