



DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of Inspector General

Washington, D.C. 20201

AUG 17 2007

The Honorable Fortney Pete Stark  
Chairman, Subcommittee on Health  
Committee on Ways and Means  
House of Representatives  
Washington, DC 20515

Dear Mr. Chairman:

On June 26, 2007, Robert A. Vito testified before the House Committee on Ways and Means, Subcommittee on Health, on behalf of the U.S. Department of Health and Human Services Office of Inspector General (OIG). His testimony discussed OIG's most recent work on comparing Medicare reimbursement amounts for separately billable end stage renal disease (ESRD) drugs to provider acquisition costs. During the hearing, questions arose regarding how Medicare reimbursement for these drugs compared to prices paid by the Department of Veterans Affairs (VA).

In response to these questions, we collected current drug pricing data from VA and compared them to current Medicare reimbursement amounts. We found that, on average, VA paid from 2 to 43 percent less than Medicare for the 11 drugs under review. We estimate that if Medicare reimbursed for ESRD drugs at the prices available to VA, total payments to dialysis facilities could be reduced by \$317 million (14 percent) per year. A detailed description of our analysis is presented in the enclosed document. It is important to note that, in comparison to Medicare, VA has a much smaller number of beneficiaries who require ESRD services and that VA purchases drugs directly from manufacturers or wholesalers while Medicare reimburses facilities for drugs administered to beneficiaries.

If you have any questions about the information presented in this letter or the enclosure or if we can provide further assistance, please contact me or your staff may contact Claire Barnard, Director of External Affairs, at (202) 205-9523. I have sent an identical letter and enclosure to the Honorable Dave Camp.

Sincerely,

A handwritten signature in cursive script that reads "Daniel R. Levinson".

Daniel R. Levinson  
Inspector General

Enclosure

cc:  
Herb Kuhn  
Acting Deputy Administrator  
Centers for Medicare & Medicaid Services

## OIG Comparison of End Stage Renal Disease Drug Reimbursement: Medicare and the Department of Veterans Affairs

### Background

End stage renal disease (ESRD) is a disease-specific entitlement under Medicare. All beneficiaries with ESRD are covered, regardless of their age, beginning in the 4<sup>th</sup> month of dialysis treatment.<sup>1 2</sup> Currently, Medicare covers approximately 400,000 dialysis patients. The Centers for Medicare & Medicaid Services (CMS) reimburses dialysis facilities for most items related to dialysis services based on a prospective payment system known as the composite rate. However, many drugs incident to dialysis treatment are not covered under this rate and are instead billed separately. These drugs, known as separately billable drugs, are typically reimbursed at 106 percent of their average sales price (ASP). Medicare and its beneficiaries spent \$2.2 billion for separately billable ESRD drugs in 2005.

The Department of Veterans Affairs (VA) currently has 2,064 beneficiaries who receive dialysis-related treatment through its facilities. According to CMS, a Medicare-eligible veteran may choose on a treatment-by-treatment basis whether to use Medicare or VA coverage for dialysis treatment. VA is the primary payer if the service is provided at a VA facility, while Medicare would typically be the primary payer at non-VA sites.

In contrast to Medicare, VA purchases drugs directly from manufacturers or wholesalers. VA has several purchasing options, including the Federal Supply Schedule and “Big 4” contracted pricing. The Federal Supply Schedule is a multiple-award, multiyear contract that allows VA to purchase drugs in various quantities while still obtaining discounts for volume buying. Using competitive procedures, contracts are awarded to companies to provide services and supplies over a given period of time. VA is not required to use the Federal Supply Schedule and is sometimes able to negotiate prices lower than the Federal Supply Schedule price. For example, the “Big 4” refers to contract prices that are available only to VA, the Department of Defense, the Public Health Service (Indian Health Service), and the U.S. Coast Guard.

In OIG’s January 2000 report, “Medicare Reimbursement of End Stage Renal Disease Drugs” (OEI-03-00-00020), we found that Government entities such as VA were able to purchase drugs at substantially lower prices than Medicare. A more recent OIG report, “Medicare Reimbursement for End Stage Renal Disease Drugs: Third Quarter of 2006” (OEI-03-06-00590), demonstrated that facility acquisition costs for a majority of high-expenditure separately billable ESRD drugs were also lower than Medicare reimbursement amounts. The results of this recent report were presented to the House Committee on Ways and Means, Subcommittee on Health, during a hearing on June 26, 2007.

### Methodology

The 11 drugs selected for review in our most recent report represented 99 percent of Medicare reimbursement for separately billable drugs in freestanding dialysis facilities and 98 percent in

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<sup>1</sup> Beneficiaries who already have Medicare based on age or disability may receive dialysis coverage during the first month of treatment.

<sup>2</sup> If a beneficiary with ESRD has employer group health coverage, Medicare will be the secondary payer for dialysis services for the first 30 months of coverage. After this period ends, Medicare is the primary payer for dialysis services.

hospital-based dialysis facilities in 2005. These 11 drugs are also the focus of the analysis presented in this document.

For the 11 selected drugs, we obtained Medicare reimbursement amounts and VA purchase prices for the third quarter of 2007. For 10 of the 11 drugs, we calculated an average VA price based on the Federal Supply Schedule, because no lower contracted prices were available. For one drug, Epogen, we calculated the average VA price based on the lower pricing available through a “Big 4” contract. We then calculated the percentage difference between the average VA price and the Medicare reimbursement amount for each drug. We estimated Medicare’s potential savings by multiplying these percentage differences by the total amount that Medicare spent on each drug in 2005.

### **Limitations**

It is important to note that VA and Medicare operate under different statutory guidelines. VA purchases drugs directly from manufacturers or wholesalers, while Medicare reimburses facilities, doctors, and suppliers for drugs that they administer or supply to beneficiaries.

When calculating potential savings, we assumed that Medicare expenditures for ESRD drugs will remain at 2005 levels in subsequent years.

### **Results**

For the 11 drugs under review, the VA price ranged from 2 to 43 percent less than the Medicare reimbursement amount. The average VA price for Epogen, the most commonly used ESRD drug, was 12 percent below the Medicare reimbursement amount. We estimate that, if Medicare reimbursed these selected drugs at the prices available to VA, total payments (including both Medicare payments and beneficiary coinsurance) could be reduced by \$317 million per year (\$280 million to freestanding facilities and \$37 million to hospital-based facilities). This represents an overall savings of 14 percent. Table 1 on the following page shows how Medicare reimbursement amounts compare to VA prices as well as potential program savings for each of the 11 drugs.

**Table 1: OIG Comparison of Medicare Reimbursement Amounts to VA Prices for 11 ESRD Drugs**

<b>Drug</b>	<b>Third-Quarter 2007 Medicare Reimbursement Amount</b>	<b>Third-Quarter 2007 Average VA Price*</b>	<b>Percentage VA Price Is Below Medicare Reimbursement</b>	<b>Estimated Savings in Freestanding Facilities**</b>	<b>Estimated Savings in Hospital-Based Facilities**</b>
Alteplase recombinant, 1 mg	\$33.56	\$20.27	40%	\$7,055,445	\$1,834,207
Calcitriol, 0.1 µg	\$0.59	\$0.58	2%	\$82,832	\$46,601
Darbepoetin alfa, 1 µg	\$3.05	\$2.25	26%	\$7,793,044	\$10,924,289
Doxercalciferol, 1 µg	\$2.55	\$1.46	43%	\$20,798,965	\$6,057,082
Epoetin alfa, per 1,000 units*	\$9.10	\$8.03	12%	\$178,414,647	\$8,655,009
Iron dextran, 50 mg	\$10.39	\$9.24	11%	\$113,998	\$73,488
Iron sucrose, 1 mg	\$0.38	\$0.34	10%	\$10,773,608	\$1,439,143
Levocarnitine, 1 gm	\$8.21	\$8.05	2%	\$193,745	\$44,485
Paricalcitol, 1 µg	\$3.77	\$3.08	18%	\$40,359,602	\$5,127,873
Sodium ferric gluconate, 12.5 mg	\$4.71	\$3.63	23%	\$13,725,691	\$2,692,371
Vancomycin HCl, 500 mg	\$3.41	\$2.43	29%	\$570,858	\$192,446
<b>Total</b>				<b>\$279,882,436</b>	<b>\$37,086,994</b>

Source: Third-quarter 2007 Medicare reimbursement amounts were downloaded from [http://www.cms.hhs.gov/McrPartBDrugAvgSalesPrice/01a\\_2007aspfiles.asp](http://www.cms.hhs.gov/McrPartBDrugAvgSalesPrice/01a_2007aspfiles.asp). Third-quarter 2007 VA prices were downloaded from <http://www.pbm.va.gov/DrugPharmaceuticalPrices.aspx>. Both were accessed on July 17, 2007.

\*VA prices for 10 of the 11 drugs are based on the Federal Supply Schedule. The VA price for Epogen is based on a contracted "Big 4" price.

\*\*The savings estimates are based on 2005 expenditures.