Memorandum

Date FEB - 1 1993

From Bryan B. Mitchell
Principal Deputy Inspector General

Subject Review of EPOGEN Reimbursement (A-01-92-00506)

To William Toby, Jr.
Acting Administrator
Health Care Financing Administration

The attached final management advisory report summarizes the results of our review of the reimbursement of the drug EPOGEN (EPO) under the Medicare end stage renal disease program. The Omnibus Budget Reconciliation Act (OBRA) of 1990 provides for a reimbursement rate to dialysis facilities of $11 per 1,000 units of EPO administered. The OBRA of 1990 also required the Secretary to determine, in 1992, an appropriate payment rate for EPO reimbursement. The objectives of our review were to determine at what price dialysis facilities purchased EPO and to provide the Health Care Financing Administration (HCFA) with information as to whether changes are needed in the Medicare reimbursement methodology and/or rate.

With respect to the price dialysis facilities pay for EPO, we found, for the facilities reviewed, the cost of EPO was between $10 and $10.10 per 1,000 units administered. This is approximately $1 less than the reimbursement rate of $11 per 1,000 units (or a 9 to 10 percent gross profit to facilities). In the shortrun, we recommend that HCFA consider reducing the reimbursement rate not to exceed $10.10 per 1,000 units administered which would result in savings of $27.5 million to the Medicare program and $6.9 million to the beneficiaries. Also, some facilities received year-end manufacturer rebates (2 to 8 percent of the purchase price) or free EPO depending upon the volume purchased. Based on the statutorily set payment mechanism, the Medicare program is unable to benefit from these rebates.

In addition to obtaining data for the dialysis facilities, we attempted to review financial information from Amgen Inc. (Amgen) on its cost of producing EPO and the price it charges its customers and wholesalers. Although Amgen refused us access to their cost data, we found, from Security and Exchange Commission filings, that in Calendar Year 1991 Amgen reported EPO sales of $409 million, a

48 percent increase over 1990 sales of $277 million. This increase was attributable in part to larger dosages administered under the new reimbursement method. In only a few years, because of its favorable position due to market exclusivity, Amgen's profits and market penetration have far exceeded the estimates used to develop the initial Medicare rate. It appears that Amgen is in a financial position to lower its price in concert with Medicare lowering its reimbursement rate. Therefore, we believe it is appropriate for a long-term solution, that HCFA enter into negotiations with Amgen to lower the rate and also consider the rebates to the Medicare program based on the volume of EPO usage.

In response to our draft report, HCFA stated it would consider our findings when calculating the future payment rate of EPO. However, the response does not provide for a timetable as to when a new rate would be established. We encourage HCFA to act upon our findings in a timely manner in order to realize economy and efficiency in the Medicare program.

Please advise us, within 60 days, on actions taken or planned on our recommendations. If you have any questions, please call me or have your staff contact George M. Reeb, Assistant Inspector General for Health Care Financing Audits at (410) 966-7104. Copies of this report are being sent to other interested Department officials.

Attachment

Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

REVIEW OF EPOGEN REIMBURSEMENT

JANUARY 1993 A-01-92-00506

Memorandum

Date FEB - 1 1993

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Principal Deputy Inspector General

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To William Toby, Jr.
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This final management advisory report summarizes the results of our review of the reimbursement of the drug EPOGEN (EPO) under the Medicare end stage renal disease (ESRD) program. The objectives of our review were to determine at what price dialysis facilities purchased EPO and to provide the Health Care Financing Administration (HCFA) with information as to whether changes are needed in the Medicare reimbursement methodology and/or rate.

On June 1, 1989, the Food and Drug Administration (FDA) approved Amgen Inc.'s (Amgen) product licensing application to manufacture the drug EPO. Amgen manufactures and markets EPO directly for dialysis patients in the United States (U.S.), the market for which Amgen has exclusive rights under the Orphan Drug Act provisions. The targeted application is the treatment of anemia resulting from kidney failure. Previously, ESRD related anemia was treated by blood transfusions. The Medicare program, through reimbursement to dialysis facilities, is the primary payer for this drug since approximately 90 percent of Amgen's EPO market are Medicare beneficiaries.

For a selection of dialysis facilities, we determined that the cost of EPO was between $10 and $10.10 per 1,000 units administered. This is approximately $1 less than the reimbursement rate of $11 per 1,000 units (or a 9 to 10 percent gross profit). In addition, some facilities also received year-end manufacturer rebates (2 to 8 percent of the purchase price) or free EPO depending upon the volume purchased. For example, our discussion with one large chain organization indicated that the EPO rebates for all its facilities totaled several million dollars. Based on the statutorily set payment mechanism, the Medicare program is unable to benefit from these rebates. We requested from Amgen the total amount of rebates it provided to all its customers, namely: drug wholesalers, dialysis facilities (including large chain organizations), or group purchasing organizations; however, we were denied this information.

Prior to the enactment of the Omnibus Budget Reconciliation Act (OBRA) of 1990, which was effective January 1, 1991, reimbursement for EPO did not vary with dosages administered under 10,000 units; thus, the incentive existed for some

facilities to provide less EPO, thereby increasing their gross profit. As noted in our prior report,[1] the flat rate was developed based on the average dose of 5,000 units; whereas, our statistical sampie showed that the average dose administered by the facilities to its patients was about 2,700 units. The OBRA of 1990 mandated a reimbursement method that, however, presents a converse problem. To maintain the same level of gross profits, facilities are now provided with the incentive to increase EPO dosages because reimbursement is now based on units administered. Increased volume is also associated with Amgen's cash rebates or free EPO based on the volume of EPO purchased during a calendar year by dialysis facilities. For Calendar Year 1991, Amgen reported EPO sales of $409 million or a 48 percent increase over 1990's sales of $277 million attributable in part to larger dosages administered under the new reimbursement method.

Based on our analysis, a further refinement in the EPO reimbursement methodology is essential to achieve economy and efficiency in the Medicare program. The demand for EPO has surpassed original estimates resulting in greater profits to Amgen. We acknowledge Amgen's position as sole manufacturer of EPO and that financial vitality is sensitive to changes in the selling price of its product. However, in the shortrun, we recommend that HCFA consider reducing the reimbursement rate not to exceed $10.10 per 1,000 units administered which would effectuate savings of $27.5 million to the Medicare program and $6.9 million to the beneficiaries (see Appendix I). For a long-term solution, we recommend that HCFA enter into negotiations with Amgen to determine a rate which takes into consideration rebates to the Medicare program based on the volume of EPO purchased and used to treat Medicare beneficiaries.

In response to our draft report, HCFA stated it would consider our findings when calculating the future payment rate of EPO. However, the response does not provide for a timetable as to wnen a new rate would be established. We encourage HCFA to act upon our findings in a timely manner in order to realize economy and efficiency in the Medicare program.

BACKGROUND

The EPO is a product which stimulates red blood cell production. Amgen markets the drug in the U.S. for use by dialysis patients in the treatment of anemia associated with chronic renal failure. In addition to FDA approval, EPO was given orphan drug status under the Orphan Drug Act which provides incentives for treatment of diseases affecting fewer than 200,000 U.S. patients. The incentives

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[1] Office of Inspector General report entitled "Effect of the Interim Rate for the Drug EPOGEN on Medicare Expenditures and Dialysis Facility Operation" (A-01-90-00512)

include a 7-year period when competitive manufacture of an identical product is prohibited. As such, Amgen has received exclusive rights to the dialysis patient market.

Shortly after FDA approval, the HCFA established an interim policy to pay for the drug as an add-on to the prospective payment rate for dialysis services. The interim rate was $40 per treatment for dosages under 10,000 units and $70 for dosages of 10,000 units and above. This reimbursement method remained in effect through December 1990. Under this fixed rate, a dialysis patient receiving the average dosage of 2,700 units of EPO 3 times per week would incur an approximate annual expense of $6,240. Of this amount, $4,992 represents the Medicare program's 80 percent share and $1,248 for the beneficiary's 20 percent coinsurance.

The OBRA of 1990 provided that EPO reimbursement beginning in January 1991 would be on a per-unit dosage basis. Under this payment method, reimbursement to dialysis facilities is equal to $11 per 1,000 units (rounded to the nearest 100 units). The OBRA of 1990 also required the Secretary to determine, starting in 1992, an appropriate payment rate for EPO reimbursement. The payment amount determined by the Secretary is to be indexed to the implicit price deflator for the gross national product. The law states the rate "...may not exceed the amount determined under this clause for the previous year increased by the percentage increase (if any) in the implicit price deflator for gross national product (as established by the Department of Commerce) for the second quarter of the preceding year over the implicit price deflator for the second quarter of the second preceding year." The adjustment factor for 1991 was calculated at an increase of 4.1 percent.

In contrast to the statutorily established rate for EPO, under 42 CFR 405.517, effective January 1, 1992, other separately billable ESRD drugs will be reimbursed based on the lower of the estimated acquisition cost (EAC) or the average wholesale price (AWP). The EAC is determined based on surveys of the actual invoice prices paid for the drug.

The number of ESRD patients benefiting from EPO has increased from 50,000 in 1989 to approximately 70,000 as of February 1992, a 40 percent increase. For the Medicare program, this represents a payment increase from $250 million to $336 million.[2] This increase in expenditures to the Medicare program is due to the increase in patients, an increase in dosages, and a change in the reimbursement methodologies.

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[2] Based on average dosages of 2,700 units and 3,500 units, market penetration of 50,000 and approximately 70,000 beneficiaries for 1989 and 1992, respectively, and 156 treatments per beneficiary per year.

METHODOLOGY

The objectives of our review were to determine at what price dialysis facilities purchased EPO and to provide the HCFA with information as to whether changes are needed in the Medicare reimbursement methodology and/or rate. To accomplish our objectives, we:

- reviewed HCFA's current reimbursement method of paying for EPO;
- reviewed congressional reports and published articles relative to EPO;
- randomly selected 30 independent dialysis facilities out of a nationwide population of 1,020 facilities using a stratified sampling plan to include 10 small, 10 medium, and 10 large facilities;
- judgmentally selected the month of May 1991 as the time frame for our analysis;
- obtained all paid invoices for EPO during May 1991 to determine the price for EPO at each of the 30 randomly selected facilities (if there were no invoices during May, invoices from the closest month were selected);
- obtained all paid invoices for EPO during May 1991 from three judgmentally selected hospital based dialysis facilities in the greater Boston area (if there were no invoices during May, invoices from the closest month were selected);
- determined the frequency of administrations at all facilities selected;
- analyzed Amgen's Annual Report and Security and Exchange Commission (SEC) filings for years ending March 31, 1984 through March 31, 1992; and
- requested financial data from Amgen regarding its cost of producing EPO, and the price it charges to its customers, i.e., wholesalers.

Our field work was conducted at Amgen's facilities in Thousand Oaks, California; the HCFA central office in Baltimore, Maryland; and the Office of Audit Service's office in Boston, Massachusetts. Amgen is unwilling to provide us access to financial data regarding its cost of producing EPO, or the price it charges to its customers. This scope impairment affects the results of our review. Our review was conducted from July 1991 to April 1992.

The draft report was issued to HCFA on September 10, 1992. The HCFA's written comments, dated December 7, 1992, are appended to this report (see Appendix IV) and addressed on page 10.

RESULTS OF REVIEW

The EPO has been instrumental in reversing anemia in ESRD patients. Clinical studies also have shown that the quality of a patient's life improves significantly through the use of EPO. As such, EPO has become a routine service provided to about 70,000 ESRD patients who dialyze on a regular basis. Although the medical benefits are encouraging, the total cost to the Medicare program cannot be overlooked. At a rate of $11 per 1,000 units administered, the present outlays for all Medicare beneficiaries per year for EPO are approximately $336 million. Our analysis has shown that EPO now contributes approximately 22 percent to the total cost of providing routine dialysis services to ESRD beneficiaries (Figure 1).[3]

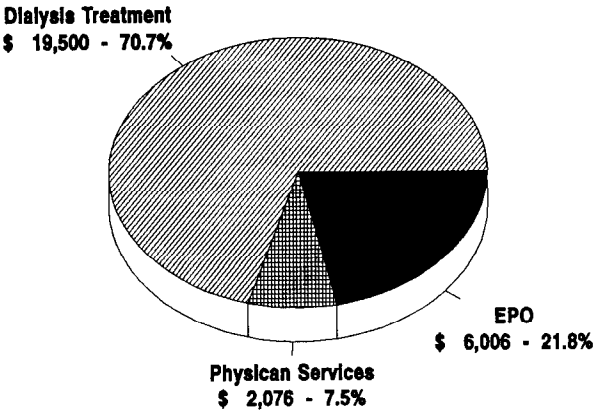

Figure 1 *- Total Routine Cost of Dialysis for a Beneficiary Per Year (includes Medicare's and beneficiaries respective shares)*

To ensure economy and efficiency in the Medicare program, we believe a change in the reimbursement rate is now needed to more closely resemble the facilities' cost for EPO. Our analysis shows 1) the facilities purchase EPO at a price as much as 10 percent below the current reimbursement rate, resulting in a reduction of $1 per 1,000 units administered, 2) year-end rebates based on volume purchased also are available which further reduces the facilities' cost, and 3) the sole manufacturer, Amgen, has enjoyed significant growth in terms of sales, net income, and stock price, much of which is largely attributed to the EPO reimbursement level. As a result, we are recommending a rate reduction of at least 90¢ per 1,000 units administered which would result in savings of $27.5 million to the Medicare program and $6.9 million to the beneficiaries (based on an average dosage of 3,500 units, market penetration of 70,000, and 156 treatments per year) (see Appendix I).

[3] Figures based on 156 treatments per year, a nationwide average facility composite rate of $125, a nationwide average physician monthly capitation payment of $173, and average dosage of EPO of 3,500 units at $11.

FACILITIES' PURCHASE PRICE OF EPO

Provisions in OBRA of 1990 set 1991 Medicare reimbursement of EPO at $11 per 1,000 units, a rate currently higher than the facilities' current acquisition cost. Our analysis disclosed that facilities purchase EPO at a price as much as 10 percent lower than the reimbursement rate.[4]

Through a random sample of 30 independent dialysis facilities and an examination of invoices, we determined that the cost to these facilities to purchase EPO is $10 per 1,000 units administered. This is $1 less than the facilities' reimbursement rate of $11 per 1,000 units or a 10 percent gross profit (see Appendix II). Likewise, through an examination of invoices from a judgmental sample of 3 local hospital-based facilities, we determined that the cost is at or slightly higher ($10.10 per 1,000 units) than the independent dialysis facilities (see Appendix III). From the results of a previous analysis we performed in 1990, we determined the cost of EPO to facilities was about $10.25 per 1,000 units administered. Accordingly, we note a slight decrease in the facilities' cost to purchase EPO.

The 30 independent dialysis facilities represent a stratified sample selection from large, medium, and small-sized facilities as categorized by HCFA. We noted that the facilities obtained EPO from Amgen either directly or through drug wholesalers. In the case of chain organizations, EPO is obtained from the same distribution channels; however, it may be purchased by several facilities joined as a group purchaser. No matter the size of the facility or how EPO was obtained, the cost differed only slightly.

REBATES FURTHER REDUCE THE COST OF EPO

The invoice price paid by ESRD facilities for EPO can be reduced by year-end rebates based on total volume purchased. These rebates reduce the cost of EPO below the $10 mark noted on the average invoice we reviewed, thus increasing the facilities' gross profit.

Since the enactment of OBRA of 1990, which changed the reimbursement methodology from a flat-rate to a units administered basis, the average dosage per treatment has risen from 2,700 units to 3,500 units. According to the Prospective Payment Assessment Commission's Congressional Report dated June 1992, "...This method reduces any incentive to administer inappropriately low dosages...." The report goes on to state, "...ESRD providers did not follow recommended practices in administering EPO, and appear to have responded to financial incentives...."

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[4] The cost of EPO can be as much as 18 percent below reimbursement if year-end rebates are taken into consideration.

Although our analysis is limited, a correlation could exist between dosages and Amgen's "Volume Purchase Incentive Program." Under this program, dialysis facilities are eligible for year-end rebates based on total volume purchased. Rebates received varied among facilities based on individual agreements but ranged from 2 percent to 8 percent of the purchase price.

Figure 2 demonstrates the application of the rebate program. For a facility with purchases over $400,000 of EPO in a given year, the applicable rebate would be 7 percent. Rebates may take the form of a cash refund or free EPO; however, the rebate can be apportioned to a single treatment dosage. As indicated below, the gross profit on a single treatment, therefore, can be as high as $1.70 per 1,000 units administered, $1 from Medicare reimbursement plus 70¢ from the Amgen rebate at yearend.

The initial cost of a single treatment - 3,500 units administered @ $10 per 1,000 units	$35.00
Applicable rebate at a facility with over $400,000 total volume purchased - 7 percent*	
The final cost of the single treatment including the rebate - 3,500 units administered @ $9.30 per 1,000 units	$32.55
The reimbursement for this treatment - @ $11 per 1,000 units	$38.50
Gross profit - 3,500 units administered @ $1.70 per 1,000 units ($1 difference between cost and reimbursement plus 70¢ rebate)	$5.95

* Assumes facility multi-withdraws from a single vial of EPO to treat more than one patient from the vial contents.

***Figure 2** - Example of the Application of the Rebate Program Per Administration*

For large chain organizations, rebates could and have totaled several million dollars. The effect of the rebates is that it reduces the actual cost of EPO to a dialysis facility, thus increasing their gross profit.

Presently, the rebates represent price reductions which benefit the facilities exclusively. No mechanism exists for the Medicare program or the beneficiaries to receive their respective share of the rebates. The rebates are not reported by the facilities on the Medicare claims form because the rebates are not calculated until yearend when Amgen accumulates the amount of EPO purchased. Amgen's rebate

agreements call for accurate reporting by the facilities on applicable cost reports; however, neither Amgen nor the facilities are required to share the rebate with Medicare or the beneficiaries. In addition, these cost reports are not used as a basis for settlement since reimbursement for EPO is a fixed fee. We requested from Amgen the total amount of rebates it provided to all its customers, namely: drug wholesalers, dialysis facilities (including large chain organizations), or group purchasing organizations; however, we were denied this information.

FAVORABLE FINANCIAL POSITION DUE TO MARKET EXCLUSIVITY

Prices for drugs to wholesalers are set by the manufacturers with the Medicare program paying for the drugs based on the lower of EAC or the national AWP. In this unique situation, with Medicare as the principal payer of EPO, the program did not intend to allow for an open-ended reimbursement policy. Initially, HCFA set a policy to control the payment rate by establishing flat rate payments. The HCFA policy was established as an add-on amount to the predetermined rate on a per treatment basis in order to control payment amounts and utilization. The payment rate, as established by Medicare, was based on financial information provided by Amgen, a reasonable rate of return, and an estimation of market penetration. Since the establishment of the initial rate, both the profits for Amgen and the market penetration of the drug have greatly exceeded initial estimates. We attempted to review financial information from Amgen on its cost of producing EPO and the price it charges its customers and wholesalers. Although Amgen refused us access to their cost data, we found, from SEC filings, data on Amgen's revenues and profits.

Amgen's financing is derived from two sources, revenues from product sales and public offerings. Prior to OBRA of 1990 and under the old reimbursement method, Amgen reported sales of EPO of $95.8 million and $277.3 million for calendar years ending 1989 and 1990, respectively. The 1990 sales represented an increase of 189 percent over the prior period. Amgen reported net income of $3.8 million and $3.9 million for the same time periods. In 1991, the period covered by OBRA of 1990 provisions, Amgen reported sales of EPO of $409.4 million, an increase of 48 percent over the prior year. Amgen also reported net income of $97.9 million. According to Amgen's March 1992 filing with the SEC, ***"this increase was primarily due to Amgen's increased penetration of the U.S. dialysis patient population and the administration of larger dosages per patient, which resulted in part from a change in Medicare reimbursement."*** Although Amgen introduced a new product in 1991, a significant portion of the $97.9 million is attributable to EPO because many of the operating expenses, i.e., research and development and selling expenses, relate more to the new product rather than EPO. Provisions of the Orphan Drug Act have also contributed to Amgen's financial vitality.

"The 1983 Orphan Drug Act (Public Law 97-414) was designed to stimulate development and market availability of products used for the treatment of rare

diseases by providing market incentives to increase profits and by clarifying regulatory processes to reduce expenses."[5] The incentives include a 7-year period when competitive manufacture of an identical product is prohibited. As such, Amgen has received exclusive rights to the U.S. dialysis patient market. Our analysis shows that the research and development of EPO was supported in part by public financing. As Figure 3 shows, the market price per share of Amgen common stock has experienced steady growth. Since FDA approval, the market price per share of Amgen common stock has climbed by 500 percent.[6]

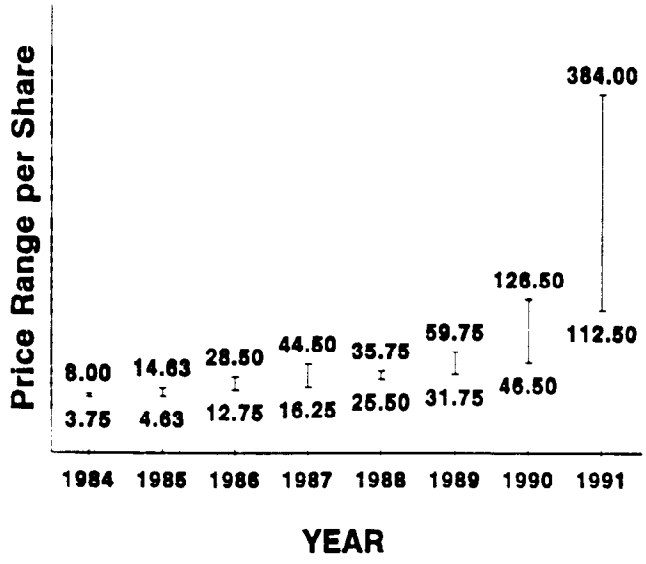

***Figure 3** - Amgen's Common Stock - Range of Selling Prices (Reassembles stock splits in 1990 and 1991)*

Amgen enjoys a strong financial position. It expects profits to continue with a marginal growth rate in the patient population and increases in dosing per treatment. Amgen's financial position allowed it to donate $60 million worth of EPO to the People's Republic of China for the treatment of dialysis patients during the fiscal year ending March 31, 1991. It also has allowed Amgen to continue its "Safety Net Program" which provides EPO at no cost to indigent dialysis patients who have no government or private medical insurance.

CONCLUSION

We believe that a Medicare reimbursement rate should be adopted that narrows the disparity between the reimbursement rate and the actual cost that facilities currently pay for EPO. Based on our analysis, this would result in estimated savings of $27.5 million to the Medicare program and $6.9 million to the beneficiaries (based on an average dosage of 3,500 units, market penetration of 70,000, 156 treatments per year, and a reimbursement rate of $10.10 per 1,000 units) (see Appendix I).

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[5] Ashby, Carolyn H, *The Orphan Drug Act*, JAMA, February 20, 1991 - Vol. 265, No. 7, p. 893

[6] This increase represents the change in the highest selling price in 1991 from the highest selling price in 1989 and takes into consideration stock splits in 1990 and 1991.

Further justification for a rate decrease is based on Amgen's purchase incentive programs. It is apparent that facilities, as buyers of the drug, have gained leverage with Amgen in obtaining rebates based on volume purchased. Higher dosages lead to larger volume purchases, higher profits for Amgen and finally, larger rebates for dialysis facilities. The Medicare program and beneficiaries, being the ultimate consumer of EPO, do not benefit from the rebates. Without a mechanism to properly treat these rebates, the Medicare program and beneficiaries are unduly subjected to additional expenditures.

Finally, changes in reimbursement methodology which have led to increased dosages coupled with unexpected market penetration have resulted in greater profits for Amgen. Any increase in a reimbursement rate to the facilities would more than likely be countered by a corresponding increase in Amgen's selling price of EPO. This too would add to Amgen's gross profits. Amgen's strong financial position is attributable to the past and present reimbursement methodologies, increased dosages, and market exclusivity all of which are at the expense of the Medicare program and beneficiaries.

RECOMMENDATIONS

(1) In the shortrun, we recommend that HCFA consider reducing the reimbursement rate not to exceed $10.10 per 1,000 units administered.

(2) For a long-term solution, we recommend that HCFA enter into negotiations with Amgen to determine a rate which takes into consideration rebates to the Medicare program based on volume purchased.

HCFA COMMENTS

In response to our draft report, HCFA stated "...the Secretary is required to review the Medicare payment rate for EPO annually. OIG's findings will be taken into consideration during this process. Also, the Health Care Financing Administration believes that the elimination of rebates based on volume purchased would not result in a change in the manufacturer's price, nor would it serve any program end. However, the possible effect of the rebates, along with other factors, will be taken into consideration when calculating the future payment rate for EPO."

OFFICE OF INSPECTOR GENERAL RESPONSE

The response does not provide for a timetable as to when a new rate would be established. We encourage HCFA to act upon our findings in a timely manner in order to realize economy and efficiency in the Medicare program.

APPENDICES

APPENDIX I

ANALYSIS OF ESTIMATED SAVINGS

Market Penetration	Reimbursement @ $11/1,000 units (Present Rate)	Reimbursement @ $10.10/1,000 units	Difference	Number of Treatments per Year	Estimated Savings*
At 3,500 units:					
90,000	$38.50	$35.35	$3.15	156	$44,226,000
80,000	38.50	35.35	3.15	156	39,312,000
70,000	38.50	35.35	3.15	156	34,398,000*
At 3,000 units:					
90,000	$33.00	$30.30	$2.70	156	$37,908,000
80,000	33.00	30.30	2.70	156	33,696,000
70,000	33.00	30.30	2.70	156	29,484,000

	Reimbursement @ $11/1,000 units (Present Rate)	Reimbursement @ $10.50/1,000 units			
At 3,500 units:					
90,000	$38.50	$36.75	$1.75	156	$24,570,000
80,000	38.50	36.75	1.75	156	21,840,000
70,000	38.50	36.75	1.75	156	19,110,000
At 3,000 units:					
90,000	$33.00	$31.50	$1.50	156	$21,060,000
80,000	33.00	31.50	1.50	156	18,720,000
70,000	33.00	31.50	1.50	156	16,380,000

*Estimated savings include the Medicare program 80 percent share plus beneficiaries 20 percent coinsurance, i.e., $27.5 million to the Medicare program and $6.9 million to the beneficiaries.

APPENDIX II

PRICES FOR EPOGEN AT 30 STATISTICALLY SELECTED INDEPENDENT DIALYSIS FACILITIES

FACILITY	INVOICE PRICE PER 1,000 UNITS	UNITS PURCHASED	TOTAL INVOICE PRICE
SMALL			
#1	$10.00	3,000	$30.00
#2	10.00	2,000	20.00
#3	10.00	4,000	40.00
#4	9.44	10,000[1]	94.35
#5	10.00	2,000	20.00
#6	10.00	4,000	40.00
#7	10.00	2,000	20.00
#8	10.00	2,000	20.00
#9	10.00	4,000	40.00
#10	10.00	2,000	20.00
MEDIUM			
#11	10.00	10,000	100.00
#12	10.00	10,000	100.00
#13	10.00	4,000	40.00
#14	10.00	4,000	40.00
#15	10.00	4,000	40.00
#16	10.00	3,000	30.00
#17	10.00	2,000	20.00
#18	10.00	4,000	40.00
#19	10.00	3,000	30.00
#20	10.00	4,000	40.00
LARGE			
#21	10.00	2,000	20.00
#22	10.00	2,000	20.00
#23	10.00	4,000	40.00
#24	10.00	4,000	40.00
#25	10.00	2,000	20.00
#26	9.68	2,000[1]	19.35
#27	10.00	4,000	40.00
#28	10.00	1,000[2]	10.00
#29	10.00	4,000	40.00
#30	10.00	2,000	20.00

Methodology: Except for those facilities noted, prices and units purchased information were taken from a single invoice given to us by the facilities management. We examined all paid invoices from the 30 facilities during the month of May 1991. If there were no invoices during May, invoices from the closest month were selected.

Notes:

1. These two facilities gave us a percentage with which EPO was discounted after receiving rebates from volume purchases. Price listed does not reflect invoice price, but does reflect actual cost.

2. No invoice available, information was obtained by interview with company personnel.

PRICES FOR EPOGEN AT THREE PRESELECTED HOSPITAL-BASED DIALYSIS FACILITIES IN GREATER BOSTON, MASSACHUSETTS

HOSPITAL	INVOICE PRICE PER 1,000 UNITS	UNITS PURCHASED	TOTAL INVOICE PRICE
#1	$10.02	4,000	$ 40.09
#2	10.09	2,000	20.18
	10.09	3,000	30.27
	10.09	4,000	40.36
#3	10.10	2,000	20.20

Methodology: Prices and units purchased information was taken from a single invoice given to us by the facilities management. We examined all paid invoices from the three facilities during the month of May 1991. If there were no invoices during May, invoices from the closest month were selected.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Care
Financing Administration

DEC 7 1992

Date

Memorandum

William Toby, Jr.
Acting Administrator

From

IC
PDIG
DIG-AS
DIG-EI
DIG-OI
AIG-MP
OGC/IG
EXSEC
DATE SENT 12/8

Subject Office of Inspector General (OIG) Draft Management Advisory Report: "Review of EPOGEN Reimbursement" (A-01-92-00506)

To Bryan B. Mitchell
Principal Deputy Inspector General

We reviewed the above-referenced draft management advisory report concerning the results of OIG's review of the payment of the drug EPOGEN (EPO) under the Medicare end-stage renal disease program. The drug manufacturer, Amgen Inc., manufactures and markets EPO directly for dialysis patients in the United States, the market for which Amgen has exclusive rights under the Orphan Drug Act provisions. The Medicare program, through payment to dialysis facilities, is the primary payer for EPO since approximately 90 percent of Amgen's EPO market is Medicare beneficiaries. The Omnibus Budget Reconciliation Act of 1990 (OBRA 90) provides for a payment rate to dialysis facilities of $11 per 1,000 units of EPO administered. OBRA 90 also requires the Secretary to determine an appropriate payment rate for EPO beginning in 1992.

OIG found the cost of EPO for the facilities reviewed was between $10 and $10.10 per 1,000 units administered, approximately $1 less than the reimbursement rate of $11 per 1,000 units (or a 9 to 10 percent gross profit to facilities). Some facilities receive year-end rebates (2 to 8 percent of the purchase price) or free EPO, depending upon the volume purchased. Due to the statutorily set payment mechanism, the Medicare program is unable to benefit from these rebates.

The payment rate, as established by Medicare, was based on financial information provided by Amgen, a reasonable rate of return, and an estimation of market penetration. Since the establishment of the initial rate, both the profits for Amgen and the market penetration of the drug have greatly exceeded initial estimates.

OIG believes that a Medicare payment rate should be adopted that narrows the disparity between the payment rate and the actual payment made by facilities for EPO. This would result in estimated savings of $27.5 million to the Medicare program and $6.9 million to beneficiaries.

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As stated in the report, the Secretary is required to review the Medicare payment rate for EPO annually. OIG's findings will be taken into consideration during this process. Also, the Health Care Financing Administration believes that the elimination of rebates based on volume purchased would not result in a change in the manufacturer's price, nor would it serve any program end. However, the possible effect of the rebates, along with other factors, will be taken into consideration when calculating the future payment rate for EPO.

Thank you for the opportunity to review and comment on this report. Please advise us if you agree with our position on the report's recommendations at your earliest convenience.