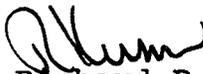


**Memorandum**

Date . SEP 4 1990

From   
Richard P. Kusserow  
Inspector General

Subject The Effect of the Interim Payment Rate for the Drug Epogen  
on Medicare Expenditures and Dialysis Facility Operations  
(A-01-90-00512)

To  
  
Gail R. Wilensky, Ph.D.  
Administrator  
Health Care Financing Administration

Attached is our final management advisory report summarizing our review of the interim rate for Epogen (EPO) and its effect on Medicare expenditures and dialysis facility operations.

Our review showed that several of the key assumptions that were made in developing Medicare's interim flat reimbursement rates of \$40 for dosages less than 10,000 units and \$70 for dosages of 10,000 units or more, are no longer valid. Specifically, we found that the average dose of EPO dispensed is approximately 2,700 units as opposed to the 5,000 estimated by the Health Care Financing Administration (HCFA) from the clinical trial data. In addition, multiple withdrawals of EPO are being dispensed from single-use vials which enhances facility profits but is contrary to labeling instructions. Moreover, the EPO market penetration in the first year is about 50 percent as opposed to the initial estimate of 20 percent. Because the facilities are administering lower dosages and dispensing multiple withdrawals from the vials, the average gross profit margin to dialysis facilities is in excess of 40 percent.

We are recommending that HCFA consider reimbursing EPO based on units administered rather than a flat rate. Assuming the current dosage level is medically appropriate, we estimate this could save Medicare about \$80 million annually. Moreover, the beneficiaries' copayment would also decrease by about \$20 million. In response to our recommendation, HCFA advised they are analyzing the data on the first year of EPO payments and will address the issue of changes to the payment rates after the analysis is complete.

Page 2 - Gail R. Wilensky, Ph.D.

Please advise us, within 60 days, on actions taken or planned on our recommendations. If you need further information, please contact Thomas D. Roslewicz, Deputy Inspector General for Audit Services. Copies of this report are being sent to other interested top Department officials.

Attachment

# U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

THE EFFECT OF THE INTERIM  
PAYMENT RATE FOR THE DRUG  
EPOGEN ON MEDICARE EXPENDITURES  
AND DIALYSIS FACILITY OPERATIONS



Office of Inspector General  
Office of Audit Services

**THE EFFECT OF THE INTERIM  
PAYMENT RATE FOR THE DRUG  
EPOGEN ON MEDICARE EXPENDITURES  
AND DIALYSIS FACILITY OPERATIONS**



**OFFICE OF INSPECTOR GENERAL  
OFFICE OF AUDIT SERVICES**

**CIN: A-01-90-00512**

# CONTENTS

	<u>Page</u>
SUMMARY	1
BACKGROUND	2
METHODOLOGY	3
RESULTS OF REVIEW	4
Current Dosage Levels	5
Multiple Withdrawals of EPO From Single-Use Vials	6
Market Penetration and Program Outlays	7
Provider Gross Profit Margins	7
RECOMMENDATION	9
APPENDIX I	Statistical Data for Nineteen Fiscal Intermediaries Reviewed
APPENDIX II	Average Dialysis Facility Gross Profit Margin for Nineteen Intermediaries Reviewed
APPENDIX III	Estimate of Cost Savings at Various Levels of Market Penetration
APPENDIX IV	Frequency Distribution of EPO Sample Claims
APPENDIX V	HCFA Response to Draft Management Advisory Report

## SUMMARY

On June 1, 1989, the Food and Drug Administration (FDA) approved Amgen Incorporated's (Amgen) product licensing application to manufacture the drug Epoetin alfa. Epogen (EPO) is Amgen's trademark name for Epoetin alfa and it's indicated use is for the treatment of anemia associated with chronic renal failure. The Medicare program covers approximately 93 percent of the patients with chronic renal disease who require dialysis or kidney transplant. The Health Care Financing Administration (HCFA) established a policy to pay for the drug as an add on to the prospective payment rate for dialysis services. The rate was established at \$40 per treatment for dosages under 10,000 units and \$70 for dosages 10,000 units and above. Total expenditures for the first year were estimated at \$125 million, with Medicare's share at 80 percent expected to be \$100 million. Our review examined the effect of the interim rate for EPO on Medicare expenditures and dialysis facility operations.

The HCFA developed the interim payment rates for EPO with assistance from the Office of Inspector General (OIG). The OIG was not able to audit or independently verify accounting records but relied on financial data supplied by Amgen. In developing the rate, there were several important assumptions made such as: (1) the average dose of EPO per treatment, (2) the method by which EPO would be dispensed, and (3) the market penetration. Our review shows that these key assumptions are no longer valid. Specifically, we found that:

- o the average dose of EPO dispensed is approximately 2,700 units as opposed to the 5,000 estimated by HCFA from the clinical trial data;
- o multiple withdrawals of EPO are being dispensed from single-use vials which enhances facility profits but is contrary to labeling instructions, and
- o the market penetration for EPO in the first year is around 50 percent as opposed to the initial estimate of 20 percent.

Because facilities are administering lower EPO dosages and practicing multiple withdrawals, the average gross profit margin to the dialysis facilities is in excess of 40 percent. Based on a 50 percent market penetration and the effect of lower dosages and multiple withdrawals we estimate that in the first year: (1) Medicare expenditures could increase to about \$265 million and (2) gross profits to the providers may reach in excess of \$100 million. We believe by changing the current methodology from a flat

rate to one that is based on units administered, the Medicare program could save \$80 million annually or \$400 million over the five-year budget cycle. Moreover, the beneficiaries co-insurance payments would decrease by about \$20 million, annually.

We believe the results of this analysis are pertinent to HCFA's consideration for developing options for changes in the payment methodology. Accordingly, we recommend that HCFA consider as one of their options, reimbursing EPO based on units administered, not to exceed \$40 per dose for less than 10,000 units. This method should begin to moderate the excessive profits at the provider level and reduce beneficiary and program expenditures due to lower dosages.

The HCFA comments to the draft management advisory report indicated concern that payment based on actual dosage could create incentives to provide more of the drug than is necessary and to provide it to more patients than require it. The HCFA also indicated they are currently analyzing data on the first year of EPO payments and will address the issue of changes to the payment rate after the analysis is completed.

We believe that Medicare payments for EPO based on actual dosage would eliminate any financial incentive to administer improper dosages. Any significant delay in adjusting the reimbursement rate will result in unnecessary payments of at least \$80 million a year to the Medicare program and an additional \$20 million to beneficiaries.

## **BACKGROUND**

Epogen is Amgen, Inc.'s trademark name for Epoetin alfa. Epogen stimulates red blood cell production and is used to combat anemia which is common in dialysis patients. The red blood cell count is monitored by hematocrit readings. The desired hematocrit range is 30 to 33 percent in dialysis patients. Epogen produces a number of benefits to dialysis patients through the increase in red blood cells, such as; reduction in transfusions, improved cardio-vascular condition, and a general feeling of improved well-being. Possible adverse effects are hypertension, iron deficiency and clots. Dosages of EPO are regulated to control these adverse effects.

Amgen, Inc. (a biotechnology company), obtained an orphan drug designation which provides exclusive marketing rights for 7 years and tax credits as incentives to drug manufacturers to develop drugs for the treatment of rare diseases. Amgen, Inc., received approval from the FDA on June 1, 1989, to market EPO for dialysis patients in the United States. Amgen, Inc., and other drug companies have been involved in litigation concerning the marketing rights of EPO in the United States. Resolution of these disputes is still ongoing.

Epogen is marketed in single-use vials of 2,000, 4,000 and 10,000 units. The Amgen, Inc., package insert states the vials should be used for only one dose and the vial should not be reentered. Unused portions should be discarded because the vial contains no

preservatives. The FDA defines a single-use vial as one designed to hold a quantity of a drug product intended for administration as a single dose. Normally, EPO is administered intravenously at the end of the dialysis treatment.

The ESRD patients are covered by the Medicare program at 80 percent of a predetermined rate (the beneficiary is responsible for the remaining 20 percent of the rate under co-insurance). The current interim reimbursement rate is \$40 for an EPO dose less than 10,000 units and \$70 for an EPO dose of 10,000 units or more. Medicare fiscal intermediaries (FI) are responsible for processing EPO claims that are submitted by dialysis facilities in accordance with rules and regulations set forth by HCFA.

Epogen is covered for the treatment of anemia for patients with chronic renal failure who are on dialysis when:

- o it is administered in the renal dialysis facility; or
- o it is administered "incident to" a physician's service.

Epogen is not covered when self administered.

It is estimated that about 106,000 beneficiaries are covered under the Medicare ESRD program. Currently, there are approximately 1,720 certified dialysis facilities who provide outpatient maintenance dialysis services.

## METHODOLOGY

The primary objective was to determine the effect of the interim rate established for EPO on Medicare expenditures and dialysis facility operations. Our examination included a review of the market penetration of the drug, dosage levels, patient administration and facility drug profit margins.

To accomplish our objective, we selected 19 Medicare FIs, 11 of which were chosen based on volume and the remaining 8 which were statistically selected (See APPENDIX I). For each FI, we statistically sampled a minimum of 200 EPO claims processed through November 30, 1989.<sup>1</sup> We analyzed the dosage levels reported by the dialysis facility on the claim and computed a mean, median and mode for each FI. There was no material difference in the average mean between the FIs selected judgmentally or statistically sampled. Validation of claims data and follow-up work was done at selected ESRD facilities in Region I.

The cost of EPO to the dialysis facilities was obtained from wholesaler invoices. Our analysis at selected facilities in Region I showed that the cost of a 4,000 unit vial was about \$41 or about \$10.25 per 1,000 units. One large chain indicated that they are

---

<sup>1</sup> Delaware Blue Cross had only 10 claims processed as of the date of our review.

currently negotiating a discount based on volume. Discussions with several dialysis facilities administrators and managers indicated that Amgen does not sell directly to dialysis facilities.

Information regarding the medical practice of dispensing EPO was obtained primarily from interviews with people involved in the Amgen clinical trials including; nephrologists, personnel at the FDA, ESRD facility administrators and nurses, and analysis of medical records. We also observed the dispensing of EPO to patients at one of the dialysis facilities included in our sample.

In estimating the market penetration (number of beneficiaries on EPO), we primarily relied upon oral testimony from several ESRD dialysis facilities, including a large chain organization. Current statistical information regarding market penetration is not always up to date due to the time lag between the date of service, the submission of the claim to the FI for payment and the reporting of this information to HCFA. Information provided to us by Amgen for the initial rate development was also utilized for comparison with current market conditions.

Methods used to estimate costs and savings are identified in the APPENDICES II & III.

Our review was performed during the period November 1989 through March 1990 at the 19 FIs listed in APPENDIX I. We also held discussions with personnel at HCFA Headquarters in Baltimore, FDA in Bethesda, Maryland, and several independent and hospital based dialysis facilities located in Region I.

On May 8, 1990, our draft report was provided to HCFA for comments. Their written comments, dated July 16, 1990, are appended to this report. (See APPENDIX V)

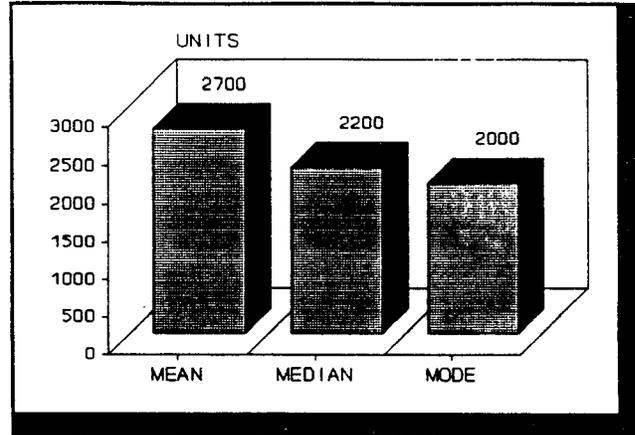
## **RESULTS OF REVIEW**

When an interim rate was established of \$40 per dosage up to 10,000 units, total annual payments for that drug were estimated at about \$125 million. Since Medicare pays 80 percent of the rate, program expenditures were estimated to be \$100 million. The interim rate was established using the assumption that the market penetration during the first year would be about 20,000 patients. Our review indicates that about 50 percent of the Medicare population or about 50,000 beneficiaries are currently using the drug which will more than double Medicare's anticipated expenditures. An additional assumption from the clinical trial data was that the average dosage per patient would be 5,000 units. Our results show that the average dosage is about 2,700 units which has generated a windfall profit of 44 percent to the facilities. The effects of each of these assumptions using the current flat rate of \$40 is discussed below.

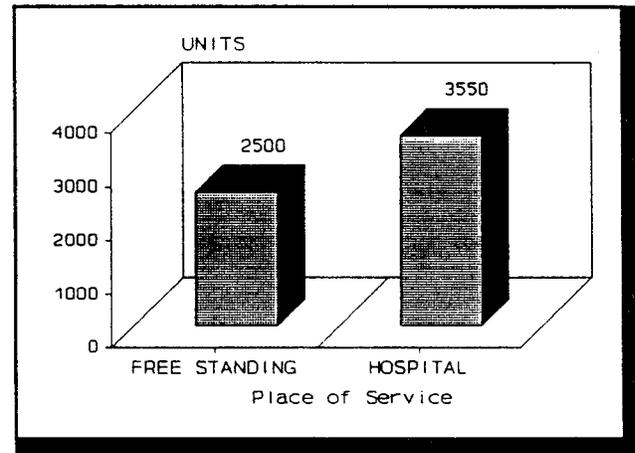
## Current Dosage Levels

The Amgen, Inc., clinical studies showed that the median maintenance dose of EPO was approximately 5,000 units. Our review of 3,622 statistically selected Medicare reimbursement claims showed an arithmetic mean EPO dosage of about 2,700 units, a median dose of 2,200 units and a mode dose of 2,000 units (Figure 1). Further analysis of the claim data also showed that: 50 percent were at 2,000 units or below, 47 percent were from 2,001 units through 4,000 units, and the remaining 3 percent exceeded 4,000 units. (See APPENDIX IV)

We also compared the average dosage level for ESRD beneficiaries at independent facilities to those at hospital based facilities. For independent facilities the mean average EPO dose was about 2,500 units, and for hospital based facilities, the mean average EPO dose was about 3,550 units (Figure 2). Medical personnel in the dialysis field informed us that the higher EPO doses at hospital based facilities may be attributable to the treatment of a case mix of patients with lower hematocrit counts, and less concern with the reimbursement of costs associated with higher dosages. On the other hand, most independent facilities are for profit and their decisions to dispense lower dosages may be twofold, i.e., medical practice and economics.



*Figure 1 - Measures of Central Tendency for EPO dosages.*



*Figure 2 - Comparison of Average Dosage - Independent Dialysis Facility vs Hospital Based Facility*

We recognize that the medical practice for EPO is very new and changing. As part of the review, we did a limited comparison of the EPO doses for 60 patients at least 3 months after the sample period to determine if their dosage and hematocrit had changed. This comparison showed:

- o for 53 patients the dosage level remained the same or decreased, while 7 patients received an increase in EPO.
- o the average EPO dosage for the 60 patients went from 2,210 to 1,940 or a decrease of about 270 units over the last 3 months.
- o 14 patients were not at the desired hematocrit level of 30 at the end of the 3-month period. Their average dosage units decreased slightly and was at 2,050 at the end of the review period.

Although our comparison was limited, we believe this type of analysis is important and needs to be expanded to determine whether lower dosages are medically appropriate.

#### Multiple Withdrawals of EPO from Single-Use Vials

Amgen, Inc.'s package insert for EPO states that only one dose should be withdrawn per vial, the vial should not be reentered, and unused portions should be discarded. The package insert also states the vial of EPO contains no preservatives. Nevertheless, we found it was widespread practice for facilities, both free-standing and hospital based, to make multiple withdrawals from the same vial.

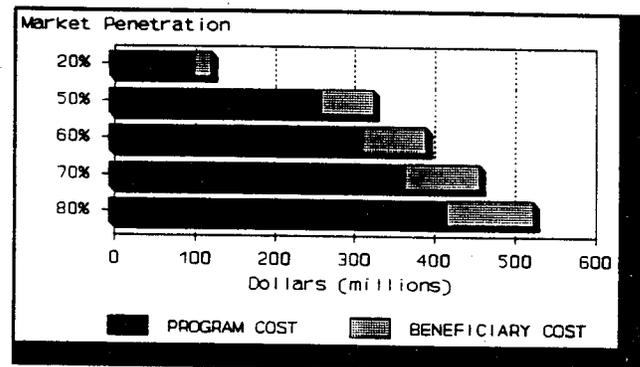
Interviews with medical personnel, who practice multiple withdrawal, indicated that if done under the proper quality control procedures, there should be minimal risk to the patient. They also noted that the level of EPO dosages can vary among patients and may fall between the 2,000 and 4,000 unit vial package size. In their opinion, it seems impracticable to discard the unused portion considering the cost of the drug.

In contrast, some medical authorities in the dialysis field have serious reservations about multi-use of the vials because of the possibility of infection of patients. However, the EPO vial sizes do not leave them with the flexibility to dispense the appropriate dose and also be economical and efficient. For example, if the appropriate dosage falls between 2,000 and 4,000 units, the facility will either incur waste and the costs associated with using a large vial size, or reduce the dosage to 2,000 units.

The multiple withdrawal from single-use vials is of great concern to us from a quality of care standpoint since it deviates from the manufacturer's prescribed method for which EPO is to be administered. We requested in a report dated March 1990, FDA's position as to whether the multiple withdrawals of EPO from single-use vials are appropriate from a medical and FDA labeling standpoint. FDA advised us the precautionary statements, in part, address the concern for the possibility of introducing microbial contamination due to multiple entries into the vial and subsequent growth of the contaminant in the absence of a preservative. In addition, FDA commented there may be unknown effects on product stability due to temperature fluctuation and unknown storage conditions during vial usage periods.

### Market Penetration and Program Outlays

In the development of the interim rate, HCFA estimated that EPO in the first year would be utilized by approximately 20,000 ESRD beneficiaries, or about 20 percent of the ESRD population. Considering that EPO is a sole source drug and Medicare is the primary payer, program outlays need to be closely monitored. Based on our survey of selected facilities and discussions with a large national chain organization, the current market penetration is about 50 percent. This rise in EPO utilization could increase the initial estimate of Medicare program outlays from \$125 million to about \$330 million in the first year (Figure 3), of which 20 percent will be absorbed by the beneficiary.



*Figure 3 - Estimated Program and Beneficiary Outlays for EPO at Different Levels.*

### Provider Gross Profit Margins

The practice of multi-withdrawal from the same single-use vial and lower dosage has a significant impact on establishing a fair and reasonable payment rate for EPO. The HCFA has established an interim payment rate to the dialysis facilities of \$40 per dose of EPO for less than 10,000 units. Our review at selected ESRD facilities disclosed that the average cost of EPO from drug wholesalers is about \$41 per 4,000 unit vial, or about \$10.25 per 1,000 units. Considering that EPO is sold only in vial sizes of 2,000, 4,000, or 10,000 units, the practice of multiple withdrawal reduces waste which in turn reduces cost and increases profits to the medical providers. In this regard, facilities are not constrained by package size and, therefore, can vary dosage levels while still maximizing their profit margin. For example, a facility administering 2,500 units of EPO to 1 patient and 1,500 units to another patient could give 2 administrations from a 4,000 unit



## RECOMMENDATION

We recommend that HCFA consider:

- o **Eliminating the flat interim rate and establish a payment rate based on actual units of EPO administered up to a capped amount.**

### HCFA Comments

The HCFA response to the draft management advisory report noted HCFA's concern that payment based on actual dosage could create incentives to provide more of the drug than is necessary and to provide it to more patients than require it. The HCFA response also stated that they are analyzing data on the first year of EPO payments and will address the issue of changes to the payment rate after the analysis is completed.

### OIG Response

We believe that Medicare payment for EPO based on actual dosage would eliminate any financial incentive to administer improper dosages. The data shows that the average dosage has declined from 5,000 units in the clinical trials to the 2,700 units being administered under HCFA's current payment mechanism. The data also shows sharp differences in the average dosage between free-standing and hospital based dialysis facilities. We believe there is a correlation between the lower dosages and HCFA's current payment policy which creates an incentive for facilities to earn higher profits by administering lower dosages of EPO. Under any payment policy, however, HCFA should have an active medical review program to assure that patients receive appropriate dosages.

We disagree that our recommended payment rate based on actual units administered would encourage the administration of EPO to more patients. In fact, under the current reimbursement policy there is a strong incentive to treat more patients with a low dosage level of EPO (2,000 units and below) because of the profit incentive. Also, our recommendation would be consistent with HCFA's current reimbursement policy for other separately billable ESRD drugs which are reimbursed based on units administered.

We recognize that the present EPO reimbursement rate is an interim one. Nevertheless, the actual EPO dosage levels identified in our review are significantly below the level anticipated in establishing the interim reimbursement rate. As a result, a significant delay in adjusting the rate will result in unnecessary payments being incurred by the Medicare program and the potential continuation of a 40 percent gross profit margin to facilities.

## **A P P E N D I C E S**

## STATISTICAL DATA FOR NINETEEN INTERMEDIARIES REVIEWED

INTERMEDIARY	MEAN DOSE	MEDIAN DOSE	MODE DOSE
JUDGMENTAL SAMPLE:			
BLUE CROSS OF MASS., INC.	1,912	2,000	2,000
EMPIRE BLUE CROSS	3,414	3,000	2,000
B.C. OF MARYLAND, INC.	2,675	2,000	2,000
B.C. OF VIRGINIA	2,548	2,000	2,000
B.C./B.S. OF ALABAMA	2,974	3,000	4,000
B.C./B.S. OF FLORIDA	2,275	2,000	2,000
HEALTH CARE SERVICE CORP. IL.	3,016	2,000	2,000
B.C./B.S. OF MICHIGAN	2,754	3,000	3,000
GROUP HOSPITAL SERVICE, TEXAS	2,488	2,000	2,000
B.C. HOSPITAL SERVICE OF MISSOURI	2,794	2,000	2,000
B.C. OF SOUTHERN CALIFORNIA	2,658	2,500	2,000
RANDOM SAMPLE:			
N.H. - VERMONT HEALTH SERVICE	2,432	2,000	2,000
B.C./B.S. OF DELAWARE, INC.	1,850	2,000	2,000
B.C./B.S. OF MISSISSIPPI	2,180	2,000	2,000
B.C./B.S. OF GEORGIA	2,495	2,000	2,000
BLUE CROSS OF IOWA	3,631	4,000	4,000
B.C./B.S. OF UTAH	3,042	3,000	*
AETNA LIFE & CASUALTY, CAL.	2,794	2,000	2,000
B.C./B.S. OF ARIZONA	2,615	3,000	3,000

\* There were an equal number of claims with dosage levels 2,000 units and 4,000 units.

## APPENDIX II

## AVERAGE DIALYSIS FACILITY GROSS PROFIT MARGIN FOR NINETEEN INTERMEDIARIES REVIEWED

## JUDGMENTAL SAMPLE:

	AVERAGE DOSE	COST PER DOSE	RATE	MARK-UP
BLUE CROSS OF MASS., INC.	1,912	\$19.60	\$40.00	\$20.40
EMPIRE BLUE CROSS	3,414	34.99	40.00	5.01
B.C. OF MARYLAND, INC.	2,675	27.42	40.00	12.58
B.C. OF VIRGINIA	2,548	26.12	40.00	13.88
B.C./B.S. OF ALABAMA	2,974	30.48	40.00	9.52
B.C./B.S. OF FLORIDA	2,275	23.32	40.00	16.68
HEALTH CARE SERVICE CORP. IL.	3,016	30.91	40.00	9.09
B.C./B.S. OF MICHIGAN	2,754	28.23	40.00	11.77
GROUP HOSPITAL SERVICE, TEXAS	2,488	25.50	40.00	14.50
B.C. HOSPITAL SERVICE OF MISSOURI	2,794	28.64	40.00	11.36
B.C. OF SOUTHERN CALIFORNIA	2,658	27.24	40.00	12.76
JUDGMENTAL SAMPLE SUMMARY	2,676	27.43	40.00	12.57
AVERAGE GROSS PROFIT MARGIN ( $\$12.57 \div \$27.43$ )				45.8%

## RANDOM SAMPLE:

N. H.- VERMONT HEALTH SERVICE	2,432	\$24.93	\$40.00	\$15.07
B.C./B.S. OF DELAWARE, INC.	1,850	18.96	40.00	21.04
B.C./B.S. OF MISSISSIPPI	2,180	22.35	40.00	17.65
B.C./B.S. OF GEORGIA	2,495	25.57	40.00	14.43
BLUE CROSS OF IOWA	3,631	37.22	40.00	2.78
B.C./B.S. OF UTAH	3,042	31.18	40.00	8.82
AETNA LIFE & CASUALTY, CAL.	2,794	28.64	40.00	11.36
B.C./B.S. OF ARIZONA	2,615	26.80	40.00	13.20
RANDOM SAMPLE SUMMARY	2,736	28.04	40.00	11.96
AVERAGE GROSS PROFIT MARGIN ( $\$11.96 \div \$28.04$ )				42.6%
TOTALS	2,700	\$27.68	\$40.00	\$12.32
GROSS PROFIT MARGIN ( $\$12.32 \div \$27.68$ )				44.5%

## Source:

A statistical sample of claims submitted by dialysis facilities.

Average doses were calculated for each intermediary by dividing the dose listed on the claim by the number of claims reviewed.

Cost data was provided by hospital based and independent dialysis facilities in Region I and a national chain of independent dialysis facilities. The cost per dose was calculated by using the cost of \$41.00 per 4,000 unit vials multiplied by the average dose, i.e.,  $\$41.00 \div 4,000 \text{ units} \times 1,912 = \$19.60$ .

Flat rate set by HCFA for 10,000 units or less of EPO administered.

ESTIMATE OF COST SAVINGS  
AT VARIOUS LEVELS OF MARKET PENETRATION

	<u>POPULATIONS</u>		DOSES PER YEAR	TOTAL ANNUAL DOSES	GROSS PROFIT PER DOSE	TOTAL GROSS PROFIT*
	ESRD	EPO				
<u>AT 20 PERCENT</u>						
JUDGMENTAL	51,940	10,388	156	1,620,528	\$12.57	\$ 20,370,037
RANDOM	<u>54,060</u>	<u>10,812</u>	156	1,686,672	11.96	<u>20,172,597</u>
TOTAL	<u>106,000</u>	<u>21,200</u>				<u>\$ 40,542,634</u>
<u>AT 50 PERCENT</u>						
JUDGMENTAL	51,940	25,970	156	4,051,320	\$12.57	\$ 50,925,092
RANDOM	<u>54,060</u>	<u>27,030</u>	156	4,216,680	11.96	<u>50,431,493</u>
TOTAL	<u>106,000</u>	<u>53,000</u>				<u>\$101,356,585</u>
<u>AT 80 PERCENT</u>						
JUDGMENTAL	51,940	41,552	156	6,482,112	\$12.57	\$ 81,480,147
RANDOM	<u>54,060</u>	<u>43,248</u>	156	6,746,688	11.96	<u>80,690,388</u>
TOTAL	<u>106,000</u>	<u>84,800</u>				<u>\$162,170,535</u>

**Sources:**

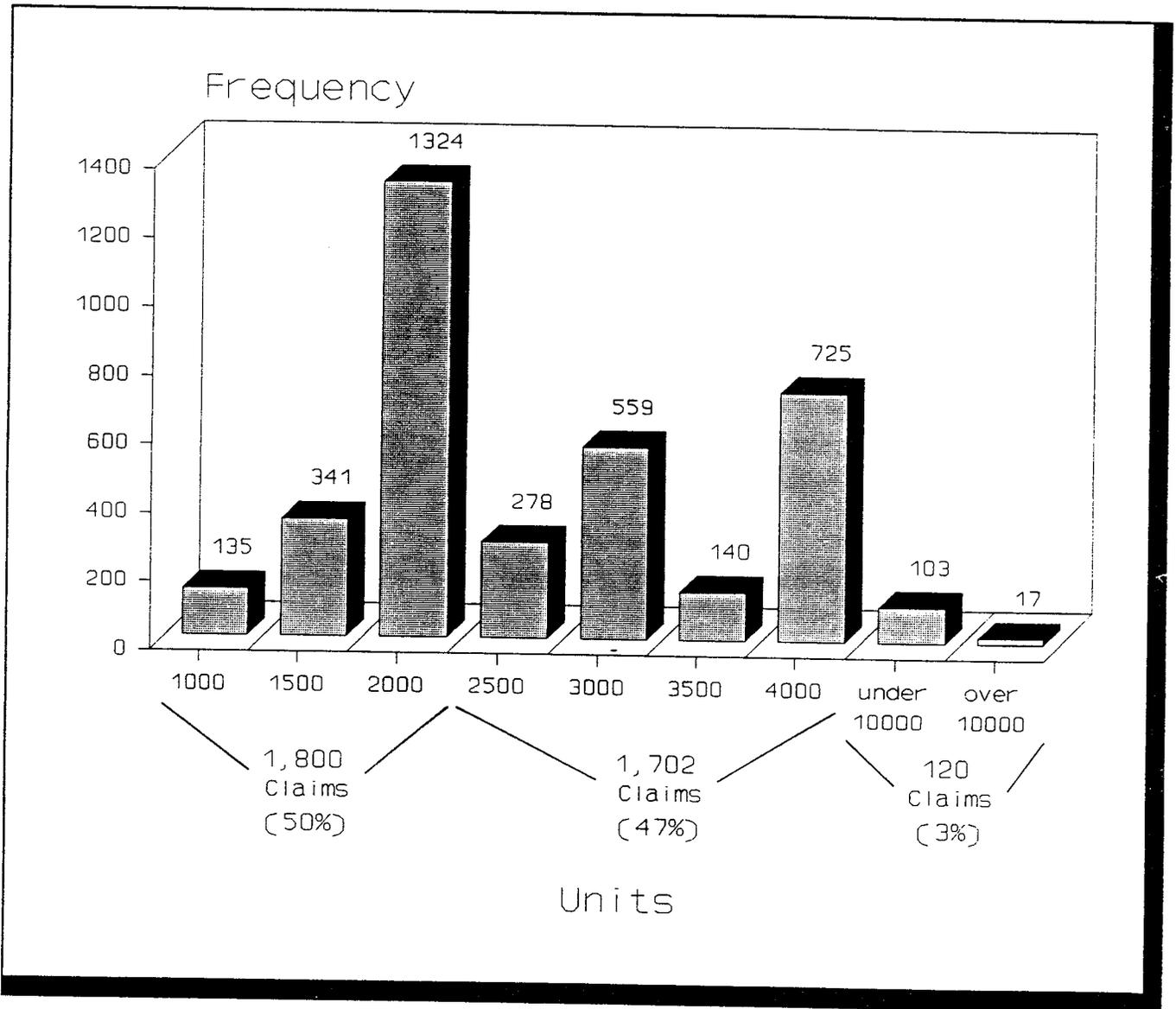
The EPO population is based on 1988 HCFA data adjusted by an 8% growth factor.

Doses per year are based on constant treatment of three doses per week.

The gross markup per dose is calculated on Appendix II.

\*Includes both the program and beneficiary share.

FREQUENCY DISTRIBUTION OF EPO SAMPLE CLAIMS




 DEPARTMENT OF HEALTH & HUMAN SERVICES  
**RECEIVED**  
 OFFICE OF INSPECTOR  
 GENERAL
**Memorandum**

JUL 16 1990

1990 JUL 17 AM 11:03

Date

From

Gail R. Wilensky, Ph.D. *GRW*  
Administrator

Subject

Draft Management Advisory Report: The Effect of the Interim Payment Rate for the Drug Epogen on Medicare Expenditures and Dialysis Facility Operations (A-01-90-00512)

To

The Inspector General  
Office of the Secretary

We have reviewed the subject draft report which reviews the effect of interim payment rates for the drug Epogen (EPO) on Medicare expenditures and dialysis facility operations.

The report includes three recommendations. The first recommendation suggests eliminating the flat interim rate for EPO and establishing a payment rate based on actual units of EPO administered. We are concerned that payment based on actual dosage could create incentives to provide more of the drug than is necessary and to provide it to more patients than require it. We are currently analyzing data on the first year of EPO payments and will address the issue of changes to the payment rate after the analysis is completed.

The second recommendation is for the Health Care Financing Administration to consider a legislative proposal that would allow the Secretary access to records of Amgen, Inc. We do not believe that "discrete access" to the books and records of Amgen, Inc., or any such manufacturer or distributor is necessary, advisable or prudent in determining Medicare payment. Also, it would establish an ominous precedent. Further, although EPO is currently available only from Amgen, at least two additional manufacturers have EPO available and should be on line shortly. These other manufacturers are already advertising in trade publications. We believe that this competition should lead to better prices.<sup>1</sup>

The third recommendation concerns the Orphan Drug Act status of EPO. It is our understanding that the Food and Drug Administration (FDA) and Congressional committees have discussed the matter and decided not to undertake a re-examination of the legislative provisions at this time. We believe amending the orphan drug provisions goes well beyond the issue of EPO and defer to the FDA on this matter.<sup>1</sup>

<sup>1</sup> These comments concern recommendations that have been deleted from the final report.

**Page 2 - The Inspector General**

Finally, we have one technical comment. We are somewhat puzzled by the remark on your cover memorandum "... we noted that multiple withdrawals of EPO are being dispensed from single-use vials which enhances facility profits but is contrary to labeling instructions." While it is our understanding that this type of labeling instruction is generally ignored, the possibility of substantial drug waste and resulting expense, if the labeling instruction were observed in the case of EPO, is worth considering.<sup>2</sup>

Thank you for the opportunity of reviewing this draft report, please advise us at your earliest possible convenience if you agree with our position.

<sup>2</sup> We brought the multi-withdrawal of EPO from single-use vials to the attention of FDA in a Management Advisory Report dated March 27, 1990. The FDA approved labeling for EPO reads as follows:

"Use only one dose per vial; do not reenter the vial. Discard unused portions. Contains no preservatives."

The FDA advised us these precautionary statements, in part, address the concern for the possibility of introducing microbial contamination due to multiple entries into the vial and subsequent growth of the contaminant in the absence of a preservative. In addition, FDA commented there may be unknown effects on product stability due to temperature fluctuation and unknown storage conditions during vial usage periods.

DISTRIBUTION SCHEDULE

No. of Copies

Office of the Secretary

Under Secretary	1
Chief of Staff	1
Asst. Secretary for Management and Budget	1
Asst. Secretary for Planning and Evaluation	1
Deputy Asst. Secretary for Program Systems, ASPE	1

Health Care Financing Administration

Administrator	2
Deputy Administrator	1
Associate Administrator for Operations	1
Associate Administrator for Program Development	1
Director, Bureau of Program Operations	3
Director, Bureau of Policy Development	1
Management Planning and Analysis Staff, OBA	5

Public Health Service

Assistant Secretary for Health	2
Deputy Asst. Secretary for Health	1
Deputy Asst. Secretary for Health Operations	1
Commissioner of Food and Drugs	2
Cost and Audit Management, DFM, ORM	5

Office of Inspector General

Inspector General	1
Principal Deputy Inspector General	1
Asst. Inspector General for Management and Policy Legislation, Regulation and Public Affairs	3
Deputy Inspector General for Investigations	1
Deputy Inspector General for Evaluation and Inspections	1
Deputy Inspector General for Audit Services	1
Asst. Inspector General for Audit Policy and Oversight	5
Asst. Inspector General for Health Care Financing Audits	10
Asst. Inspector General for Human, Family and Departmental Services Audits	1
Asst. Inspector General for Public Health Service Audits	1
Asst. Inspector General for Social Security Audits	1
Regional Inspectors General for Audit Services	8
Audit Policy and Operations	1
Technical Analysis and Research	1

TOTAL 67