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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.

GAO/HRD-85-39
FEBRUARY 26, 1985

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,

Charles A. Bowsher

Comptroller General
of the United States

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.)

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

Contents

ILLUSTRATIONS

ABBREVIATIONS

AMI	acute myocardial infarction
CHF	congestive heart failure
DRG	diagnosis related group
FDA	Food and Drug Administration
GAO	General Accounting Office
HCFA	Health Care Financing Administration
HHS	Department of Health and Human Services
MEDPAR	Medicare provider analysis and review
PRO	Utilization Review and Quality Control Peer Review Organization

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.

Technological advances since the early 1960's resulted in the development of simple-programmable pacemakers, which did accept rate adjustment after implant. However, physiologic changes requiring alteration in pulse width or sensitivity, etc., still required pacemaker replacement surgery. Further technological advances have resulted in the development of multi-programmable units, which allow the physician to modify without surgery the programming parameters, such as the beat rate and the level of electrical stimulation.

MEDICARE AND ITS PAYMENT POLICIES

Medicare, administered by the Health Care Financing Administration (HCFA) within the Department of Health and Human Services (HHS), is a health insurance program which covers most Americans who are age 65 and over and certain individuals under 65 who are disabled or have chronic kidney disease. The program is authorized under title XVIII of the Social Security Act and provides protection under two parts. Part A, or the hospital insurance program, covers services of institutional providers of health care, primarily hospitals. Part B, or the supplementary medical insurance program, covers primarily physician services.

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,[1] of which about $400 million represented hospital payments to manufacturers for pacemakers.

From Medicare's initiation on July 1, 1966, until fiscal year 1984, the program paid hospitals, on a retrospective basis, their reasonable costs of providing covered services to beneficiaries. Although the reasonable cost methodology included provisions designed to control Medicare cost growth, there was a general concern that this payment system did not give hospitals sufficient incentives to provide care economically and efficiently. As a result of this concern, the Congress enacted as part of the Social Security Amendments of 1983 (Public Law 98-21, Apr. 20, 1983) a hospital prospective payment system for Medicare. Under the new system, the amount a hospital will be paid is determined before the period in which the payments are made, and normally payments are not adjusted retrospectively to

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[1]This estimate is based on the industry estimate of 114,000 pacemaker implants times the estimated percentage of pacemaker patients covered by Medicare (85 percent) times the national average federal DRG payment rate for pacemaker surgeries.

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

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

[3]For 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.

converted MEDPAR data were used to establish relative cost weights for each DRG; that is, the ratio of the average cost for the cases in the DRG to the average cost for all Medicare discharges. To compute a DRG payment rate, the DRG's relative weight is multiplied by a standardized amount which represents the average cost of treating a Medicare patient.

The Social Security Amendments of 1983 also strengthened the role of Utilization and Quality Control Peer Review Organizations (PROs), which are usually statewide bodies of medical professionals under contract with HCFA to review the medical necessity and appropriateness of health care services provided under Medicare. The amendments require hospitals, as a condition of receiving Medicare payments, to enter into a contract with the PRO covering their area,[4] if one has been designated, to review such factors as quality of care and utilization of services. The legislation also specifies that PROs will review the validity of diagnostic information provided by hospitals and the appropriateness of admissions and discharges. HCFA required PROs to review every permanent cardiac pacemaker implantation or reimplantation procedure and to deny payment for all that are unnecessary. PROs are also required to obtain warranty information for every pacemaker reimplantation to identify pacemaker costs reimbursable to Medicare.

OBJECTIVES, SCOPE, AND METHODOLOGY

The Chairman, Senate Special Committee on Aging, requested us to review issues related to Medicare and pacemaker implantations. As agreed with the Committee, the objectives of our review were to evaluate

- --pacemaker manufacturers' warranty policies in the United States and compare them to the warranty policies in overseas areas;
- --pacemaker manufacturers' marketing policies;
- --at selected hospitals the amount paid for pacemakers, how pacemakers were charged to Medicare, and how hospitals and pacemaker industry practices in 1981--the base year for computing DRG payment rates--affected those rates.

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[4]HCFA has entered into contracts with PROs for all areas of the nation and its territories. All contractors are physician organizations except the one for Idaho, which is the Medicare part A claims processor for that state.

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

credit and warranty policies, (3) overseas pricing policies, (4) actual pacemakers sold by model and type in both overseas and U.S. markets, (5) analysis results for pacemakers returned under warranty, (6) memorandums dealing with company marketing policies and instructions to sales representatives, (7) contractual agreements with distributors and/or sales representatives, and (8) product performance data by pacemaker model. Information in this report is not considered by the manufacturers as company-identifiable proprietary data.

We reviewed all pacemaker procedures at 12 selected hospitals during their cost reporting periods ended in fiscal year 1981. To select the hospitals, we first obtained from the four manufacturers a list of hospitals that represented their largest 150 customers and the number of pacemakers each hospital purchased. We decided to review three hospitals that predominantly purchased from each of the manufacturers. We also decided not to select more than one hospital in a given geographic area that was predominantly supplied by the same manufacturer.

Although the marketing data the manufacturers provided were reasonably accurate, many hospitals were dealing with more than one manufacturer. As a result, in some cases a manufacturer other than the one initially identified as having the predominant position was in fact predominant. Our data base includes information on 1,063 pacemaker surgeries, which includes at least 111 pacemakers for each of the four manufacturers. The 12 hospitals that we selected ranged from small rural facilities with fewer than 50 pacemaker implants annually to large metropolitan hospitals with more than 150 pacemaker implants a year. Four of the hospitals selected are in California, one is in Nevada, three are in Arizona, three are in Florida, and one is in Texas. We selected both for-profit and nonprofit hospitals. Six of the hospitals are owned and operated by large chain organizations, and the others are independent entities.[5]

Following the selection process, we visited each hospital and reviewed patients' medical records on all pacemaker implants and replacements during the hospitals' 1981 cost reporting year. We selected 1981 because that was the most recent year for which complete data were available and it also is the base year used

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[5]It was estimated that in 1981, approximately 5,600 physicians were implanting pacemakers at about 3,670 facilities and that about 118,000 initial implants were performed in that year. See Victor Parsonnet, MD, Candice C. Crawford, MA, and 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.

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.

CHAPTER 2

CHANGES IN PACEMAKER WARRANTY POLICIES INDICATE MEDICARE'S PROSPECTIVE PAYMENT RATES MAY BE TOO HIGH FOR REPLACEMENT PACEMAKER SURGERIES

In 1984, two of the four major pacemaker manufacturers instituted product warranties in the United States, and now all four manufacturers offer warranties. Also, Medicare's prospective payment system provides incentives to hospitals to obtain, whenever possible, warranty credits for pacemakers replaced after failure, because the hospital receives the same Medicare payment whether or not a warranty credit is received. Medicare's old cost reimbursement system did not have such incentives because obtaining a warranty credit resulted only in a lower Medicare payment to the hospital and Medicare paid the hospital its cost of the replacement pacemaker if a warranty credit was not obtained. When credits were obtained, there was no assurance that Medicare benefited from the credits because the hospitals lacked procedures for crediting Medicare.

In addition, manufacturers' marketing policies, such as incentives to replace competitors' pacemakers with their own, reduced opportunities to obtain warranty credits. These factors--combined with data indicating that many explanted pacemakers were not returned to the manufacturer for testing, thus precluding the possibility of obtaining a credit--lead us to believe that Medicare did not receive the full benefits of warranties under its prior cost reimbursement system. Therefore, Medicare's prospective payment rates for pacemaker replacements, which are based on 1981 historical data before the changes outlined above occurred, may be too high in view of the current availability of credits and the new incentives to seek them.

TYPES OF WARRANTIES OFFERED BY PACEMAKER MANUFACTURERS

Pacemaker manufacturers historically have offered two basic types of warranties. First, some manufacturers have offered a product or hardware warranty. With this type of warranty, the manufacturer provides a credit for, or replacement of, products that are found to be functioning out of specifications within the warranty period. The credit is typically in the amount of the original purchase price of the replaced unit or the cost of a functionally comparable unit. Also, most warranties require that the product be replaced with a product manufactured by

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

[1]The 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.

than the current list price for the pacemaker. On the other hand, one model had a 6-year warranty in Europe, but only a 5-year warranty in the United States.

One company also made available to certain customers in the United States and Switzerland a warranty for the life of the patient. However, benefits paid in Switzerland under this provision were equivalent to the current list price of a functionally comparable unit, whereas in the United States the replacement credit was limited to the lower of (1) the list price for the failed unit as of the date of purchase of that unit or (2) the list price for the replacement pacemaker as of its purchase date. Also, the company paid warranty benefits to its customers in European countries (except France, see below) and in the United States only when the explanted unit was replaced with a unit made by the manufacturer.

Another manufacturer offered a money-back guarantee in several European countries when a pacemaker failed to perform according to specifications within the warranty period. This policy evolved in these countries because the physician community, or paying authority, had an ethical problem with a "replacement in kind" policy. Our understanding of this issue is that these groups were contending that it was unethical to require anyone to use a pacemaker manufactured by the same company whose pacemaker had failed.

Finally, at the time of our visit in late 1983, a number of European countries were promulgating regulations requiring companies to provide warranties to customers inside their borders. One country, France, already required manufacturers to provide warranties for their pacemakers. France required that all pacemakers sold in the country be warranted for 4 years. France also set allowable pacemaker prices and mandated that manufacturers' warranties provide for cash reimbursement for failed units. In addition, France did not allow manufacturers to make warranty benefits conditional upon replacing explanted units with units manufactured by their own company.

ADDITIONAL MANUFACTURERS' EXTENSION OF WARRANTY BENEFITS IN THE UNITED STATES SHOULD DECREASE PACEMAKER REPLACEMENT COSTS

From 1981 through early 1984, two of the four reviewed manufacturers, which accounted for about 34 percent of U.S. pacemaker sales, offered product warranties in their overseas markets but not in the United States. However, during the first half of 1984 the two manufacturers implemented product warranties in the U.S. market. This change in warranty policies could

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

Pacemaker model	Number of observations in in U.S.	Warranty Period[a]					Pacemakers replaced in the U.S. within the European warranty period	
		U.S.	Germany	France	Spain	U.K.	Number	Percent
		(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	6	none	4(mb)	4(mb)	4(rep)	4(mb)	6	100
Total	209						169	81

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

In interpreting the data, it is important to keep in mind that pacemakers are replaced for reasons other than product failure. Consequently, all pacemakers explanted during the warranty period may not be subject to warranty credits (see p. 49). However, the table shows that, assuming the units had failed to function properly, most of the units could have been replaced without charge for the pacemaker if a warranty had been in effect.[2] The analysis also indicates that the manufacturer's recent decision to provide a product warranty in the U.S. market could have a material effect on hospitals' pacemaker costs because it appears that a substantial portion of the company's replaced units can be expected to be covered by warranties and thus subject to replacement at no cost.

The impact of the decision by the second manufacturer to offer a product warranty in this country is demonstrated by the following table. It shows our analysis of the 35 pacemakers returned to the company during a 10-month period in 1982-83 because of battery failure or other malfunctions and compares the implantation period to the overseas warranty periods and the newly established U.S. warranty periods.

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[2]In a 3-year period ended in November 1983, 53 percent of the pacemakers explanted and returned to this manufacturer were not operating properly because of either battery failure or other defects. Some of these pacemakers could have been subject to being replaced at the manufacturer's expense under the warranty provisions implemented in 1984.

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 Before 1984	United States 1984	Outside the U.S. and Canada[a]
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.

[b]Warranty 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.

HOSPITALS DID NOT RETURN MANY EXPLANTED PACEMAKERS TO THE MANUFACTURER, THUS PRECLUDING WARRANTY CREDITS

To limit Medicare expenditures for pacemaker operations, the government has an interest in assuring that the data used to set prospective payment rates reflect all the benefits available under pacemaker warranties. Manufacturers provide these benefits only if explanted pacemakers are returned to them so they can ascertain whether their product has failed within the warranty period.

However, many hospitals did not return explanted pacemakers to the manufacturers. Because the failure to return pacemakers precludes issuance of warranty credits, we believe that hospitals and ultimately the Medicare program did not receive the full benefits available under the pacemaker warranties. This, in turn, probably resulted in DRG rates for pacemaker replacement surgeries being overstated.

About 53 percent of the pacemakers explanted at the 12 hospitals we reviewed were not returned to the manufacturer.[3] At one company, officials told us that only about 60 percent of its explanted pacemakers were returned for analysis. Two other manufacturers estimated considerably higher percentages. A company official for the fourth manufacturer told us that it could not provide an estimate of the percentage of pacemakers that are explanted and returned. This manufacturer told us that exact data are not available because it does not have accurate data on the number of explanted pacemakers. One reason is that hospitals have no incentive to return explanted pacemakers when they are replaced by another manufacturer's model because the warranty does not apply unless the replacement unit is of the same make. However, 64 percent of the explanted pacemakers not returned to the manufacturer by the 12 reviewed hospitals were replaced by a model from the same manufacturer.

None of the hospitals in our sample had established procedures to assure that explanted pacemakers were returned to the manufacturer. Instead, the hospitals treated explanted pacemakers in a variety of ways. The administrator of one hospital that did not return explanted pacemakers to the manufacturer said his hospital offered explanted pacemakers to patients, disposed of them, or kept them for teaching purposes.

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[3]We asked the manufacturers to provide us data on 118 of 128 pacemakers produced by them that were explanted at the 12 hospitals we reviewed. Of the 118, only 56 had been returned to the manufacturers.

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

were not returned to the manufacturer even though many were within the warranty period and appeared to meet the warranty provisions necessary for a replacement credit. The hospital's failure to seek replacement credits may have resulted in unnecessary Medicare costs. The following examples illustrate this.

Example 1. A pacemaker with a 6-year replacement warranty was implanted in a beneficiary on April 8, 1977, and was explanted on March 10, 1981, about 4 years later. The pacemaker was explanted because it no longer properly stimulated the heart, 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--which is the last warranty condition--so no credit was issued. The available credit was the original purchase price of the explanted pacemaker--$2,325--so Medicare may have expended this amount unnecessarily.

Example 2. A pacemaker with a lifetime-replacement warranty was implanted in a beneficiary on July 14, 1980, and was explanted on February 3, 1981, about 7 months later. The pacemaker was explanted because it malfunctioned, 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--$3,795.

Example 3. A pacemaker with a 6-year replacement warranty was implanted in a beneficiary on October 26, 1977, and was explanted on February 3, 1981, about 40 months later. The unit was explanted because of pacemaker failure, 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--$2,325.

Example 4. A pacemaker with a lifetime-replacement warranty was implanted in a beneficiary on March 13, 1980, and was explanted on August 28, 1981, about 17 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--$3,100.

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]

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[4]In 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.

MANUFACTURERS' COMPETITIVE SALES POLICIES RESULTED IN HOSPITALS FAILING TO OBTAIN WARRANTY BENEFITS

Many pacemaker replacements are performed under marketing practices which provide for an incentive payment to explant a competitor's pacemaker and replace it with one manufactured by the company that offers the incentive (see p. 50). However, warranty benefits are lost when explanted pacemakers covered by warranties are replaced with a competitor's unit.

During an 8-month period in 1983, one manufacturer that had a competitive replacement marketing policy sold about 44 pacemakers to be implanted in patients who had pacemakers made by a competitor. The following table shows the reason, where available, for removing the 44 pacemakers replaced under the company's marketing policy.

Units removed because of battery failure	19
Units removed because of pacemaker malfunction	6
Units removed because of problems with lead	2
Units for which complete data were not available	17
Total units removed	44

According to company officials, to assure that claims for incentive payments were legitimate, the manufacturer until recently required that a claim be accompanied by the competitor's explanted pacemaker. Pacemakers submitted as proof by the physician or hospital were sterilized by the manufacturer and sent to the patient, not the company that manufactured the pacemaker.[5]

Replacing an explanted pacemaker that is within the warranty period with one manufactured by another company can substantially increase health care costs. For example, as shown by the above table, the data available show that 25 of the 44 pacemakers explanted were removed because the pacemaker failed. We were unable to ascertain whether the removed units would have been classified as being out of specification and thus covered by the manufacturers' warranties because the company neither returned them to the manufacturers that originally produced them for analysis nor analyzed them itself. We noted, however, that the period during which these units were implanted ranged from as little as 21 days to about 7 years. It is thus likely that

[5]A company official told us that this manufacturer has recently adopted a policy of sending all explanted pacemakers back to the original manufacturer rather than to patients.

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'

accounts for warranty credits at 2 of the 12 hospitals; 2 other hospitals had policies to credit the patient's account, but at 1 we were unable to verify that credits were handled in this manner and at another the policy was not followed because the staff responsible for handling the warranty credits was not aware of it; 4 hospitals used the warranty credit as an offset against pacemaker costs; and the remaining 4 hospitals had no policy and we were unable to ascertain the disposition of warranty credits. Thus, in most cases there was no assurance that Medicare benefited from warranty credits.

The Deficit Reduction Act of 1984 established a framework under which the problems with warranty credits for pacemakers could be alleviated. This law

--requires HHS to establish a registry for all pacemakers and leads that are paid for under Medicare, including warranty information;

--requires hospitals and physicians to report the information necessary for the registry for all implantations and replacements;

--specifies that HHS may require the return of all replaced pacemakers or leads to the manufacturer and may require the manufacturer to test returned products and report the results to the hospital; and

--specifies that HHS can deny Medicare payment for services if any of the above conditions are not met.

As of February 1985, HHS had not issued regulations implementing these provisions.

In our view, these provisions can be used to assure that the Medicare program benefits from warranties. The registry will enable Medicare to determine when a pacemaker or lead is replaced and whether it is covered by a warranty. If HHS requires hospitals to return all explanted pacemakers and leads to the manufacturer and requires the manufacturer to test them and report the results, this information could be used to assure that Medicare benefits from the warranty. This could be done, for example, by deducting the amount of the credit from the hospital's DRG payments.

CONCLUSIONS

We believe that the lack of incentives under Medicare's 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, when warranty

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.

CHAPTER 3

RETURNING EXPLANTED PACEMAKERS TO THE MANUFACTURERS CAN HELP ASSURE QUALITY OF CARE

As discussed in the previous chapter, hospitals frequently did not return explanted pacemakers to the manufacturer. Failure to do so impairs the manufacturers' ability to maintain an effective pacemaker quality control program. Manufacturers need to examine returned pacemakers to identify the probable cause of failure so they can, if necessary, make changes in manufacturing processes and notify physicians of problems that could harm patients.

RETURN OF EXPLANTED PACEMAKERS IS CRUCIAL TO QUALITY OF MEDICAL CARE

Explanted pacemakers need to be returned to manufacturers so that they can be tested to determine if a systemic problem resulted in their failure. Studies done by the manufacturers to assure the quality of pacemakers depend on the return of explanted pacemakers. Manufacturers need to examine returned pacemakers to identify the probable cause of failure so they can, if necessary, make changes in manufacturing processes or notify physicians of problems that could harm patients. As part of their quality control programs, manufacturers maintain and operate laboratories to evaluate the pacemakers explanted from patients. The manufacturers use various analytic techniques and equipment to identify the cause of anomalous pacemaker behavior. According to a manufacturer this testing is performed for several reasons, including the following:

1. To determine whether the pacemaker has failed and, if so, by what mechanism and (provided other conditions of the warranty are met, such as replacement with a pacemaker of the same manufacturer) to issue applicable warranty credits.

2. To determine whether the failure mechanism, if any, is random (isolated) or of a type requiring an advisory or recall.

3. To determine whether the failure mechanism, if any, is attributable to a component of the pacemaker obtained from an independent supplier, for the purpose of determining whether such component supplier has met its contractual obligations to the pacemaker manufacturer and/or of notifying the supplier.

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.

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[1]The 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.

[2]For 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).

CONCLUSIONS

Section 2304 of the Deficit Reduction Act of 1984 authorizes HHS to require hospitals to return to the manufacturer all explanted pacemakers and leads when Medicare payments are involved and to require manufacturers to test such returned items and report the results of the tests.

The law also requires HHS to establish a registry of all pacemakers and leads implanted and replaced under Medicare as well as requiring hospitals and physicians to report the information necessary to the registry. We believe that this registry, combined with a mandatory testing program, could be used by FDA to help it fulfill its requirements to assure the safety and efficacy of pacemakers and leads.

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.

Information we obtained from the manufacturers shows that relatively few hospitals obtained discounts. For one manufacturer, in 1982 only 0.7 percent of total domestic sales to nonfederal hospitals represented sales where discounts were granted. For another manufacturer, this percentage was 0.5 percent during the 11-month period ended March 31, 1983. For a third manufacturer discounts on total sales equaled 1.2 percent of revenues. The fourth manufacturer could not provide a figure on percentage of sales discounted but said only six nonfederal hospitals had obtained discounts during 1982.

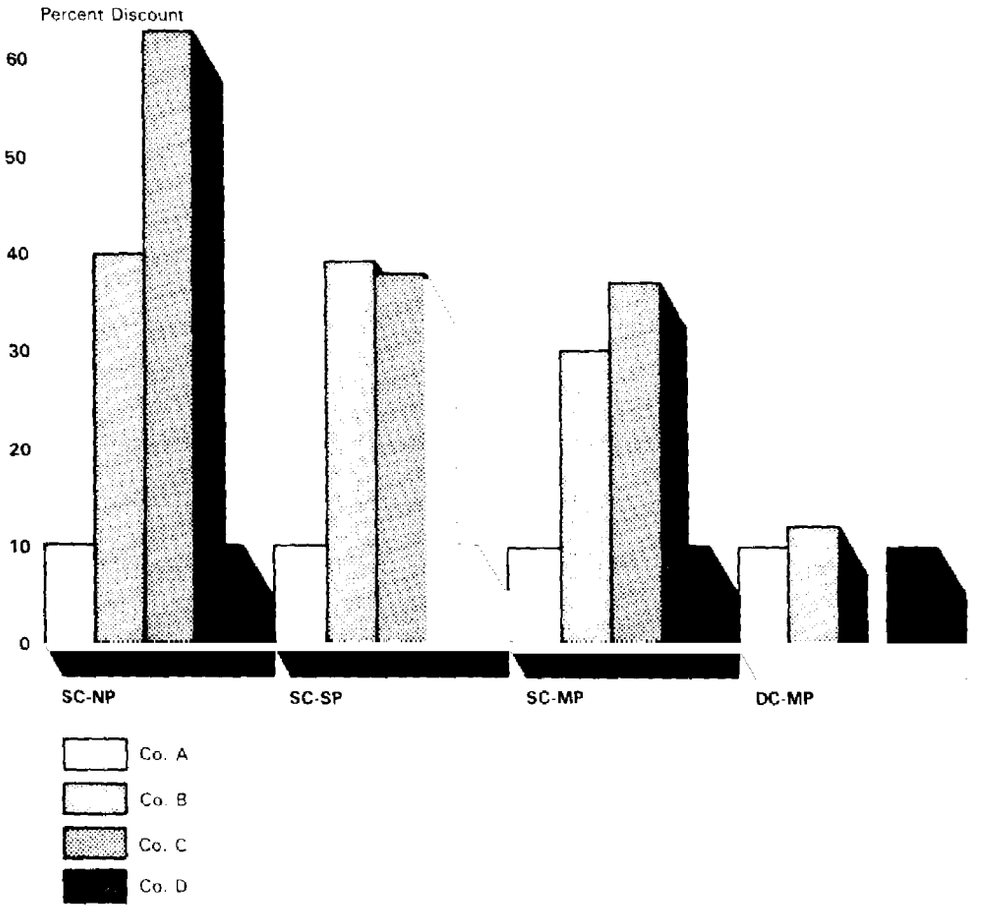
Pacemaker manufacturers make available various contractual discounts ranging from about 5 percent for the models that incorporate the newer technology to over 60 percent for the single chamber nonprogrammable units. The graph on the following page presents examples of discounts offered by the four manufacturers.

Only 3 of the 12 hospitals obtained discounts. One hospital received a discount from 2 manufacturers that had entered into an agreement with the parent organization that owned or managed this hospital and 15 others. Both manufacturers' agreements provided for combining all 16 hospitals' pacemaker purchases regardless of model to arrive at the total quantity applicable to the discounts. Quantity discounts for one manufacturer were as follows: for 1 to 80 units, no discount; for 81 to 160 units, 5-percent discount; for 161 to 420 units, 10-percent discount; and for 421 or more units, 20-percent discount. The other manufacturer's agreement provided for a discount that was tied to its share of total pacemaker purchases by the hospitals; for example, a 15-percent discount from list price was allowed if this manufacturer's share exceeded 50 percent.

Another hospital, after inviting bids, obtained discounts ranging up to about 40 percent depending on the type of pacemaker purchased. The contract between the manufacturer and the hospital did not tie the discount to any specific quantity of pacemakers, and the hospital was free to purchase all or none of its needs at the indicated discount price.

A third hospital belonged to a group-purchasing organization that had negotiated a contract with one pacemaker manufacturer providing a 10-percent discount. Some of the pacemakers purchased by this hospital were obtained through this contract.

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.

IMPROVED PROCUREMENT PRACTICES CAN LEAD TO LOWER COSTS

Another way hospitals can control their purchasing costs is through coordination and consolidation of their procurement activities. Coordinated purchasing involves 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 can lead to larger discounts. Consolidated purchasing of pacemakers allows administrators to combine the needs of several hospitals, which in turn can result in larger discounts based on combined purchasing power. However, in most of the hospitals in our sample, the decision to use a particular pacemaker is usually made by the physician, and the hospital acts only as the purchasing agent and the payor in the acquisition process.

One hospital in our sample annually coordinated its pacemaker purchases and thus was able to increase its savings from pacemaker manufacturer discounts. A chain organization that owned one of the reviewed hospitals consolidated pacemaker requirements and negotiated discounts. The other 10 hospitals in our sample did not solicit discounts.[1]

At the hospital that annually coordinated its pacemaker purchases, officials told us that the hospital management meets with cardiologists and surgeons to arrive at an annual estimate of the types of pacemakers needed to accommodate the hospital's pacemaker requirements. Physicians are required to select pacemakers from the approved manufacturer; any deviations must be submitted by the physician to the hospital administrator in writing, and there were no deviations authorized by the hospital administrator during 1981. Once the requirement has been established, the hospital administration asks as many as nine pacemaker manufacturing companies to submit bids for the types of pacemakers the hospital will need in the coming year.

By following this procedure, the hospital was able to obtain more favorable prices. In addition, the hospital's coordinated procurement procedure considered the compatibility of equipment used to monitor implanted pacemakers and allowed the hospital to consider pacemakers with the best warranties. In fiscal year 1981 the hospital was able to obtain discounts of up to about 40 percent on an annual purchase of fewer than 50 pacemakers.

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[1]However, one hospital received a discount from one pacemaker manufacturer which was negotiated by a group-purchasing organization to which the hospital belonged.

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.

Hospital A is 1 of 10 hospitals operated by a nonprofit organization which had a total estimated annual volume of 390 pacemaker surgeries. Hospital A performed 86 pacemaker implants in its cost reporting year 1981. About 60 of the 86 pacemakers were purchased from one manufacturer who had allowed quantity discounts in another contract ranging from 5 percent to 10 percent or more depending on the volume purchased. Neither hospital A nor the parent organization which operates the hospital availed itself of the manufacturer's discount policy. The total cost of pacemakers purchased by hospital A was $265,000. The parent organization had an opportunity to negotiate a discount that could have reduced the pacemaker costs. About 88 percent of pacemaker surgeries at hospital A were paid for by Medicare.

Hospital B is 1 of over 30 acute care hospitals owned and operated by a for-profit corporation. Although we were unable to ascertain the chain's total pacemaker volume, a hospital official estimated that the chain's total implants would exceed 400 pacemakers annually. Hospital B had 112 pacemaker surgeries in its cost reporting year 1981. About 77 of the 112 pacemakers were purchased from a manufacturer that in another contract had allowed quantity discounts of 10 percent for the model most frequently purchased and up to 26 percent for another model. Neither hospital B nor the chain that owns it has taken advantage of the discounts available. The total cost of pacemakers purchased by the hospital was $369,000. An average discount of 10 percent, which is not unreasonable to expect from this manufacturer for a quantity of 77 pacemakers, would have resulted in a reduction in the hospital's cost of about $36,900. About 92 percent of the pacemaker surgeries at hospital B were paid for by Medicare.

The three hospitals included in our review that received discounts incurred little, if any, additional costs to obtain the discounts. This resulted because the manufacturers provided the hospitals the pacemakers on consignment. The hospitals did not pay for a pacemaker until it was implanted and were not responsible for paying for pacemakers whose shelf life expired. The only additional costs to the hospitals were for soliciting the discounts, and these were minimal.

CONCLUSIONS

In 1981, relatively few hospitals were seeking discounts from pacemaker manufacturers although discounts, while not advertised, were available. The introduction of Medicare's prospective payment system gave hospitals incentives to be more prudent purchasers. Hospitals have the opportunity to become more efficient through coordination of pacemaker usage within the hospital and consolidation of pacemaker purchasing by chain organizations and group purchasing organizations.

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.

CHAPTER 5

MEDICARE PROSPECTIVE PAYMENT RATES BASED ON FLAWED DATA

As part of our review, we compared the information included in the data bases HHS used to set the DRG payment rates for pacemaker surgeries with the data we obtained at the 12 hospitals reviewed. We found a number of problems, such as the use of unaudited cost reports, that may inflate the prospective rates. Others, such as the erroneous classification of cases under DRGs, may inflate payment rates for nonpacemaker DRGs. Still others, such as hospital billing errors, may reallocate costs among DRGs, which can result in understatement of payment rates for some DRGs and inflation of rates for others. Because DRGs other than those for pacemakers were affected by these problems and because our review was limited to 12 hospitals, we could not determine the overall impact of the problems on the pacemaker DRG payment rates.

DEVELOPMENT OF DRG RATES

HHS developed the DRG payment rates using 1981 as the base year because it was the most recent year for which complete data were available. HHS developed base year cost data and DRG weighting factors from hospitals' 1981 Medicare cost reports and from the 1981 MEDPAR file, a file containing coded clinical information and billed charge data from a 20-percent sample of all calendar year 1981 Medicare claims.[1] HHS derived an average cost per discharge from the Medicare cost reports and DRG weighting factors by converting the billed charges on the MEDPAR file to costs.

The average cost per discharge was standardized by adjustments designed to eliminate the effects of variations in case mix among hospitals, indirect medical education costs which are only incurred by teaching hospitals, and differences in hospital wage levels among areas within the nation. The data were also screened to eliminate cases of unusually long or short duration

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[1]Maryland and Michigan non-MEDPAR discharge records were used to calculate DRG weighting factors for 109 DRGs that contained no MEDPAR cases or too few cases to provide a reasonable estimate of average cost. Pacemaker DRGs did not use non-MEDPAR data.

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

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

unaudited costs.[3] Thus, the use of audited cost reports could have resulted in a lower standardized cost per discharge.

MEDPAR pacemaker DRG classification errors

About 10 percent of the pacemaker cases included in the MEDPAR file from our sample hospitals were erroneously classified. Such errors can distort the relative costs of the respective DRGs and, hence, the weighting factors used in determining the payment rates.

There are four DRGs for pacemaker cases--two for initial implants and two for replacements or revisions. The specific pacemaker-related DRGs are:

--115: permanent cardiac pacemaker implant with acute myocardial infarction (AMI) or congestive heart failure (CHF).

--116: permanent cardiac pacemaker implant without AMI or CHF.[4]

--117: cardiac pacemaker replacement and revision, excluding pulse generator replacement only.

--118: cardiac pacemaker pulse generator replacement only.

Although we were not always able to classify our cases into a specific DRG because we did not always know whether the patient also had AMI or CHF, we could distinguish between initial implants and replacements. Comparison of the 94 MEDPAR pacemaker cases from the 12 hospitals[5] with our hospital data showed 9 cases (or about 10 percent) that were erroneously

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[3]Due to format differences in the data available to us, we only compared ancillary service costs.

[4]A separate DRG was established for patients with AMI or CHF because such patients have more complications and typically require longer lengths of stay.

[5]Although the MEDPAR file contained 123 pacemaker cases from the 12 hospitals, only 94 of these cases were from our hospital sample periods. We selected our cases from the hospitals' 1981 accounting year, which would coincide with their 1981 cost reports. However, MEDPAR consists of calendar year 1981 cases. The 29 cases outside our sample period were from the hospitals' 1982 accounting periods. Eight of the 12 hospitals reviewed had accounting years other than the calendar year.

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.

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[6]Of 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.

Problems with use of cost-to-charge ratios

A cost-to-charge ratio is the ratio of total costs to operate a given hospital department or cost center to the total billed charges for services provided by that department or cost center.

In comparing the MEDPAR pacemaker cases for the 12 sample hospitals against our data, we noted several problems with the cost-to-charge ratios used to convert MEDPAR charge data into cost data. These problems affect the accuracy of the costs used to establish the DRG weights. Specific errors in the cost-to-charge ratios used by HHS relate to the use of unaudited cost reports, the effect of hospital billing errors, and inconsistent treatment of pacemaker costs.

Use of unaudited cost reports

None of the cost-to-charge ratios used for the 12 hospitals reviewed were based on audited cost reports. The audited cost reports generally had lower cost-to-charge ratios than those used to convert MEDPAR charges into costs. The table on the following page illustrates differences between audited and unaudited cost-to-charge ratios for one hospital and their effect on pacemaker costs for one case.

Under Medicare's cost reimbursement system, cost-to-charge ratios are used to determine costs for which Medicare will reimburse hospitals.[7] The cost-to-charge ratios were also used to convert a hospital's charges in the MEDPAR file into the costs used to compute the prospective payment rates.

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[7]For example, if a particular hospital department incurred costs of $1 million and made total charges of $2 million, the cost-to-charge ratio would be 0.5. If Medicare's portion of the charges were $500,000, Medicare would pay the hospital $250,000 (0.5 x $500,000).

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

Cost center	Unaudited cost-to-charge ratio	Audited cost-to-charge ratio	MEDPAR charges	Charges converted to costs for DRG rate setting	Charges converted to costs based on audited report
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				$6,612.35	$5,274.31

[a]Not 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.

For the 12 hospitals, total pacemaker and lead billing errors amounted to about $290,000 in undercharges. This represents about 6 percent of the hospitals' total pacemaker and lead charges. At one hospital, pacemaker and lead undercharges amounted to 12 percent of the total pacemaker and lead charges. This understatement of charges causes an overstatement of cost-to-charge ratios.

Lack of uniform treatment

The placement of pacemaker costs in different cost centers also affects the MEDPAR charge to cost conversions. Specifically, for 6 of the 10 sample hospitals with pacemaker cases in the MEDPAR file during our sample period,[8] pacemakers were included in the supply cost center. Although Medicare policy on cost reporting standards prohibits including pacemaker costs in the operating room cost center,[9] the remaining four hospitals included pacemaker costs in that cost center. For three of the four hospitals that included pacemaker costs and charges in the operating room cost center, the operating room cost-to-charge ratio was considerably higher than the supply center ratio, as indicated below. Even after adjusting the affected cost centers for the costs and charges of pacemakers and leads, we found that MEDPAR pacemaker DRG charges converted to costs would have been lower at three hospitals if the pacemakers had been included in the supply cost center.

	Cost-to-charge ratio		
Hospital	Operating room as used to convert MEDPAR charges	Supply	Supply (adjusted)
1	.83184	.41371	.46765
2	.77988	.54552	.65855
3	.74009	.55002	.54440
4	.42555	.80015	.76739

Thus, the lack of uniform cost center placement of pacemaker costs and charges probably affected the data used to set prospective payment rates for pacemaker cases.

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[8]For one hospital, no pacemaker cases were included in the MEDPAR file (see p. 35). For another hospital, the only MEDPAR file case was outside our sample period.

[9]See Provider Reimbursement Review Board decisions 78-D31 and 83-D83.

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.

Case	Total MEDPAR charges	Total MEDPAR charges converted to cost	Pacemaker charge	Percent of total charge	Lead charge	Percent of total charge
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]

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[10]The $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.

Although we generally did not review cases that entailed only repositioning a pacemaker or lead, our data on 1,063 cases showed that 33 cases, or 3 percent, entailed only replacing the lead and 54 cases entailed replacing both the pacemaker and the lead. All of these cases would fall under DRG 117. Cost differences between cases in which the pacemaker is replaced and cases in which the pacemaker is not replaced may warrant establishing a new DRG for cases that do not involve replacing the pacemaker.

CONCLUSIONS

Errors in the data bases used to develop the DRG payment rates raise questions regarding the appropriateness of the rates established. HHS should assess the effect of the problems noted in this chapter.

These problems could affect both the standardized costs and the relative weighting factors of the individual DRGs. Errors in the data bases include the use of unaudited cost reports and misclassifications of cases in the MEDPAR file. Although the precise impact of the identified problems on the DRG payment rates could not be assessed, it is clear that better data are needed to update DRG payment rates.

There are also problems with the DRG classifications for pacemakers. The present system groups cases that involve significantly different levels of resource use, and hospitals are overpaid for some cases and underpaid for others. This, in turn, can give hospitals an incentive to provide some procedures and a disincentive to provide others. Also, unless a hospital had the same mix of procedures as that used to compute the payment rate, it could receive a profit or suffer a loss without merit. HHS should review the appropriateness of DRG 117, specifically the classification of pacemaker procedures that do not involve replacing the pacemaker with those that do.

RECOMMENDATION

We recommend that the Secretary of HHS direct the Administrator of HCFA to review the appropriateness of the classification under DRG 117 of procedures that involve replacement of pacemaker systems with those that do not.

Implementation of the recommendations included in chapters 2 and 4 to obtain additional data on pacemakers and to use better data to update DRG rates would help address the data problems discussed in this chapter.

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

receiving a dual chamber pacemaker can be longer than they would be for single chamber pacemakers. For example, because dual chamber pacemakers have two leads rather than one, it takes the physician additional time to implant and test the second lead, and dual chamber pacemaker implants require more operating room time than single chamber pacemaker implants. (See app. IV for price comparisons among single and dual chamber pacemaker models.)

The table below compares the average costs, for major components of total costs, to implant a dual chamber pacemaker and a single chamber unit at the reviewed hospitals.

Cost Difference Between Surgeries Involving Single Chamber and Dual Chamber Pacemakers

	Single chamber		Dual chamber		Difference
Average pacemaker cost[a]		$3,153		$3,700	$ 547
Average cost for leads[a]		334		700	366
Average operating room minutes x cost[b]	(49 x $6.80)	333	(79 x $6.80)	537	204
Average routine costs—average length of stay[c] x average per diem rate[d]	(11.2 x $141)	1,579	(12.7 x $141)	1,791	212
Total		$5,399		$6,728	$1,329

[a]Based on average cost experienced by the 12 hospitals reviewed. For the average cost per pacemaker model, see appendix IV.

[b]The average cost per minute based on data obtained from 9 of 12 hospitals. For average surgery times, see appendixes I and II.

[c]For average length of stay data on initial implants and replacements for the 12 hospitals, see appendixes V through X.

[d]Per diem rates are based on cost report data for the reviewed hospitals.

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.

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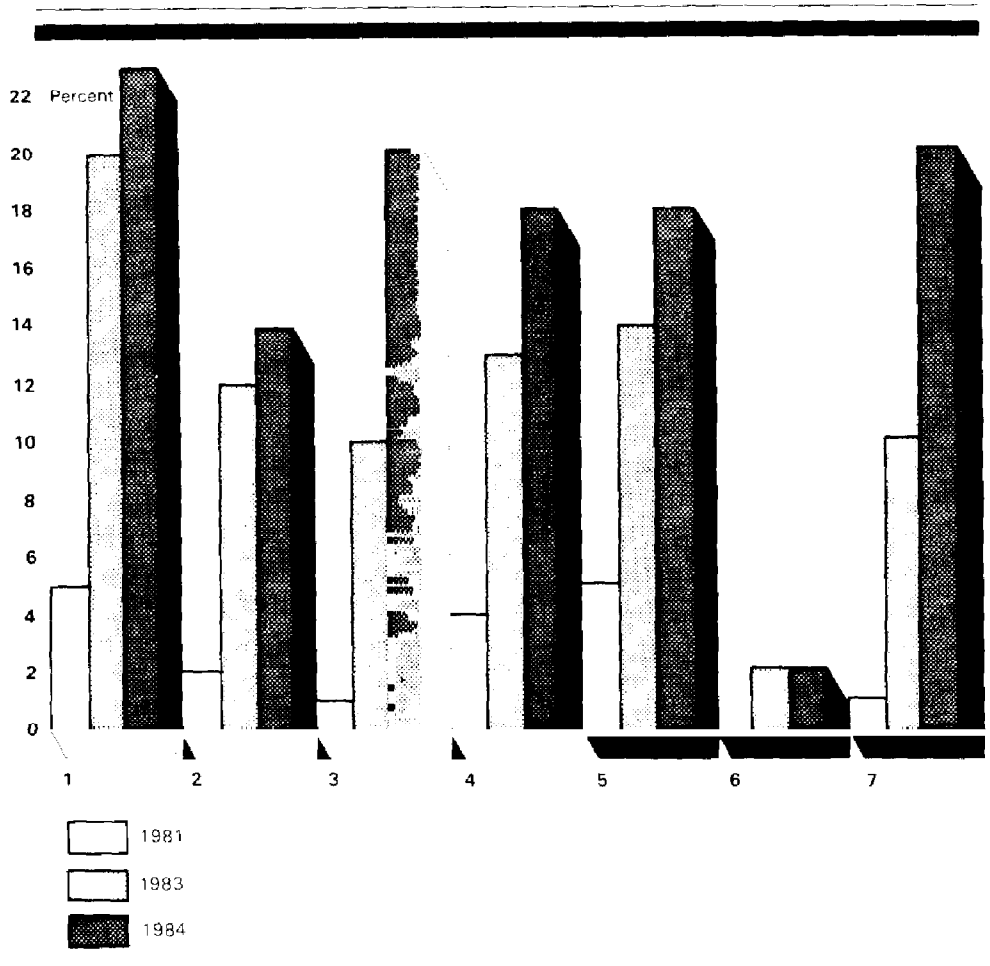
[1]William J. Stewart, MD, et al, "Doppler Ultrasound Measurement of Cardiac Output in Patients with Physiologic Pacemakers," The American Journal of Cardiology, Vol. 54, Aug. 1, 1984.

The graph below shows the increased use of dual chamber pacemakers in many countries including the United States during the period 1981-83 and presents the estimated use of such pacemakers in 1984.[2]

Dual Chamber Implants
as a Percent of Total Implants (Note a)



1. United States
2. Japan
3. France
4. Denmark, Norway, Sweden
5. Italy, Austria, Belgium, Netherlands, Switzerland, West Germany
6. Greece
7. United Kingdom

Note a: Percentages for 1981 are actual; percentages for 1983 are actual except those for the United States, Greece, and Japan, which are estimated; and percentages for 1984 are estimated.

[2]More detailed data on the relative use of various pacemaker models in various countries is contained in appendix III.

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.

A new DRG for implanting dual chamber pacemakers might be justified if the effect of the current DRG structure is to provide economic disincentives to the use of such pacemakers when they are warranted. If a new DRG is established, it should be accompanied by criteria identifying those conditions warranting the use of the dual chamber pacemakers to prevent the unnecessary upgrading of pacemakers.

Medicare has established conditions and limitations for the coverage of pacemakers. These guidelines include the medical indications for pacemaker implantation broken into three groups: (1) conditions under which pacemaker use is considered appropriate, (2) conditions under which pacemaker use may be appropriate when the patients' medical history and prognosis document the need, and (3) conditions under which the use of a pacemaker would not normally be appropriate. However, these guidelines do not distinguish between when dual chamber as opposed to single chamber models are appropriate. We believe that, if Medicare were to establish higher paying DRGs for dual chamber models to prevent an economic disincentive toward their use, it would be necessary to expand these pacemaker guidelines to cover the conditions where dual chamber pacemaker use is appropriate. This would help assure that Medicare pays for these higher priced models only when their use is necessary. As discussed in the following section, this type of guidance will also be valuable

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.

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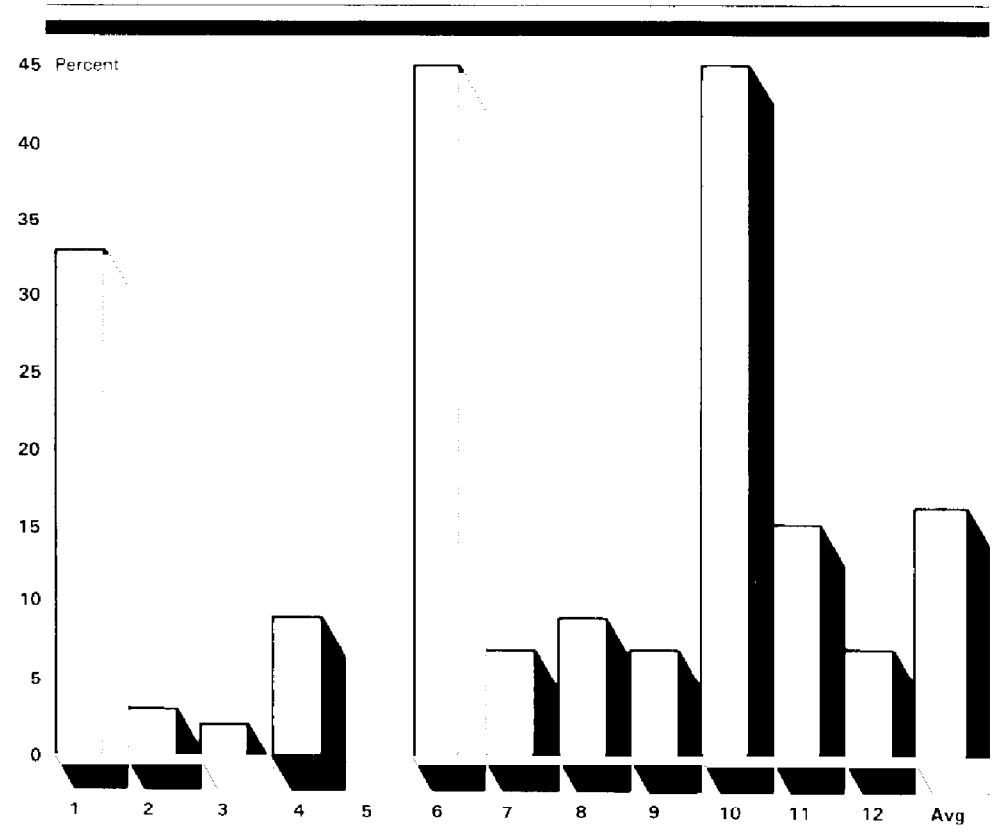
[3]This chapter discusses whether hospitals receive adequate reimbursement for increasingly expensive pacemaker technology under current DRG rates. However, one intermediary official told us that hospitals could resort to a stratagem to get around the DRG rate limitations. The stratagem would involve 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.)

Dual Chamber Pacemakers as a Percent of Total Implants



Twelve Reviewed Hospitals in 1981

The percentage of dual chamber models implanted ranged from 0 to about 45 percent; the average for all 12 hospitals was about 16 percent compared to the 5-percent national average. The higher average is primarily due to three hospitals in which from 33 to 45 percent of all implants in 1981 were of the dual chamber type. We could not account for the high utilization of dual chamber models at these three hospitals; however, several physicians indicated to us that this may be due to the enthusiasm for the new technology. On the other hand, industry sources point out that as with all advances in the medical field, certain hospitals and physicians are quicker to understand and take advantage of new technology than others.

In view of the trend toward increasing use of dual chamber pacemakers, HHS should examine the medical justification for particular types of pacemakers. This is important because of the higher costs associated with dual chamber models. In 1981 the cost of implanting a dual chamber pacemaker was about $1,300

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

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

patient that many necessitate replacing a pacemaker even though it functions within specifications.[5]

Manufacturers also told us, and the medical literature indicates, that physicians may replace pacemakers that are still functioning within their specifications for various legitimate medical reasons. However, the high ratio of explanted pacemakers that are within specifications leads manufacturers to believe that reasons other than changes in the condition of the patient result in physicians removing pacemakers that are functioning within specifications. The rest of this section presents the manufacturers' viewpoints on the reasons for explanting working pacemakers.

Marketing policies and incentive payments could affect utilization of pacemaker services

All four manufacturers we reviewed had pacemaker marketing programs that provided for payment of unreimbursable medical expenses,[6] in part to financially assist patients but also as an inducement to use one of their pacemakers as a replacement of

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[5]Since 1981, there has been a significant shift from nonprogrammable pacemakers to simple and multiprogrammable units, and the manufacturers maintain that this shift in model mix will affect the need for and frequency of replacement procedures. The manufacturers explain that programmability permits the physician to change any one of several of the pacemaker's operating parameters. This, in turn, enables the physician to match the pacemaker's operation to the patient's current and future cardiac condition. Pacing patients often have progressive heart disease, so the patient's condition may change sufficiently over a number of years to warrant either a new pacing unit or extensive reprogramming. In addition, programmability provides an effective means of analyzing and correcting many of the pacing problems that occur during the life of the pacemaker. Through the use of trouble-shooting procedures, made possible by programming, physicians can analyze and correct pacing problems that otherwise would require pulse generator or lead system replacement. Several studies show that multiprogrammability significantly reduces the need for pacemaker replacement surgeries.

[6]Other pacemaker manufacturers not included in our detailed audit had similar programs.

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.

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[7]Payment 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.)

The manufacturer paid out about $85,000 during the 14-month period, of which $52,000 went to physicians, $10,000 to hospitals, and $23,000 to patients.[8]

Another manufacturer promoted a pacemaker exchange program that applied only to the elective replacement of properly functioning pacemakers.[9] The program had two parts. The first part provided for the payment of $1,000 in unreimbursed physicians' fees and hospital expenses incurred in connection with the pacemaker replacement procedure. Unreimbursed medical expenses are those expenses that the Medicare program or any other third party insurer does not pay, including copayments, deductibles and charges deemed not reasonable. About 26 payments of $1,000 were made during a recent 18-month period for surgeries in which a pacemaker manufactured by a competitor was replaced by one from the manufacturer that sponsored the program.

The manufacturer's second incentive program applied to pacemaker replacement surgeries where there were no unreimbursed medical expenses. This program provided for the payment of $500 to hospitals toward the cost of a more advanced pacemaker. About 11 payments of $500 were made under this program for surgeries in which a pacemaker manufactured by a competitor was

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[8]According to company attorneys, a present and a former officer of this company were convicted of violating section 1877(b) of the Social Security Act (see footnote 6) for offering inducements to doctors. Officers of this company stated that they have been advised that any payments, incentives, or consideration to doctors, hospitals, or patients could be illegal and may also be unfair because the Medicare program, which pays for about 85 percent of all pacemaker surgeries, does not receive its share of the incentive payments.

Additionally, in clarification of the above, the company's attorneys add that in their opinion, the federal government should not permit payments to doctors or hospitals of unreimbursed medical or hospital expenses because such payments create a potential pool of money that could be an inducement to doctors or hospitals to purchase pacemakers that are not necessary. They believe that this could be true whether such payments are labeled warranty, sales incentives, or programs by any other name. Such payments also tend to defeat the policies underlying the DRG system because they result in indirect increases in medical and hospital payments.

[9]Elective, in this instance, means that the pacemaker may be nearing the end of its life and may need to be replaced at the convenience of the physician and/or the patient.

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 program[11] 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

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[10]This 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.

[11]This 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.

period. The average medical expense payment by the company was $475 for replacement of its own pacemakers.

Pacemakers replaced under manufacturers' incentive programs are often replaced with more expensive units. HHS should determine the degree to which the tendency toward upgrading pacemakers used in replacements is medically justified.

An analysis of 433 cases involving pacemakers replaced under a manufacturer's incentive program shows a tendency for physicians to upgrade the category of pacemakers when making a replacement. The table below summarizes how the replacement pacemaker compared with the explanted pacemaker category:

	Number of cases	Percent
Upgraded	279	65
Downgraded	10	2
Remained the same	144	33
Total	433	100

The table below is a more detailed comparison of the 433 cases by pacemaker category and shows the extent of changes in the type of pacemaker at replacement:

Explant category[a]	Total replaced	Replacement category[a]			
		S/NP	S/SP	S/MP	D/MP
S/NP	28	6	8	12	2
S/SP	349	7	107	182	53
S/MP	44	-	-	25	19
D/MP	12	-	1	2	9
Total	433	13	116	221	83

[a]S/NP = Single chamber, nonprogrammable.
S/SP = Single chamber, simple programmable.
S/MP = Single chamber, multiprogrammable.
D/MP = Dual chamber, multiprogrammable.

Differences in testing

Industry sources indicate that evaluating whether a pacemaker is functioning normally or is out of specification involves two distinct steps. First the physician must properly evaluate the operation of the pacing system based on standard

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

is complex, requiring precise and time-consuming measurements. For example, several pulse generator models have parameters that vary with temperature. At reoperation, the pulse generator temperature can decrease quickly. This can cause pulse duration to be lengthened considerably and interval to be lengthened somewhat. In these cases it is necessary to estimate how much of the observed measurement variation is due to temperature and how much is due to normal power cell depletion.

Also, pacing system analyzer measurements are not always performed in the same manner as the specifications require, so the results may be inaccurate. For example, once the pulse generator is connected to the analyzer, the physician should allow at least a minute for the pulse generator to stabilize with the load of the analyzer or readings may be inaccurate. In cases where the pulse generator has been connected to a low impedance failed lead, the physician should allow 10 or more minutes before testing the pulse generator to allow the power cell to return to its regular voltage. If the generator is tested too soon, it may falsely appear to be out of specification.

Manufacturers also noted that not all pacing system analyzers will accurately measure the parameters of all pulse generators. Calibrations are defined differently for different analyzers. Also, accuracy is somewhat reduced if the analyzer is one manufactured by someone other than the pacemaker's manufacturer. Generally, the measurements by competitors' analyzers of pulse width and rate are reasonably comparable, but amplitude and current measurements may vary as much as 10 percent, and sensitivity measurements will show greater variations. Also, some pacing system analyzers cannot handle the newer dual-chamber units. Manufacturers believe, however, that limitations of the equipment are likely to be of less significance than the problems described above in how the analysis is conducted.

Another factor that may lead to physicians replacing pacemakers that are still within specifications is that physicians' and hospitals' equipment for testing pacemaker failure is not as sophisticated as the manufacturers' equipment. The reason is that the equipment used by physicians and hospitals is designed for noninvasive testing, while the pacemaker is still in the patient's body, whereas the manufacturers' equipment is designed for testing after the pacemaker has been removed. Physicians, thus, judge the performance of the pacemaker under conditions that are different from those available to the manufacturer.

Physicians may also tend to decide to remove a pacemaker that has not reached the replacement stage when the patient is in the hospital for another reason and the physician does not want to subject the patient to another hospitalization in the

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.

RECOMMENDATIONS

We recommend that the Secretary of HHS direct the Administrator of HCFA to

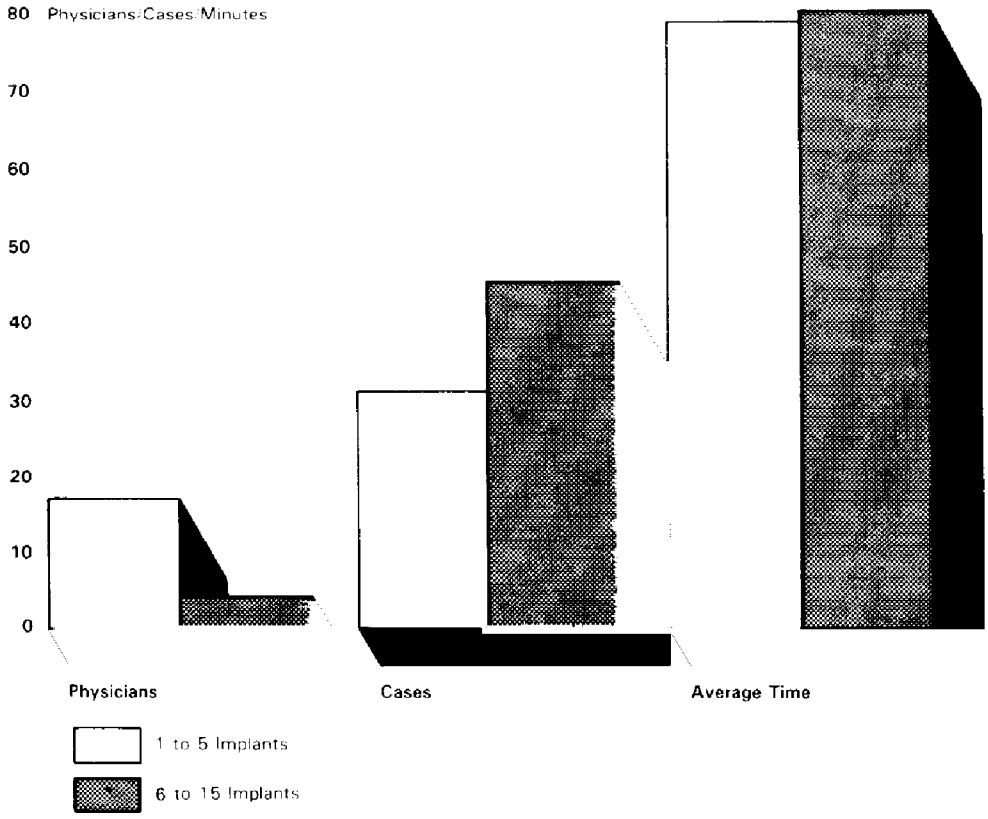
--determine the conditions under which the use of dual chamber pacemakers is medically warranted;

--determine if the increased use of dual chamber pacemakers, to the extent justified by medical necessity, warrants establishing separate DRGs for them; and

--review the situations resulting in the replacement of pacemakers that are still functioning within specifications to determine if unnecessary replacements occur and, if so, take action to minimize unnecessary replacements. The information that would be obtained by implementing our recommendation in chapter 2 to require the return to manufacturers and testing of all explanted pacemakers would help provide the data necessary for this review.

APPENDIX I

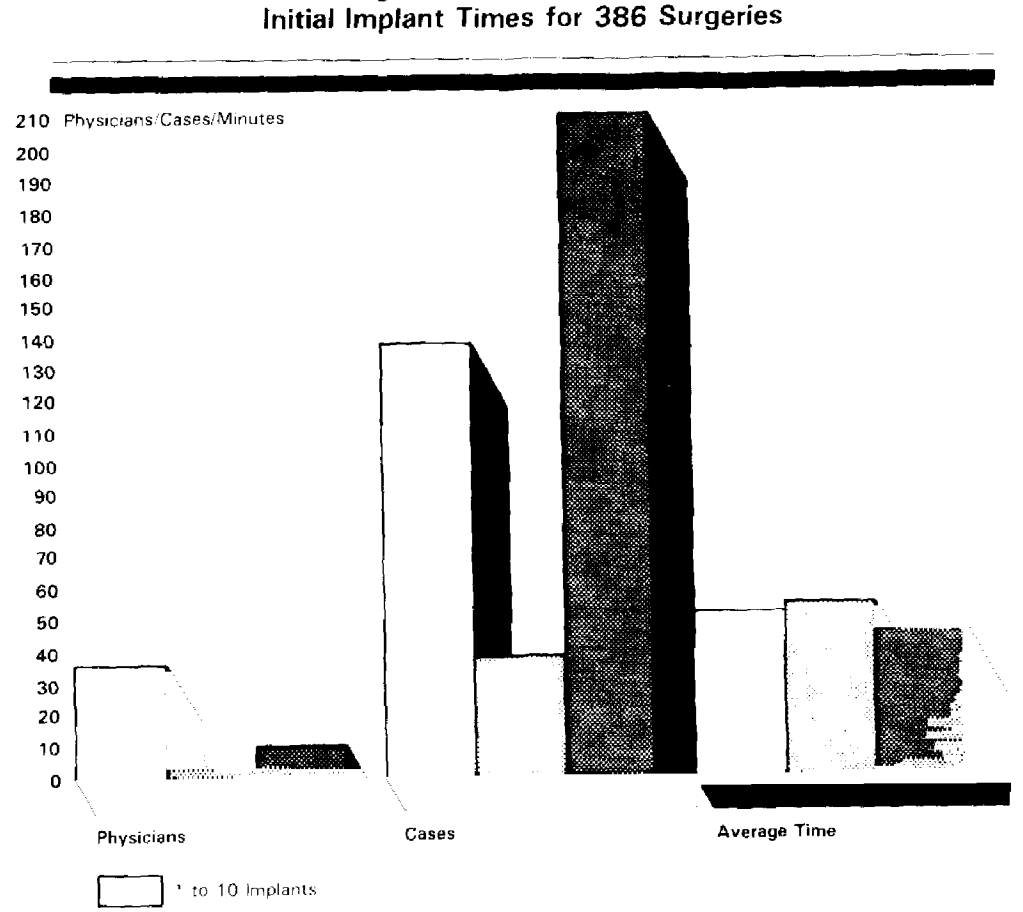
Dual Chamber Pacemakers
Initial Implant Times for 76 Surgeries



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.

Single Chamber Pacemakers
Initial Implant Times for 386 Surgeries

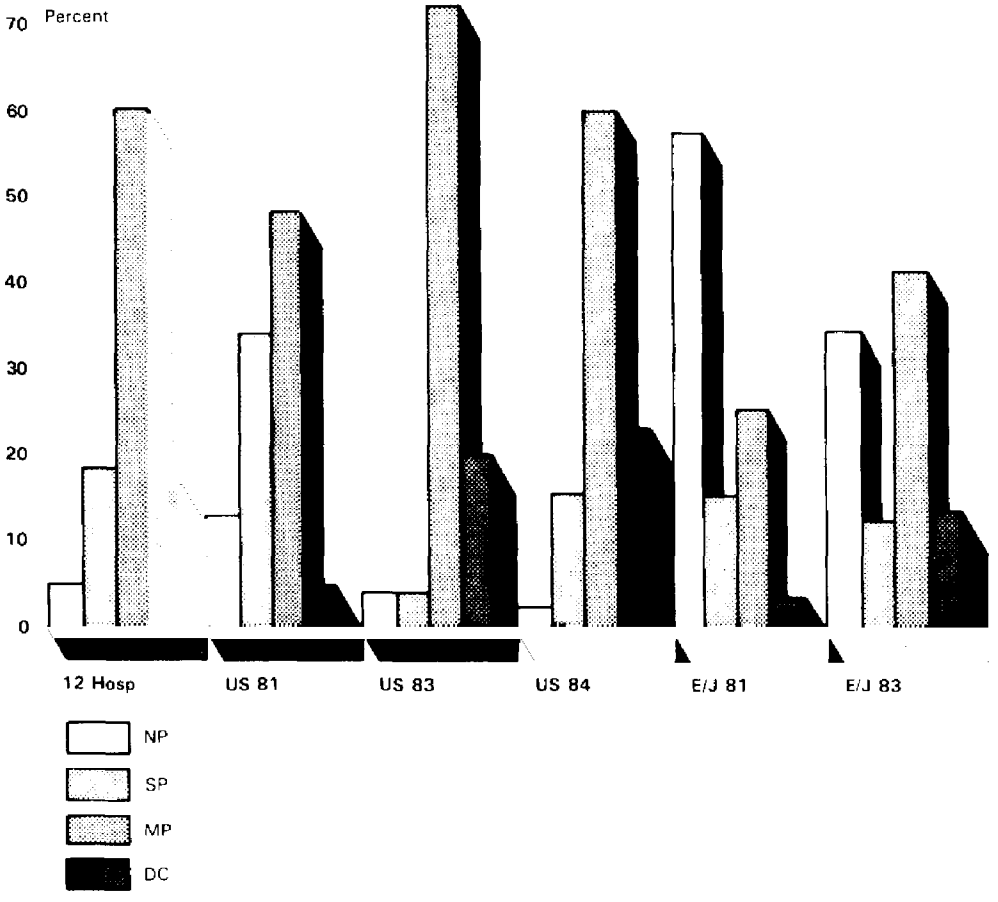


For 36 physicians who performed from 1 to 10 surgeries, implanting a total of 137 single chamber pacemakers, the average time was about 51 minutes per surgery.

For 3 physicians who performed from 11 to 20 surgeries, implanting a total of 38 single chamber pacemakers, the average time was about 54 minutes per surgery.

For 10 physicians who performed more than 20 surgeries, implanting a total of 211 single chamber pacemakers, the average time was about 46 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

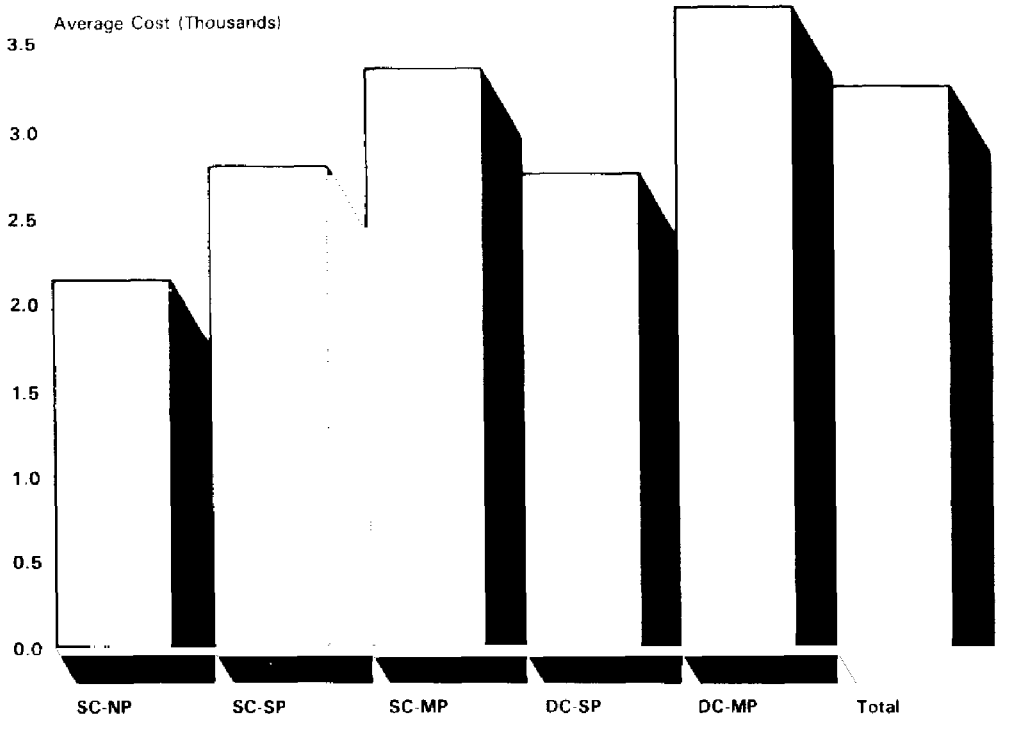
NP = Single chamber nonprogrammable

SP = Single chamber simple programmable

MP = Single chamber multiprogrammable

DC = Dual chamber pacemakers

Average Cost by Pacemaker Type
Twelve Hospitals, 1981



SC-NP = 52 single chamber nonprogrammable implantations

SC-SP = 199 single chamber simple programmable implantations

SC-MP = 639 single chamber multiprogrammable implantations

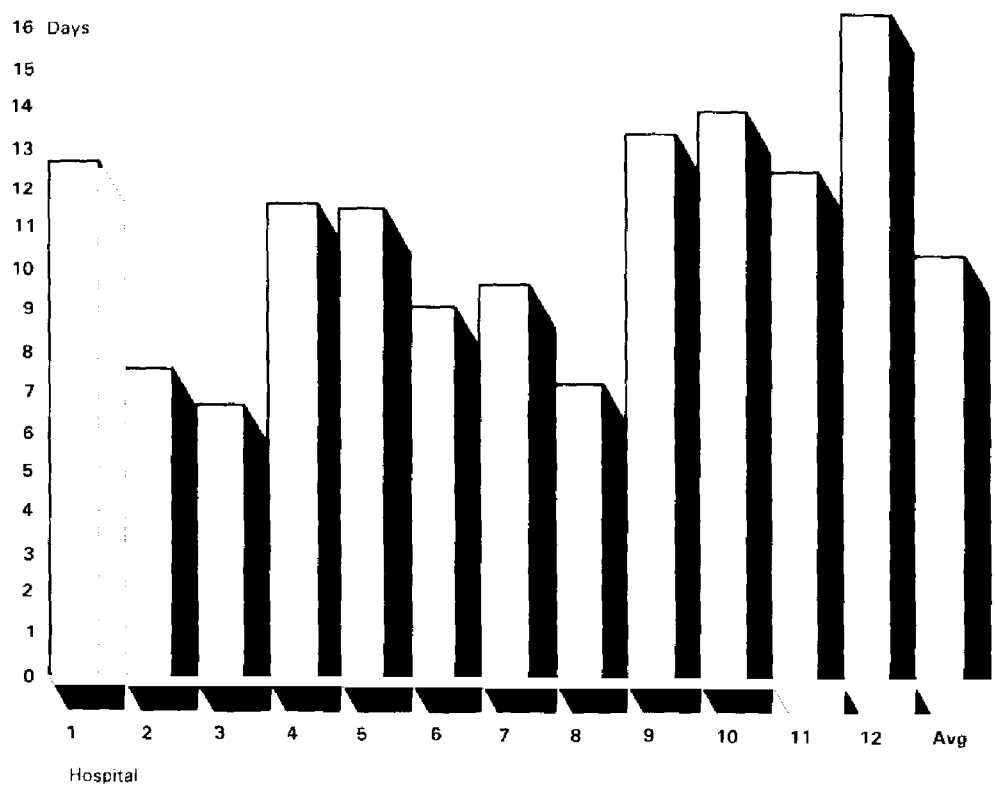
DC-SP = 3 dual chamber simple programmable implantations

DC-MP = 170 dual chamber multiprogrammable implantations

TOTAL = 1,063 total implantations

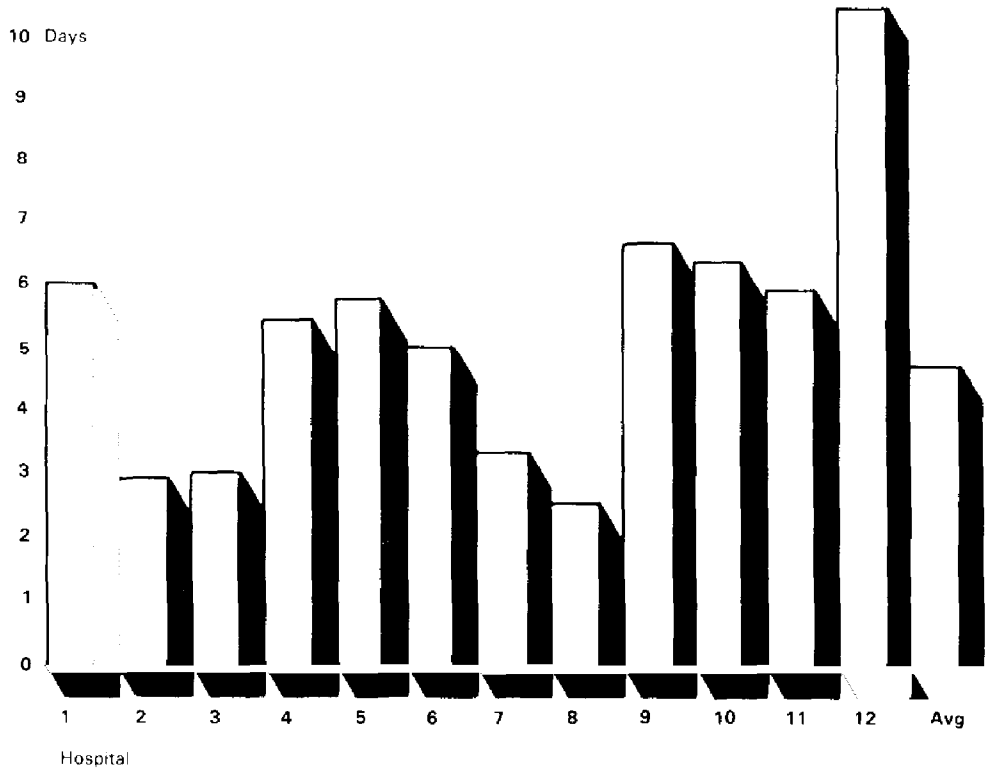
APPENDIX V

Average Length of Stay
Initial Implants, 1981



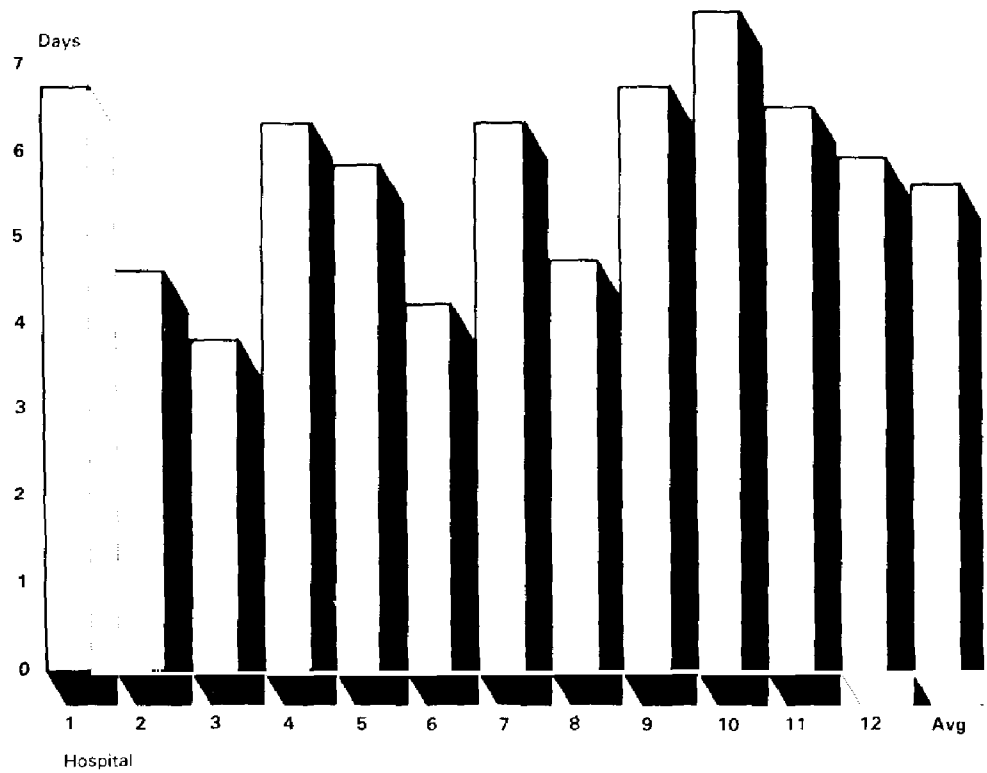
APPENDIX VI

Average Length of Stay
Initial Implant, Admission to Operation



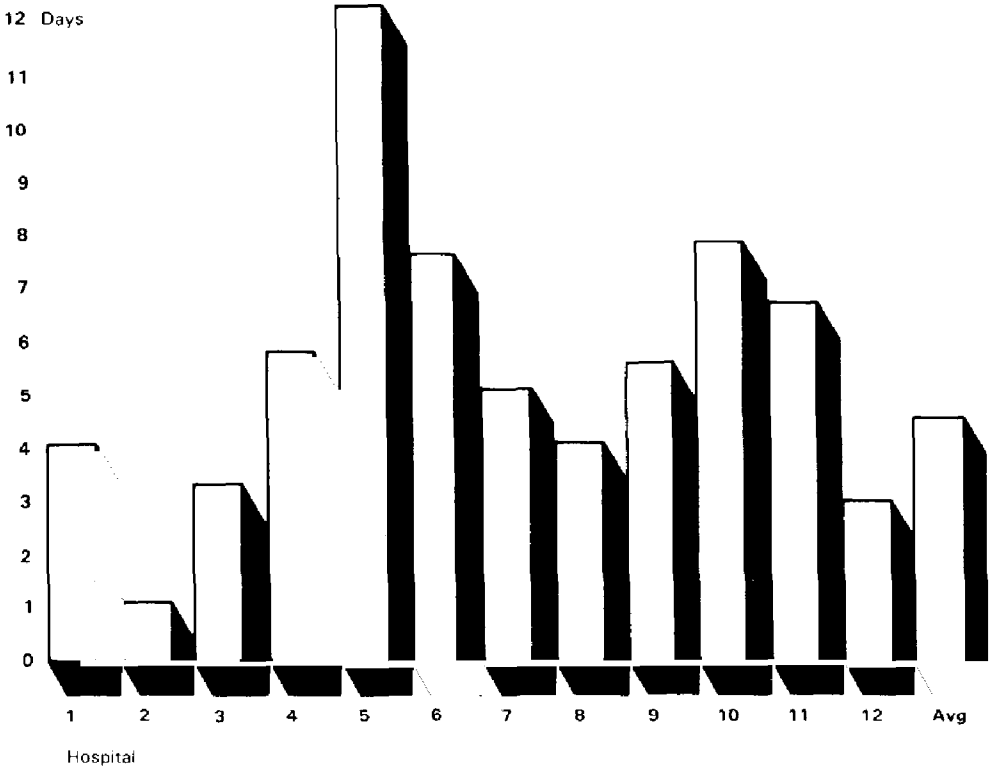
APPENDIX VII

Average Length of Stay
Initial Implant, Operation to Discharge



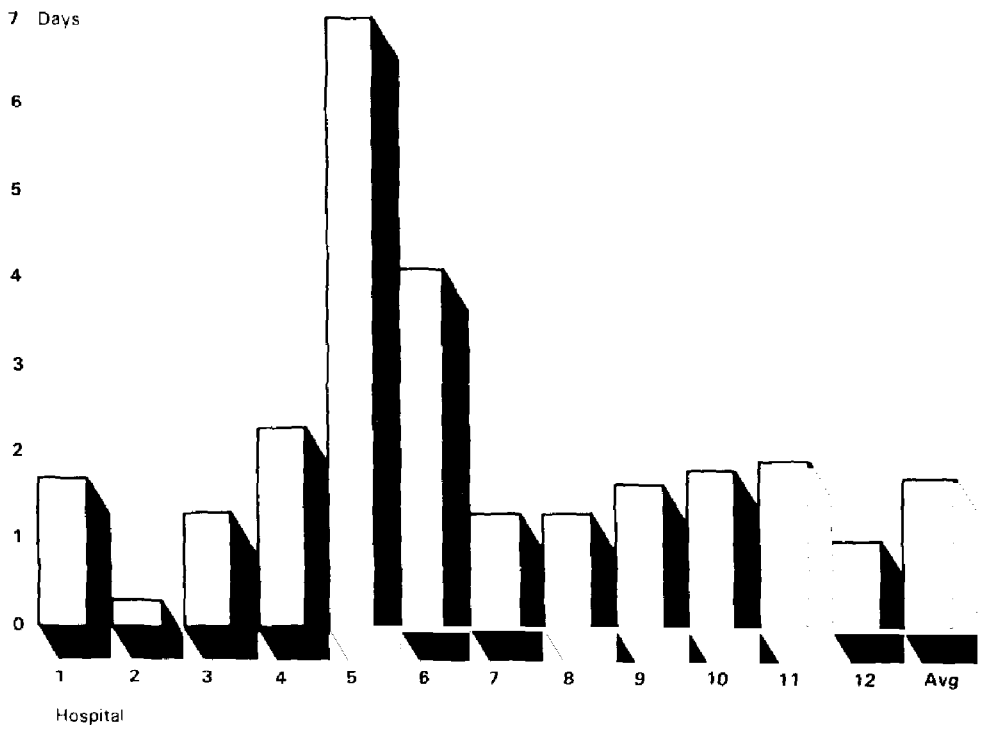
APPENDIX VIII

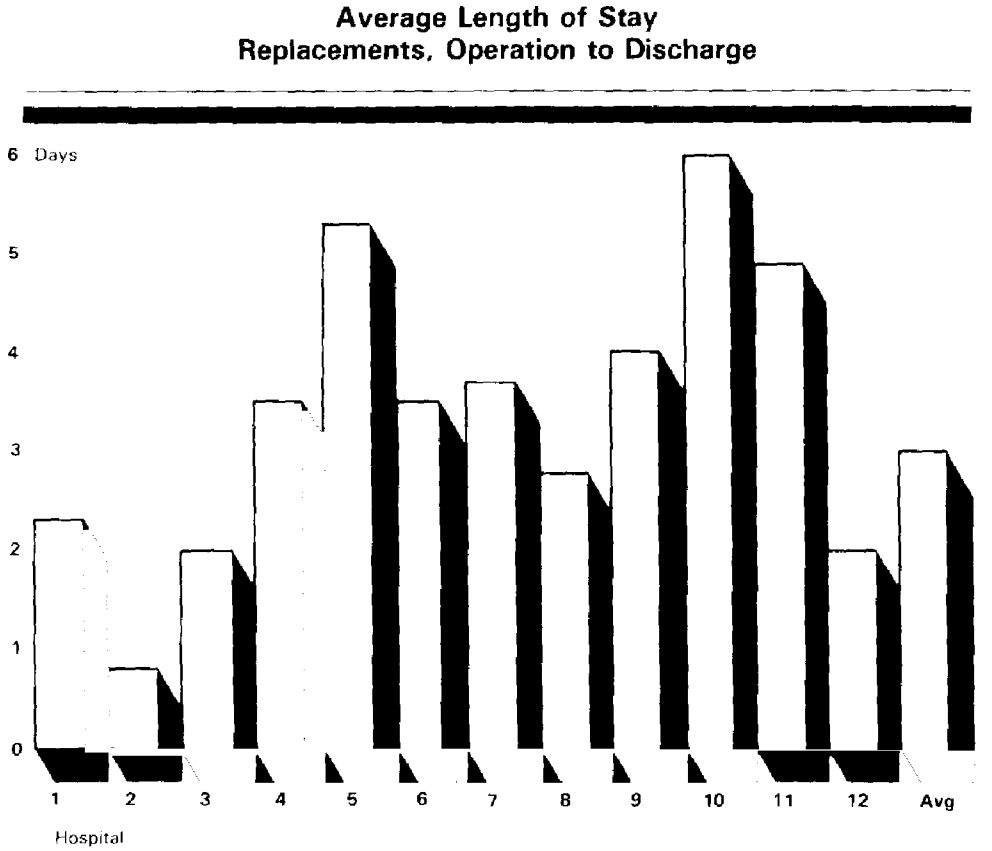
Average Length of Stay
Replacements, 1981



APPENDIX IX

Average Length of Stay
Replacements, Admission to Operation




Average Length of Stay
Replacements, Operation to Discharge
6 Days
5
4
3
2
1
0
1
2
3
4
5
6
7
8
9
10
11
12
Avg
Hospital

APPENDIX XI

medicare
Part A Intermediary Letter
Part B Intermediary Letter

Department of Health and Human Services

Health 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.

(3) Paragraphs (1) and (2) shall not apply to--
(A) a discount or other reduction in price obtained by a provider of services or other entity under this title if the reduction in price is properly disclosed and appropriately reflected in the costs claimed or charges made by the provider or entity under this title; and
(B) any amount paid by an employer to an employee (who has a bona fide employment relationship with such employer) for employment in the provision of covered items or services."

II. Possible Violations

Some suppliers may be offering rebates, kickbacks, or free goods, such as the following:

(A) Some pacemaker manufacturers offer pacemaker monitoring equipment to hospitals and physicians at no charge, to induce the purchase, or the recommendation for purchase, of their pacemakers rather than competing models.

(B) Some manufacturers of intraocular lenses and related products are furnishing additional products or other gifts to ophthalmologists at no charge in exchange for ordering their products.

III. Action

Instances of this type of activity which come to your attention should be reported to the Office of the Inspector General for investigation.

Attached are copies of letters to pacemaker and intraocular lens suppliers from the Administrator advising them that this type of activity may be in violation of 1877(b). Carriers should date, address, and send a copy of this letter to each supplier of pacemakers or intraocular lenses who has submitted bills to the carrier in the past year.

Attachment

(106241)

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