# Memorandum

Date NOV 24 1997

From for Michael Mangano
June Gibbs Brown
Inspector General

Subject Review of EPOGEN Reimbursement (A-01-97-00509)

To Nancy-Ann Min DeParle
Administrator
Health Care Financing Administration

Attached is our final report entitled, *Review of EPOGEN Reimbursement.* The objective of our review was to determine if Medicare's reimbursement for the drug EPOGEN (EPO) should be reduced to reflect current market prices. We found that the current EPO reimbursement rate of $10 per 1,000 units administered exceeds the current cost of purchasing EPO by approximately $1. Section 1881 (b)(11)(B) of the Social Security Act provides that the Secretary of the Department of Health and Human Services can set an appropriate reimbursement level for EPO beginning January 1, 1995. Accordingly, we recommend that the Secretary consider reducing Medicare reimbursement to $9 per 1,000 units administered resulting in savings to Medicare of approximately $94 million and to its beneficiaries of approximately $24 million per year beginning in 1998.

In response to our draft report, the Health Care Financing Administration concurred with our finding and recommendation and intends to pursue this change either through the rulemaking process or as a legislative initiative in the President's Fiscal Year 1999 Budget.

Please advise us within 60 days on actions taken or planned on our recommendation. 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) 786-7104. We would also like to take this opportunity to thank your staff in the Bureau of Program Development, Division of End Stage Renal Disease for their assistance in completing this review.

To facilitate identification, please refer to Common Identification Number A-01-97-00509 in all correspondence relating to this report.

Attachment

Department of Health and Human Services

# OFFICE OF INSPECTOR GENERAL

# REVIEW OF EPOGEN REIMBURSEMENT


JUNE GIBBS BROWN
Inspector General

NOVEMBER 1997
A-01-97-00509

DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of Inspector General

NOV 24 1997

# Memorandum

Date

From for June Gibbs Brown
Inspector General

Subject Review of EPOGEN Reimbursement (A-01-97-00509)

To Nancy-Ann Min DeParle
Administrator
Health Care Financing Administration

This final report presents the results of the subject review. The objective of our review was to determine if Medicare's reimbursement for the drug EPOGEN (EPO) should be reduced to reflect current market prices. We found that the current EPO reimbursement rate of $10 per 1,000 units administered exceeds the current cost of purchasing EPO by approximately $1. Specifically, we found that 95 out of the 105 providers randomly selected for review paid under $9.00 per 1,000 units of EPO. Section 1881 (b)(11)(B) of the Social Security Act (the Act) provides that the Secretary of the Department of Health and Human Services can set an appropriate reimbursement level for EPO beginning January 1, 1995. Accordingly, we recommend that the Secretary consider reducing Medicare reimbursement to $9 per 1,000 units administered. This reduction would result in savings to Medicare of approximately $94 million and to its beneficiaries of approximately $24 million per year beginning in 1998.

In response to our draft report, the Health Care Financing Administration (HCFA) concurred with our finding and recommendation and intends to pursue this change either through the rulemaking process or as a legislative initiative in the President's Fiscal Year 1999 Budget.

In a related matter, we found that Amgen, the manufacturer of EPO, includes an additional 25 percent of EPO in each vial sold. As such, if a facility purchases one 10,000 unit vial of EPO they actually receive 12,500 units. While we were unable to determine if all providers use this additional EPO, there are indications that some free-standing dialysis facilities in our sample were able to use, on average, one half of the overfill which would materially affect each provider's cost.

# INTRODUCTION

## BACKGROUND

The drug EPO is a substitute for the protein erythropoietin, which is secreted by the kidneys and stimulates the production and development of red blood cells. Low levels of erythropoietin often result in anemia with symptoms including rapid heartbeat, chest pain, fatigue, and limitations in performance of daily activities. Prior to the development of EPO, end stage renal disease (ESRD) beneficiaries with low levels of erythropoietin required frequent blood transfusions, an expensive procedure that can introduce significant medical risk.

The drug EPO was developed in 1983 by Amgen Inc., the sole supplier in the United States, for use by dialysis patients in the treatment of anemia associated with chronic renal failure. Amgen dispenses EPO in preservative-free vials labeled as containing 2,000, 3,000, 4,000, or 10,000 units and in preserved vials labeled as containing 20,000 units.

Reimbursement for EPO has changed since it was first covered by Medicare in 1989. Medicare first reimbursed EPO on a per treatment basis[1] of $40 for up to 10,000 units and $70 for treatment above 10,000 units. The reimbursement methodology was changed by the Omnibus Budget Reconciliation Act (OBRA) of 1990 which provided that EPO reimbursement, beginning in January 1991, would be on a per-unit basis setting the reimbursement rate at $11 per 1,000 units administered. The OBRA of 1990 also required the Secretary to determine, starting in 1992, an appropriate payment rate for EPO reimbursement.

In a report (A-01-92-00506) dated February 1, 1993, the Office of Inspector General (OIG) determined that the cost of EPO was between $10 and $10.10 per 1,000 units administered, or approximately $1 less than the reimbursement rate of $11 per 1,000 units. In addition, the OIG found that some facilities received year-end manufacturer rebates ranging from 2 to 8 percent of the purchase price depending on the volume purchased. As a result, the OIG recommended that HCFA consider reducing the reimbursement rate not to exceed $10.10 per 1,000 units administered. The HCFA agreed and, in fact, reduced the payment rate to $10 per 1,000 units administered.

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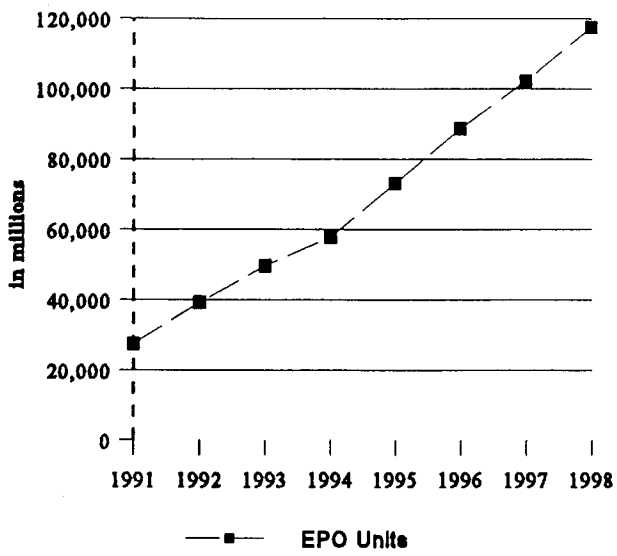
[1] EPO and supplies used to administer EPO are reimbursed in addition to the composite rate paid for each dialysis session. However, staff time incurred administering EPO is not reimbursed separately but rather as part of the composite rate.




During Calendar Years (CY) 1991 through 1995, EPO usage increased an average of 28 percent each year resulting in greater Medicare expenditures. Furthermore, Amgen expects that EPO sales will continue to increase; however, at a slower rate. This "slowdown" is evidenced in its first and second quarter of 1997 financial reports, showing that EPO sales increased 15 percent over the same period in 1996.

*Figure 1 - EPO Usage*
*1991-1995 Actual and 1996-1998 Estimated*

## SCOPE

We conducted our review in accordance with generally accepted government auditing standards. The objective of our review was to determine if Medicare's reimbursement for the drug EPO should be reduced to reflect current market prices. Our review focussed on the most current purchase invoices supporting the price ESRD facilities paid for EPO. The invoice dates ranged between September of 1996 and May of 1997.

As part of our examination, we obtained an understanding of the internal control structure relative to the processing of claims for EPO reimbursement. However, the objective of this audit did not require an assessment of these internal controls or of the providers' payment controls over the purchase of EPO.

To accomplish our objective, we:

- reviewed applicable Medicare laws and regulations;

- performed a computer application using a database of CY 1995 ESRD paid claims compiled by HCFA to extract claims for EPO valued at $730,755,934 paid to 771 hospital-based dialysis facilities and 2,023 free-standing dialysis facilities;

- employed a stratified attribute sampling approach (see APPENDIX I) consisting of 3 stratas: strata 1 included 308 facilities that accounted for the top 33 percent of paid EPO units; strata 2 included 620 facilities that accounted for the middle 33 percent of paid EPO units; and strata 3 included 1,866 facilities that accounted for the lowest 34 percent of paid EPO units. For each strata we randomly selected 35 facilities;

- obtained EPO invoices from the 105 ESRD facilities randomly selected for review. For each invoice, we (1) determined the total number of EPO units purchased (which consists of the size vial purchased, the number of vials per each carton, and the number of cartons purchased); (2) determined the amount facilities paid for each of the different vials; (3) factored into the purchase price any discounts which the facility received from its wholesaler such as prompt pay discounts as well as any sales tax or freight incurred; and (4) factored into the purchase price any rebates received from Amgen by obtaining the facility's Epogen Statement Calculation which lists the purchases made, the rebate percentage earned, and resulting dollar rebate;

- estimated the number of EPO units billed in 1996 based on historical trends between 1991 and 1995. Further, we estimated the number of EPO units in 1997 and 1998 based on Amgen's sales experience for the first two quarters of 1997 which increased over the same period in 1996 by 15 percent;

- used a stratified attribute appraisal program to estimate the number of facilities in the population that paid under various reimbursement levels; and

- discussed our results with HCFA officials on June 5, 1997.

We did not determine if the facility received additional discounts or verify that the facility actually made the appropriate payment for the purchase invoice amount.

We conducted our work from January 1997 through June 1997 at the OIG Office of Audit Services' regional office located in Boston, Massachusetts.

We issued our draft report on June 16, 1997. The HCFA's response to the draft report, dated October 13, 1997, is appended to this report (see Appendix V) and is addressed on page 7.

# FINDINGS AND RECOMMENDATIONS

We found that ESRD facilities purchase EPO at a rate substantially less than the current Medicare reimbursement of $10 per 1,000 units. Of the 105 providers in our sample, we found that 95 paid under $9.00 per 1,000 units of EPO purchased. Amgen has experienced increasingly higher EPO sales due to increases in the dialysis patient population, administration of higher average doses, and increased penetration of the dialysis market. We believe that these factors have allowed Amgen to pass price reductions on to its customers. In order to achieve cost efficiency in the Medicare program, we recommend that the Secretary, in accordance with section 1881(b)(11)(B) of the Act, consider reducing Medicare reimbursement to $9 per 1,000 units administered. This reduction would result in savings to Medicare of approximately $94 million and to its beneficiaries of approximately $24 million per year beginning in 1998.

In a related matter, we found that Amgen, the manufacturer of EPO, includes an additional 25 percent of EPO in each vial sold. As such, if a facility purchases one 10,000 unit vial of EPO they actually receive 12,500 units. While we were unable to determine if all providers use this additional EPO, there are indications that some free-standing dialysis facilities in our sample were able to use, on average, one half of the overfill which would materially affect each provider's cost.

## CURRENT PURCHASE PRICE OF EPO

To determine facilities' current acquisition costs, we randomly selected a sample of 105 providers that billed Medicare for EPO during 1995. For these providers we (1) reviewed purchase invoices to determine the number of EPO units purchased (e.g. 10,000 unit vials, 4,000 unit vials, etc), the number of vials per each carton, and the number of cartons received, (2) determined the amount facilities paid for each of the different vial sizes, and (3) factored into the purchase price any discounts which the facility received from its wholesaler such as prompt pay discounts as well as any sales tax or freight paid.

In addition to the purchase price, facilities receive rebates directly from Amgen. The type and amount of rebates range by facility based on the dollar amount of purchases made (Volume Performance Incentives), and whether the facility supplies Amgen with Hematocrit[2] results (Optional Hematocrit Incentive). We computed an average rebate for each facility and applied this against the facility's average cost, computed above, to derive a net cost after rebate (see APPENDIX II for example computation). We did not verify if the facility received additional discounts/rebates or if the facility made the appropriate payment for the invoice amount.

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[2] Hematocrit is one clinical laboratory blood test performed to determine whether EPO is medically necessary.

We determined that facilities' current acquisition cost to purchase EPO ranged from $7.30 to $9.54 per 1,000 units (see APPENDIX III). However, of the 105 providers, 95 paid under $9.00 per 1,000 units or over $1 less than current reimbursement amount. The 10 providers that paid over $9.00 either paid a 6 percent State sales tax, did not participate in the Optional Hematocrit incentive, or did not supply us with rebate information. The cost for these 10 providers were $9.08, $9.09, $9.10, $9.12, $9.18, $9.19, $9.20, $9.23, $9.25, and $9.54.

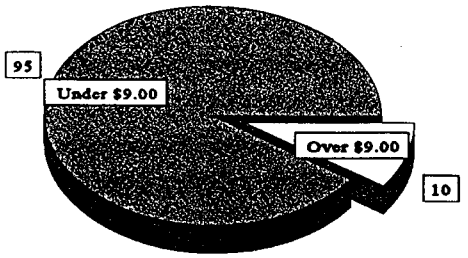


*Figure 2 - Number of providers with average cost over/under $9.00 per 1,000 units.*

Further, of the 95 providers that paid under $9.00 per 1,000 units of EPO, 79 of these providers paid under $8.75 per 1,000 units. We found that there was no substantial difference among the costs paid by small, medium, and large providers or hospital-based versus free-standing facilities (see APPENDIX IV).

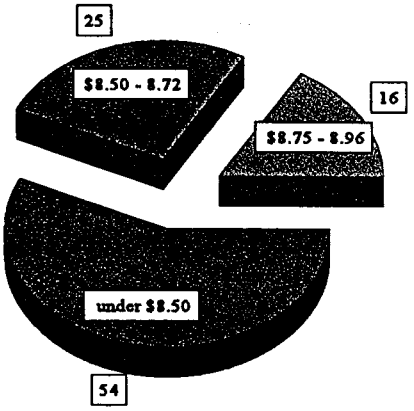


*Figure 3 - Breakdown of providers with average cost under $9.00 per 1,000 units of EPO.*

We projected our results from the 105 facilities in our sample to the population of 2,794 hospital-based and free-standing facilities. We estimated that 2,572 providers paid under $9.00 per 1,000 units with a precision of this estimate at the 90 percent confidence level of +/- 4.895 percent. We also projected our results to different dollar attributes to determine the number of providers that paid under certain dollar attributes. The results of this projection are:

| Dollar Attribute | Estimated # of Providers | Ratio of Providers | Precision of the Estimate |
|---|---|---|---|
| $9.25 & Under | 2,785 | 99.685 % | +/- 0.488 % |
| Under $9.00 | 2,572 | 92.069% | +/- 4.895 % |
| Under $8.75 | 2,120 | 75.875 % | +/- 8.394 % |
| Under $8.50 | 1,535 | 54.932 % | +/- 9.726 % |

## SAVINGS TO MEDICARE AND BENEFICIARIES

To compute the savings to Medicare and its beneficiaries, we extracted from HCFA's CY 1995 National Claims History File EPO units of 73,075,593,440 billed to Medicare in 1995. We then estimated 1996 EPO units based on the most conservative increase in EPO units between 1991 and 1995, that is 21.39 percent. This equates to 1996 EPO units of approximately 88.7 billion units. Finally, we estimated 1998 EPO units based on Amgen's sales experience for EPO. Specifically, in the first two quarters of 1997, Amgen experienced a 15 percent increase in EPO sales over the same period in 1996. Further, Amgen stated that it believes EPO sales will continue to increase at this rate for the remainder of 1997. Applying this increase of 15 percent to current EPO units billed to Medicare equates to 1998 EPO billings to Medicare of approximately 117.6 billion EPO units.

If EPO reimbursement were reduced to reflect the current market price of under $9.00 per 1,000 units administered, we estimate that, based on 1998 EPO units above, Medicare and its beneficiaries would save approximately $94 million and $24 million, respectively, per year beginning in 1998.

## RECOMMENDATION

We recommend that the Secretary consider reducing Medicare reimbursement to $9 per 1,000 units administered resulting in savings to Medicare of approximately $94 million and to its beneficiaries of approximately $24 million per year beginning in 1998.

## HCFA'S RESPONSE

In response to our draft report, HCFA concurred with our finding and recommendation and intends to pursue this change either through the rulemaking process or as a legislative initiative in the President's Fiscal Year 1999 Budget.

## OTHER MATTERS

In a related matter, we found that Amgen, the manufacturer of EPO, includes an additional 25 percent of EPO in each vial sold because of complaints it received from providers that the vials did not contain the labeled dose. Amgen investigated the matter and found that a thin film of EPO adhered to the inner walls of the vial as well as the underside of the stopper and when users attempted to retrieve EPO, they injected air into the vial causing the EPO to foam. As such, providers could not extract a full dose.

To ensure that users could extract a full dose, Amgen now includes an additional 25 percent of EPO in each vial. For example, if a facility purchases one 10,000 unit vial of EPO they actually receive 12,500 units. However, our review did not focus on the amount of EPO actually used by

facilities. To do so would require us to also determine if there was any breakage at facilities. While we did not determine if all providers actually used this additional EPO, there are indications that some free-standing dialysis facilities were able to use a portion of it. Hospital outpatient dialsysis facilities are not required to submit EPO cost and units administered data on their cost reports. As such, we could not determine if the overfill is utilized. With respect to free-standing dialysis facilities, we used 1995 cost report data for 56 of the 78 facilities in our sample. We computed an average cost per 1,000 units using the cost report data. This cost report information consists of the amount providers paid to wholesalers for EPO as well as the actual amount of EPO administered during the year. Therefore, this data would also contain the amount of any additional EPO that providers extracted from each vial. We then compared this cost per 1,000 units adminstered to invoices received by these facilities. This analysis showed that the average amount facilities were able to extract was approximately one half of the 25 percent overfill. The use of this additional EPO would materially affect each provider's cost.

# APPENDICES

# METHODOLOGY FOR THE STATISTICAL SAMPLE SELECTION

Utilizing HCFA's National Claims History File for CY 1995, we extracted all claims submitted for the drug EPO administered to ESRD beneficiaries. This extract identified 73,075,593,440 units of EPO administered by 2,794 ESRD providers (both free-standing dialysis facilities and hospital-based facilities).

We employed a stratified sampling approach for an attribute sample. The 2,794 facilities were stratified into 3 strata based on a ratio of 33 percent-33 percent-34 percent applied to the total units identified. This stratification was intended to group the providers into three strata based on a measure of size of facility - large, medium, and small. The resulting stratification was as follows:

| STRATA | UNITS of EPO | NUMBER of PROVIDERS |
|---|---|---|
| 1 | 24,149,739,912 | 308 |
| 2 | 24,096,167,479 | 620 |
| 3 | 24,829,686,049 | 1,866 |
| TOTAL | 73,075,593,440 | 2,794 |

A sample size of 35 providers was selected from each stratum. As such, the total sample size for the review was 105 providers. Using the Office of Audit Services (OAS) Statistical Software, dated February 1995, three sets of random numbers were generated given the respective populations in each stratum. Each provider was assigned a number sequentially within each stratum. The providers were selected based on a match between the assigned and random number.

With respect to the appraisal of the sample results, we employed an attribute appraisal for a stratified sample approach. Again using the OAS Statistical Software, we appraised the results of the sample using the following attributes (or cost per 1,000 units of EPO) - $9.25 and under, less than $9.00, less than $8.75, and less than $8.50. We reported the point estimate +/- the standard error of the estimate at the 90 percent confidence interval.

APPENDIX II

**EXAMPLE COMPUTATION OF AVERAGE COST**
**SAMPLE NUMBER 2 - LARGE PROVIDERS**

| DATE PURCHASED | UNITS | # IN CASE | CARTONS PURCHASED | TOTAL UNITS | TOTAL @ 1,000 UNITS | COST BEFORE REBATE | REBATE | COST AFTER REBATE |
|---|---|---|---|---|---|---|---|---|
| 03/05 | 2,000 | 10 | 20 | 400,000 | 400 | 3,571.20 | 3.86% | 3,433.35 |
| 03/05 | 10,000 | 10 | 10 | 1,000,000 | 1,000 | 8,928.00 | 3.86% | 8,583.38 |
| 03/05 | 4,000 | 10 | 30 | 1,200,000 | 1,200 | 10,713.60 | 3.86% | 10,300.06 |
| 03/05 | 3,000 | 10 | 30 | 900,000 | 900 | 8,035.20 | 3.86% | 7,725.04 |
| 03/12 | 2,000 | 10 | 10 | 200,000 | 200 | 1,785.60 | 3.86% | 1,716.68 |
| 03/12 | 4,000 | 10 | 20 | 800,000 | 800 | 7,142.40 | 3.86% | 6,866.70 |
| 03/12 | 3,000 | 10 | 20 | 600,000 | 600 | 5,356.60 | 3.86% | 5,149.84 |
| 03/19 | 10,000 | 10 | 10 | 1,000,000 | 1,000 | 8,928.00 | 3.86% | 8,583.38 |
| 03/19 | 4,000 | 10 | 40 | 1,600,000 | 1,600 | 14,284.80 | 3.86% | 13,733.41 |
| 03/19 | 3,000 | 10 | 30 | 900,000 | 900 | 8,035.20 | 3.86% | 7,725.04 |
| 03/20 | 2,000 | 10 | 10 | 200,000 | 200 | 1,785.60 | 3.86% | 1,716.68 |
| 03/20 | 10,000 | 10 | 5 | 500,000 | 500 | 4,464.00 | 3.86% | 4,291.69 |
| 03/20 | 4,000 | 10 | 30 | 1,200,000 | 1,200 | 10,713.60 | 3.86% | 10,300.06 |
| 03/20 | 3,000 | 10 | 30 | 900,000 | 900 | 8,035.20 | 3.86% | 7,725.04 |
| | | | | TOTALS | 11,400 | 101,779.00 | | 97,850.33 |
| | | | | AVG COST BEFORE REBATE | | 8.93 | | |
| | | | | AVG COST AFTER REBATE | | | | 8.58 |

**STRATA 1 - LARGE PROVIDERS**
**AVERAGE COST AFTER REBATE**

| SAMPLE NUMBER | H - HOSPITAL F - FREESTANDING | AVG COST AFTER REBATE | REBATE | INVOICE MONTH |
|---|---|---|---|---|
| 1 | H | 8.49 | 3.83% | 12/96 |
| 2 | F | 8.58 | 3.86% | 03/97 |
| 3 | H | 8.43 | 3.34% | 04/97 |
| 4 | F | 8.38 | 12.46% | 12/96 |
| 5 | H | 8.20 | 1.60% | 12/96 |
| 6 | F | 8.57 | 4.76% | 12/96 |
| 7 | F | 8.63 | 4.30% | 12/96 |
| 8 | F | 8.57 | 4.76% | 12/96 |
| 9 | F | 8.46 | 4.81% | 03/97 |
| 10 | F | 8.41 | 9.13% | 03/97 |
| 11 | F | 8.41 | 9.13% | 03/97 |
| 12 | F | 9.18 | 1.26% | 09/96 & 11/96 |
| 13 | F | 8.77 | 1.77% | 12/96 |
| 14 | F | 9.20 | 8.00% | 12/96 |
| 15 | F | 9.54 | 2.87% | 12/96 |
| 16 | F | 8.85 | 1.90% | 12/96 |
| 17 | F | 8.66 | 3.00% | 12/96 |
| 18 | F | 8.41 | 5.86% | 12/96-01/97 |
| 19 | F | 8.14 | 2.00% | 12/96 |
| 20 | F | 8.41 | 9.13% | 03/97 |
| 21 | H | 8.31 | 1.91% | 03/97 |
| 22 | F | 8.41 | 9.13% | 03/97 |
| 23 | F | 8.38 | 12.46% | 12/96 |
| 24 | F | 8.41 | 9.13% | 03/97 |
| 25 | H | 8.49 | 0.00% | 12/96 |
| 26 | H | 8.77 | 3.50% | 01/97 |
| 27 | F | 8.57 | 4.76% | 12/96 |
| 28 | F | 8.38 | 12.46% | 12/96 |
| 29 | H | 8.17 | 1.35% | 12/96 |
| 30 | H | 8.36 | 2.33% | 12/96 & 03/97 |
| 31 | F | 8.57 | 4.00% | 12/96 |
| 32 | F | 8.90 | 0.80% | 12/96 |
| 33 | F | 8.51 | 5.01% | 12/96 |
| 34 | F | 8.41 | 9.13% | 03/97 |
| 35 | H | 8.84 | 3.00% | 01/97 |

**STRATA 2 - MEDIUM PROVIDERS**
**AVERAGE COST AFTER REBATE**

| SAMPLE NUMBER | H - HOSPITAL F - FREESTANDING | AVG COST AFTER REBATE | REBATE | INVOICE MONTH |
|---|---|---|---|---|
| 1 | F | 8.57 | 3.50% | 03/97 |
| 2 | F | 8.41 | 9.13% | 03/97 |
| 3 | F | 8.41 | 5.86% | 12/96-01/97 |
| 4 | F | 8.41 | 9.13% | 03/97 |
| 5 | F | 9.12 | 2.56% | 12/96 |
| 6 | F | 9.08 | 4.76% | 12/96 |
| 7 | F | 8.55 | 4.28% | 12/96 |
| 8 | F | 8.67 | 3.38% | 02/97 |
| 9 | H | 8.58 | 3.34% | 03/97 |
| 10 | F | 8.38 | 12.46% | 12/96 |
| 11 | F | 8.41 | 9.13% | 03/97 |
| 12 | H | 9.25 | 0.75% | 12/96 |
| 13 | F | 8.41 | 9.13% | 03/97 |
| 14 | F | 8.59 | 4.76% | 12/96 |
| 15 | F | 8.41 | 9.13% | 03/97 |
| 16 | F | 8.38 | 12.46% | 12/96 |
| 17 | F | 8.77 | 1.77% | 12/96 |
| 18 | F | 9.09 | 2.30% | 12/96 - 2/97 |
| 19 | H | 8.08 | 3.56% | 12/96 |
| 20 | F | 8.77 | 1.77% | 12/96 |
| 21 | F | 8.41 | 5.32% | 02/97 |
| 22 | F | 8.57 | 3.50% | 03/97 |
| 23 | H | 9.23 | 0.00% | 12/96 |
| 24 | F | 8.82 | 1.69% | 03/97 |
| 25 | F | 8.38 | 12.46% | 12/96 |
| 26 | F | 8.59 | 4.76% | 12/96 |
| 27 | H | 8.62 | 1.50% | 12/96 |
| 28 | H | 8.30 | 1.35% | 03/97 |
| 29 | F | 8.86 | 2.79% | 04/97 |
| 30 | H | 8.61 | 1.46% | 12/96 |
| 31 | F | 8.57 | 3.50% | 03/97 |
| 32 | F | 8.72 | 3.02% | 01/97 |
| 33 | F | 8.41 | 9.13% | 03/97 |
| 34 | H | 8.43 | 3.70% | 12/96 |
| 35 | F | 8.78 | 2.14% | 03/97 |

**STRATA 3 - SMALL PROVIDERS**
**AVERAGE COST AFTER REBATE**

| SAMPLE NUMBER | H - HOSPITAL F - FREESTANDING | | AVG COST AFTER REBATE | REBATE | INVOICE MONTH |
|---|---|---|---|---|---|
| 1 | F | | 8.41 | 9.13% | 03/97 |
| 2 | | H | 8.41 | 2.00% | 12/96 |
| 3 | F | | 9.10 | 4.76% | 12/96 |
| 4 | F | | 8.44 | 12.15% | 12/97 |
| 5 | F | | 8.40 | 5.47% | 05/97 |
| 6 | F | | 8.39 | 5.53% | 03/97 |
| 7 | | H | 8.41 | 5.86% | 12/96-01/97 |
| 8 | F | | 8.41 | 9.13% | 03/97 |
| 9 | F | | 8.41 | 9.13% | 03/97 |
| 10 | | H | 8.83 | 2.13% | 01/97 - 04/97 |
| 11 | F | | 8.69 | 3.36% | 02/97 |
| 12 | | H | 8.08 | 2.00% | 12/96 |
| 13 | F | | 8.41 | 9.13% | 03/97 |
| 14 | F | | 8.75 | 2.00% | 12/96 |
| 15 | | H | 8.96 | 0.00% | 01/97-04/97 |
| 16 | | H | 8.51 | 0.00% | 12/96 & 03/97 |
| 17 | F | | 8.38 | 12.46% | 12/96 |
| 18 | | H | 8.35 | 3.00% | 12/96 |
| 19 | F | | 8.56 | 5.54% | 03/97 |
| 20 | | H | 7.81 | 0.00% | 12/96 & 03/97 |
| 21 | F | | 8.41 | 9.13% | 03/97 |
| 22 | F | | 8.86 | 1.80% | 01/97 |
| 23 | F | | 8.77 | 1.77% | 12/96 |
| 24 | F | | 8.41 | 5.86% | 12/96-01/97 |
| 25 | F | | 8.41 | 9.13% | 03/97 |
| 26 | F | | 8.52 | 4.48% | 12/96 |
| 27 | | H | 8.54 | 2.00% | 12/96 |
| 28 | | H | 7.30 | 0.00% | 01/97 |
| 29 | F | | 8.41 | 9.13% | 03/97 |
| 30 | F | | 8.70 | 3.00% | 12/96 |
| 31 | F | | 8.79 | 2.31% | 12/96 |
| 32 | F | | 8.41 | 9.13% | 03/97 |
| 33 | F | | 8.38 | 12.46% | 12/96 |
| 34 | F | | 8.41 | 9.13% | 03/97 |
| 35 | F | | 9.19 | 3.25% | 02/96 - 12/96 |

DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Care Financing Administration

The Administrator
Washington, D.C. 20201

NOV 19 1997

**DATE:**

**TO:** June Gibbs Brown
Inspector General

**FROM:** Nancy-Ann Min DeParle
Administrator

**SUBJECT:** Office of Inspector General (OIG) Draft Report: "Review of EPOGEN Reimbursement," (A-01-97-00509)

We reviewed the above-referenced report that discusses whether Medicare's reimbursement for the drug EPOGEN (EPO) should be reduced to reflect current market prices. Reimbursement for EPOGEN has changed since it was first covered by Medicare in 1989. Medicare reimbursed for EPO on a per-treatment basis of $40 for up to 10,000 units administered and $70 for treatment above 10,000 units. The reimbursement methodology was changed by the Omnibus Budget Reconciliation Act (OBRA) of 1990 which provided that EPO reimbursement, beginning in January 1991, would be on a per-unit basis, and set the reimbursement rate at $11 per 1,000 units administered. Also, OBRA 1990 required the Secretary to determine, beginning in 1992, an appropriate payment rate for EPO reimbursement. In February 1993, OIG determined that the cost of EPO ranged between $10 and $10.10 per 1,000 units administered, or approximately 41 percent less than the previous reimbursement rate of $11 per 1,000 units. As a result, the Health Care Financing Administration (HCFA), in agreement with OIG, reduced the payment rate to $10 per 1,000 units administered.

The findings contained in the report indicate the current EPO reimbursement rate of $10 per 1,000 units exceeds the current cost of purchasing EPO by approximately $1. Specifically, 95 of the 105 providers randomly selected for review paid under $9 per 1,000 units of EPO. Accordingly, OIG is recommending that the reimbursement level for EPO be further reduced to reflect a payment rate of $9 per 1,000 units administered.

OIG Recommendation

Recommend that the Secretary consider reducing Medicare reimbursement for EPO to $9 per 1,000 units administered.

HCFA Response

We concur. HCFA and the OIG have been working very closely on this issue and we agree with the OIG's findings and recommendations in this report. We are currently determining how best to implement the recommendation. We intend to pursue this change either through the rulemaking process or as a legislative initiative in the President's Fiscal Year 1999 Budget.