Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

How Inflated Published Prices Affect Drugs Considered for the Federal Upper Limit List

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OBJECTIVE

To determine (1) the extent to which the mandated method for calculating Medicaid Federal upper limit amounts causes qualified products to be excluded from the Federal upper limit list and (2) the potential financial implications of these exclusions to Medicaid.

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.

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 average wholesale price (AWP) (upon which reimbursement is typically based), CMS does not include the product.

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 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 average manufacturer prices (AMP) for each of their covered drugs on a quarterly basis. Pursuant to Federal statute, the 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 the AMP as a potential measure to be substituted in Medicare reimbursement calculations.

For each drug product approved between 2001 and 2003 that met all statutory and regulatory criteria for inclusion on the Federal upper limit list but did not meet CMS's additional criterion, we calculated the minimum AMP, average AMP, and maximum AMP in the first and second quarters of 2004. 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 first two quarters of 2004.

To determine the potential implications if CMS were able to use AMPs rather than published prices to set Federal upper limit amounts, we: (1) multiplied the minimum, average, and maximum AMPs for the reviewed drugs by 150 percent (the percentage stated in current regulation); (2) subtracted 150 percent of the minimum, average, and maximum AMPs from the average Medicaid reimbursement amount (less the dispensing fee) in each of the first two quarters of 2004; and (3) multiplied the difference calculated in step two by the number of units of the drug product reimbursed during these quarters. This figure provided us with the savings that could have resulted in just two quarters for drugs that were not included on the Federal upper limit list due to issues with their published prices.

FINDINGS

In the first two quarters of 2004, 58 drug products that met all statutory and regulatory requirements were not added to the Federal upper limit list due to inflated published prices. Of the 252 first-time generic drug products approved between 2001 and 2003, 58 met all statutory and regulatory requirements as of June 30, 2004, but were not included on the Federal upper limit list because their addition would not have lead to savings. Each of these 58 products had at least 3 A-rated versions and 3 suppliers, but did not have a published price that when multiplied by 150 percent was less than the AWP.

Overall, average AWPs were more than three times higher than the average AMPs for the reviewed drug products. Even the minimum published prices for these drugs were substantially higher than the

average AMP. Given that Federal law requires that these "minimum" published prices be multiplied by 150 percent, the difference between Federal upper limit amounts and AMPs would grow even wider.

Basing Federal upper limit amounts on AMPs could save Medicaid over $100 million per year by allowing otherwise qualified products to be included on the Federal upper limit list. As the previous finding shows, inflated published prices are causing CMS to exclude otherwise qualified drug products from the Federal upper limit list because their Federal upper limit amount would exceed the reimbursement amount set under the usual methods. However, if Medicaid based Federal upper limit amounts on 150 percent of the average reported AMP rather than 150 percent of the lowest published price, the program may have saved $75 million in just two quarters of 2004 due to these excluded drugs being added to the Federal upper limit list. Furthermore, if Medicaid could have used the lowest reported AMP multiplied by 150 percent when calculating Federal upper limit amounts, the program would have saved an estimated $111 million in the first and second quarters of 2004 for these drugs. Even if Federal upper limit calculations were based on 150 percent of the highest reported AMP, the program would have saved almost $39 million.

CONCLUSION

In the past several months, the President, Congress, and individual State Medicaid programs have expressed heightened interest in ensuring that Medicaid drug reimbursement amounts more closely resemble actual acquisition costs. In addition, the Office of Inspector General (OIG) has recently released a number of reports that once again showed that the published prices used as the basis for Medicaid reimbursement bear little or no resemblance to prices based on actual sales, especially for generic drugs. The Federal upper limit program is particularly affected by this disconnect between published prices and acquisition costs among generic drugs.

Congress created the Federal upper limit program to help Medicaid take advantage of current market prices for lower-cost generic drugs. However, Federal regulation requires that Federal upper limit amounts be based on 150 percent of the prices published in national compendia. Not only does the pricing methodology prescribed by Federal law cause artificially high Federal upper limit amounts for those products on the

Federal upper limit list, it also causes other qualified drugs to never be included on the list in the first place. This secondary effect is costing Medicaid millions of dollars per year, in addition to the considerable losses the program faces due to the inflated prices of drugs already on the Federal upper limit list.

Based on years of work by OIG, the Government Accountability Office, and others revealing the inflated nature of AWPs and other published prices, the Medicare program eliminated the use of AWP in its pricing methodology for Part B covered drugs. The fact that Medicaid still uses these published prices to determine Federal upper limit amounts makes little sense. We believe that reimbursement in general and Federal upper limit amounts in particular should reliably reflect the actual costs of drugs to pharmacies. Consequently, there is an urgent need for the Medicaid policymaking community to revise Federal upper limit policies, thereby ensuring that reimbursement amounts for generic drugs accurately reflect market prices, and that the Federal upper limit program better meets its original intent.

Agency Comments

CMS concurred with our findings, stating that the use of published prices as the basis for Federal upper limit amounts precludes the addition of some drugs to the Federal upper limit list. CMS also noted the recent changes to the basis of reimbursement for Medicare drugs made by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, and indicated that the same types of measures should be enacted for Medicaid. The full text of CMS's comments is presented in Appendix A.

TABLE OF CONTENTS

EXECUTIVE SUMMARY i

INTRODUCTION 1

FINDINGS

Fifty-eight drugs were not added to list due to inflated prices 9

Current calculation method could be costing Medicaid millions ... 9

CONCLUSION 11

APPENDIX

A: Centers for Medicare & Medicaid Services Comments 13

ACKNOWLEDGMENTS 15

OBJECTIVE

To determine (1) the extent to which the mandated method for calculating Medicaid Federal upper limit amounts causes qualified products to be excluded from the Federal upper limit list and (2) the potential financial implications of these exclusions to Medicaid.

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 the 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 the published compendia of cost information for drugs available for sale nationally. Section 4401 of 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 in the "State Medicaid Manual" and on its Web site.[3] 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 (the Act) mandates that the manufacturer must enter into a rebate agreement with CMS and pay quarterly rebates to States. Under these rebate agreements and the law, manufacturers must provide CMS with the average manufacturer price (AMP) for each of their covered drugs on a quarterly basis. Pursuant to section 1927(k)(1) of the Act, the 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 Act requires that, subject to certain exceptions, AMPs reported to CMS should not be publicly disclosed.

In a December 2004 report, the Congressional Budget Office used the 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 the AMP, the wholesaler

[3] www.cms.hhs.gov/medicaid/drugs/drug10.asp

markup is estimated to be a small proportion (approximately 3 percent) of the actual price.[4] The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) also recognizes the AMP as a potential measure to be substituted in Medicare reimbursement calculations.[5]

Related Work by the Office of Inspector General

In June 2005, the Office of Inspector General (OIG) issued "Comparison of Medicaid Federal Upper Limit Amounts to Average Manufacturer Prices" (OEI-03-05-00110). OIG found that, overall, Federal upper limits were five times higher than the average AMPs for generic drug products in the third quarter of 2004. 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 a year by basing Federal upper limit amounts on reported AMPs. We recommended that CMS work with Congress in an effort to lower Federal upper limit amounts.

In December 2004, OIG issued "Addition of Qualified Drugs to the Medicaid Federal Upper Limit List" (OEI-03-04-00320). 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 the drugs were qualified for inclusion. Qualified drugs not being added to the list 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

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

[5] Medicare typically uses the 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 the MMA allows the program to base reimbursement on 103 percent of the AMP instead. In 2005, this threshold is 5 percent.

2001 despite meeting the criteria established by Federal laws and regulations. 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 set by Federal laws and regulations 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 cost savings, including a lack of accurate drug price information and stakeholder opposition to cost containment efforts.

In September 2002, OIG issued "Medicaid Pharmacy - Additional Analyses of the Actual Acquisition Cost of Prescription Drug Products" (A-06-02-00041). The audit found that there was a wide range of discounts from the AWP for pharmacy purchases depending on the category of drug that is being purchased. For multiple-source drugs included on the Federal upper limit list, OIG estimated that pharmacy acquisition costs were 72.1 percent below the AWP.

Recent Interest in Medicaid Drug Pricing Issues

In June 2005, the U.S. Senate Committee on Finance held a hearing entitled "Medicaid Fraud, Waste, and Abuse: Threatening the Health Care Safety Net." Excessive payments for Medicaid-covered drugs was a major focus area. Representatives from OIG, CMS, the Department of Justice, State Medicaid agencies, and the drug industry provided testimony.

In December 2004, the U.S. 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.

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 (GAO) that found that AWPs were significantly inflated, Congress required that Medicare begin basing reimbursement amounts on 106 percent of the ASP instead. Section 303 of the MMA defines the 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. ASPs are reported to CMS by drug manufacturers.

METHODOLOGY

Identifying Drugs Not Included Due to Pricing Issues

In our December 2004 report, "Addition of Qualified Drugs to the Medicaid Federal Upper Limit List" (OEI-03-04-00320), we identified all first-time generic drug products approved between 2001 and 2003 that met the statutory and regulatory criteria for being included on the Federal upper limit list. During our analysis, we determined that a number of these drugs did not meet CMS's additional pricing criterion. Each of these products had at least three A-rated versions and three suppliers, but did not have any published prices that when multiplied by 150 percent were less than the AWP. None of these drugs had been included on the Federal upper limit list as of June 30, 2004.

Using data obtained from a national drug compendium, we compiled a list of all the national drug codes (NDC)[6] associated with generic versions of each drug product not included on the Federal upper limit list during the first and second quarters of 2004 due to a failure to meet CMS's additional pricing criterion. For each of these drug products, we calculated the average AWP among all therapeutically equivalent NDCs in the proper package size listed in the compendium. We also calculated the Federal upper limit amount that would have been set for each drug product under the required formula by multiplying the lowest published price among all relevant NDCs by 150 percent.

[6] Each individual drug product manufactured or distributed in the United States has a unique NDC. An NDC identifies the manufacturer of the drug product, the product dosage form, and the package size.

Obtaining Medicaid Utilization Data

We downloaded 50 State Medicaid payment and utilization files for 2004 from CMS's Web site.[7] We limited our analysis to utilization occurring in the first or second quarters of 2004.[8]

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 the drug product only, we removed the amount paid in dispensing fees for each corresponding NDC. We then calculated the average Medicaid reimbursement amount per quarter for each of the drugs under review by dividing the total reimbursement for the product (without the dispensing fee) by the total number of units reimbursed.

Determining AMPs for Drugs Under Review

We obtained AMP data for the first and second quarters of 2004 from CMS. We matched those data against the Medicaid utilization data to verify that all products upon which the comparisons would be made had actually been reimbursed by Medicaid.

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. We also determined the most common package size listed in the compendium, and removed any NDCs that did not match this package size. We then calculated the minimum, average, and maximum AMPs among the remaining NDCs in each quarter for the drug products not included on the Federal upper limit list due to inflated published prices.[9]

Calculating Potential Savings

To determine the potential savings if CMS were able to use AMPs rather than published prices to set Federal upper limit amounts, we:

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[7] The 50 files represent 49 States and the District of Columbia. 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.

[8] Both first- and second-quarter utilization data for Delaware and Rhode Island were missing from CMS's files. Second-quarter utilization data were missing for Colorado and Vermont.

[9] Two drug products under review did not have any AMPs listed on CMS's first quarter AMP file. One of the two products also did not have AMPs listed on the second quarter file. These products were excluded from any calculations in the respective quarter(s).

(1) multiplied the minimum, average, and maximum AMPs for the reviewed drugs by 150 percent (the percentage stated in current regulation);

(2) subtracted 150 percent of the minimum, average, and maximum AMPs from the average Medicaid reimbursement amount (net of dispensing fees) in each of the first two quarters of 2004; and

(3) multiplied the difference calculated in step 2 by the number of units of the drug product reimbursed during these two quarters.

This figure provided us with the savings that could have resulted in just two quarters for drugs that were not included on the Federal upper limit list due to not meeting CMS's additional criterion.[10]

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.

[10] Nine of the drug products did not become eligible for the Federal upper limit list until April 1, 2004. Therefore, these drugs were only included in the savings calculations for the second quarter of that year.

FINDINGS

In the first two quarters of 2004, 58 drug products that met all statutory and regulatory requirements were not added to the Federal upper limit list due to inflated published prices

Of the 252 first-time generic drug products approved between 2001 and 2003, 58 met all statutory and regulatory requirements as of June 30, 2004, but were not included on the Federal upper limit list because their addition would not have lead to savings. Each of these 58 products had at least 3 A-rated versions and 3 suppliers, but did not have a published price that, when multiplied by 150 percent, was less than the AWP.[11]

Overall, average AWPs were more than three times higher than the average AMPs for the reviewed drug products in the second quarter of 2004. Among the 58 individual drug products, the average AWP exceeded the average AMP by as much as 10 times. Even the minimum published prices for these drugs were substantially higher than AMPs. On average, the lowest manufacturer-reported AWP or wholesale acquisition cost was almost two-and-a-half times the average AMP. Given that Federal regulation requires that these "minimum" published prices be multiplied by 150 percent, the difference between Federal upper limit amounts and AMPs would grow even wider.

Basing Federal upper limit amounts on AMPs could save Medicaid over $100 million per year by allowing otherwise qualified products to be included on the Federal upper limit list

As the previous finding shows, inflated published prices are causing CMS to exclude otherwise qualified drug products from the Federal upper limit list because their Federal upper limit amount would exceed the reimbursement amount set under the usual methods. However, if Medicaid based Federal upper limit amounts on 150 percent of the average reported AMP rather than 150 percent of the lowest published price, the program may have saved $75 million in just two quarters of 2004 due to these excluded drugs being added to the Federal upper limit list. Ten versions of two drugs were responsible for more than half of the $75 million in

[11] For 50 of the 58 drug products, both wholesale acquisition costs and AWPs were published in the compendium. Although wholesale acquisition costs are generally lower than the AWP, none of the published wholesale acquisition costs for these 58 drugs was low enough to result in a Federal upper limit amount that could potentially lead to savings; i.e., 150 percent of the lowest wholesale acquisition cost was not less than the AWP.

potential savings. Adding six versions of amoxicillin/potassium clavulanate at 150 percent of their average AMP would have saved almost $21 million in the first and second quarters of 2004. Adding four versions of paroxetine would have saved nearly $19 million in just the one quarter that it was qualified.[12]

Furthermore, if Medicaid used the lowest reported AMP multiplied by 150 percent when calculating Federal upper limit amounts, the program could have saved an estimated $111 million in just two quarters of 2004. Even if Federal upper limit calculations were based on 150 percent of the highest reported AMP, the program could have saved almost $39 million.

[12] According to our analysis, paroxetine (brand name Paxil) first qualified for the Federal upper limit list on April 1, 2004. Four versions of paroxetine were added to the Federal upper list on February 14, 2005. While the Federal upper limit amounts for the four versions were slightly below their average AWP, the amounts were at least 20 percent higher than average Medicaid reimbursement for the products in the second quarter of 2004. Therefore, adding paroxetine at 150 percent of its lowest published price (the current method) is unlikely to save Medicaid a significant amount.

CONCLUSION

In the past several months, the President, Congress, and individual State Medicaid programs have expressed heightened interest in ensuring that Medicaid drug reimbursement amounts more closely resemble actual acquisition costs. In addition, the OIG has recently released a number of reports that once again showed that the published prices used as the basis for Medicaid reimbursement bear little or no resemblance to prices based on actual sales, especially for generic drugs. The Federal upper limit program is particularly affected by this disconnect between published prices and acquisition costs among generic drugs.

Congress created the Federal upper limit program to help Medicaid take advantage of current market prices for lower-cost generic drugs. However, Federal regulation requires that Federal upper limit amounts be based on 150 percent of the prices published in national compendia. Not only does the pricing methodology prescribed by Federal law cause artificially high Federal upper limit amounts for those products on the Federal upper limit list, it also causes other qualified drugs to never be included on the list in the first place. This secondary effect is costing Medicaid millions of dollars per year, in addition to the considerable losses the program faces due to the inflated prices of drugs already on the Federal upper limit list.

Based on years of work by OIG, GAO, and others revealing the inflated nature of AWPs and other published prices, the Medicare program eliminated the use of AWP in its pricing methodology for Part B covered drugs. The fact that Medicaid still uses these published prices to determine Federal upper limit amounts makes little sense. We believe that reimbursement in general and Federal upper limit amounts in particular should reliably reflect the actual costs of drugs to pharmacies. Consequently, there is an urgent need for the Medicaid policymaking community to revise Federal upper limit policies, thereby ensuring that reimbursement amounts for generic drugs accurately reflect market prices, and that the Federal upper limit program better meets its original intent.

Agency Comments

CMS concurred with our findings, stating that the use of published prices as the basis for Federal upper limit amounts precludes the addition of some drugs to the Federal upper limit list. CMS also noted the recent changes to the basis of reimbursement for Medicare

drugs made by the MMA, and indicated that the same types of measures should be enacted for Medicaid. The full text of CMS's comments is presented in Appendix A.

OIG Response

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

A P P E N D I X ~ A

Comments from the Centers for Medicare & Medicaid Services

DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

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FROM: Mark B. McClellan, M.D., Ph.D.
Administrator

SUBJECT: Office of Inspector General (OIG) Draft Report: "*How Inflated Published Prices Affect Drugs Considered for the Federal Upper Limit List*," (OEI-03-05-00350)

Thank you for the opportunity to review and comment on the subject draft report. The OIG report addresses the extent to which the statutorily mandated method for calculating Medicaid Federal Upper Limit (FUL) amounts causes qualified products to be excluded from the FUL list. This report also addresses the potential losses to the Medicaid program. The OIG findings and our response follows.

Federal regulation (42 CFR Section 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 average wholesale price (AWP), wholesale acquisition cost (WAC), or direct price (DP), as reported by the national compendia, to arrive at the FUL price.
Basing FUL amounts on average manufacturer prices (AMP) could save hundreds of millions of dollars per year by allowing otherwise qualified products to be included on the FUL list.

We concur with the OIG that using published prices as the basis for Medicaid reimbursement in the FUL program precludes the addition of some drugs to the FUL list. The OIG report makes 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.

The President's budget proposal would 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 rely on prices that are not based on true prices paid to manufacturers, states have no means to set appropriate payment amounts. Current wholesale acquisition cost

and average wholesale price (AWP) cost 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 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.

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