Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

THE IMPACT OF HIGH-PRICED GENERIC DRUGS ON MEDICARE AND MEDICAID

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EXECUTIVE SUMMARY

PURPOSE

To determine the impact of high-priced generic drugs on the Medicare and Medicaid programs.

BACKGROUND

Both Medicaid and Medicare pay billions of dollars each year for prescription drugs. The Medicaid program paid nearly $10 billion for prescription drugs in 1995. Although Medicare provides reimbursement for only certain types of drugs, the Part B program still paid more than $2.3 billion dollars for prescription drugs in 1996.

On January 1, 1998, Medicare Part B began to reimburse covered drugs at 95 percent of the average wholesale price (AWP). This change in reimbursement was the result of legislation enacted by Congress. Previously, Medicare carriers determined the amounts that Medicare paid for prescription drugs based on the lower of the Estimated Acquisition Cost (EAC) or the national (AWP). Historically, carriers had used 100 percent of AWP and not estimated acquisition cost to determine Medicare reimbursement allowances for prescription drugs.

For drugs with generic versions, Medicare carriers determine reimbursement based on 95 percent of the median AWP for all generic versions of the drug. Prior to January 1998, Medicare reimbursed drugs with generic versions at 100 percent of the median AWP. Medicare reimbursement amounts include both the amount that Medicare and its beneficiaries pay a drug supplier.

In general, State Medicaid agencies use either a discounted AWP or estimated/wholesale acquisition cost method to reimburse prescription drugs. State Medicaid agencies also receive manufacturer drug rebates.

This inspection report resulted from a Congressional request concerning high-priced generic drugs. Using the drugs identified in the request, we collected data from three main sources. To verify NDC codes and average wholesale prices, we reviewed data from the July 1997*Red Book* CD-ROM update. We compiled Medicare statistics from the National Claims History (NCH) File. We collected drug rebate data from the Medicaid Drug Rebate Initiative (MDRI) System.

FINDINGS

Medicare and its beneficiaries could have saved $5 million to $12 million for four drugs if 1997 reimbursement had not been based on higher-priced generic versions.

We found several cases where average wholesale prices for generic products were three to four times greater than the brand price. For the four drugs reviewed, we determined that the Medicare program and its beneficiaries could have saved $5 million dollars if 1997 reimbursement had been based on the average wholesale price of the brand-name products. If reimbursement had been

based on the median of generic drugs with prices less than the brands, Medicare and its beneficiaries could have saved $12 million for the four drugs.

Florida's Medicaid program could have saved half a million dollars for just eight drugs in 1996 if higher-priced generic drugs had been reimbursed at brand prices.

Using the current reimbursement formula, Florida Medicaid in some cases paid three times more for a generic than it did for the brand version of the eight drugs reviewed. After factoring in manufacturer rebates, the program paid more than five to eight times more for generics than brand products. If Florida Medicaid had capped reimbursement for higher-priced generic drugs at the reimbursement level for the highest-priced brand drug, nearly half a million dollars would have been saved for just eight drugs in 1996.

RECOMMENDATIONS

There is evidence that high-priced generic drugs have a significant financial impact on Medicare and Medicaid reimbursement. We found that the inclusion of higher-priced generic drugs in Medicare payment calculations can raise allowances above the price of brand-name drugs. In the Medicaid program, utilization of higher-priced generic drugs was widespread among the drugs reviewed.

We believe further reductions need to be made in Medicare and Medicaid reimbursement for prescription drugs. We continue to support the Health Care Financing Administration's legislative proposal to link Medicare reimbursement to the acquisition cost of prescription drugs. However, until broader legislation is enacted, we believe refinements to the current system are needed. Since the changes recently enacted by Congress continue to link reimbursement to average wholesale prices, we believe that mechanisms should be in place to limit the impact that high-priced generic drugs have on reimbursement. Medicare's new reimbursement methodology for prescription drugs will not prevent higher-priced generics from increasing Medicare allowances. Higher-priced generic drugs will still be included in the median calculation. When the median generic policy was implemented, generic prices were normally less than those of the brand-name product. However, what may have originally been a cost-saving mechanism has, for certain categories of drugs, become a losing proposition.

We believe that the Medicare program should take action to prevent these situations. **We recommend that the Health Care Financing Administration 1) not include higher-priced generic drugs in the median calculation to determine Medicare allowances, or 2) propose limiting Medicare allowances to brand prices when higher-priced generic drugs are involved.**

In contrast to the Medicare program which pays for brand and generic drugs at the same rate, Medicaid reimburses based on the specific drug supplied. **Therefore, we recommend that the Health Care Financing Administration limit Medicaid reimbursement of higher-priced generic drugs to the amount reimbursed (prior to rebate) for lower-priced brand or appropriately-priced generic drugs.**

AGENCY COMMENTS

The HCFA concurred with our recommendation for the Medicare program. The agency stated that they will consider these options in regulations implementing provisions of the Balanced Budget Act of 1997.

Although not addressed in the agency comments, the HCFA did issue a program memorandum in January 1998 to Medicare contractors instructing that "if the brand name product AWP is lower than the median of the generic AWP, calculate a new median with the brand AWP included." We believe this revision of the reimbursement calculation will reduce some of the impact that high-priced generic drugs have on Medicare payments.

The HCFA did not concur with our recommendation for the Medicaid program. The agency agreed that high-priced drugs can have an adverse impact on Medicaid reimbursement but believed that States are in a better position to assure that lower-priced brand-named drugs are dispensed before higher-priced generics. The HCFA believes that States already have the authority to institute programs to ensure appropriate payments for prescription drugs. However, HCFA will forward the information from this report to the States and will continue to encourage them to use existing mechanisms to prevent higher-priced generics rather than less costly brand drugs from being dispensed.

We recognize HCFA's continued efforts to provide guidance to States in implementing cost-savings mechanisms for prescription drugs. However, the current authorities provided to the States did not prevent Medicaid from paying more for generic versions of drugs than they did for the brand-name product. Therefore, we continue to believe that HCFA should limit Medicaid reimbursement for higher-priced generic drugs.

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INTRODUCTION

PURPOSE

To determine the impact of high-priced generic drugs on the Medicare and Medicaid programs.

BACKGROUND

Both Medicaid and Medicare pay billions of dollars each year for prescription drugs. The Medicaid program paid nearly $10 billion for prescription drugs in 1995. This $10 billion represented nearly 10 percent of Medicaid's total reimbursement budget for all services. Although Medicare provides reimbursement for only certain types of drugs, the Part B program still paid more than $2.3 billion dollars for prescription drugs in 1996.

Medicare Drug Reimbursement

While Medicare does not pay for over-the-counter or many self-administered drugs, it does pay for certain categories of prescription drugs used by Medicare beneficiaries. Under certain circumstances, Medicare Part B covers drugs that are used with durable medical equipment or infusion equipment. Medicare will cover certain drugs used in association with dialysis or organ transplantation. Drugs used for chemotherapy and pain management in cancer treatments are also covered. The program also covers certain types of vaccines such as those for flu and hepatitis B.

On January 1, 1998, Medicare Part B began to reimburse covered drugs at 95 percent of the average wholesale price (AWP). This change in reimbursement was the result of legislation enacted by Congress. Previously, Medicare carriers determined the amounts that Medicare paid for prescription drugs based on the lower of the Estimated Acquisition Cost (EAC) or the national (AWP). The AWP is reported in the *Red Book* and other pricing publications and databases used by the pharmaceutical industry. The AWPs are mainly provided to these sources by pharmaceutical manufacturers. Historically, carriers had used 100 percent of AWP and not estimated acquisition cost to determine Medicare reimbursement allowances for prescription drugs. Allowances include both the amount that Medicare and its beneficiaries pay a drug supplier.

For drugs with generic versions, Medicare carriers determine reimbursement based on 95 percent of the median AWP for all generic versions of the drug. If a brand-name product is priced lower than the median calculated, a new median including the brand AWP must be calculated. Prior to January 1998, Medicare reimbursed drugs with generic versions at 100 percent of the median AWP.

Drugs are currently billed to the Medicare program based on codes developed by the Health Care Financing Administration (HCFA). These codes are developed as part of the HCFA Common Procedure Coding System (HCPCS). The codes define the type of drug and, in most cases, a dosage amount. The codes do not indicate whether a brand or generic version of the drug was

administered; nor do the codes provide information on the manufacturer or distributor of the drug provided.

Medicaid Drug Reimbursement

Prescription drug coverage under the Medicaid program is an optional benefit. Each State program can choose whether to provide recipients with prescription drug coverage. At the present time, all 50 States and the District of Columbia have chosen to provide a prescription drug benefit.

Each State Medicaid agency has the authority to develop its own reimbursement mechanism for prescription drugs subject to upper payment limits established by HCFA. For the most part, State Medicaid agencies use either a discounted AWP or estimated/wholesale acquisition cost method to reimburse prescription drugs.

Unlike Medicare, most drug suppliers bill Medicaid for reimbursement using a national drug code (NDC). These NDCs identify the manufacturer or distributor of the drug, the product dosage form, and the package size. From the NDCs, the drug can be identified as a brand or generic version. Each drug manufactured or distributed for sale in the United States has its own unique NDC code.

State Medicaid agencies also receive manufacturer drug rebates according to Federal law (Section 1927 of the Social Security Act). With the enactment of the Omnibus Budget Reconciliation Act of 1990 (OBRA 90), pharmaceutical manufacturers are required to have rebate agreements with the Medicaid program for drugs dispensed to recipients. Manufacturers are required to have these rebate agreements in order to be eligible for Medicaid reimbursement of their drug products.

The quarterly rebate for brand-name drugs is currently based on the greater of 15.1 percent of Average Manufacturer Price (AMP) or the difference between the AMP and the Best Price. The AMP is the average price paid by wholesalers for products distributed to the retail class or trade. Best Price is the lowest price available from the manufacturer to any purchaser (other than those excluded by law). For generic drugs, the quarterly rebate amount is 11 percent of AMP.

METHODOLOGY

This inspection report resulted from a Congressional request concerning high-priced generic drugs. The request identified a number of high-priced generic drugs and provided information on current reimbursement for drugs by the Florida Medicare carrier and Florida Medicaid agency. Our data collection was conducted and the draft inspection report was issued in 1997 prior to the change in prescription drug reimbursement that was implemented in January 1998.

Using the drugs identified in the Congressional request, we collected data from three main sources. To verify the NDC codes and average wholesale prices, we reviewed data from the July 1997 *Red Book* CD-ROM update. For information on Medicare allowances for prescription

drugs, we compiled statistics from HCFA's National Claims History (NCH) File. We collected drug rebate data from HCFA's Medicaid Drug Rebate Initiative (MDRI) System.

We verified reimbursement amounts with both the Florida Medicaid agency and the Florida Medicare carrier. We selected Florida because it was the State identified in the Congressional request. We verified Medicaid rebate amounts with HCFA Central Office staff.

Medicare Savings

For the five Medicare drugs identified in the request, we compiled NDC codes and average wholesale prices for all brand and generic drugs that matched the HCPCS code's description and dosage. We collected this information from the July 1997 *Red Book* update. We determined whether a drug was a brand or generic formula based on the data provided in the *Red Book*. For one of the drugs identified (Code J9190 - Fluorouracil, 500 mg), we could not find a brand-name version of the drug that met the HCPCS description. The NDC code provided was identified in the *Red Book* as a generic drug. Therefore this drug was not included in our savings calculation. The NDC codes and prices for the remaining four drug codes are detailed in Appendix A.

We determined possible savings to the Medicare program if higher-priced generic drugs were excluded from reimbursement calculations using two different methods. For both methods, we calculated prices based on the unit dose defined by the HCPCS code. We also used the Medicare allowances calculated by the Florida Medicare carrier in January 1997 for both methods. Since the 1997 utilization data contained in the NCH file was incomplete at the time our review, we employed utilization data from 1996 for both savings calculations.

For the first method, we determined the possible Medicare savings if the brand drug price was utilized for reimbursement rather than the median of generic prices. We calculated the difference between the Medicare allowance and the highest-priced brand-name drug. Using data extracted from the NCH file, we identified the utilization for each drug code. To calculate savings, we multiplied the Medicare units reimbursed by the difference between the Medicare allowance and the highest-priced brand product. We chose to use the high-priced brand since it would provide a more conservative savings estimate. In cases where brand prices varied, using the lower-priced brand would have resulted in even greater savings.

For the second method, we determined the potential savings if reimbursement was based only on the median of generics with prices lower than the highest-priced brand product. We compiled all of the generic prices available in the *Red Book* for each drug code. We excluded generic drugs with prices greater than the highest brand price. We then determined the median statistic for the remaining prices. The difference between the current Medicare allowance and the recalculated median allowance was then applied to Medicare utilization to determine the potential savings.

To determine if there were other Medicare-reimbursed drugs with generic versions priced higher than the brand products, we reviewed average wholesale prices for Medicare HCPCS codes with greater than $20 million in 1996 expenditures. There were 22 codes with over $20 million in expenditures. Thirteen of the 22 codes were brand or multiple brand products. Two were "not-

otherwise-classified" codes where the specific drug provided cannot be identified. One code was for a drug where a common dosage among products is difficult to determine. Another code was for general IV infusion. Of the five remaining codes, one was already in our review. For the remaining four codes, we did not find evidence that higher-priced generics had over-inflated the Medicare allowance. However, we did find that some generics for one of the drug codes had prices higher than the brand products. Due to the large number of generic products under this code, these high generic prices did not greatly skew the median statistic.

Medicaid Savings

For the ten Medicaid drug examples identified in the request, we compiled NDC codes and average wholesale prices for all brand and generic drugs that met the described dosages. We collected this information from the July 1997 *Red Book* update. We determined whether a specific drug was a brand or generic version based on information provided in the *Red Book*.

We used the NDC codes to extract information from the MDRI system. This system provides Medicaid utilization, reimbursement, and rebate information for prescription drugs. To be consistent with the data provided in the request, we extracted information on Medicaid prescription drugs for the State of Florida. For the NDCs identified, we collected information for all four quarters of 1996. We could not find any Florida Medicaid utilization for one of the ten drugs identified. For a second drug, we found only brand use in one quarter of 1996. Therefore, potential savings calculations were performed on only eight of the ten drugs identified.

The reimbursement data provided in the MDRI system includes both actual drug payments and dispensing fees. For every prescription billed to Medicaid, the program will pay an established fee to the supplier for dispensing the medication. To compare actual drug payments for brands versus generics, we needed to remove the dispensing fee payments from the reimbursement figures for each NDC code.

The MDRI system provides utilization data in two formats -- number of prescriptions and number of drug units reimbursed. We used both of these formats for our calculations.

We performed a series of calculations to determine the unit reimbursement for each NDC code. The steps are outlined below.

Step 1. We determined the dollars associated with dispensing fees by multiplying the number of prescriptions reimbursed with Florida's current dispensing fee.

Step 2. The reimbursement for dispensing fees was subtracted from the total reimbursement amount for the code.

Step 3. The drug reimbursement calculated in Step 2 was then divided by the units of drug reimbursed to determine the unit reimbursement for each NDC code.

To evaluate the impact of Medicaid rebates on the payments for brand and generic drugs, we extracted the rebate amount per unit for each NDC code and multiplied this by the number of units Florida Medicaid reimbursed. This total rebate amount was then subtracted from the total drug payments determined in Step 2 above. The resulting reimbursement was divided by the number of units reimbursed to determine the unit reimbursement after rebate for each NDC code. The unit reimbursement amounts both before and after rebates for each NDC code are provided in Appendix B.

We determined what the potential savings to Florida Medicaid could have been if reimbursement for higher-priced generic drugs was capped at the reimbursement level of the highest-priced brand product. For each generic NDC code that was reimbursed at a higher rate per unit than the brand, we calculated savings by determining the difference between actual reimbursement for the generic drug and the amount that would have been paid if reimbursement had been based on the brand drug payment. This difference provided the savings estimate for each NDC code. We aggregated the savings for each code to determine an overall savings for that particular drug.

FINDINGS

MEDICARE AND ITS BENEFICIARIES COULD HAVE SAVED $5 MILLION TO $12 MILLION FOR FOUR DRUGS IF 1997 REIMBURSEMENT HAD NOT BEEN BASED ON HIGHER-PRICED GENERIC VERSIONS.

All four drug codes reviewed had at least two generic versions available in 1997. As one might expect, some of the generic versions identified had average wholesale prices lower than the brand price. However, these drug codes also had between one and four generic versions with published prices higher than brand prices. In several cases, prices for generic products were three to four times greater than the brand price. Actual unit prices for all codes are provided in Appendix A.

We calculated that the Medicare program and its beneficiaries could have saved $5 million dollars if 1997 reimbursement had been based on the brand prices of the four drugs. Medicare now bases payment for these drugs on the median of generic wholesale prices. Because of the higher-priced generics, the Medicare contractor in Florida determined allowance amounts for these drugs that were higher than the brand prices. The savings calculation is detailed in the table below.

1997 Medicare Savings Based on Brand Price

HCPCS Code	Generic Drug Name	Highest Brand AWP	Florida Medicare Allowance	Medicare Units	Potential Savings
J3370	Vancomycin	$8.28	$12.91	876,506	$4,058,223
J9182	Etoposide	$136.49	$141.97	202,106	$1,107,541
J1840	Kanamycin Sulfate	$3.36	$6.69	1,270	$4,229
J1160	Digoxin	$2.43	$2.53	2,061	$206
TOTAL					**$5,170,199**

We calculated that Medicare and its beneficiaries could have saved $12 million if reimbursement had been based on the median of generic drugs with prices less than brand prices. Allowance amounts for three drugs would have decreased by more than half if the median computation used to determine Medicare's allowance was based only on lower-priced generics. The fourth drug's Medicare allowance would have decreased by 23 percent. The table on the next page details these savings calculations.

1997 Medicare Savings Based on Median of Lower-Priced Generics					
HCPCS Code	Drug Name	Recalculated Allowance	Florida Medicare Allowance	Medicare Units	Potential Savings
J3370	Vancomycin	$6.38	$12.91	876,506	$5,723,584
J9182	Etoposide	$110.00	$141.97	202,106	$6,461,329
J1840	Kanamycin Sulfate	$2.25	$6.69	1,270	$5,639
J1160	Digoxin	$1.04	$2.53	2,061	$3,071
TOTAL					**$12,193,623**

Higher-priced generic drugs will continue to impact Medicare despite the recent 5 percent reduction in drug reimbursement.

As of January 1998, Medicare determines drug allowances based on 95 percent of a drug's average wholesale price. For drugs with both brand and generic versions, Medicare will determine allowances by calculating the median average wholesale price of the generic versions and then reducing it by 5 percent. If a brand-name product is priced lower than the median calculated, a new median including the brand AWP must be calculated. However, this method of calculating allowances can still allow higher-priced generics to raise Medicare allowances.

For the drugs we reviewed, the 5 percent decrease will not offset the impact that high-priced generics have on Medicare allowances. Extremely high-priced generics can cause Medicare allowance rates to be higher than brand prices. In the case of kanamycin sulfate (J1840), the Medicare allowance rate was almost double the price of the brand product.

FLORIDA'S MEDICAID PROGRAM COULD HAVE SAVED HALF A MILLION DOLLARS FOR JUST EIGHT DRUGS IN 1996 IF HIGHER-PRICED GENERIC DRUGS HAD BEEN REIMBURSED AT BRAND PRICES.

Unlike the Medicare program, Medicaid can reimburse each brand and generic version of a drug at a different level. Many States use some form of discounted average wholesale price as a basis for reimbursement. The Florida Medicaid program based 1996 reimbursement on the wholesaler acquisition cost plus seven percent.

Using the current reimbursement formula, Florida Medicaid in some cases paid three times more for a generic than it did for the brand version of the eight drugs reviewed. After factoring in manufacturer rebates, the program paid more than five to eight times more for generics than brand products.

If Florida Medicaid had capped reimbursement for higher-priced generic drugs at the reimbursement level for the highest-priced brand drug, nearly half a million dollars would have been saved for just eight drugs in 1996. Florida's drug reimbursement accounts for about 5 percent of the Medicaid program's national reimbursement for drugs. If the savings developed for Florida were extended to other States, the Medicaid program as a whole could have saved $10 million in 1996 reimbursement for just these eight drugs. The table below details the Florida Medicaid savings calculations for each of the eight drugs. Since Medicaid costs are shared by both Federal and State governments, these estimates include both Federal and State savings.

1996 Medicaid Savings Based on Brand Reimbursement

Generic Drug Name	Dosage	Savings	Savings with Rebates
Vancomycin	500 mg	$48,055	$61,680
Vancomycin	1 gm	$263,597	$347,251
Pentamidine	300 mg	$13,369	$25,527
Vincristine Sulfate	1 ml	$34	$59
Etoposide	5 ml	$8	$31,671
Amikacin Sulfate	2 ml	$79,825	$113,192
Clindamycin Phosphate	2 ml	$761	$920
Clindamycin Phosphate	4 ml	$3,608	$4,617
TOTAL		**$409,257**	**$584,917**

As shown in the table, savings increase when Medicaid rebate amounts are factored into drug payments. Medicaid receives rebates of 11 percent for generic drugs but 15 percent or more for brand drugs. So a higher-priced generic will often provide less of a rebate to the program than a lower-priced brand product. If one considers the after-rebate impact, the reimbursement differences between the brand and higher-priced generic drugs become even more significant. Appendix B provides a comparison of Florida's unit reimbursement before and after rebate for both the brand and generic versions of the eight drugs reviewed.

Since Medicaid reimburses based on the specific NDC code, higher-priced generics only become an issue if they are the particular drugs billed to the program. For the eight drugs reviewed, these higher-priced generics represented a significant portion of generic billing. Higher-priced generics accounted for 46 to 100 percent of all generics billed for the eight drugs.

RECOMMENDATIONS

There is evidence that high-priced generic drugs have a significant financial impact on Medicare and Medicaid reimbursement. We found that the inclusion of higher-priced generic drugs in Medicare payment calculations can raise allowances above the price of brand-name drugs. In the Medicaid program, utilization of higher-priced generic drugs was widespread among the drugs reviewed.

As a result of recent Congressional action, Medicare reimbursement for prescription drug codes will be set at 95 percent of the published average wholesale price beginning in 1998. For drugs with generic versions, Medicare will reimburse 95 percent of the median price of all generic drugs.

We believe further reductions need to be made in Medicare and Medicaid reimbursement for prescription drugs. We continue to support the Health Care Financing Administration's legislative proposal to link Medicare reimbursement to the acquisition cost of prescription drugs. However, until broader legislation is enacted, we believe refinements to the current system are needed. Since the changes recently enacted by Congress continue to link reimbursement to average wholesale prices, we believe that mechanisms should be in place to limit the impact that high-priced generic drugs have on reimbursement. Medicare's new reimbursement methodology for prescription drugs will not prevent higher-priced generics from increasing Medicare allowances. Higher-priced generic drugs will still be included in the median calculation. When the median generic policy was implemented, generic prices were normally less than those of the brand-name product. However, what may have originally been a cost-saving mechanism has, for certain categories of drugs, become a losing proposition.

We believe that the Medicare program should take action to prevent these situations. **We recommend that the Health Care Financing Administration 1) not include higher-priced generic drugs in the median calculation to determine Medicare allowances, or 2) propose limiting Medicare allowances to brand prices when higher-priced generic drugs are involved.**

In contrast to the Medicare program which pays for brand and generic drugs at the same rate, Medicaid reimburses based on the specific drug supplied. **Therefore, we recommend that the Health Care Financing Administration limit Medicaid reimbursement of higher-priced generic drugs to the amount reimbursed (prior to rebate) for lower-priced brand or appropriately-priced generic drugs.**

AGENCY COMMENTS

The HCFA concurred with our recommendation for the Medicare program. The agency stated that they will consider these options in regulations implementing provisions of the Balanced Budget Act of 1997.

Although not addressed in the agency comments, the HCFA did issue a program memorandum in January 1998 to Medicare contractors instructing that "if the brand name product AWP is lower

than the median of the generic AWP, calculate a new median with the brand AWP included." We believe this revision of the reimbursement calculation will reduce some of the impact that high-priced generic drugs have on Medicare payments.

The HCFA did not concur with our recommendation for the Medicaid program. The agency agreed that high-priced drugs can have an adverse impact on Medicaid reimbursement but believed that States are in a better position to assure that lower-priced brand-named drugs are dispensed before higher-priced generics. The HCFA believes that States already have the authority to institute programs to ensure appropriate payments for prescription drugs. However, HCFA will forward the information from this report to the States and will continue to encourage them to use existing mechanisms to prevent higher-priced generics rather than less costly brand drugs from being dispensed.

We recognize HCFA's continued efforts to provide guidance to States in implementing cost-savings mechanisms for prescription drugs. However, the current authorities provided to the States did not prevent Medicaid from paying more for generic versions of drugs than they did for the brand-name product. Therefore, we continue to believe that HCFA should limit Medicaid reimbursement for higher-priced generic drugs.

APPENDIX A

Impact of High-Priced Generic Drugs on Medicare

Code J3370: Injection, Vancomycin HCL, up to 500 mg
Florida Medicare Allowable as of 1/1/97 - $12.91

BRAND		
Drug Name	NDC Code	Red Book AWP
Vancocin	00002-7297-01	$8.28
Vancocin	00002-7297-10	$8.28
Vancocin	00002-1444-01	$7.80
Vancocin	00002-1444-25	$7.80
GENERIC		
Lycophin	00469-2210-30	$10.97
Vancoled	00205-3154-88	$5.76
Vancomycin	00074-6534-01	$12.48
Vancomycin	00074-4332-01	$34.66
Vancomycin	00364-2472-33	$7.00

Code J1840: Injection, Kanamycin Sulfate, up to 500 mg
Florida Medicare Allowable as of 1/1/97 - $6.69

BRAND		
Drug Name	NDC Code	Red Book AWP
Kantrex	00015-3502-20	$3.36
GENERIC		
Kanamycin Sulfate	00686-0064-02	$2.25
Kanamycin Sulfate	39769-0064-02	$11.13

Code J1160: Injection, Digoxin, up to 0.5 mg
Florida Medicare Allowable as of 1/1/97 - $2.53

BRAND		
Drug Name	NDC Code	Red Book AWP
Lanoxin	00173-0260-10	$2.43
Lanoxin	00173-0260-35	$1.93
GENERIC		
Digoxin	00641-1410-35	$1.04
Digoxin	00008-0480-01	$2.47

Code J9182: Etoposide, 100 mg
Florida Medicare Allowable as of 1/1/97 - $141.97

BRAND		
Drug Name	NDC Code	Red Book AWP
Vepesid	00015-3095-20	$136.49
Vepesid VHA Plus	00015-3095-30	$136.49
GENERIC		
Etoposide	00186-1571-31	$38.75
Etoposide	55390-0291-01	$110.00
Etoposide	00703-5653-01	$141.97
Etoposide	00703-5643-01	$141.97
Etoposide	00364-3028-53	$141.50
Etoposide	58406-0711-12	$141.00
Toposar	00013-7336-91	$136.49

APPENDIX B

Impact of High-Priced Generic Drugs on Medicaid

Vancomycin, 500 mg			
BRAND			
NDC Code	Units Reimbursed	Reimbursement per Unit	Reimbursement with Rebate
00002-1444-01	1,953	$6.68	$2.70
00002-1444-25	0	N/A	N/A
00002-7297-01	0	N/A	N/A
00002-7297-10	450	$7.12	$3.04
GENERIC			
00469-2210-30	220	$7.49	$7.12
00205-3154-88	918	$4.62	$3.46
00074-4332-01	2,400	$26.40	$26.07
00074-6534-01	551	$10.20	$9.81
00364-2472-33	422	$6.36	$6.33

Vancomycin, 1 gm			
BRAND			
NDC Code	Units Reimbursed	Reimbursement per Unit	Reimbursement with Rebate
00002-7321-01	0	N/A	N/A
00002-7321-25	100	$13.91	$5.57
00002-7298-01	218	$14.32	$6.31
00002-7298-10	1,210	$13.75	$5.77
GENERIC			
00074-6533-01	7,845	$47.40	$46.74
00074-6535-01	747	$19.81	$19.05
00205-3154-15	2,147	$9.27	$8.11
00364-2473-91	1,290	$12.40	$12.38
00469-2840-40	1,293	$13.91	$13.19

Pentamidine, 300 mg			
BRAND			
NDC Code	Units Reimbursed	Reimbursement per Unit	Reimbursement with Rebate
00469-0113-10	232	$84.24	$61.68
54868-2568-00	0	N/A	N/A
57317-0210-06	1,486	$84.03	$62.88
GENERIC			
00074-4548-01	757	$101.90	$96.60
00053-1000-05	0	N/A	N/A
00209-8560-20	0	N/A	N/A
11098-0512-99	0	N/A	N/A

Vincristine Sulfate, 1 ml			
BRAND			
NDC Code	Units Reimbursed	Reimbursement per Unit	Reimbursement with Rebate
00002-7194-01	208	$29.63	$6.38
00013-7456-86	113	$30.93	$29.96
00002-7198-01	0	N/A	N/A
00002-7198-09	0	N/A	N/A
GENERIC			
54868-3196-00	0	N/A	N/A
61703-0309-06	51	$31.59	$31.11

Etoposide, 5 ml			
BRAND			
NDC Code	Units Reimbursed	Reimbursement per Unit	Reimbursement with Rebate
00015-3095-20	1,167	$23.36	$7.09
00015-3095-30	0	N/A	N/A
GENERIC			
53905-0291-01	0	N/A	N/A
00013-7336-91	1,320	$23.37	$22.09
00186-1571-31	0	N/A	N/A
00364-3028-53	0	N/A	N/A
00703-5643-01	793	$22.50	$22.05
00703-5653-01	0	N/A	N/A
55390-0291-01	0	N/A	N/A
58406-0711-12	0	N/A	N/A

Amikicin Sulfate, 2 ml			
BRAND			
NDC Code	Units Reimbursed	Reimbursement per Unit	Reimbursement with Rebate
00015-3020-20	4,287	$16.33	$10.13
GENERIC			
00074-1956-01	47	$45.94	$45.18
00074-1958-01	90	$51.60	$50.76
00641-0123-23	4,102	$27.27	$24.53
00703-9032-03	2,474	$27.82	$27.60
00024-0016-11	0	N/A	N/A
00186-1703-13	0	N/A	N/A
39769-0237-02	7	$30.82	$30.81
55390-0226-02	189	$18.71	$18.28
61703-0201-07	298	$15.78	$15.33
61703-0202-07	176	$24.20	$23.66

Clindamycin Phosphate, 2 ml			
BRAND			
NDC Code	Units Reimbursed	Reimbursement per Unit	Reimbursement with Rebate
00009-0870-26	205	$3.28	$2.91
GENERIC			
00074-4050-01	511	$4.68	$4.61
00074-4053-03	25	$5.14	$5.05
39769-0226-02	73	$2.41	$2.36
00186-1450-04	240	$0.93	$0.86
00205-2801-83	0	N/A	N/A
00686-0226-02	0	N/A	N/A
00703-9102-04	237	$2.69	$2.63
54868-3695-00	0	N/A	N/A

Clindamycin Phosphate, 4 ml			
BRAND			
NDC Code	Units Reimbursed	Reimbursement per Unit	Reimbursement with Rebate
00009-0775-26	336	$2.93	$2.47
GENERIC			
0074-4051-01	2,468	$4.34	$4.28
00074-4054-03	71	$4.63	$4.56
39769-0226-04	1,198	$2.24	$2.19
00186-1451-04	1,645	$0.55	$0.50
00205-2801-93	81	$1.02	$0.89
00686-0226-02	0	N/A	N/A
00703-9110-04	0	N/A	N/A

APPENDIX C

Health Care Financing Administration Comments

DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Care Financing Administration

The Administrator
Washington, D.C. 20201

DATE: MAY 8 1998

TO: June Gibbs Brown
Inspector General

FROM: Nancy-Ann Min DeParle
Administrator

SUBJECT: Office of Inspector General (OIG) Draft Report: "The Impact of High Priced Generic Drugs on Medicare and Medicaid," (OEI-03-97-00510)

We reviewed the above-referenced draft report on the impact of high-priced generic drugs on Medicare and Medicaid.

Both Medicaid and Medicare pay billions of dollars each year for prescription drugs. The Medicaid program paid nearly $10 billion for prescription drugs in 1995. Although Medicare provides reimbursement for only certain types of drugs, the Part B program still paid more than $2.3 billion dollars for prescription drugs in 1996.

Prior to January 1, 1998, Medicare carriers determined the amounts that Medicare would pay for prescription drugs based on either the lower of the Estimated Acquisition Cost (EAC) or the national Average Wholesale Price (AWP). Historically, they used AWP to determine Medicare reimbursement. For drugs with generic versions, the carriers determined reimbursement based on the median of all AWPs for the generic drugs. Due to legislation recently enacted by Congress, Medicare Part B will begin to reimburse covered drugs at 95 percent of the average wholesale price on January 1, 1998.

This inspection report resulted from a Congressional request concerning high-priced generic drugs. Our detailed comments are as follows:

OIG Recommendation 1

The Health Care Financing Administration should not include higher-priced generic drugs in the median calculation to determine Medicare allowances, or propose limited Medicare allowances to brand prices when higher-priced generic drugs are involved.

HCFA Response

We concur with the draft report's recommendations for Medicare, and will consider this proposal in regulations implementing provisions of the Balanced Budget Act of 1997.

OIG Recommendation 2

The Health Care Financing Administration should limit Medicaid reimbursement of higher-priced generic drugs to the amount reimbursed (prior to rebate) for lower-priced brand or appropriately-priced generic drugs.

HCFA Response

We do not concur. We are aware that high-priced drugs have a significant financial impact on Medicaid reimbursement but believe States are in a better position to assure that lower priced brand-name drugs are dispensed before higher priced generics. States currently have authority to institute programs to require the use of lower priced brand or appropriately priced generic drugs. In addition, already existing regulatory authority generally requires States to look at the estimated acquisition costs of all drugs to assure reimbursement levels reflect the true cost to the pharmacy for purchasing these drugs rather than what may be an overflated published price.

HCFA continues to encourage and provide guidance to states to assist in cost-savings mechanisms. In furtherance of that effort, we will forward information from the final OIG report to the states in a release, such as a state Medicaid Directors letter, and encourage states to use existing mechanisms already available to them to prevent higher-priced genetics from being dispensed over less costly brand name drugs. We believe this addresses the problem with a minimal amount of Federal intervention into existing State operations in this area.

Furthermore, HCFA is undertaking a more comprehensive review of drug prices and how they affect the Medicaid program and will issue future guidance to the states on this as appropriate.