

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**MEDICARE REIMBURSEMENT FOR
EXISTING END-STAGE RENAL
DISEASE DRUGS**



Inspector General

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Office of Inspector General

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⌄ A B S T R A C T

According to section 623(c) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), this study is to determine the difference between the Medicare payment amount for separately billable end-stage renal disease drugs and the acquisition costs of these drugs for facilities. The study must also estimate the rate of growth of facilities' expenditures for these drugs. In 2003, the 4 largest dialysis providers paid between 12 percent and 68 percent less than the current Medicare reimbursement amount for the 10 drugs we reviewed. When weighted by 2002 total Medicare reimbursement for each of the drugs, acquisition costs for the 4 largest providers averaged 22 percent below current Medicare reimbursement amounts. Facilities not owned or managed by the 4 largest providers paid between 5 percent and 58 percent less than the Medicare reimbursement amount for the 10 drugs. On average, these facilities paid 14 percent less than the Medicare reimbursement amount. In 2003, average sales prices (ASPs) for the drugs under review were between 6 percent and 66 percent below the Medicare reimbursement amount. When weighted by 2002 total Medicare reimbursement for each of the drugs, ASP was, on average, 17 percent below the Medicare reimbursement amount. According to our projections, Medicare reimbursement for all separately billable drugs will rise by 11 percent (\$216 million) between calendar years 2003 and 2005.

‡ E X E C U T I V E S U M M A R Y

OBJECTIVE

To (1) determine the difference between the Medicare reimbursement amount for selected separately billable end-stage renal disease (ESRD) drugs and the acquisition cost of these drugs to facilities, and (2) estimate the growth rate of expenditures for ESRD drugs billed by these facilities, as required by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA).

BACKGROUND

The Centers for Medicare & Medicaid Services (CMS) reimburses all ESRD facilities based on a prospective payment system known as the composite rate. Facilities receive a fixed composite rate payment for each dialysis treatment they provide. The composite rate does not include many drugs that may be part of dialysis treatment, including erythropoietin (EPO) and numerous other drugs.

Medicare reimbursement for EPO is limited by statute. Hospital-based ESRD facilities are reimbursed for drugs other than EPO based on Medicare principles of reasonable cost. In contrast, independent dialysis facilities are reimbursed for separately billable drugs (other than EPO) based on the lower of the submitted charge or 95 percent of the drugs' average wholesale prices. In calendar year (CY) 2002, Medicare reimbursed more than \$1.8 billion for separately billable drugs provided by independent dialysis facilities.

We conducted this study based on a mandate set forth in section 623(c) of MMA. According to section 623(c), this study is to determine the difference between the Medicare payment amount for separately billable ESRD drugs and the acquisition costs of these drugs for facilities. This study must also estimate the rate of growth of facilities' expenditures for these drugs. CMS is to use data from this study to set CY 2005 reimbursement rates for ESRD drugs. CMS is also directed to increase the composite rate payment to offset any reductions in drug reimbursement resulting from this study.

We collected acquisition cost data from the 4 largest national dialysis providers for 10 drugs that amounted to 98.4 percent of the total Medicare reimbursement in 2002. These 4 providers accounted for 73 percent of Medicare reimbursement that year. We also collected cost data from a sample of facilities that are not owned or managed by these four providers. We collected average sales price (ASP) data for the 10

drugs from drug manufacturers. We compared acquisition cost and ASP data to the current Medicare reimbursement amount (including copayment amount).

To estimate the growth rate of expenditures, we obtained EPO and non-EPO reimbursement for each month from July 2000 to September 2003 from CMS. Using a commercial time-series program, we developed autoregressive moving average (ARMA) models to obtain monthly forecasts of EPO and non-EPO reimbursement from October 2003 to December 2005. We summed these monthly forecasts to obtain the yearly projections for 2004 and 2005.

FINDINGS

In 2003, the 4 largest dialysis providers paid, on average, 22 percent less than the Medicare reimbursement amount for 10 drugs. The 4 largest dialysis providers paid between 12 percent and 68 percent less than the current Medicare reimbursement amount for the 10 drugs we reviewed. Four of the 10 drugs had average acquisition costs that were at least 50 percent below the current Medicare reimbursement amount. The average acquisition cost for EPO, which accounts for roughly two-thirds of Medicare reimbursement for separately billable drugs, was 12 percent less than the reimbursement amount based on the statutory limit. When weighted by 2002 total Medicare reimbursement for each of the drugs, acquisition costs for the 4 largest providers were an average of 22 percent below current Medicare reimbursement amounts.

In 2003, 122 facilities in our sample paid, on average, 14 percent less than the Medicare reimbursement amount for 10 drugs. For the 10 drugs we reviewed, the 122 facilities not owned or managed by the 4 largest providers had an average acquisition cost that was between 5 percent and 58 percent less than the current Medicare reimbursement amount. When weighted by 2002 total Medicare reimbursement for each of the drugs, acquisition costs for the 122 facilities averaged 14 percent below current Medicare reimbursement amounts (compared to 22 percent below for the 4 largest providers). According to the facilities, actual acquisition costs for the drugs varied widely.

In 2003, manufacturer-reported ASPs for 10 drugs were, on average, 17 percent below the Medicare reimbursement amount. In 2003, ASPs for the 10 drugs under review were between 6 percent

and 66 percent below the Medicare reimbursement amount. When weighted by 2002 total Medicare reimbursement for each of the drugs, ASP was, on average, 17 percent below the Medicare reimbursement amount.

Medicare expenditures for all separately billable drugs are estimated to increase by 11 percent between 2003 and 2005. According to our projections, we expect that Medicare's expenditures for all separately billable drugs will rise by 11 percent (\$216 million) between 2003 and 2005. We estimate that Medicare reimbursement for EPO will increase by \$146 million (11 percent) during this period, and that reimbursement for other separately billable drugs will grow by \$70 million (11 percent).

In calculating future growth rates, we looked exclusively at past monthly growth rates for the reimbursement for separately billable drugs. We did not account for the potential effects of future changes, such as adjustments to the drug reimbursement methodology, the approval of new dialysis drugs, unforeseen increases in the number of beneficiaries eligible for the benefit, or the establishment of new quality standards on drug utilization. We realize, however, that these factors may play a key role in any future growth. Therefore, we would like to stress that CMS should update our projections as new reimbursement data become available.

CONCLUSION

MMA required the Office of Inspector General to provide to CMS a report that (1) determined the difference between the Medicare payment amount for separately billable ESRD drugs and the acquisition costs of these drugs for facilities, and (2) estimated the rate of growth of facilities' expenditures for these drugs. This information is to be used by CMS in its efforts to set CY 2005 reimbursement amounts for separately billable ESRD drugs.

The information in this report represents average acquisition costs to independent dialysis facilities for 10 drugs in 2003. According to respondents, the prices of some of these drugs have already increased in 2004, and may change again by the time a new pricing methodology goes into effect in 2005. In addition, while the goal of this study was to establish the acquisition cost of certain drugs to independent dialysis facilities, the data make it clear that different facilities sometimes pay different prices for the same product. Because of this, any

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reimbursement amount set by CMS may still allow some facilities to profit from purchasing drugs, and others to potentially lose money.

In conclusion, we hope that these data are useful to CMS in establishing a methodology for reimbursing separately billable ESRD drugs. We would be pleased to assist CMS as they move forward with any new pricing methodology.

Agency Comments

In accordance with the statutory mandate, we issued a draft report to CMS on April 1, 2004 that contained much of the data presented in this report. CMS thanked us for the opportunity to review the draft report. They included several technical comments that have been addressed in the final version.

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OBJECTIVE

To (1) determine the difference between the Medicare reimbursement amount for selected separately billable end-stage renal disease (ESRD) drugs and the acquisition cost of these drugs to facilities, and (2) estimate the growth rate of expenditures for ESRD drugs billed by these facilities, as required by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA).

BACKGROUND

Medicare Payments for Dialysis Services

The Medicare program currently covers dialysis services for more than 265,000 patients under its ESRD benefit. Payments for dialysis and accompanying services account for approximately \$5 billion of the \$13 billion Medicare spends annually on dialysis patients. In accordance with 42 U.S.C. § 1395rr, the Centers for Medicare & Medicaid Services (CMS) reimburses all dialysis facilities based on a prospective payment system known as the composite rate. Facilities receive a fixed composite rate payment for each dialysis treatment they provide. The composite rate includes most items related to dialysis services, including labor costs, related supplies, routine tests, and some drugs. However, the composite rate does not include certain drugs that may be part of dialysis treatment, including erythropoietin (EPO) and numerous other drugs.

Medicare Payments for Separately Billable ESRD Drugs

According to CMS's *Provider Reimbursement Manual*, Medicare coverage of separately billable drugs in dialysis facilities is limited to products that cannot be self-administered, *i.e.*, drugs that are administered by a health care professional. The exception to this requirement is EPO, a drug that stimulates the production of red blood cells in patients with anemia. EPO furnished by dialysis facilities is covered even if it is self-administered by the patient.

Medicare reimbursement for EPO is limited by statute. Hospital-based ESRD facilities are reimbursed for drugs other than EPO based on Medicare principles of reasonable cost. In contrast, independent dialysis facilities are reimbursed for separately billable drugs other than EPO through a different payment methodology. Medicare reimbursement for a drug furnished in an independent dialysis facility is based on the lower of the billed amount or 95 percent of its average

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wholesale price. In calendar year (CY) 2002, Medicare reimbursed more than \$1.8 billion for separately billable drugs provided by independent dialysis facilities.

Studies Mandated By the MMA

We conducted this study based on a mandate set forth in the MMA. Section 623(c)(1) of MMA states:

The Inspector General of the Department of Health and Human Services shall conduct two studies with respect to drugs and biologicals (including erythropoietin) furnished to end-stage renal disease patients under the medicare program which are separately billable by end-stage renal disease facilities.

According to MMA, the studies are to determine the difference between the Medicare payment amount for separately billable ESRD drugs and the acquisition costs of these drugs for facilities. The studies must also estimate the rate of growth of facilities' expenditures for these drugs. The first study, which focuses on existing ESRD drugs, must be completed by April 1, 2004. The second study, which focuses on new ESRD drugs, is to be completed by April 1, 2006.

CMS is to use data from the first study to set CY 2005 reimbursement rates for ESRD drugs, including EPO, billed by independent dialysis facilities. CMS is also directed to increase the composite rate payment to offset any reductions in drug reimbursement recommended by the study.

METHODOLOGY

Medicare Reimbursement Amounts

We determined total Medicare reimbursement¹ for separately billable ESRD drugs in independent dialysis facilities in CY 2002 by accessing CMS's National Claims History File. We created a summary of total Medicare reimbursement made to independent dialysis facilities for 3 revenue center codes (0634, 0635, 0636) used to bill for drugs. Revenue center codes 0634 and 0635 represent EPO. Code 0636 represents drugs requiring further identification via procedure codes.

¹ "Total Medicare reimbursement" only reflects program expenditures, and does not include beneficiary copayments.

According to data in the National Claims History File, Medicare reimbursed independent dialysis facilities \$1.84 billion for the selected revenue center codes in CY 2002. Reimbursement for revenue center codes 0634 and 0635 (EPO) was \$1.23 billion of the total, with the remaining \$610 million being for revenue center code 0636 (drugs requiring a procedure code). We ranked the procedure codes listed with revenue center code 0636 from those with the most total reimbursement to those with the least total reimbursement. The top 13 procedure codes represented 11 different drugs, and accounted for \$594 million of the \$610 million reimbursed for revenue center code 0636 in 2002.

We removed two procedure codes representing Hepatitis B vaccines from the list of reviewed drugs. We removed these codes because vaccines appear to be excluded from any new pricing methodology, and will apparently be reimbursed at previous levels. With the two vaccine codes removed, Medicare reimbursement for the remaining 11 procedure codes and EPO totaled \$1.81 billion, or 98.4 percent of total Medicare reimbursement in 2002.

For EPO, we determined the Medicare reimbursement amount based on the statutory limit. For the 11 procedure codes, we determined the current Medicare reimbursement amount (including copayment amount) by accessing the January 2004 Medicare Single Drug Pricer file.² We found that several of the 11 procedure codes under review had been changed since 2002. Some codes were changed to account for new dosage sizes, while others were combined into new codes. These coding changes reduced the number of procedure codes in our study from 11 to 9 (1 code for each of the 9 drugs).

Identifying Products Represented by Procedure Codes

We used the October 2003 publication of *Drug Topics Red Book* to identify all drug products that met the definition of the 9 procedure codes and EPO. Five of the nine procedure codes were for single-source drugs, meaning only one product (in varying unit sizes) met the procedure code definition. EPO is also a single source drug. The other four procedure codes represented multiple-source drugs, meaning more

² The "Medicare Reimbursement Amount," as published in the Single Drug Pricer File, consists of 2 separate payments: 80 percent of this amount is reimbursed to the provider by the Medicare program itself, with the remaining 20 percent being coinsurance that is to be paid to the provider by the beneficiary. Though EPO for ESRD patients is not listed in the Single Drug Pricer file, it is also subject to the 80 percent program payment and the 20 percent beneficiary coinsurance.

than one drug product met the definition of the code. Using the information listed in *Drug Topics Red Book*, we then identified the manufacturers for each of the drug products.

Determining Facility Acquisition Costs

A large majority of independent dialysis facilities are owned or managed by national dialysis corporations. Using an industry publication, we identified the four largest corporations that provide dialysis services (hereinafter referred to as providers). We asked the four providers to provide a list of Medicare provider numbers for all of the facilities that they owned or managed. In 2002, 3,538 provider numbers appeared on reimbursed claims for separately billable drugs used in independent dialysis facilities, of which 2,396 represented facilities owned or managed by the 4 largest providers.³ We matched the 2,396 provider numbers against the National Claims History File, and determined that facilities owned or managed by the 4 providers received 73 percent of Medicare reimbursement for separately billable drugs in 2002.

We sent a request to the 4 providers asking them to provide CY 2003 acquisition cost information for the drugs under review. The requested information was to include data on the total cost of the purchases, the number of units purchased, and the amount of discounts and rebates received. We calculated an overall acquisition cost for each drug by adding the total cost of purchases (net of all rebates and discounts) made by all four providers and dividing the total by the number of units purchased. We did not remove prompt pay discounts from our calculations as we believe they are a key factor that should be accounted for when computing actual acquisition cost. At the request of the providers, we also obtained a list of any additional costs associated with acquiring separately billable drugs. For this report, we did not verify any of the cost information given by the providers.

According to the National Claims History File, Medicare reimbursed 1,142 facilities that were not owned or managed by the 4 largest providers in 2002. To estimate the costs of drugs for these facilities, we selected a random sample of 200 facilities. We sent a similar request to the sampled facilities as was sent to the four providers. Ten of the 200 facilities informed us that they were now owned or managed by 1 of the

³ According to the lists provided by the 4 largest providers, they owned or managed 2,396 facilities. However, we later determined that these providers had acquired other facilities that were not represented in their lists. Therefore, these 4 providers may now actually account for more than 73 percent of Medicare reimbursement.

4 largest providers. We received responses from 122 of the 190 facilities (64 percent) remaining in the sample. We calculated an overall acquisition cost in CY 2003 for each drug by taking the average price of the drug among all the responding facilities. We did not verify any of the cost information given by the facilities.

Determining Manufacturer Average Sales Prices

According to *Drug Topics Red Book*, there are 11 different manufacturers of the 10 drugs under review. We sent a request to each of the manufacturers asking them to provide for each of their products:

- The average sales price (ASP) in CY 2003 to all purchasers. ASP, which will become the basis for Part B drug reimbursement in 2005, is defined by MMA as the total sales to all purchasers (net of all rebates and discounts and excluding certain exempted sales) divided by the number of units sold to all purchasers.
- ASP to independent dialysis facilities only
- The 75th and 90th percentile sales prices to all purchasers (*e.g.*, 75 percent of sales were at X price or lower, and 90 percent were at Y price or lower).
- The 75th and 90th percentile sales prices to independent dialysis facilities only

All 11 manufacturers responded to our request. For drugs with products distributed by more than one manufacturer, we calculated the median of the supplied ASPs and percentile data. Although we requested from the manufacturers ASP data for independent dialysis facilities only, as well 75th percentile and 90th percentile pricing data, we did not receive this information for all of the drugs. Furthermore, the data that was provided varied widely in comparison to the ASP for all purchasers, and we concluded that it was not meaningful to report.

In their responses, most manufacturers indicated that the data they provided were to be considered confidential. We specifically requested that manufacturers consent to having their reported ASPs included in this report. Because not every manufacturer provided such consent, we are not listing specific ASPs for any individual drugs. We will only discuss ASPs in general terms in this report.

Comparing Medicare Reimbursement to Acquisition Costs

We compared the Medicare reimbursement amount for each drug to facility acquisition costs and reported ASPs by calculating the

percentage difference between the Medicare reimbursement amount and each number. To determine the overall amount that the acquisition costs and ASPs were below Medicare reimbursement, we:

- 1) Assigned a weight to each drug based on its percentage of Medicare reimbursement
- 2) Multiplied this weight by the percentage difference between the Medicare reimbursement amount and the acquisition cost/ASP
- 3) Totaled the weight-adjusted percentage differences

Estimating Growth Rate of Expenditures

From CMS's National Claims History File, we obtained reimbursement totals for all separately billable EPO and non-EPO drugs for each month from June 2000 to September 2003⁴. Using a combination of a commercial time-series program called ITSM[®] and Microsoft Excel[®], we first removed trend and seasonal components from the data to obtain stationary residuals. We then used ITSM[®] to find autoregressive moving average (ARMA) models for each set of residuals. Using these models, we obtained monthly forecasts of EPO and non-EPO reimbursement from October 2003 to December 2005. We summed these monthly forecasts to obtain the yearly projections for 2003, 2004, and 2005.

While these models pass all standard tests for goodness-of-fit, they should be refined using additional data as they become available. In addition, it is important to note that these models were based entirely from past data on reimbursement for EPO and non-EPO drugs. To the extent that any underlying factors governing reimbursement for ESRD drugs were to change significantly, then our projection may become less accurate in the future.

⁴ The variable for Medicare reimbursement was not fully populated until June 2000. In order to get an estimate of total Medicare reimbursement for all of 2000, we calculated a ratio of Medicare reimbursement to Medicare total charges for June through December of 2000, and then multiplied Medicare total charges for January through May by this ratio. We added the estimate of reimbursement for the first 5 months to the actual reimbursement for the last 7 months to get a figure for total 2000 reimbursement.

SCOPE

This inspection focused only on drugs that were separately billed by independent dialysis facilities. We limited the focus to independent dialysis facilities because drugs that they provide are currently reimbursed at a percentage of published average wholesale prices. Other types of facilities are reimbursed for separately billable drugs based on Medicare principles of reasonable cost.

Almost 250 separately billable drugs were reimbursed by Medicare in 2002. We reviewed pricing data for 10 drugs (9 procedure codes plus EPO) that accounted for 98.4 percent of all Medicare reimbursement. We did not independently verify any of the cost or price information provided by corporations, facilities, or manufacturers.

The cost data reported for the sampled facilities are meant to portray costs for the 122 facilities only. We did not project the data to other facilities.

In calculating future growth rates, we looked exclusively at past monthly growth rates for the reimbursement for separately billable drugs. We did not account for the potential effects of changes to the drug reimbursement methodology, the approval of new dialysis drugs, unforeseen increases in the number of beneficiaries eligible for the benefit, or the establishment of new quality standards on drug utilization. We realize, however, that these factors may play a key role in any future growth. Therefore, we would like to stress that CMS should update our projections as new reimbursement data become available.

► FINDINGS

In 2003, the 4 largest dialysis providers paid, on average, 22 percent less than the Medicare reimbursement amount for 10 drugs.

As shown in Table 1, the 4 largest dialysis providers paid between 12 percent and 68 percent less than the current Medicare

reimbursement amount for the 10 drugs we reviewed. Four of the 10 drugs had average acquisition costs that were at least 50 percent below the current Medicare reimbursement amount. The average acquisition cost for EPO, which accounts for roughly two-thirds of Medicare reimbursement for separately billable drugs, was 12 percent less than the reimbursement amount based on the statutory limit. When weighted by 2002 total Medicare reimbursement for each of the drugs, acquisition costs for the 4 largest providers averaged 22 percent below current Medicare reimbursement amounts.

Table 1: Acquisition Costs of Four Largest Providers Compared to Medicare Reimbursement

Procedure Code	Drug Description	Current Medicare Reimbursement Amount	2003 Average Acquisition Cost	Percent Acquisition Cost Is Below Medicare	2002 Total Medicare Reimbursement
N/A	EPO, 1000 units	\$10.00	\$8.79	12%	\$1,225,249,269
J0636	Calcitriol, .1 mcg	\$1.38	\$0.87	37%	\$22,075,118
J1270	Doxercalciferol, 1 mcg	\$5.50	\$2.32	58%	\$23,143,397
J1750	Iron Dextran, 50 mg	\$17.91	\$10.00	44%	\$11,716,368
J1756	Iron Sucrose, 1 mg	\$0.66	\$0.32	51%	\$90,251,738
J1955	Levocarnitine, 1 gm	\$34.20	\$10.93	68%	\$30,254,432
J2501	Paricalcitol, 1 mcg	\$5.33	\$3.50	34%	\$287,086,139
J2916	Sodium Ferric Gluconate Complex, 12.5 mg	\$8.17	\$4.40	46%	\$108,979,052
J2997	Alteplase, Recombinant, 1 mg	\$36.70	\$28.84	21%	\$3,443,736
J3370	Vancomycin HCl, 500 mg	\$7.03	\$2.68	62%	\$3,602,902
TOTAL	WEIGHTED BY 2002 REIMBURSEMENT			22%	\$1,805,802,151

Source: 2004 OIG Survey of 4 Largest Dialysis Providers

Each provider reported that several of the prices listed in Table 1 are not representative of 2004 acquisition costs because manufacturers have recently instituted price increases for several of the drugs. For example, all 4 providers reported a 5 percent price increase for Paricalcitol that went into effect on August 1, 2003. Recent or future price increases of between 3 percent and 18 percent were also reported for Doxercalciferol, Alteplase, and EPO.

Three providers reported that they are able to lower actual acquisition costs through the utilization of overfill for EPO. According to one

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respondent, the manufacturer of EPO overfills its vials (e.g., puts more than the stated amount of EPO in a vial) to “guarantee a minimum dosing level for effective use of the product. The overfill ranges from 7 to 14 percent based on type of vials.” Another provider reported a similar overfill percentage for Paricalcitol. Because the amount of overfill varies, and because facilities may have different practices regarding the utilization of overfill, it was not accounted for in any of the acquisition cost calculations.

The providers also supplied data on additional costs they believe are associated with acquiring drugs. These costs included inventory costs, working capital costs, and spoilage/waste costs. The providers estimated these additional expenses accounted for as much as 1.5 percent of total drug costs. We did not perform any independent analysis of this data.

In 2003, 122 facilities in our sample paid, on average, 14 percent less than the Medicare reimbursement amount for 10 drugs.

As shown in Table 2 on the following page, the 122 facilities not owned or managed by the 4 largest providers had an average

acquisition cost that was between 5 percent and 58 percent less than the current Medicare reimbursement amount for the 10 drugs we reviewed. The 122 facilities that responded to our request paid more, on average, for each of the 10 drugs than the 4 largest providers. When weighted by 2002 total Medicare reimbursement for each of the drugs, acquisition costs for the 122 facilities averaged 14 percent below current Medicare reimbursement amounts (compared to 22 percent below for the 4 largest providers).

According to the data, actual acquisition costs for each drug varied widely among facilities. For example, the average acquisition cost for EPO was \$9.50, 5 percent less than the statutorily limited reimbursement amount of \$10.00. The lowest acquisition cost for EPO reported by a facility in our sample was \$8.68, while the highest reported cost was \$10.96. Approximately one-quarter of the respondents in the sample reported paying more than the current Medicare reimbursement amount of \$10.00 for EPO.

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Table 2: Acquisition Costs of Sampled Facilities Compared to Medicare Reimbursement

Procedure Code	Drug Description	Current Medicare Reimbursement Amount	2003 Average Acquisition Cost	Percent Acquisition Cost Is Below Medicare	2002 Total Medicare Reimbursement
N/A	EPO, 1000 units	\$10.00	\$9.50	5%	\$1,225,249,269
J0636	Calcitriol, .1 mcg	\$1.38	\$0.92	33%	\$22,075,118
J1270	Doxercalciferol, 1 mcg	\$5.50	\$2.59	53%	\$23,143,397
J1750	Iron Dextran, 50 mg	\$17.91	\$10.25	43%	\$11,716,368
J1756	Iron Sucrose, 1 mg	\$0.66	\$0.39	41%	\$90,251,738
J1955	Levocarnitine, 1 gm	\$34.20	\$16.87	51%	\$30,254,432
J2501	Paricalcitol, 1 mcg	\$5.33	\$4.15	22%	\$287,086,139
J2916	Sodium Ferric Gluconate Complex, 12.5 mg	\$8.17	\$4.96	39%	\$108,979,052
J2997	Alteplase, Recombinant, 1 mg	\$36.70	\$30.15	18%	\$3,443,736
J3370	Vancomycin HCl, 500 mg	\$7.03	\$2.92	58%	\$3,602,902
TOTAL	WEIGHTED BY 2002 REIMBURSEMENT			14%	\$1,805,802,151

Source: 2004 OIG Survey of Facilities not Owned or Managed by 4 Largest Providers

In 2003, manufacturer-reported ASPs for 10 drugs were, on average, 17 percent below the Medicare reimbursement amount.

In 2003, ASPs for the 10 drugs under review were between 6 percent and 66 percent below the Medicare reimbursement amount.

Three of the 10 separately billed drugs had reported ASPs that were more than 50 percent below Medicare reimbursement. When weighted by 2002 total Medicare reimbursement for each of the drugs, ASP was, on average, 17 percent below the Medicare reimbursement amount. This figure falls between the average acquisition costs of the 4 largest providers (22 percent below Medicare) and the 122 providers in our sample (14 percent below Medicare).

ASPs for the 10 drugs ranged from 11 percent below the acquisition costs to 35 percent above the acquisition costs of the 4 largest providers, averaging 6 percent above acquisition cost. In comparison, ASPs for the 10 drugs ranged from 19 percent below the acquisition costs to 3 percent above the acquisition costs of the 122 responding facilities in our sample, averaging 4 percent below acquisition cost. While multiple source drugs represented the more extreme values in the ranges, they also accounted for fairly small percentages of total Medicare reimbursement.

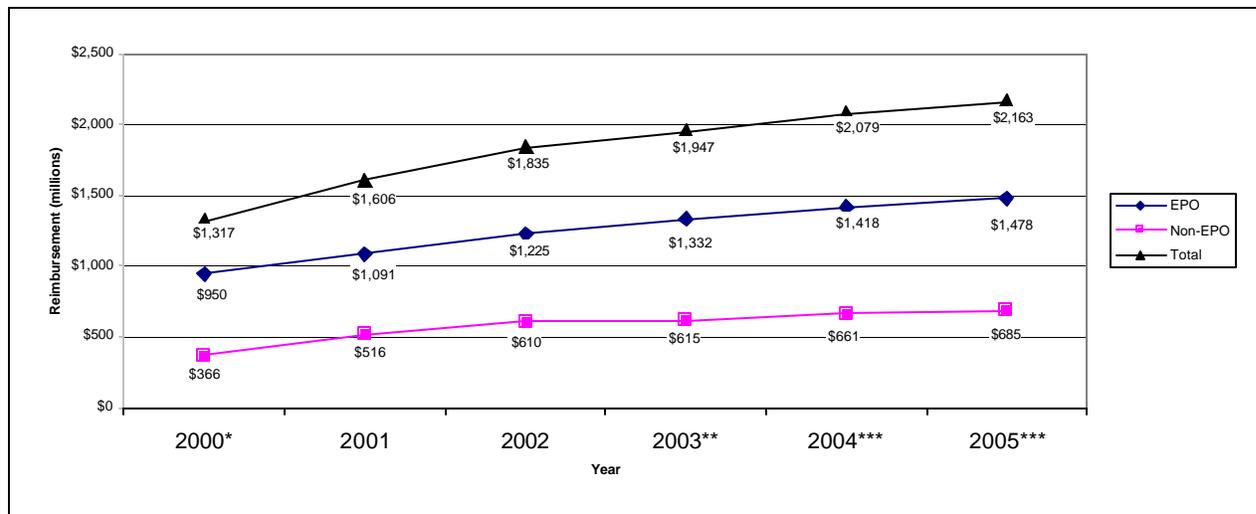
FINDINGS

Medicare expenditures for all separately billable drugs are estimated to increase by 11 percent between 2003 and 2005.

According to our projections, we expect that Medicare's expenditures for all separately billable drugs will rise by 11 percent (\$216 million) between 2003 and 2005. We estimate that Medicare reimbursement for EPO will increase by \$146 million (11 percent) during this period, and that reimbursement for other separately billable drugs will grow by \$70 million (11 percent). Graph 1 on the following page illustrates the projected growth.

As Graph 1 shows, the growth of expenditures for both EPO and non-EPO drugs has been slowing in recent years. For example, total Medicare reimbursement for EPO increased by 15 percent between 2000 and 2001, 12 percent between 2001 and 2002, and just 9 percent between 2002 and 2003. Similarly, Medicare reimbursement for non-EPO drugs increased by 41 percent between 2000 and 2001, 18 percent between 2001 and 2002, and only 1 percent between 2002 and 2003.

Graph 1: Future Growth of Medicare Expenditures for Separately Billable Drugs



* Estimated ** Projected, Based on Partial-Year Data and Prior Growth Rates *** Projected, Based on Prior Growth Rates

In calculating future growth rates, we looked exclusively at past monthly growth rates for the reimbursement for separately billable drugs. We did not account for the potential effects of future changes, such as adjustments to the drug reimbursement methodology, the approval of new dialysis drugs, unforeseen increases in the number of

F I N D I N G S

beneficiaries eligible for the benefit, or the establishment of new quality standards on drug utilization. We realize, however, that these factors may play a key role in any future growth. Therefore, we would like to stress that CMS should update our projections as new reimbursement data become available.

‡ C O N C L U S I O N

MMA required the Office of Inspector General to provide to CMS a report that (1) determined the difference between the Medicare payment amount for separately billable ESRD drugs and the acquisition costs of these drugs for facilities, and (2) estimated the rate of growth of facilities' expenditures for these drugs. This information is to be used by CMS in its efforts to set CY 2005 reimbursement amounts for separately billable ESRD drugs.

The information in this report represents average acquisition costs to independent dialysis facilities for 10 drugs in 2003. According to respondents, the prices of some of these drugs have already increased in 2004, and may change again by the time a new pricing methodology goes into effect in 2005. In addition, while the goal of this study was to establish the acquisition cost of certain drugs to independent dialysis facilities, the data make it clear that different facilities sometimes pay different prices for the same product. Because of this, any reimbursement amount set by CMS may still allow some facilities to profit from purchasing drugs, and others to potentially lose money.

In conclusion, we hope that these data are useful to CMS in establishing a methodology for reimbursing separately billable ESRD drugs. We would be pleased to assist CMS as they move forward with any new pricing methodology.

Agency Comments

In accordance with the statutory mandate, we issued a draft report to CMS on April 1, 2004 that contained much of the data presented in this report. CMS thanked us for the opportunity to review the draft report. They included several technical comments that have been addressed in the final version. The full text of CMS's comments is presented in the Appendix.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

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DATE: APR 15 2004
TO: Dara Corrigan
Acting Principal Deputy Inspector General
Office of Inspector General

FROM: Mark B. McClellan, M.D., Ph.D. *Mark McClellan*
Administrator
Centers for Medicare & Medicaid Services

SUBJECT: Office of Inspector General Draft Report: "Medicare Reimbursement for Existing End Stage Renal Disease Drugs," (OEI-03-04-00120)

Thank you for the opportunity to review and comment on the Office of Inspector General's (OIG) draft report titled "Medicare Reimbursement for Existing End Stage Renal Disease (ESRD) Drugs." The Centers for Medicare & Medicaid Services (CMS) has the following comments.

Section 623 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) requires the OIG to determine the difference between the Medicare payment amounts for drugs and biologicals that are billed and paid separately from the ESRD composite rate (these drugs are referred to as "separately billable" ESRD drugs) and the acquisition costs for the ESRD facilities that bill for these drugs. This section of the MMA also requires that the OIG estimate the growth rate of expenditures for these drugs. This draft report is in response to this statutory requirement.

Technical Comments:

- Where the phrase "Medicare reimbursement" is used, the report should specify whether the amounts shown are for the program's share of the payment (i.e., the allowed charge less Part B coinsurance and unmet Part B deductible amounts) or the total amount including copay and deductible amounts.
- Where the phrase "reimbursement amount set by statute" is used with respect to payments for erythropoietin (EPO), the report should instead use the phrase "payment amount based on the statutory limit." The statute does not specify a payment rate for EPO, but rather sets a cap which the Secretary may not exceed.
- Where the report states that "a drug furnished by an independent dialysis facility is currently reimbursed at 95 percent of its average wholesale price (AWP)", the report

should state instead that the program's payment is based on the lower of the submitted charge or 95 percent of the AWP. Again, the phrase "is based on" is more accurate than "reimbursed at" because of the Part B coinsurance and deductible requirements that apply.

- Where the report states that hospital-based dialysis facilities are reimbursed for separately billable drugs "at cost," the report should state instead that these facilities are reimbursed for separately billable drugs "based on Medicare principles of reasonable cost."
- In regard to the OIG's memorandum to CMS -- Page 1, first paragraph, line starting with "According to MMA," could read as follows: According to MMA Section 623(c), "the Inspector General of the Department of Health and Human Services, shall conduct two studies with respect to drugs and biologicals (including erythropoietin, i.e. EPO) furnished to end-stage renal dialysis (ESRD) patients under the Medicare program which are separately billed by ESRD facilities." This draft report is in response to the first study, which requires OIG to provide these data to the Centers for Medicare & Medicaid Services (CMS) by April 1, 2004.

The OIG should discuss the second study under Section 623(c) and identify when it is due.

- In regard to the OIG's memorandum to CMS -- Page 2, first paragraph, line starting with "According to our projections" could read: According to our projections, Medicare reimbursement for all separately billable drugs will rise by 11 percent (\$216 million) between calendar years 2003 and 2005. We estimate that Medicare reimbursement for EPO will increase by \$146 million (11 percent) over the next 2 years, and that reimbursement for other separately billable drugs will grow by \$70 million (11 percent), accounting for the \$216 million total between calendar years 2003 and 2005.
- In the Abstract Section -- please add after each "MMA," section 623(c) (e.g., second sentence, "According to MMA (Section 623(c)), this study...." - may want to add Section 623(c) throughout the document after the MMA acronyms.
- In the Abstract Section -- Last sentence starting with "According to our projections" could read: According to our projections, Medicare reimbursement for all separately billable drugs will rise by 11 percent (\$216 million) between calendar years 2003 and 2005.

‡ A C K N O W L E D G E M E N T S

This report was prepared under the direction of Robert A. Vito, Regional Inspector General for Evaluation and Inspections in the Philadelphia Regional Office, and Linda M. Ragone, Deputy Regional Inspector General. Other principal Office of Evaluation and Inspections staff who contributed include:

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