Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

COMPARISON OF MEDICAID FEDERAL UPPER LIMIT AMOUNTS TO AVERAGE MANUFACTURER PRICES

Daniel R. Levinson
Inspector General

June 2005
OEI-03-05-00110

Office of Inspector General

http://oig.hhs.gov

The mission of the Office of Inspector General (OIG), as mandated by Public Law 95-452, as amended, is to protect the integrity of the Department of Health and Human Services (HHS) programs, as well as the health and welfare of beneficiaries served by those programs. This statutory mission is carried out through a nationwide network of audits, investigations, and inspections conducted by the following operating components:

Office of Audit Services

The OIG's Office of Audit Services (OAS) provides all auditing services for HHS, either by conducting audits with its own audit resources or by overseeing audit work done by others. Audits examine the performance of HHS programs and/or its grantees and contractors in carrying out their respective responsibilities and are intended to provide independent assessments of HHS programs and operations in order to reduce waste, abuse, and mismanagement and to promote economy and efficiency throughout the department.

Office of Evaluation and Inspections

The OIG's Office of Evaluation and Inspections (OEI) conducts short-term management and program evaluations (called inspections) that focus on issues of concern to the department, the Congress, and the public. The findings and recommendations contained in the inspections reports generate rapid, accurate, and up-to-date information on the efficiency, vulnerability, and effectiveness of departmental programs.

Office of Investigations

The OIG's Office of Investigations (OI) conducts criminal, civil, and administrative investigations of allegations of wrongdoing in HHS programs or to HHS beneficiaries and of unjust enrichment by providers. The investigative efforts of OI lead to criminal convictions, administrative sanctions, or civil monetary penalties. The OI also oversees state Medicaid fraud control units, which investigate and prosecute fraud and patient abuse in the Medicaid program.

Office of Counsel to the Inspector General

The Office of Counsel to the Inspector General (OCIG) provides general legal services to OIG, rendering advice and opinions on HHS programs and operations and providing all legal support in OIG's internal operations. The OCIG imposes program exclusions and civil monetary penalties on health care providers and litigates those actions within the department. The OCIG also represents OIG in the global settlement of cases arising under the Civil False Claims Act, develops and monitors corporate integrity agreements, develops compliance program guidances, renders advisory opinions on OIG sanctions to the health care community, and issues fraud alerts and other industry guidance.

EXECUTIVE SUMMARY

OBJECTIVE

To (1) determine how prices for drugs set under the Medicaid Federal upper limit program compare to reported average manufacturer prices (AMP) and (2) estimate the savings that could be achieved if Federal upper limit amounts were based on reported AMPs.

BACKGROUND

The Federal upper limit program was put in place to ensure that the Federal Government acts as a prudent payer by taking advantage of current market prices for multiple-source drugs. Statutory and regulatory criteria generally require the Centers for Medicare & Medicaid Services (CMS) to include a drug on the Federal upper limit list if: (1) at least three versions of the drug are rated as therapeutically equivalent by the Food and Drug Administration (FDA), and (2) the drug has at least three suppliers listed in current editions of national compendia. The Federal upper limit amount for a drug is set at 150 percent of the published price for the least costly, therapeutically equivalent product found in national compendia plus a reasonable dispensing fee.

For the covered outpatient drugs of a manufacturer to be eligible for Federal matching funds under Medicaid, the manufacturer must enter into a rebate agreement with CMS and pay quarterly rebates to State Medicaid agencies. Under these rebate agreements and the law, manufacturers must provide CMS with the AMPs for each of their covered drugs on a quarterly basis. Pursuant to Federal statute, AMP is the average price paid to a manufacturer for a drug in the United States by wholesalers for drugs distributed to the retail pharmacy class of trade, net of customary prompt pay discounts. The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 recognizes AMP as a potential measure to be substituted in Medicare reimbursement calculations.

We obtained the third-quarter 2004 version of the Federal upper limit list and third-quarter 2004 AMP data from CMS. For each drug on the Federal upper limit list, we determined the minimum AMP, average AMP, and maximum AMP. To follow current procedures prescribed by Federal regulation, we limited the calculation to products that (1) were rated therapeutically equivalent by FDA, and (2) were available in the most commonly listed package size. We also limited the analysis to

products with Medicaid utilization in the third quarter of 2004. We calculated the percentage difference between the Federal upper limit amount and the minimum, average, and maximum AMPs.

To determine the potential implications of using AMPs rather than published prices to set Federal upper limit amounts, we multiplied the minimum and average AMPs for the drugs by 150 percent. We then subtracted 150 percent of the minimum and average AMPs from the average Medicaid reimbursement amount in the third quarter of 2004. Finally, we multiplied the difference by the number of units of the drug product reimbursed during the time period.

FINDINGS

Federal upper limit amounts were five times higher than the average AMP. Overall, Federal upper limit amounts were five times higher than the average AMPs for generic drug products in the third quarter of 2004. Among individual generic drug products, Federal upper limits exceeded average AMPs by as much as 19 times. During the same period, the Federal upper limit amount was, on average, 22 times higher than the lowest reported AMP, and usually exceeded even the highest reported AMP.

Medicaid could save hundreds of millions of dollars per year by basing Federal upper limit amounts on reported AMPs. If Medicaid based Federal upper limit amounts on 150 percent of the average AMP, the financial implications would be substantial. In the third quarter of 2004, the program could have saved an estimated $161 million (or almost $650 million in 1 year) had Medicaid used the average AMP instead of the lowest published price when calculating Federal upper limits.

Furthermore, if Medicaid based Federal upper limit amounts on 150 percent of the lowest reported AMP rather than 150 percent of the lowest published price, the program may have saved up to $300 million in just one quarter of 2004. This figure represents 75 percent of the $396 million spent on generic versions of Federal upper limit drugs during that period. Assuming spending in the following three quarters would be similar to the previous quarter, basing Federal upper limit amounts on 150 percent of the lowest reported AMP rather than 150 percent of the lowest published price could save Medicaid up to $1.2 billion per year.

RECOMMENDATION

The Centers for Medicare & Medicaid Services should work with Congress to set Federal upper limit amounts that more closely approximate acquisition costs. In the past several months, the President, Congress, and individual Medicaid State agencies have expressed renewed interest in reducing excessive Medicaid reimbursement for prescription drugs. The original purpose of the Federal upper limit program was to do just that by allowing Medicaid to take advantage of current market prices for generic drugs. However, the applicable regulation requires Federal upper limit amounts to be based on prices published in the national drug compendia. As studies by the Office of Inspection General and numerous other entities have shown, published prices for many products bear little or no resemblance to the actual prices paid by providers. Because the already inflated published prices are multiplied by 150 percent when calculating Federal upper limit amounts, Medicaid reimbursement for qualified products has the potential to greatly exceed acquisition costs. The findings of this report further illustrate this point.

We understand that pharmacies need to make some profit from the drugs they supply. In addition, we realize that reimbursement amounts should be sufficient to provide pharmacies with incentives to dispense lower-cost generic drugs rather than the more expensive brand name versions. However, that Federal upper limit amounts are typically 5 times higher (and as much as 19 times higher) than the average AMP seems excessive.

Therefore, we recommend that CMS work with Congress to set Federal upper limit amounts that more closely approximate acquisition costs. At a time when States are trying to most effectively allocate resources due to shrinking Medicaid budgets, revised Federal upper limit laws and regulations would allow States and the Federal Government to share in the cost savings that should be associated with lower-priced generic drugs. Subsequently, these cost savings should help States to continue providing needed care to Medicaid beneficiaries.

Agency Comments

CMS concurred with our recommendation, stating that Congress should take action to ensure that Medicaid reimbursement amounts more closely relate to actual transaction prices.

TABLE OF CONTENTS

EXECUTIVE SUMMARY i

INTRODUCTION 1

FINDINGS

Federal upper limits five times higher than the average AMP 8

Savings from using AMPs could exceed $1 billion per year 9

RECOMMENDATION 11

APPENDICES

A: Methodology 13

B: Centers for Medicare & Medicaid Services Comments 16

ACKNOWLEDGMENTS 19

INTRODUCTION

OBJECTIVE

To (1) determine how prices for drugs set under the Medicaid Federal upper limit program compare to reported average manufacturer prices (AMP) and (2) estimate the savings that could be achieved if Federal upper limit amounts were based on reported AMPs.

BACKGROUND

Medicaid Program.

Medicaid is a jointly funded, Federal and State health insurance program for certain low-income and medically needy people. Individual States establish eligibility requirements, benefits packages, and payment rates for their Medicaid programs under broad Federal standards administered by the Centers for Medicare & Medicaid Services (CMS). Medicaid requirements mandate that States provide basic services to beneficiaries to receive Federal matching funds. States may also receive Federal funding if they provide other optional services. One universally offered optional service is prescription drug coverage. All 50 States and the District of Columbia currently offer prescription drug coverage under the Medicaid program. In calendar year 2003, CMS estimates that Medicaid payments for prescription drugs totaled over $34 billion.[1]

Medicaid Drug Reimbursement Methodology.

Each State is required to submit a Medicaid State plan to CMS describing its payment methodology for covered drugs. Federal regulations require, with certain exceptions, that each State's reimbursement for a drug not exceed the lower of its estimated acquisition cost plus a reasonable dispensing fee or the provider's usual and customary charge to the public for the drug.

CMS allows States flexibility to define estimated acquisition cost. Most States base their calculation of estimated acquisition cost on a drug's average wholesale price (AWP) discounted by a certain percentage. As of the first quarter of 2005, this discount ranged from 5 to 50 percent of AWP. A small number of States use wholesale acquisition costs plus a percentage markup rather than, or in addition to, discounted AWPs when determining estimated acquisition cost.

[1] This amount includes both the Federal and State shares of payments. Rebates collected under the Medicaid Drug Rebate program have not been subtracted from the total.

For certain drugs, States also use the Federal upper limit and/or State maximum allowable cost programs in determining reimbursement amounts. CMS has established Federal upper limit amounts for more than 400 drugs. In addition, numerous States have implemented a maximum allowable cost program to limit reimbursement amounts for certain drugs. Individual States determine the types of drugs that are included in their maximum allowable cost programs and the methods by which the maximum allowable cost for a drug is calculated.

In summary, States use a variety of mechanisms when setting drug reimbursement amounts. In most cases, States reimburse for a drug at the lower of the estimated acquisition cost, the Federal upper limit amount, or the State maximum allowable cost, plus a reasonable dispensing fee.

Federal Upper Limit Program.

According to CMS's "State Medicaid Manual," the Federal upper limit program was created to ensure that the Federal Government acts as a prudent payer by taking advantage of current market prices for multiple-source drugs. Under 42 CFR § 447.332, CMS is to establish a Federal upper limit amount for a drug when: (1) all formulations of a drug have been rated as therapeutically equivalent by the Food and Drug Administration (FDA), and (2) at least three suppliers of the drug are listed in current editions (or updates) of published compendia of cost information for drugs available for sale nationally. The Omnibus Budget Reconciliation Act of 1990 (OBRA '90) established new criteria requiring a drug to be included on the Federal upper limit list when three or more versions of a drug had been rated therapeutically and pharmaceutically equivalent by FDA, regardless of the ratings of other versions.[2] FDA designates drugs that are therapeutically equivalent as "A-rated."

Federal regulation (42 CFR § 447.332) sets the Federal upper limit amount at 150 percent of the published price for the least costly, therapeutically equivalent product that can be purchased by pharmacists in quantities of 100 tablets or capsules plus a reasonable

[2] According to the "State Medicaid Manual," the language of OBRA '90 "augments" the upper limits established by the regulation and creates "new criteria" for adding drugs to the Federal upper limit list. CMS has not modified the language of the regulation since it was promulgated in 1987, nor has the regulation been withdrawn. In practice, CMS relies on the language of the regulation and the OBRA '90 provisions in establishing Federal upper limits.

dispensing fee. If the drug is not typically available in quantities of 100 or if the drug is a liquid, the Federal upper limit amount is based on a commonly listed size.

CMS applies an additional standard in determining which drugs should be subject to Federal upper limits. According to CMS staff, only drugs for which a Federal upper limit could potentially lead to savings should be included on the Federal upper limit list. Therefore, if a drug does not have a published price that, when multiplied by 150 percent, is lower than the AWP, CMS does not include the product.

CMS publishes the Federal upper limit list on its Web site at www.cms.hhs.gov/medicaid/drugs/drug10.asp and in the "State Medicaid Manual." Any revisions to the Federal upper limit list are typically noted on the Web site as well. CMS establishes an upper limit for specific forms and strengths for each multiple-source drug on the list. The Federal upper limit list also provides the source of the pricing information used to calculate the upper limit amount for each drug.

The Medicaid Drug Rebate Program and Average Manufacturer Price. For the covered outpatient drugs of a manufacturer to be eligible for Federal matching funds under Medicaid, section 1927(a)(1) of the Social Security Act mandates that drug manufacturers enter into rebate agreements with CMS and pay quarterly rebates to States. Under these rebate agreements and the law, manufacturers must provide CMS with the AMP for each of their covered drugs on a quarterly basis. Pursuant to section 1927(k)(1) of the Social Security Act, AMP is defined as the average price paid to a manufacturer for a drug in the United States by wholesalers for drugs distributed to the retail pharmacy class of trade, net of customary prompt pay discounts. The AMP is calculated as a weighted average of prices for all of a manufacturer's package sizes of a drug sold during a given quarter. Section 1927(b)(3)(D) of the Social Security Act requires that, subject to certain exceptions, AMPs reported to CMS not be publicly disclosed.

In a December 2004 report, the Congressional Budget Office used AMP to estimate what pharmacies pay to acquire drugs. While the acquisition costs for pharmacies that buy through wholesalers rather than directly from manufacturers may exceed AMP, the wholesaler markup is estimated to be a small proportion (approximately 3 percent)

of the actual price.[3] The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) also recognizes AMP as a potential measure to be substituted in Medicare reimbursement calculations.[4]

Related Work by the Office of Inspector General.
In December 2004, the Office of Inspector General (OIG) issued "Addition of Qualified Drugs to the Medicaid Federal Upper Limit List" (OEI-03-04-00320) as requested by a Congressional subcommittee. OIG found that CMS does not add qualified drugs to the Federal upper limit list in a timely manner. Of the 252 first-time generic drugs approved between January 2001 and December 2003, 109 drugs met the criteria for inclusion on the Federal upper limit list; however, only 25 of these drugs were actually added. For the 25 that were added, CMS took an average of 36 weeks to place the products on the Federal upper limit list once they were qualified for inclusion. CMS's not adding qualified drugs in a timely manner cost the Medicaid program an estimated $167 million between 2001 and 2003. We recommended that CMS establish an administrative procedure and schedule to govern the determination and publication of Federal upper limits.

In February 2004, OIG issued "Omission of Drugs from the Federal Upper Limit List in 2001" (OEI-03-02-00670). OIG found that 90 drug products were not included on the Federal upper limit list in 2001 despite meeting the criteria established by Federal law and regulation. Medicaid could have saved $123 million in 2001 by adding 55 of the 90 drug products to the Federal upper limit list. OIG recommended that CMS take steps to ensure that all drugs meeting the criteria are included on the Federal upper limit list.

In October 2003, OIG issued "State Strategies to Contain Medicaid Drug Costs" (OEI-05-02-00680). OIG found that States employ three main drug cost containment strategies: (1) limiting Medicaid reimbursement for drugs, (2) shifting use from higher to lower cost drugs, and (3) limiting the amount of prescription drugs a beneficiary can obtain. States reported facing challenges in their attempts to maximize drug

[3] As reported by the National Association of Chain Drug Stores in the Congressional Budget Office report, "Medicaid's Reimbursement to Pharmacies for Prescription Drugs."

[4] Medicare typically uses manufacturer-reported average sales price (ASP) plus 6 percent as the basis for drug reimbursement. However, if the ASP for a drug exceeds the AMP by a threshold percentage, section 303 of MMA allows the program to base reimbursement on 103 percent of AMP instead. In 2005, this threshold percentage is 5 percent.

cost savings, including a lack of accurate drug price information and stakeholder opposition to cost containment efforts.

Recent Interest in Medicaid Drug Pricing Issues.
In December 2004, the United States House Committee on Energy and Commerce Subcommittee on Oversight and Investigations held a hearing entitled "Medicaid Prescription Drug Reimbursement: Why the Government Pays Too Much." Representatives from OIG, CMS, several State Medicaid agencies, and the drug industry testified at this hearing. The role that Federal upper limits play in reducing costs for prescription drugs was a key area of interest to the subcommittee.

In addition, the President's 2006 budget proposes changes that would cause Medicaid reimbursement amounts to more closely approximate pharmacy acquisition costs. Specifically, the budget recommends that Medicaid reimbursement for prescription drugs be at 106 percent of a drug's ASP.

Prior to 2005, Medicare, like Medicaid, based drug reimbursement on published AWPs. However, due in part to numerous reports by OIG and the Government Accountability Office that found that AWPs were significantly inflated, Congress required that Medicare begin basing reimbursement amounts on 106 percent of ASP instead. Section 303 of MMA defines ASP as the manufacturer's sales to all purchasers (with certain exemptions) divided by the number of units sold. The ASP is to be net of chargebacks, discounts, rebates, and other price concessions. The ASPs are reported to CMS by drug manufacturers.

METHODOLOGY

Identifying Drugs on the Federal Upper Limit List.
We obtained a list of drugs subject to Federal upper limits as of the third quarter of 2004 from the CMS Web site. Using data obtained from the publisher of a national drug compendium, we compiled a list of all the national drug codes (NDC) associated with generic versions of each drug product.

Obtaining Medicaid Utilization Data.
We downloaded 50 State Medicaid payment and utilization files for 2004 from CMS's Web site. We limited our analysis to utilization occurring in

the third quarter of 2004.[5] We calculated the average Medicaid reimbursement amount for each of the 415 drugs on the Federal upper limit list by dividing the total reimbursement for the product (net of dispensing fees) by the total number of units reimbursed.[6]

Determining AMPs for Drugs Subject to Federal Upper Limits.
We obtained third-quarter 2004 AMP data from CMS. We matched the AMP data with the Medicaid utilization data to verify that all products on which the comparisons would be made had actually been reimbursed by Medicaid. Consistent with Federal regulations, we removed any NDCs that represented drug products that were not A-rated, and also removed any NDCs that did not match the most commonly listed package size. We then determined the minimum, average, and maximum AMPs among the remaining NDCs for each of the drug products. We did not verify that the AMPs reported to CMS were correct.

Comparing Federal Upper Limit Amounts to AMPs.
We compared the third-quarter 2004 Federal upper limit amounts to the third-quarter 2004 AMPs. We calculated the percentage difference between the Federal upper limit amount and the minimum, average, and maximum AMPs for each of the 415 drug products under review. We then calculated an overall percentage difference weighted by Medicaid reimbursement. We will not be reporting the actual dollar differences between the Federal upper limit amounts and AMPs for individual drug products due to confidentiality issues.

Estimating Potential Savings.
To determine the potential impact of using AMPs rather than published prices to set Federal upper limit amounts, we:

(1) multiplied the minimum and average AMPs for the drugs on the Federal upper limit list by 150 percent (consistent with current regulation),

[5] Third-quarter data for seven States were not yet available, and an additional State had no data in the system because its drug benefit is provided completely through managed care organizations. Therefore, our analysis is limited to information from 42 States and the District of Columbia.

[6] As of the third quarter of 2004, there were 419 drug products on the Federal upper limit list. Four of these drug products were removed from the analysis for reasons detailed in Appendix A, leaving 415 drugs in our review.

(2) subtracted 150 percent of the minimum and average AMPs from the average Medicaid reimbursement amount in the third quarter of 2004, and[7]

(3) multiplied the difference calculated in step two by the number of units of the drug product reimbursed during the time period.

A complete discussion of our methodology is presented in Appendix A.

This evaluation was conducted in accordance with the "Quality Standards for Inspections" issued by the President's Council for Integrity and Efficiency and the Executive Council for Integrity and Efficiency.

[7] In calculating potential savings, we used average Medicaid reimbursement amounts rather than Federal upper limit amounts. Because of State maximum allowable cost programs, some States may reimburse substantially less than the Federal upper limit amount for certain drugs. Therefore, using Federal upper limit amounts in our calculations would tend to exaggerate potential savings. Using average Medicaid reimbursement amounts provides a much more accurate estimate of the potential savings.

Federal upper limit amounts were five times higher than the average AMP

Overall, Federal upper limit amounts were five times higher than the average AMPs for generic drug products in the third quarter of 2004. Among individual generic drug products, Federal upper limits exceeded average AMPs by as much as 19 times ($1.20 per tablet compared to $0.063 per tablet). For 327 of the 415 drug products reviewed, the Federal upper limit amount was at least double the average generic AMP, with Federal upper limits being more than 4 times higher in 131 cases. The Federal upper limit amount was below the average AMP for just 13 of the 415 drug products during the third quarter of 2004.

Among the 20 reviewed drug products with the highest total Medicaid reimbursement, the Federal upper limit amount was between 2 and 14 times higher than the average generic AMP during the third quarter of 2004.[8] Ten of the top twenty drug products had a Federal upper limit amount that was at least 5 times more than the average generic AMP.

On average, Federal upper limit amounts were more than 20 times higher than the lowest reported AMPs.

During the third quarter of 2004, the Federal upper limit amount for 415 drug products was, on average, 22 times higher than the minimum generic AMP reported by drug manufacturers. For 29 drug products, the Federal upper limit amount exceeded the minimum reported AMP for generic versions by at least 40 times. All but 12 of the 415 drug products had Federal upper limit amounts that were at least double the minimum generic AMP.

For the 20 drug products with the highest total Medicaid reimbursement, Federal upper limit amounts ranged from 4 times more than the minimum AMP up to 61 times more than the minimum AMP. The drug with highest total reimbursement during the third quarter of 2004, albuterol inhalation aerosol, had a Federal upper limit amount that was 36 times higher than the lowest reported generic AMP.

[8] These 20 drugs accounted for 36 percent of total Medicaid reimbursement for generic versions of Federal upper limit drugs during the third quarter of 2004. A list of these drugs is presented in Table 1 on page 10.

Federal upper limit amounts were usually greater than even the highest reported AMPs.

On average, Federal upper limit amounts were more than double the highest reported generic AMPs during the third quarter of 2004. Only 75 of the 415 drugs under review had a Federal upper limit amount that was less than the maximum AMP. In the case of the drug product with the highest total Medicaid reimbursement, albuterol inhalation aerosol, the Federal upper limit amount was approximately five times more than the maximum reported AMP among generic versions of the product.

Medicaid could save hundreds of millions of dollars per year by basing Federal upper limit amounts on reported AMPs

If Medicaid based Federal upper limit amounts on 150 percent of the average AMP, the program could have saved an estimated $161 million in the third quarter of 2004.[9] Assuming spending in the following three quarters would be similar to the previous quarter, basing Federal upper limit amounts on 150 percent of the average AMP rather than 150 percent of the lowest published price could save Medicaid almost $650 million per year.[10] Table 1 (see page 10) shows the potential savings for the 20 drugs with the highest total Medicaid reimbursement in the third quarter of 2004. The potential savings for these 20 drugs alone exceeded $75 million for the quarter.

If Medicaid based Federal upper limit amounts on 150 percent of the lowest reported AMP rather than 150 percent of the lowest published price, the program may have saved up to $300 million in just a single quarter. This figure represents 75 percent of the $396 million spent on generic versions of Federal upper limit drugs during the third quarter of 2004. Assuming spending in the following three quarters would be similar to the previous quarter, basing Federal upper limit amounts on 150 percent of the lowest reported AMP rather than 150 percent of the lowest published price could save Medicaid up to $1.2 billion per year.

[9] All savings in this report represent estimates for 42 States and the District of Columbia only. We did not perform calculations for eight states without third-quarter data.

[10] The President's 2006 budget recommends using 106 percent of ASP as the basis for Medicaid drug reimbursement, an identical method to Medicare Part B. The ASP for most of the drugs included in this review are not provided to CMS since they are not covered under Medicare Part B.

Table 1: Potential Savings Based on Average AMP for 20 Drugs With Highest Reimbursement

Generic Name	Medicaid Reimbursement 7/1/2004 - 9/30/2004	Savings at 150% of Average AMP
Albuterol aerosol 90 mcg/act	$16,391,640	$12,105,942
Metformin HCl tab 500 mg	$13,430,697	$6,354,068
Fluoxetine HCl cap 40 mg	$9,292,817	$6,711,161
Tramadol HCl tab 50 mg	$8,921,358	$5,141,661
Tizanidine HCl tab 4 mg	$7,785,526	$4,286,990
Ranitidine HCl tab 150 mg	$7,570,846	$5,954,356
Albuterol sulfate solution 0.083%	$7,180,644	$3,553,728
Lorazepam tab 1 mg	$6,409,259	$4,204,818
Lisinopril tab 20 mg	$6,358,915	$3,590,489
Hydrocodone-acetaminophen tab 10-500 mg	$5,873,425	$3,099,228
Hydroxyzine HCl tab 25 mg	$5,737,177	-$555,585
Amiodarone HCl tab 200 mg	$5,550,813	$3,759,315
Propoxyphene-N w/APAP tab 100-650 mg	$5,464,571	$109,935
Famotidine tab 20 mg	$5,428,734	$4,474,399
Lisinopril tab 10 mg	$5,373,003	$2,752,882
Lisinopril tab 40 mg	$5,164,975	$2,527,996
Baclofen tab 10 mg	$5,116,346	$2,347,817
Lovastatin tab 40 mg	$5,007,263	$2,808,319
Lorazepam tab 0.5 mg	$4,934,603	$2,601,946
Cephalexin cap 500 mg	$4,670,980	$2,492,166
Total	**$141,663,592**	**$78,321,631**

Source: Third-Quarter 2004 CMS Federal Upper Limit and AMP Data; OIG Analysis, April 2005.

RECOMMENDATION

The Centers for Medicare & Medicaid Services should work with Congress to set Federal upper limit amounts that more closely approximate acquisition costs.

In the past several months, the President, Congress, and individual Medicaid State agencies have expressed renewed interest in reducing excessive Medicaid reimbursement for prescription drugs. The original purpose of the Federal upper limit program was to do just that by allowing Medicaid to take advantage of current market prices for generic drugs. However, the applicable regulation requires Federal upper limit amounts to be based on prices published in the national drug compendia. As studies by the Office of Inspector General and numerous other entities have shown, published prices for many products bear little or no resemblance to the actual prices paid by providers. Because the already inflated published prices are multiplied by 150 percent when calculating Federal upper limit amounts, Medicaid reimbursement for qualified products has the potential to greatly exceed acquisition costs. The findings of this report further illustrate this point.

We understand that pharmacies need to make some profit from the drugs they supply. In addition, we realize that reimbursement amounts should be sufficient to provide pharmacies with incentives to dispense lower cost generic drugs rather than the more expensive brand name versions. However, that Federal upper limit amounts are typically 5 times higher (and as much as 19 times higher) than the average AMP seems excessive.

Therefore, we recommend that CMS work with Congress to set Federal upper limit amounts that more closely approximate acquisition costs. At a time when States are trying to more effectively allocate resources due to shrinking Medicaid budgets, revised Federal upper limit laws and regulations would allow States and the Federal Government to share in the cost savings that should be associated with lower priced generic drugs. Subsequently, these cost savings should help States to continue providing needed care to Medicaid beneficiaries.

Agency Comments

CMS concurred with our recommendation, stating that Congress should take action to ensure that Medicaid reimbursement amounts more closely relate to actual transaction prices. CMS notes that

Congress recently acted to reform Medicare's payment methodology for prescription drugs based on similar pricing issues, and goes on to state, "Congress should now enact similar legislation to ensure that Medicaid payment for drugs is related to actual prices paid by pharmacies." The full text of CMS's comments is presented in Appendix B.

OIG Response

OIG appreciates CMS's comments on this report, and looks forward to assisting CMS and Congress in their efforts reform Medicaid's current reimbursement methodology.

METHODOLOGY

Identifying Drugs on the Federal Upper Limit List.
We obtained a list of drugs subject to Federal upper limits as of the third quarter of 2004 from the CMS Web site. At that time, 419 drug products (i.e., individual dosage forms and sizes of a generic drug ingredient) were included on the Federal upper limit list.

Using data obtained from the publisher of a national drug compendium, we compiled a list of all the national drug codes (NDC) associated with generic versions of each of the 419 drug products. Each individual drug product manufactured or distributed in the United States has a unique NDC. An NDC identifies the manufacturer or labeler of the drug product, the product dosage form, and the package size. For each NDC, compendia provide published prices (usually average wholesale prices and wholesale acquisition costs), manufacturer information, and FDA therapeutic equivalency data. The compendia also identify whether the individual drug product is a brand name or generic version. According to the compendium used in our analysis, 2 of the 419 drug products on the Federal upper limit list did not have any matching generic NDCs. The remaining 417 drug products were represented by 17,945 generic NDCs.

Obtaining Medicaid Utilization Data.
To ensure that the comparisons between Federal upper limit amounts and AMPs were meaningful, we verified that all products upon which the comparisons were based had actually been reimbursed by Medicaid. We downloaded 50 State Medicaid payment and utilization files for 2004 from CMS's Web site.[11] Each file contained variables representing total State reimbursement, number of units reimbursed, and number of prescriptions written for every NDC by calendar quarter.

We limited our analysis to utilization occurring in the third quarter of 2004. CMS had third-quarter utilization figures available for 42 States and the District of Columbia.[12] Of the 17,945 NDCs subject to

[11] Arizona's data were not available for download because the State's drug benefit is administered completely through managed care organizations and not the traditional fee-for-service system.

[12] The seven States without third-quarter data on CMS's Web site were Colorado, Georgia, Kansas, Louisiana, Ohio, Vermont, and Washington.

Federal upper limits, 4,699 had Medicaid utilization in the third quarter of 2004.

The total State reimbursement amount listed in the State utilization files included both the payments made for the NDC and the dispensing fees paid to the pharmacy. To determine a State's reimbursement for only the drug product during the third quarter of 2004, we:

(1) calculated the total amount paid in dispensing fees for the NDC by multiplying the State's dispensing fee by the number of prescriptions written for the NDC in each State,

(2) subtracted total dispensing fees from the total reimbursement for the NDC in each State,

(3) aggregated reimbursement (net of dispensing fees) and the number of units reimbursed for each NDC for all States, and

(4) summarized the data from step 3 to obtain reimbursement and utilization totals for each of the 417 drug products.

We then calculated the average Medicaid reimbursement amount for each of the drugs by dividing the total reimbursement for the product (without the dispensing fee) by the total number of units reimbursed.

Determining AMPs for Drugs Subject to Federal Upper Limits.
We obtained third-quarter 2004 AMP data from CMS. We matched the AMP data with the Medicaid utilization data to verify that all products on which the comparisons would be made had actually been reimbursed by Medicaid. We determined that 4,526 NDCs that were subject to Federal upper limits appeared on both the AMP file and Medicaid utilization files that quarter.

Federal regulations require that the prices on which Federal upper limit amounts are based be for therapeutically equivalent (A-rated) products in common package sizes. Therefore, we removed from the analysis any NDCs that represented drug products that were not A-rated. At this point, we removed another drug from the analysis because the drug did not have any A-rated versions with third-quarter 2004 utilization. For the 416 remaining drug products, we determined the most common package size listed in the compendia. We removed from our analysis any NDCs that did not match this package size. We then determined the minimum, average, and maximum AMPs for the remaining NDCs for each of the 416 drug products. We did not verify that the AMPs reported to CMS were correct.

Comparing Federal Upper Limit Amounts to AMPs.
We compared third-quarter 2004 Federal upper limit amounts to the third-quarter 2004 AMPs. We first ensured that the unit (i.e., tablet, gram, etc.) upon which the Federal upper limit was based equaled the unit amount upon which AMP was based. For one product, the unit differed significantly and we could not readily determine an appropriate conversion factor. This drug product was removed from the analysis, leaving 415 products in our review.

We calculated the percentage difference between the Federal upper limit amount and the minimum, average, and maximum AMP for each of the 415 drug products. We then calculated an overall percentage difference weighted by Medicaid reimbursement. We will not report the actual dollar differences between the Federal upper limit amounts and AMPs for individual drug products due to confidentiality issues.

Estimating Potential Savings.
To determine the potential savings of using AMPs rather than published prices to set Federal upper limit amounts, we:

(1) multiplied the minimum and average AMPs for the 415 drugs on the Federal upper limit list by 150 percent (consistent with current regulation),

(2) subtracted 150 percent of the minimum and average AMPs from the average Medicaid reimbursement amount in the third quarter of 2004, and [13]

(3) multiplied the difference calculated in step 2 by the number of units of the drug product reimbursed during the time period.

This evaluation was conducted in accordance with the "Quality Standards for Inspections" issued by the President's Council for Integrity and Efficiency and the Executive Council for Integrity and Efficiency.

[13] In calculating potential savings, we used average Medicaid reimbursement amounts rather than Federal upper limit amounts. Because of State maximum allowable cost programs, some States may reimburse substantially less than the Federal upper limit amount for certain drugs. Therefore, using Federal upper limit amounts in our calculations would tend to exaggerate potential savings. Using average Medicaid reimbursement amounts provides a much more accurate estimate of the potential savings.

APPENDIX ~ B

Comments from the Centers for Medicare & Medicaid Services

DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Administrator
Washington, DC 20201

DATE: JUN 21 2005

TO: Daniel R. Levinson
Acting Inspector General

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

SUBJECT: OIG Draft Reports: "*Comparison of Medicaid Federal Upper Limit Amounts to Average Manufacturer Prices*," (OEI-03-05-00110);

"*Medicaid Drug Price Comparison: Average Sales Price to Average Wholesale Price,"* (OEI 03-05-00200); and

"*Medicaid Drug Price Comparison: Average Manufacturer Price to Average Wholesale Price*," (OEI-05-05-00240)

Thank you for the opportunity to review and comment on the Office of Inspector General's (OIG) draft reports entitled "*Comparison of Medicaid Federal Upper Limit Amounts to Average Manufacturer Prices," "Medicaid Drug Price Comparison: Average Sales Price to Average Wholesale Price,"* and *"Medicaid Drug Price Comparison: Average Manufacturer Price to Average Wholesale Price."* The first OIG report addresses how prices for drugs set under the Medicaid Federal Upper Limit (FUL) program compare to reported average manufacturer prices (AMP), and estimates potential savings if FUL amounts were based on reported AMPs. The latter two reports compare how prices that most states currently use to set Medicaid reimbursement, average wholesale price (AWP), and wholesale acquisition cost (WAC), compare to statutorily defined prices based on actual sales transactions, i.e., average sales price (ASP) and AMP.

The OIG reports make clear that the current payment rules result in overpayments for drugs and emphasize the need for reform. The President's 2006 budget proposes to solve this problem by the use of average sales prices (ASP) so Medicaid drug prices will reflect actual costs.

OIG Recommendation
CMS should work with Congress to set Medicaid drug reimbursement amounts that more closely approximate pharmacy acquisition cost.

Page 2 – Daniel R. Levinson

CMS Response

We concur with the OIG that the Congress needs to address drug prices paid by Medicaid to more closely relate Medicaid reimbursement to actual transaction prices.

Federal regulation (42 CFR 447.332) requires the FUL amount to be 150 percent of the published price for the least costly therapeutic equivalent using data from all available national compendia. The FUL system selects the lowest price of AWP, WAC, or direct price (DP), as reported by the national compendia to arrive at the FUL price.

States reimburse pharmacies for single source drugs at the lower of Estimated Acquisition Cost (EAC), or the pharmacy's usual and customary charge (UCC) to the general public. EAC is based on the state's reimbursement formula, generally AWP minus a percentage or WAC plus a percentage.

Neither AWP nor WAC is related to the market price of drugs. Rather, they are prices based on reports by manufacturers. Manufacturers often report inflated prices in order to increase the profit for pharmacies and, thereby, encourage pharmacies to dispense their product. State Medicaid Agencies need information on market prices in order to set appropriate payment rates. The President has proposed in the fiscal year 2006 budget to require drug manufacturers to report ASP for drugs and to cap Federal matching for drug expenditures, in the aggregate, to ASP plus 6 percent.

OIG Findings

Overall, FUL prices were five times higher than the average AMPs for generic drug products in the third quarter of 2004. If Medicaid based FUL amounts on 150 percent of the average AMP instead of the compendia prices, the program could have saved an estimated $161 million in the third quarter of 2004.

For the comparison of AMP to compendia price, AMP is substantially lower than both AWP and WAC for all National Drug Codes (NDCs) reviewed. The median price comparison for all evaluated drugs was that AMP is equal to AWP – 59 percent and AMP is equal to WAC - 25 Percent. Generic drugs exhibited the largest differences between AMP and the list prices – The median price comparison for generic drugs was AMP is equal to AWP - 70 percent and AMP is equal to WAC – 40 percent. States' median AWP based estimated acquisition cost is AWP – 12 Percent. States' median WAC based estimated acquisition cost is WAC plus 8.5 percent.

For the comparison of ASP to compendia price, ASP is substantially lower than AWP and WAC for all NDCs reviewed. For 2,077 NDCs with ASP and AWP data, ASP is equal to AWP – 49 percent. The difference between ASP and AWP was greatest for generic drugs. For 1,152 generic NDCs, ASP is equal to AWP – 68 Percent.

CMS Response/Conclusion

These reports provide additional supportive evidence that when published compendia prices are used as a basis for Medicaid drug reimbursement, Medicaid payment greatly exceeds actual acquisition cost. Legislation would be needed to define a price that manufacturers must report that can be used as a basis for state Medicaid agencies to set pharmacy payment.

In the fiscal year 2006 budget, the President proposed to require drug manufacturers to report the ASP for each drug and to cap Federal payment at an aggregate level to ASP plus 6 percent. As long as states must rely on prices that are not based on true prices paid to manufacturers, states have no means to set appropriate payment amounts. Current WACs and AWPs are greatly inflated and this inflation is encouraged by setting Medicaid payment in relation to these inflated prices. Requiring manufacturers to report true prices and to limit Medicaid payment to a reasonable amount above these prices will eliminate the opportunity for manufacturers and pharmacies to gain through the reporting of inflated prices, yield substantial state and Federal government savings, and retain flexibility for states to set prices for individual drugs as they find appropriate within the overall cap.

Prior to 2005, Medicare also used AWP as the basis for Part B drug reimbursement. However, numerous studies by the OIG and the Government Accountability Office, (GAO), indicated that Medicare's reimbursement rate was significantly higher than the prices that drug manufacturers and wholesalers actually charged physicians and suppliers who purchased these drugs. Consequently, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) changed the basis of reimbursement for prescription drugs from AWP to ASP. Congress should now enact similar legislation to ensure that Medicaid payment for drugs is related to actual prices paid by pharmacies.

ACKNOWLEDGMENTS

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:

David Tawes, *Team Leader*

Linda Boone Abbott, *Program Specialist*