

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**DEFICIT REDUCTION ACT OF
2005: IMPACT ON THE MEDICAID
FEDERAL UPPER LIMIT
PROGRAM**



Daniel R. Levinson
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OBJECTIVES

1. To compare Federal upper limit amounts under the previous calculation method to estimated pharmacy acquisition costs for selected high-expenditure drugs.
2. To estimate how previous Medicaid Federal upper limit amounts may change under the new calculation method requiring payment limits for a drug to be set at 250 percent of the lowest average manufacturer price (AMP).
3. To compare Federal upper limit amounts under the new calculation method to estimated pharmacy acquisition costs for selected high-expenditure drugs.
4. To compare the lowest AMP to other AMPs for Federal upper limit drugs.
5. To determine whether the relationship between the lowest AMP and other AMPs for selected high-expenditure drugs could help identify instances in which pharmacy acquisition costs may exceed the new Federal upper limit amounts.

BACKGROUND

Previous Office of Inspector General (OIG) work consistently found that the published prices that were used to set Medicaid Federal upper limit amounts often greatly exceeded prices available in the marketplace. Based in part on this work, the Deficit Reduction Act of 2005 (DRA) required that, beginning January 1, 2007, Medicaid Federal upper limits be based on 250 percent of the lowest AMP rather than on 150 percent of the lowest price published in the national compendia. The Congressional Budget Office estimates that this will reduce Medicaid expenditures for Federal upper limit drugs by \$3.6 billion over 5 years.

In response to these changes, industry groups have expressed concerns that pharmacies will not be able to acquire drugs for prices at or below the new Federal upper limit amounts. In an effort to ensure that Medicaid providers are reimbursed appropriately and, in turn, that Medicaid beneficiaries continue to have access to needed drugs, this study provides a preliminary assessment of the expected impact of the DRA reductions.

E X E C U T I V E S U M M A R Y

We identified all drugs on the Federal upper limit list in the second quarter of 2006. To estimate Federal upper limit amounts for these 521 drugs under the new methodology set forth in the DRA, we obtained AMP data from the second quarter of 2006. We then multiplied the lowest AMP for each drug by 250 percent and compared the result to the actual Federal upper limit amounts from the second quarter of 2006, which were based on 150 percent of the lowest published prices.

To estimate pharmacy acquisition costs, we collected second-quarter 2006 sales and pricing data from five distributors for the 25 selected drugs with the highest total Medicaid expenditures in 2005 included on the Federal upper limit list. We then compared our estimate of pharmacy acquisition costs to the previous and new Federal upper limit amounts for each of the 25 selected high-expenditure drugs.

To determine whether the lowest AMPs used to set the new Federal upper limit amounts were representative of other AMPs for the same drugs, we determined whether the lowest AMP was more than 60 percent below the second-lowest AMP and/or volume-weighted AMP (weighted by the number of units reimbursed by Medicaid in 2005). In a recently issued proposed regulation, the Centers for Medicare & Medicaid Services (CMS) announced plans to use a similar threshold (70 percent) involving the second-lowest AMP to identify potential issues. We chose to use 60 percent in our analysis because whenever the lowest AMP exceeds this threshold relative to the second-lowest AMP, then the second-lowest AMP (and all other AMPs) for a drug would be higher than the new Federal upper limit amount.

For any of the 25 selected high-expenditure drugs for which the second-lowest AMP and/or volume-weighted AMP exceeded our 60-percent threshold, we determined whether the estimated average pharmacy acquisition cost exceeded the new Federal upper limit amount. We repeated this analysis for drugs that did not exceed the 60-percent threshold. This analysis enabled us to determine whether, for these 25 drugs, exceeding the 60-percent threshold was linked to a drug's average acquisition cost being higher than new Federal upper limit amount.

FINDINGS

For 23 of the 25 drugs under review, Federal upper limit amounts set under the previous calculation method were more than double the average pharmacy acquisition costs. Pre-DRA Federal upper limit amounts substantially exceeded our estimate of average pharmacy acquisition costs for the 25 selected high-expenditure drugs in the second quarter of 2006. For 23 of these 25 drugs, Federal upper limit amounts based on 150 percent of the lowest published price were more than double the average pharmacy acquisition costs. For 13 drugs, the second-quarter 2006 Federal upper limit amounts were at least 5 times higher.

As intended by the Deficit Reduction Act of 2005, Federal upper limit amounts are likely to decrease under the new calculation method.

We estimate that Federal upper limit amounts will decrease by a median of 61 percent under the new calculation method set forth in the DRA. Based on AMP data from the second quarter of 2006, we determined that Federal upper limit amounts for 492 of the 521 drugs (94 percent) under review would be reduced under the new DRA requirements, with 334 (64 percent) decreasing by at least half. Federal upper limit amounts for 90 of the 521 drugs would be at least 90 percent below the second-quarter 2006 amounts.

Six of twenty-five selected high-expenditure drugs had estimated average pharmacy acquisition costs that would be below the new Federal upper limit amounts. Based on pricing and sales data provided by distributors, we determined that, on average, pharmacies would have been able to purchase only 6 of 25 selected high-expenditure drugs for less than the new Federal upper limit amounts during the second quarter of 2006. For the remaining 19 drugs, the average pharmacy acquisition costs would have been higher than the new Federal upper limit amounts that quarter. We estimate that 12 of these 19 drugs had average pharmacy acquisition costs that would have been more than double the new reimbursement limit. For 13 of the 25 selected high-expenditure drugs, at least one individual drug product was available for a price at or below the new Federal upper limit amount.

The average manufacturer price used to set a new Federal upper limit amount may be substantially lower than other average manufacturer prices associated with a drug. For 14 percent of the drugs on the Federal upper limit list, the lowest AMP was more than

60 percent below the second-lowest AMP. In addition, for 29 percent of reviewed drugs, the lowest AMP was more than 60 percent less than the volume-weighted AMP.

Among the 25 selected high-expenditure drugs, examining the volume-weighted AMPs helped identify instances in which pharmacy acquisition costs may exceed the new Federal upper limit amounts. In the second quarter of 2006, the lowest AMP was more than 60 percent below the volume-weighted AMP for 20 of the 25 selected high-expenditure drugs under review. For all but one of these drugs, the estimated average pharmacy acquisition cost exceeded the new Federal upper limit amount. Likewise, for the five drugs for which the lowest AMP did not exceed the 60-percent threshold compared to the volume-weighted AMP, the average pharmacy acquisition costs were below the new Federal upper limit amount. In other words, in all but one case, determining whether or not the lowest AMP for any of the 25 selected high-expenditure drugs exceeded the 60-percent threshold compared to the volume-weighted AMP would have accurately determined whether or not its average acquisition cost was higher than the new Federal upper limit amount.

Examining the second-lowest AMP, rather than the volume-weighted AMP, was not as effective in identifying instances in which pharmacy acquisition costs exceeded the new Federal upper limit amount for the 25 selected high-expenditure drugs.

RECOMMENDATIONS

The findings of this report again illustrate why changes to the previous calculation method were needed, as this method (based on published prices) led to inflated Medicaid payments for many high-dollar generic drugs. However, we have concerns that, at least initially, the new formula mandated by the DRA (based on lowest AMPs) may result in some Federal upper limit amounts that are below pharmacy acquisition costs. This could occur because for certain drugs the lowest AMPs may not reflect prices generally available in the marketplace.

As part of the proposed Federal upper limit regulation, CMS announced plans to identify potential reimbursement issues by removing the lowest AMP if it appears to be an outlier. The proposed regulation defines an outlier as a lowest AMP that is more than 70 percent below the second-lowest AMP. We support CMS's attempts to proactively resolve potential problems with the new formula. However, our analysis

(applying a more limited 60-percent threshold) indicates that using the second-lowest AMP may not alleviate all reimbursement issues.

In addition to CMS's efforts, drug manufacturers and pharmacies also have important roles in helping to ensure that the new Federal upper limit amounts are appropriate. Manufacturers of generic drugs should make certain that the AMPs they are reporting to CMS are accurate. In turn, pharmacies should inform CMS if the new Federal upper limit amounts are lower than the prices at which they can purchase certain drugs.

We recognize that for various reasons (e.g., definitional changes in AMP, market forces, etc.), the relative relationship between the Federal upper limit amounts and other price points presented in this report may change once the new method of calculation is implemented. However, new Federal upper limit amounts should be monitored closely to help ensure that reimbursement changes do not lead to access problems for Medicaid beneficiaries. Specifically, we recommend that:

CMS should take steps to identify when a new Federal upper limit amount may not be representative of a drug's acquisition cost to pharmacies. These steps could include:

- issuing a final regulation that would remove the lowest AMP from the Federal upper limit calculation when it is significantly lower than the volume-weighted AMP (rather than the second-lowest AMP) for a drug,
- contacting manufacturers to verify reported data in situations for which the lowest AMP appears to be significantly lower than other AMPs for a drug,
- examining Medicaid utilization data to ensure that the product on which the Federal upper limit is based is actually utilized in the marketplace, and
- providing an opportunity for pharmacies to alert the States and CMS when they can demonstrate an inability to purchase a drug at prices at or below the new Federal upper limit amount.

In situations where 250 percent of the lowest AMP may not be sufficient to cover pharmacy acquisition costs, CMS should determine the proper course of action (working with Congress, if necessary).

AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

CMS concurred with our recommendation that the new Federal upper limit amount should be monitored closely during initial implementation and agreed that manufacturers play an important role in this regard. However, CMS strongly disagreed with our findings concerning the effect of the DRA-related changes to the Federal upper limit calculation. CMS suggested that OIG should have waited until the final AMP regulation is promulgated before completing its study, stating “it is only after a final definition of AMP has been issued that an accurate analysis of the impact of DRA can be conducted.” Once that occurs, CMS believes that an analysis based on actual AMPs would yield substantially different results. CMS stated that the analysis in OIG’s report is deficient in numerous ways and such deficiencies lead to flawed results and misleading conclusions. Therefore, CMS requested that we (1) revise our analysis to address these flaws and (2) delay issuing this report while considering earlier discussions and working collaboratively with the agency.

OIG will continue to work collaboratively with CMS in an effort to address any potential issues with the new calculation method for Federal upper limits. However, issuing this report prior to CMS’s publication of its final regulation provides the agency with the opportunity to consider our findings and incorporate our recommendations. The data presented in this report are the best available for the timeframe, and any limitations have marginal impact and do not change the overall findings and conclusions. We note that a similar report by the Government Accountability Office identified the same issues and reached similar conclusions.

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OBJECTIVES

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5. To determine whether the relationship between the lowest AMP and other AMPs for selected high-expenditure drugs could help identify instances in which pharmacy acquisition costs may exceed the new Federal upper limit amounts.

BACKGROUND

Previous Office of Inspector General (OIG) work consistently found that the published prices that were used to set Medicaid Federal upper limit amounts often greatly exceeded prices available in the marketplace. Based in part on this work, the Deficit Reduction Act of 2005 (DRA), Public Law 109-171, made substantial changes to the way Federal upper limit amounts are to be calculated. Beginning January 1, 2007, Federal upper limits are to be based on 250 percent of the lowest reported AMP for each drug rather than 150 percent of the lowest price published in the national compendia. The Congressional Budget Office estimates that this new methodology will reduce Medicaid expenditures for Federal upper limit drugs by \$3.6 billion over 5 years.

In response to these changes, industry groups have expressed concerns that pharmacies will not be able to acquire drugs for prices at or below the new Federal upper limit amounts.¹ In an effort to ensure that

¹ An example includes “Implications of Federal Medicaid Generic Drug Payment Reduction for State Policymakers.” National Association of Chain Drug Stores, February 2006.

Medicaid providers are reimbursed appropriately and, in turn, that Medicaid beneficiaries continue to have access to needed drugs, this study provides a preliminary assessment of the expected impact of the DRA reductions.

Medicaid Reimbursement for Prescription Drugs

Currently, all 50 States and the District of Columbia offer prescription drug coverage under Medicaid. Medicaid beneficiaries typically obtain covered drugs from pharmacies. Pharmacies bill State Medicaid agencies using national drug codes (NDC), which are 11-digit identifiers that indicate a drug's manufacturer, product dosage form, and package size. Pharmacies are then reimbursed for these drugs by State Medicaid agencies. In calendar year (CY) 2005, Medicaid payments for prescription drugs totaled over \$41 billion.²

Federal regulations require, with certain exceptions, that each State Medicaid agency's reimbursement for covered outpatient drugs not exceed (in the aggregate) the lower of their estimated acquisition cost plus a reasonable dispensing fee or the provider's usual and customary charge to the public for the drugs.³ The Centers for Medicare & Medicaid Services (CMS) allows States the flexibility to define estimated acquisition cost, with most States basing their calculation on list prices published in the national compendia. For certain drugs, States also use the Federal upper limit and/or State maximum allowable cost programs in setting reimbursement amounts.⁴

Medicaid Federal Upper Limit Requirements Prior to January 1, 2007

According to CMS's Web site, the Federal upper limit program was created to ensure that the Federal Government acts as a prudent buyer by taking advantage of current market prices for multiple-source drugs.⁵

² Calculated using national summary data for 2005. This amount includes both Federal and State payments. Rebates collected by States under the Medicaid drug rebate program (section 1927 of the Social Security Act) were not subtracted from this figure. Available online at <http://www.cms.hhs.gov/MedicaidDrugRebateProgram/SDUD/list.asp>. Accessed on October 30, 2006.

³ 42 CFR § 447.331(b). On December 22, 2006, CMS issued a proposed regulation that would remove 42 CFR § 447.331 but include the unchanged substance of this section in a new section, 42 CFR § 447.512.

⁴ Many States have implemented maximum allowable cost programs 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.

⁵ Available online at <http://www.cms.hhs.gov/FederalUpperLimits>. Accessed on September 8, 2006.

For purposes of the time covered by our review, pursuant to section 1927(e)(4) of the Social Security Act and 42 CFR § 447.332, CMS is generally to establish a Federal upper limit amount for a drug when three or more formulations of a drug have been rated as therapeutically equivalent by the Food and Drug Administration and 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 (e.g., Micromedex “RedBook”).

Prior to January 1, 2007, Federal regulations (42 CFR § 447.332) set the Federal upper limit amount at 150 percent of the lowest price published in the national compendia for therapeutically equivalent products that can be purchased by pharmacists in quantities of 100 tablets or capsules, plus a reasonable dispensing fee.⁶ If the drug is not typically available in quantities of 100 or if the drug is a liquid, then the Federal upper limit amount is based on the price for a commonly listed size of the product.

CMS publishes the Federal upper limit list in the “State Medicaid Manual” and on its Web site. Revisions to the list are typically noted on the Web site. CMS establishes a Federal upper limit for specific forms and strengths for each multiple-source drug on the list. As of June 30, 2006, CMS had set Federal upper limit amounts for 530 drugs. According to CMS data, generic drugs included on the Federal upper limit list account for approximately 8 percent of total Medicaid expenditures for all prescription drugs.

New Federal Upper Limit Requirements in Effect January 1, 2007

Section 6001(a) of the DRA makes significant changes to the Federal upper limit program. As of January 1, 2007, a drug needs only two therapeutically equivalent versions to be included on the Federal upper limit list.⁷ Beginning that same date, Federal upper limit amounts are to be based on 250 percent of the lowest reported AMP for each drug rather than 150 percent of the lowest price published in the national compendia.⁸

⁶ States are required to meet Federal upper limit requirements only in the aggregate, i.e., a State can pay more than the Federal upper limit amount for certain products as long as these payments are balanced out by lower payments for other products.

⁷ Section 6001(a)(1)(B) of the DRA.

⁸ Section 6001(a)(2) of the DRA.

For the period of time covered by this review, section 1927(k)(1) of the Social Security Act defines the AMP as the average price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to the retail pharmacy class of trade after deducting customary prompt pay discounts. Pursuant to sections 6001(c)(1) and 6001(c)(2) of the DRA, as of January 1, 2007, the AMP is required to be determined without regard to customary prompt pay discounts extended to wholesalers, and such discounts shall be reported separately to CMS.

On December 22, 2006, CMS issued a proposed regulation to implement certain provisions of the DRA.⁹ For example, 42 CFR § 447.504 of the proposed regulation outlines the manner in which the AMP is to be determined, and 42 CFR § 447.514 addresses the new criteria for the establishment of Federal upper limit amounts. The latter section (447.514(b)) implements the use of 250 percent of the AMP for the least costly therapeutically equivalent drug as the basis for Federal upper limit amounts. Section 447.514(c) of the proposed regulation establishes an alternative methodology to be used in setting Federal upper limit amounts if the lowest AMP is significantly below the next highest AMP for a drug. As further explained in the background to the proposed regulation, CMS will use the AMP of the lowest-priced therapeutically equivalent drug “except in cases where this AMP is more than 70 percent below the second lowest AMP.”¹⁰ CMS is currently soliciting public comment on the proposed regulation. Section 6001(c) of the DRA requires CMS to publish a final regulation by July 1, 2007.

In addition, prior to the enactment of the DRA, section 1927(b)(3)(D) of the Social Security Act prohibited the disclosure of AMP data except in certain narrow circumstances. At that time, AMP data were used primarily by CMS for purposes of the Medicaid drug rebate program. However, pursuant to sections 6001(a) and 6001(b) of the DRA, AMP data will also be used to calculate Federal upper limit amounts and will be made available to State Medicaid agencies and the public. These changes allow States to use AMP data in their determination of estimated acquisition costs for drugs covered under Medicaid.¹¹

⁹ Proposed Rule, “Medicaid Program; Prescription Drugs,” 71 Federal Register 77174.

¹⁰ Ibid at 77188.

¹¹ OIG examines AMP-based reimbursement issues in “States’ Use of New Drug Pricing Data To Establish Medicaid Reimbursement for Prescription Drugs” (OEI-03-06-00490) and “Examining Fluctuations in Average Manufacturer Prices” (OEI-03-06-00350).

Previous OIG Work Regarding the Federal Upper Limit Program

In the past 3 years, OIG has issued four reports detailing potential problems with the Federal upper limit program.¹² These reports focused on two main concerns: (1) qualified drugs were not being included on the Federal upper limit list in a timely manner and (2) Federal upper limit amounts often greatly exceeded pharmacy acquisition costs. For example, we found that Federal upper limit amounts were five times higher than average AMPs (a figure that we used as an estimate of pharmacy acquisition costs) in the third quarter of 2004. At that time, we recommended that CMS work with Congress to set Federal upper limit amounts that more closely approximate pharmacy acquisition costs.

The findings and recommendations from all four reports were presented at several congressional hearings, with the most recent testimony delivered before the Senate Finance Committee in June 2005.¹³

METHODOLOGY

Please see Appendix A for a detailed methodology.

Data Sources

Using Federal upper limit data from CMS's Web site and the national drug compendium "Redbook," we identified the 530 drugs included on the Federal upper limit list in the second quarter of 2006.¹⁴ We obtained Medicaid drug reimbursement and utilization data from CMS's Web site and then identified the 25 drugs on the Federal upper limit list with the highest total Medicaid expenditures in CY 2005.

For the 25 selected drugs with the highest total Medicaid expenditures in 2005, we collected second-quarter 2006 pricing and sales data from the three largest national distributors and two smaller regional

¹² "Omission of Drugs From the Federal Upper Limit List in 2001" (OEI-03-02-00670, February 2004); "Addition of Qualified Drugs to the Federal Upper Limit List" (OEI-03-04-00320, December 2004); "Comparison of Medicaid Federal Upper Limit Amounts to Average Manufacturer Prices" (OEI-03-05-00110, June 2005); and "How Inflated Published Prices Affect Drugs Considered for the Federal Upper Limit List" (OEI-03-05-00350, September 2005).

¹³ Available online at <http://www.oig.hhs.gov/testimony/docs/2005/50629-vito-fin.pdf>. Accessed on September 8, 2006.

¹⁴ In this report, "drug" refers to the specific drug name/dosage size/product form combination that is used as the basis for setting Federal upper limit amounts (e.g., Gabapentin 400 mg tablets).

distributors. According to industry sales reports, these three national companies account for the vast majority of market share among drug distributors. We obtained second-quarter 2006 AMP data from CMS.

Data Analysis

Estimating Pharmacy Acquisition Costs for Selected Drugs. To estimate average pharmacy acquisition costs for each of the 25 selected high-expenditure drugs, we totaled the dollar amount sold (net of any discounts or rebates, when provided) by the five distributors and divided this amount by the total number of units sold. For the purpose of this report, these estimates will hereinafter be referred to as “average pharmacy acquisition costs.” We also determined the lowest price reported to OIG by the distributors for any NDC associated with the 25 drugs.

Estimating Federal Upper Limit Amounts Under New Calculation Method. We determined the lowest AMP reported by manufacturers for each of the 530 drugs on the Federal upper limit list in the second quarter of 2006. Of the 530 drugs on the list that quarter, 9 did not have AMP data for any nonterminated, therapeutically equivalent NDCs of a commonly listed size. Therefore, we did not include these nine drugs in our analysis. For the remaining 521 drugs, we multiplied the lowest AMP by 250 percent to estimate the new Federal upper limit amounts under the methodology mandated by the DRA. For the purpose of this report, these estimates will hereinafter be referred to as “new Federal upper limit amounts.” We calculated the difference between the new Federal upper limit amounts and the second-quarter 2006 Federal upper limit amounts for each of the 521 drugs.

Comparing Pharmacy Acquisition Costs to Federal Upper Limit Amounts. We calculated the percentage difference between the second-quarter 2006 Federal upper limit amounts and the average pharmacy acquisition costs for each of the 25 selected high expenditure drugs. We then calculated the difference between the new Federal upper limit amounts and the average pharmacy acquisition costs. We also compared the lowest price reported to OIG by the distributors for each drug with the new Federal upper limit amounts.

Comparing the Lowest AMP to Other AMPs. To determine whether the lowest AMPs used to set the new Federal upper limit amounts were representative of other AMPs, we determined the second-lowest and

volume-weighted AMPs for each of the 521 drugs under review.¹⁵ We then compared the lowest AMP to both the second-lowest and volume-weighted AMPs for each of the 521 drugs and identified instances when the lowest AMP was more than 60 percent below either of these two figures.¹⁶ We subset out the results for the 25 selected high-expenditure drugs for further analysis.

Determining Whether Other AMPs Could Help Identify Potential Issues.

Among the 25 selected high-expenditure drugs, we identified any instances in which the lowest AMP was more than 60 percent below the second-lowest and/or volume-weighted AMP. For any of the 25 drugs that met this threshold, we determined whether the average pharmacy acquisition cost exceeded the new Federal upper limit amount. We repeated this analysis for any of the 25 drugs that did not meet the 60-percent threshold. This enabled us to determine whether, for these 25 drugs, exceeding the 60-percent threshold (compared to either the second-lowest or volume-weighted AMP) was linked to a drug's average acquisition cost being higher than the new Federal upper limit amount.

Limitations

This study uses AMP data from the second quarter of 2006 to estimate Federal upper limit amounts under the new methodology mandated by the DRA. For some drugs, the lowest AMP may have increased or decreased by the time the changes took effect in January 2007.

Furthermore, although sections 6001(a) and 6001(c)(1) of the DRA provide that new Federal upper limit amounts will be based on AMPs as computed without regard to customary prompt pay discounts, AMPs used in this study did reflect the customary prompt pay discounts offered by manufacturers, because this is how AMPs were reported at the time of our analysis. After January 1, 2007, AMPs that are used to

¹⁵ We calculated the volume-weighted AMP among all NDCs for the drug by weighting the AMP for each individual NDC by the number of units of the NDC reimbursed by Medicaid in the second quarter of 2006.

¹⁶ In its proposed regulation, CMS uses a 70-percent rather than a 60-percent threshold in comparing the lowest AMP to the second-lowest AMP. We chose to use 60 percent in our analysis because whenever the lowest AMP exceeds this threshold relative to the second-lowest AMP, then the second-lowest AMP (and all other AMPs) for a drug would be higher than the new Federal upper limit amount. For example, a drug with a lowest AMP of \$0.40 would have a new Federal upper limit amount of \$1.00 (\$0.40 times 250 percent). If the second-lowest AMP is higher than this new Federal upper limit amount (e.g., \$1.01), then the lowest AMP would be at least 60 percent below the second-lowest AMP (\$0.40 is 60.4 percent below \$1.01).

calculate Federal upper limit amounts may be higher than earlier AMPs because customary prompt pay discounts should no longer be included.

As mentioned previously, we asked distributors for the amount of discounts and rebates provided to purchasers. Two of the five distributors provided these data, which were then used in our acquisition cost calculations. However, the three remaining distributors did not provide discount and rebate data. Therefore, pharmacies' bottom-line costs for some drugs may be lower than our estimates in instances for which discounts and rebates were not captured in our data collection. Two of the distributors that did not provide this information stated that discounts and rebates are not captured on a quarterly basis and are negotiated on a customer-by-customer basis, making it extremely difficult to supply these data. One distributor did not provide an explanation for the lack of discount and rebate data. In addition, we did not determine whether the prices reported by the distributors were nationally available to all pharmacies.

Because many States use maximum allowable cost programs to further reduce drug expenditures, States may actually be reimbursing less than the Federal upper limit amount for certain drugs. Therefore, the differences between the pre-DRA Federal upper limit amount and the new Federal upper limit amount may overstate the actual changes to pharmacy reimbursement in these cases.

This study examines only drugs that were on the Federal upper limit list as of the second quarter of 2006. Our review did not include any drugs that may be added to the list based on the expanded criteria set forth in the DRA (i.e., the establishment of Federal upper limits based on two rather than three therapeutically equivalent products).

Finally, this study addresses Federal upper limit amounts and not dispensing fees paid to pharmacies for providing drugs to Medicaid beneficiaries. Both components of reimbursement are important to ensure that Medicaid reimburses pharmacies appropriately for prescription drugs.

Standards

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

► FINDINGS

For 23 of the 25 drugs under review, Federal upper limit amounts set under the previous calculation method were more than double the average pharmacy acquisition costs

As in previous studies that found Federal upper limit amounts to be excessive, we estimate that Federal upper limit amounts under the pre-DRA methodology exceeded average pharmacy

acquisition costs for each of the 25 selected high-expenditure drugs in the second quarter of 2006. For 23 of these 25 drugs, second-quarter 2006 Federal upper limit amounts (based on 150 percent of the lowest published price) were more than two times higher than the average pharmacy acquisition costs. In 13 cases, second-quarter 2006 Federal upper limit amounts were at least five times higher. Table 1 illustrates the percentage difference between the actual Federal upper limit amounts and the pharmacy acquisition costs for the 25 selected drugs in the second quarter of 2006.

Table 1: Comparison of Estimated Pharmacy Acquisition Costs to Previous Federal Upper Limit Amounts

Drug	Average Pharmacy Acquisition Cost	Second-Quarter 2006 Federal Upper Limit Amount	Difference
Lorazepam, 1MG, Tablet	\$0.040	\$0.572	-93.0%
Ranitidine Hydrochloride, 150MG, Tablet	\$0.030	\$0.341	-91.2%
Gabapentin, 300MG, Capsule	\$0.157	\$1.308	-88.0%
Gabapentin, 400MG, Capsule	\$0.203	\$1.570	-87.1%
Glyburide/Meformin Hydrochloride, 5MG-500MG, Tablet	\$0.142	\$1.003	-85.8%
Metformin Hydrochloride, 500MG, Tablet	\$0.055	\$0.356	-84.5%
Omeprazole, 20MG, Enteric Coated Tablet	\$0.638	\$3.979	-84.0%
Tramadol Hydrochloride, 50MG, Tablet	\$0.049	\$0.307	-84.0%
Paroxetine Hydrochloride, 20MG, Tablet	\$0.445	\$2.520	-82.3%
Gabapentin, 600MG, Tablet	\$0.447	\$2.470	-81.9%
Paroxetine Hydrochloride, 40MG, Tablet	\$0.517	\$2.700	-80.9%
Gabapentin, 800MG, Tablet	\$0.573	\$2.959	-80.6%
Metformin Hydrochloride, 1000MG, Tablet	\$0.091	\$0.460	-80.2%
Glimepiride, 4MG, Tablet	\$0.084	\$0.410	-79.5%
Glyburide, 5MG, Tablet	\$0.069	\$0.283	-75.6%
Potassium Chloride, 20MEQ, Tablet Extended Release	\$0.121	\$0.463	-73.8%
Acetaminophen/Propoxyphene Napsylate, 650MG-100MG, Tablet	\$0.049	\$0.180	-72.8%
Ribavirin, 200MG, Capsule	\$2.304	\$7.576	-69.6%
Albuterol Sulfate, 0.83%, Solution	\$0.041	\$0.115	-64.3%
Acetaminophen/Hydrocodone Bitartrate, 500MG-5MG, Tablet	\$0.032	\$0.083	-61.6%
Oxycodone Hydrochloride, 80MG, Tablet Extended Release	\$2.633	\$6.118	-57.0%
Oxycodone Hydrochloride, 40MG, Tablet Extended Release	\$1.445	\$3.260	-55.7%
Oxycodone Hydrochloride, 20MG, Tablet Extended Release	\$0.875	\$1.837	-52.4%
Zonisamide, 100MG, Capsule	\$0.657	\$1.174	-44.0%
Albuterol, 0.09MG/Actuation, Aerosol Solid (Inhaler)	\$0.335	\$0.437	-23.3%

Source: OIG analysis of second-quarter 2006 Federal upper limit amounts and drug distributor data, 2006.

As intended by the Deficit Reduction Act of 2005, Federal upper limit amounts are likely to decrease under the new calculation method

In an effort to lower inflated Federal upper limit amounts and bring Medicaid reimbursement for generic

drugs more in line with actual costs, the DRA established a new method for determining Federal upper limit amounts. Using data from the second quarter of 2006 to assess the impact of the DRA changes, we estimate that Federal upper limit amounts will decrease by a median of 61 percent under the new calculation method. Overall, based on second-quarter 2006 data, we determined that Federal upper limit amounts for 492 of the 521 (94 percent) drugs under review would be reduced under the new DRA requirements, with 334 (64 percent) expected to decrease by at least half. Federal upper limit amounts for 90 of the 521 drugs would be at least 90 percent below the second-quarter 2006 amounts.

Although our analysis indicates Federal upper limit amounts for the vast majority of included drugs may be substantially reduced as a result of the new law, we estimate that Federal upper limits for 29 drugs (6 percent) would increase. Table 2 describes the estimated changes to the 521 Federal upper limit drugs that were included in this part of our review. As mentioned previously, it is important to note that because of State maximum allowable cost programs, these percentage differences may not reflect the actual changes to pharmacy reimbursement for all drugs on the Federal upper limit list.

Table 2: Estimated Changes to Federal Upper Limit Amounts Under the DRA

Difference Between New and Second Quarter 2006 Federal Upper Limit Amount	Number of Drugs	Percentage of Drugs
-99.9% to -90%	90	17.3
-89.9% to -80%	59	11.3
-79.9% to -50%	185	35.5
-49.9% to -20%	129	24.8
-19.9% to 0%	29	5.6
0.1% to 19.9%	16	3.1
20% to 49.9%	4	0.8
50% to 79.9%	4	0.8
80% and above	5	1.0
Total	521	100 *

Source: OIG analysis of second-quarter 2006 AMP data, 2006.

*Note: Percentages do not add to 100 because of rounding.

F I N D I N G S

Six of twenty-five selected high-expenditure drugs had estimated average pharmacy acquisition costs that would be below the new Federal upper limit amounts

Based on pricing and sales data provided by distributors, we determined that, on average, pharmacies would have been able to purchase 6 of the 25 selected

high-expenditure drugs for less than the new Federal upper limit amount in the second quarter of 2006. For the remaining 19 drugs, average pharmacy acquisition costs would have been higher than the new Federal upper limit amounts. Twelve of these nineteen drugs had average pharmacy acquisition costs that would have been more than double the new limits. For one drug, the average acquisition cost would have been 18 times higher than the new Federal upper limit amount. Table 3 illustrates the percentage difference between the new Federal upper limit amounts and the pharmacy acquisition costs for the 25 selected drugs in the second quarter of 2006.

Drug	Average Pharmacy Acquisition Cost	New Federal Upper Limit Amount	Difference
Albuterol, 0.09MG/Actuation, Aerosol Solid (Inhaler)	\$0.335	\$0.767	-56%
Ranitidine Hydrochloride, 150MG, Tablet	\$0.030	\$0.042	-29%
Acetaminophen/Hydrocodone Bitartrate, 500MG-5MG, Tablet	\$0.032	\$0.039	-18%
Gabapentin, 800MG, Tablet	\$0.573	\$0.669	-14%
Gabapentin, 600MG, Tablet	\$0.447	\$0.476	-6%
Oxycodone Hydrochloride, 80MG, Tablet Extended Release	\$2.633	\$2.719	-3%
Glimepiride, 4MG, Tablet	\$0.084	\$0.077	9%
Lorazepam, 1MG, Tablet	\$0.040	\$0.033	21%
Glyburide/Meformin Hydrochloride, 5MG-500MG, Tablet	\$0.142	\$0.105	35%
Potassium Chloride, 20MEQ, Tablet Extended Release	\$0.121	\$0.086	41%
Gabapentin, 300MG, Capsule	\$0.157	\$0.108	45%
Zonisamide, 100MG, Capsule	\$0.657	\$0.405	62%
Tramadol Hydrochloride, 50MG, Tablet	\$0.049	\$0.027	82%
Acetaminophen/Propoxyphene Napsylate, 650MG-100MG, Tablet	\$0.049	\$0.024	104%
Metformin Hydrochloride, 500MG, Tablet	\$0.055	\$0.026	112%
Omeprazole, 20MG, Enteric Coated Tablet	\$0.638	\$0.299	113%
Glyburide, 5MG, Tablet	\$0.069	\$0.031	123%
Paroxetine Hydrochloride, 40MG, Tablet	\$0.517	\$0.158	227%
Albuterol Sulfate, 0.83%, Solution	\$0.041	\$0.011	273%
Ribavirin, 200MG, Capsule	\$2.304	\$0.400	476%
Gabapentin, 400MG, Capsule	\$0.203	\$0.030	577%
Oxycodone Hydrochloride, 40MG, Tablet Extended Release	\$1.445	\$0.191	657%
Oxycodone Hydrochloride, 20MG, Tablet Extended Release	\$0.875	\$0.080	994%
Paroxetine Hydrochloride, 20MG, Tablet	\$0.445	\$0.025	1,680%
Metformin Hydrochloride, 1000MG, Tablet	\$0.091	\$0.005	1,720%

Source: OIG analysis of second-quarter 2006 AMP data and drug distributor data, 2006.

For 13 of the 25 selected high-expenditure drugs, at least one individual drug product was available for a price at or below the new Federal upper limit amount. In the second quarter of 2006, 13 of the 25 selected high-expenditure drugs had at least one associated NDC with an average price from a distributor that would have been at or below the new Federal upper limit amount. Of the remaining 12, there were 6 drugs for which even the lowest price would be at least double the new Federal upper limit amount. We did not determine whether the lowest-priced NDCs were nationally available to all pharmacies.

The average manufacturer price used to set a new Federal upper limit amount may be substantially lower than other average manufacturer prices associated with a drug

In the second quarter of 2006, the lowest AMP was more than 60 percent below the second-lowest AMP (among therapeutically equivalent

products in a commonly-listed size) for 72 of the 521 listed drugs (14 percent). In other words, the second-lowest AMPs (and all other AMPs associated with the drug) for these drugs would be higher than the new Federal upper limit amount.¹⁷ That same quarter, the lowest AMP for 149 of the 521 listed drugs (29 percent) was more than 60 percent below the volume-weighted AMP.¹⁸

Volume-weighted AMPs sometimes differed from the lowest AMPs by a large margin because NDCs associated with the lowest AMPs often accounted for a small portion of Medicaid utilization. For 109 of the 521 drugs (21 percent) on the Federal upper limit list, the NDC with the lowest AMP was responsible for less than 2 percent of all units of the drug reimbursed by Medicaid in the second quarter of 2006. For 23 of these drugs, NDCs whose AMPs would be used to set the Federal upper limit accounted for less than 0.01 percent of the utilization, with 14 having no utilization at all in the second quarter of 2006.

¹⁷ For example, a drug with a lowest AMP of \$0.40 would have a new Federal upper limit amount of \$1.00 (\$0.40 times 250 percent). If the second-lowest AMP is higher than this new Federal upper limit amount (e.g., \$1.01), then the lowest AMP would be at least 60 percent below the second-lowest AMP (\$0.40 is 60.4 percent below \$1.01). In its proposed regulation, CMS uses a 70-percent rather than 60-percent threshold in comparing the lowest AMP to the second-lowest AMP.

¹⁸ We calculated the volume-weighted AMP among all NDCs for the drug by weighting the AMP for each individual NDC by the number of units of the NDC reimbursed by Medicaid in the second quarter of 2006.

Among the 25 selected high-expenditure drugs, examining the volume-weighted AMPs helped identify instances in which pharmacy acquisition costs may exceed the new Federal upper limit amounts

In the second quarter of 2006, the lowest AMP was more than 60 percent below the volume-weighted AMP for 20 of the 25 selected high-expenditure drugs under review. In all but one

of these cases, the average pharmacy acquisition costs exceeded the new Federal upper limit amount. Likewise, for the five drugs for which the lowest AMP did not exceed the 60-percent threshold compared to the volume-weighted AMP, the average pharmacy acquisition costs were below the new Federal upper limit amount. In other words, in all but one case, determining whether or not the lowest AMP for any of the 25 selected high-expenditure drugs exceeded the 60-percent threshold compared to the volume-weighted AMP would have accurately determined whether or not its average acquisition cost was higher than the new Federal upper limit amount.

Examining the second-lowest AMP was not as effective in identifying instances in which pharmacy acquisition costs may exceed the new Federal upper limit amounts.

In the second quarter of 2006, the lowest AMP was more than 60 percent below the second-lowest AMP for 5 of the 25 selected high-expenditure drugs under review. In each of these cases, the average pharmacy acquisition cost was at least double the new Federal upper limit amount.

However, 14 of the 20 high-expenditure drugs for which the lowest AMP did not exceed the 60-percent threshold compared to the second-lowest AMP also had pharmacy acquisition costs that were higher than the new Federal upper limit amount. In fact, for 6 of these 14 drugs, the lowest AMP was no more than 10 percent below the second-lowest AMP. Therefore, potential reimbursement issues for these 14 drugs would not have been identified by using the second-lowest AMP as a point of comparison during the second quarter of 2006.

Table 4 on the following page illustrates the relationship between the new Federal upper limit amounts, average acquisition costs, second-lowest AMPs, and volume-weighted AMPs for the 25 selected high-expenditure drugs.

Table 4: Relationship Between New Federal Upper Limit Amounts, Estimated Acquisition Costs, and Other AMPs

Drug	Average Acquisition Cost Exceeds New Federal Upper Limit	Lowest AMP More Than 60 Percent Below Second Lowest AMP	Lowest AMP More Than 60 Percent Below Volume-Weighted AMP
Albuterol, 0.09MG/Actuation, Aerosol Solid (Inhaler)			
Ranitidine Hydrochloride, 150MG, Tablet			
Acetaminophen/Hydrocodone Bitartrate, 500MG-5MG, Tablet			
Gabapentin, 800MG, Tablet			
Gabapentin, 600MG, Tablet			
Oxycodone Hydrochloride, 80MG, Tablet Extended Release			X
Glimepiride, 4MG, Tablet	X		X
Lorazepam, 1MG, Tablet	X		X
Glyburide/Meformin Hydrochloride, 5MG-500MG, Tablet	X		X
Potassium Chloride, 20MEQ, Tablet Extended Release	X		X
Gabapentin, 300MG, Capsule	X		X
Zonisamide, 100MG, Capsule	X		X
Tramadol Hydrochloride, 50MG, Tablet	X		X
Acetaminophen/Propoxyphene Napsylate, 650MG-100MG, Tablet	X		X
Metformin Hydrochloride, 500MG, Tablet	X		X
Omeprazole, 20MG, Enteric Coated Tablet	X		X
Glyburide, 5MG, Tablet	X	X	X
Paroxetine Hydrochloride, 40MG, Tablet	X	X	X
Albuterol Sulfate, 0.83%, Solution	X		X
Ribavirin, 200MG, Capsule	X		X
Gabapentin, 400MG, Capsule	X		X
Oxycodone Hydrochloride, 40MG, Tablet Extended Release	X	X	X
Oxycodone Hydrochloride, 20MG, Tablet Extended Release	X	X	X
Paroxetine Hydrochloride, 20MG, Tablet	X		X
Metformin Hydrochloride, 1000MG, Tablet	X	X	X

Source: OIG analysis of second-quarter 2006 AMP data and drug distributor data, 2006.

► R E C O M M E N D A T I O N S

Based in part on OIG work that consistently found that the published prices used to set Federal upper limit amounts often greatly exceed prices available in the marketplace, the DRA has substantially changed the way Medicaid Federal upper limit amounts are calculated. As of January 1, 2007, Federal upper limits are based on 250 percent of the lowest reported AMP rather than 150 percent of the lowest price published in the national compendia.

The findings of this report again illustrate why changes to the previous calculation method were needed, as this method led to inflated Medicaid payments for many high-dollar generic drugs. Furthermore, using actual sales data (such as AMP) rather than published prices to calculate Federal upper limit amounts present several additional advantages, i.e., they are defined by statute, are based on real-world transactions, and can be audited. However, we have concerns that, at least initially, the new formula may result in some Federal upper limit amounts that are below pharmacy acquisition costs. This could occur because for certain drugs the lowest AMPs may not reflect prices generally available in the marketplace.

As part of the proposed Federal upper limit regulation, CMS announced plans to identify potential reimbursement issues by removing the lowest AMP if it appears to be an outlier. The proposed regulation defines an outlier as a lowest AMP that is more than 70 percent below the second-lowest AMP. We support CMS's attempts to proactively resolve potential problems with the new formula. However, our analysis (applying a more limited 60-percent threshold) indicates that using the second-lowest AMP may not alleviate all reimbursement issues.

In addition to CMS's efforts, drug manufacturers and pharmacies also have important roles in helping to ensure that the new Federal upper limit amounts are appropriate. Manufacturers of generic drugs should make certain that the AMPs they are reporting to CMS are accurate. In turn, pharmacies should inform CMS if the new Federal upper limit amounts are lower than the prices at which they can purchase certain drugs.

We recognize that for various reasons (e.g., definitional changes in AMP, market forces, etc.) the relative relationship between the Federal upper limit amounts and other price points presented in this report may change once the new method of calculation is implemented. However, new Federal upper limit amounts should be monitored closely to help

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ensure that reimbursement changes do not lead to access problems for Medicaid beneficiaries. Specifically, we recommend that:

CMS should take steps to identify when a new Federal upper limit amount may not be representative of a drug’s acquisition cost to pharmacies.

These steps could include:

- issuing a final regulation that would remove the lowest AMP from the Federal upper limit calculation when it is significantly lower than the volume-weighted AMP (rather than the second-lowest AMP) for a drug,
- contacting manufacturers to verify reported data in situations for which the lowest AMP appears to be significantly lower than other AMPs for a drug,
- examining Medicaid utilization data to ensure that the product on which the Federal upper limit is based is actually utilized in the marketplace, and
- providing an opportunity for pharmacies to alert the States and CMS when they can demonstrate an inability to purchase a drug at prices at or below the new Federal upper limit amount.

In situations where 250 percent of the lowest AMP may not be sufficient to cover pharmacy acquisition costs, CMS should determine the proper course of action (working with Congress, if necessary).

AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

CMS concurred with our recommendation that the new Federal upper limit amount should be monitored closely during initial implementation and agreed that manufacturers play an important role in this regard. However, CMS strongly disagreed with our findings concerning the effect of the DRA-related changes to the Federal upper limit calculation. CMS suggested that OIG should have waited until the final AMP regulation is promulgated before completing its study, stating “it is only after a final definition of AMP has been issued that an accurate analysis of the impact of DRA can be conducted.” Once that occurs, CMS believes that that an analysis based on actual AMPs would yield substantially different results. CMS stated that the analysis in the OIG report is deficient in numerous ways and such deficiencies lead to flawed results and misleading conclusions. Therefore, CMS requested that we (1) revise our analysis to address these flaws and (2) delay

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issuing this report while considering earlier discussions and working collaboratively with the agency.

OIG will continue to work collaboratively with CMS in an effort to address any potential issues with the new calculation method for Federal upper limits. However, issuing this report prior to CMS's publication of its final regulation provides the agency with the opportunity to consider our findings and incorporate our recommendations. The data presented in this report are the best available for the timeframe, and any limitations have marginal impact and do not change the overall findings and conclusions. We note that a similar report by the Government Accountability Office (GAO) identified the same issues and reached similar conclusions.¹⁹

A detailed discussion of CMS's specific comments is presented below. The full text of CMS's comments is presented in Appendix B.

Detailed Discussion of CMS Comments

AMP-related issues: CMS stated that AMPs used in OIG's analysis are lower than appropriate, noting that we did not account for the exclusion of prompt pay discounts from AMP starting in 2007 or other changes to AMP that may occur under the new AMP regulation. Therefore, OIG should have waited until this regulation takes effect before conducting this study. CMS also stated that it will not calculate Federal upper limit amounts based on AMPs for terminated products and that our analysis does not address this. Furthermore, CMS disagreed with our use of volume-weighted average AMPs in part of our analysis. The agency stated that current market volume is not indicative of a drug product's national availability because of the incentives in the previous system that may have lead pharmacies to purchase drugs with the most inflated price.

OIG addresses several of these issues in the report. While OIG does plan to undertake similar work once the new regulation goes into effect, it was also important to conduct a pre-implementation study to identify any potential issues with the new calculation method so that CMS could consider them in the development of its final regulation.

¹⁹ "Medicaid Outpatient Prescription Drugs: Estimated 2007 Federal Upper Limits for Reimbursement Compared with Retail Pharmacy Acquisition Costs," (GAO-07-239R, December 2006). Available online at <http://www.gao.gov/new.items/d07239r.pdf>. Accessed January 22, 2007.

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We agree with CMS that the AMPs we used may have increased since the time of our analysis, as prompt-pay discounts are no longer included in manufacturers' calculations. However, in previous studies, we found that prompt-pay discounts typically range from 1 percent to 3 percent—not a substantial enough margin to change the overall impact of the data presented in this report. In regard to terminated products, AMPs for terminated NDCs were excluded from our analysis and therefore were not a factor in our calculations. Finally, the lowest AMP, second-lowest AMP, and volume-weighted AMP were all important comparison points we used in our analysis. The advantages of using volume-weighted AMP are that (1) it reflects the products actually used in the marketplace; (2) it is very similar to the average sales prices used as the basis for Medicare drug reimbursement; and (3) based on our analysis of 25 drugs, it was a more accurate predictor of drugs for which acquisition costs may exceed the Federal upper limit amount than was the second-lowest AMP.

Acquisition cost-related issues. CMS stated that the acquisition costs presented in our report are higher than appropriate because (1) our analysis does not fully account for discounts and rebates, and (2) our analysis should have focused on the lowest acquisition costs available to pharmacies rather than the average acquisition costs.

Overall, the data provided in this report are the best available for the timeframe. We note that CMS has also used these data to perform its own analysis. In this report, OIG states that we asked distributors to provide information on discounts and rebates, but only two of the five respondents did so. The other three distributors described the difficulty in capturing these data on a drug-by-drug basis. However, given the magnitude of the difference between the new Federal upper limit amount and pharmacy acquisition cost for a number of drugs, this limitation does not negate our underlying concerns.

With respect to the lowest acquisition costs, numerous pricing points could have been used in our analysis. The lowest price reported by distributors is one important pricing point, and the report includes a subfinding that addresses how the new Federal upper limit amounts compare to these figures. Even when using the lowest price reported by distributors, potential reimbursement issues would still exist, as we found that the lowest acquisition costs for half of the drugs exceeded the new Federal upper limit amount. We chose the volume-weighted average acquisition cost for the primary analysis because it reflects the

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prices of the drugs that pharmacies actually purchased and because we could not determine whether the lowest prices reported by distributors were readily available to most purchasers.

Aggregate cost-related issues. Under current law, Federal upper limits apply in the aggregate. In other words, States may set reimbursement for some drugs at amounts above the Federal upper limit if other drugs are reimbursed at amounts that are below (as long as a State's overall spending is below the aggregate spending that would occur at the CMS-determined Federal upper limit amounts). CMS stated that our analysis does not address the mitigating effects of applying Federal upper limits in the aggregate.

OIG recognizes the importance of the aggregate concept and agrees with CMS that States should continue to use this flexibility when appropriate. However, balancing reimbursements above and below the Federal upper limit amounts while meeting the aggregate spending limit was easier when Federal upper limit amounts were highly inflated. Before the DRA-related changes, Federal upper limit amounts for most drugs exceeded acquisition costs (often by a large margin), meaning that few drugs would warrant an increase in their reimbursement amounts. Furthermore, the many drugs with Federal upper limit amounts above acquisition costs provided States with numerous choices for balancing out these price increases.

With the move to AMPs as the basis for calculating Federal upper limit amounts, OIG anticipates that it will be more difficult to apply the flexibility afforded by an aggregate limit. Using our findings in this report as an example, reimbursement amounts for the 6 drugs with average acquisition costs below the Federal upper limit amount would need to be decreased sufficiently to balance out an increase in the reimbursement amounts for the 19 drugs with average acquisition costs above the new Federal upper limit amount.

State maximum allowable cost programs. CMS stated that the comparison between pre- and post-DRA Federal upper limit amounts is improper because it does not account for the impact of State maximum allowable cost programs (i.e., States often pay less than the Federal upper limit amount for many drugs).

OIG discusses the relevance of State maximum allowable cost to our findings in this report. The objective of this report was to determine how Federal upper limits were impacted under the DRA methodology, and we focused our analysis on that objective.

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Attached chart containing CMS analysis. CMS attached a chart with its comments showing that, based on (1) February 2007 AMPs, (2) application of an outlier policy, and (3) the lowest reported acquisition costs, 20 of 25 drugs would be available at or below the new Federal upper limit amount. CMS also used the chart to conclude that, in the aggregate, pharmacies would not have been underreimbursed in the second quarter of 2006 if they all purchased drugs at the lowest price reported by distributors (but not at the average price).

Even if OIG accepts CMS's assumptions regarding the data presented in its chart (including the assumption that all pharmacies could have purchased the drug for the lowest report acquisition cost, discussed on pages 18 and 19), we continue to have concerns about the potential impact of the new Federal upper limit amounts for certain drugs. According to CMS's aggregate calculations, pharmacies would have made up for a \$3 million total quarterly loss on 24 of the 25 drugs in the second quarter of 2006 by receiving \$11 million in excessive reimbursement for one drug, albuterol aerosol (a drug for which the new Federal upper limit amount was well above acquisition cost). In other words, pharmacies could make up (in the aggregate) for losses on most other drugs by filling albuterol prescriptions. However, pharmacies that do not sell a large volume of albuterol would find it difficult to receive adequate reimbursement for the entire group of drugs. Therefore, while OIG acknowledges the aggregate application of the Federal upper limit program, we also see important advantages to striving to set reimbursement for all drugs at appropriate levels, with cross-subsidies being limited whenever possible.

DETAILED METHODOLOGY

Data Sources

Identifying Drugs for Review. Using data from CMS's Web site and the national drug compendium "Redbook," we identified all drugs included on the Federal upper limit list in the second quarter of 2006. Federal upper limit amounts for these drugs were based on 150 percent of the lowest price published in the national compendia. During that quarter, CMS had established Federal upper limits for 530 drugs.

We then obtained calendar year (CY) 2005 Medicaid drug reimbursement and utilization data from CMS's Web site and identified the 25 drugs (of the 530) on the Federal upper limit list with the highest total Medicaid expenditures that year.²⁰

Acquisition Cost Data. For the 25 listed drugs with the highest total Medicaid expenditures in 2005, we collected second-quarter 2006 pricing and sales data from the three largest national distributors (AmerisourceBergen, McKesson, and Cardinal Health)²¹ and two smaller regional distributors (Mutual Drug Company and Burlington Drug Company). Each distributor was asked to provide the total dollar amount sold, the amount of discounts and rebates paid to purchasers, the net dollar amount sold, the total number of units sold, and the average selling price during the second quarter of 2006 for all NDCs associated with the top 25 Federal upper limit drugs.

AMP Data. We obtained AMP data for the second quarter of 2006 from CMS.

Data Analysis

Estimating Pharmacy Acquisition Costs for Selected Drugs. Among the five distributors, we totaled the dollar amount sold (net of reported discounts and rebates, when possible) for all NDCs associated with each of the 25 selected high-expenditure drugs, and divided this amount by the total number of units of each NDC sold. We also determined the

²⁰ CY 2005 reimbursement and utilization data were the most current available at the time of our sample selection.

²¹ According to industry sales reports, these three national companies account for the vast majority of market share among drug distributors.

lowest price reported to OIG by the distributors for any NDC associated with the 25 drugs.²²

Estimating Federal Upper Limit Amounts Under New Calculation Method. To estimate what Federal upper limit amounts would be under the new methodology set forth in section 6001(a) of the DRA, we determined the lowest AMP reported by manufacturers among NDCs associated with the 530 drugs on the Federal upper limit list in that quarter.

Under 42 CFR 447.332 (in effect during the time of our review), a Federal upper limit amount should be based on the least costly therapeutically equivalent drug that can be purchased by pharmacists in quantities of 100 (or if the drug is not commonly available in quantities of 100, a commonly listed package size). In determining the lowest AMP for any given Federal upper limit drug, we examined only NDCs in a commonly listed size that were identified as therapeutically equivalent in either CMS's drug product file²³ or the national drug compendium "Redbook." For the purpose of this study, AMPs for terminated NDCs were not used to estimate new Federal upper limit amounts.²⁴

Of the 530 drugs included on the Federal upper limit list in the second quarter of 2006, 9 did not have AMP data for any nonterminated, therapeutically equivalent NDCs of a commonly listed size. Therefore, we did not include these drugs in our analysis. For the remaining 521 drugs, we multiplied the lowest AMP by 250 percent to estimate the new Federal upper limit amounts under the methodology mandated by the DRA.

Comparing New and Second-Quarter 2006 Federal Upper Limit Amounts. For each of the 521 drugs included in our review, we calculated the percentage difference between the new Federal upper limit amounts (based on 250 percent of AMP) and the second-quarter 2006 Federal upper limit amounts (based on 150 percent of the lowest published

²² One of the five distributors did not provide sales and utilization data broken down by the NDC. Therefore, this distributor's data were not included in the determination of the lowest price for a drug.

²³ Available online at http://www.cms.hhs.gov/MedicaidDrugRebateProgram/09_DrugProdData.asp. Accessed on September 8, 2006.

²⁴ As reported in the national drug compendium "RedBook," a terminated NDC is one assigned to a product that has been deactivated by a manufacturer.

price). We categorized the drugs into ranges based on the percentage increases or decreases in their Federal upper limit amounts.

Comparing Federal Upper Limit Amounts to Pharmacy Acquisition Costs.

We calculated the percentage difference between the second-quarter 2006 Federal upper limit amounts and the average pharmacy acquisition costs for each of the 25 selected high-expenditure drugs. We then calculated the difference between the new Federal upper limit amounts (based on 250 percent of the lowest AMP) and the average pharmacy acquisition costs. For each of the 25 drugs, we also compared the lowest price reported by any of the distributors for any associated NDC to the new Federal upper limit amount.

Comparing the Lowest AMP to the Other AMPs. To assess whether the lowest AMPs used to set the new Federal upper limit amounts were representative of other AMPs for the same drug, we determined the second-lowest and volume-weighted AMPs for each of the 521 drugs under review. In identifying the second-lowest AMPs, we limited our analysis to nonterminated, therapeutically equivalent NDCs of a commonly listed size. We calculated the volume-weighted AMP among all NDCs for the drug by weighting the AMP for each individual NDC by the number of units of the NDC reimbursed by Medicaid in the second quarter of 2006. We then compared the lowest AMP to the second-lowest and volume-weighted AMPs for each of the 521 drugs and identified instances in which the lowest AMP was more than 60 percent below either of these other two figures.²⁵ We subset out the results for the 25 selected high-expenditure drugs for further analysis.

Determining if Other AMPs Could Help Identify Potential Issues. Among the 25 selected high-expenditure drugs, we identified any instances in which the lowest AMP was more than 60 percent below the second-lowest and/or volume-weighted AMP. For any drugs that exceeded this threshold, we determined whether the average pharmacy acquisition costs exceeded the new Federal upper limit amount. We repeated this

²⁵ In its proposed regulation, CMS uses a 70 percent rather than a 60-percent threshold in comparing the lowest AMP to the second-lowest AMP. We chose to use 60 percent in our analysis because whenever the lowest AMP exceeds this threshold relative to the second-lowest AMP, then the second-lowest AMP (and all other AMPs) for a drug would be higher than the new Federal upper limit amount. For example, a drug with a lowest AMP of \$0.40 would have a new Federal upper limit amount of \$1.00 (\$0.40 times 250 percent). If the second-lowest AMP is higher than this new Federal upper limit amount (e.g., \$1.01), then the lowest AMP would be at least 60 percent below the second-lowest AMP (\$0.40 is 60.4 percent below \$1.01).

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analysis for drugs that did not meet the 60-percent threshold. This analysis allowed us to determine whether exceeding the 60-percent threshold (compared to either the second-lowest or volume-weighted AMP) was linked to a drug's average acquisition cost being higher than the new Federal upper limit amount for these 25 drugs.

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Agency Comments



DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Administrator
Washington, DC 20201

DATE: APR 25 2007

TO: Daniel R. Levinson
Inspector General

FROM: Leslie V. Norwalk, Esq.
Acting Administrator 

SUBJECT: Office of Inspector General's (OIG) Draft Report: "Deficit Reduction Act of 2005: Impact on the Medicaid Federal Upper Limit Program," (OEI-03-06-00400)

The Centers for Medicare & Medicaid Services (CMS) appreciates the opportunity to review and comment on the OIG draft report entitled, "*Deficit Reduction Act of 2005: Impact on the Medicaid Federal Upper Limit Program.*" This report provides a preliminary assessment of how the change in methodology for calculating the Medicaid Federal Upper Limit (FUL) under the Deficit Reduction Act (DRA) of 2005 may change reimbursement to pharmacy providers.

As we further explain below, CMS strongly disagrees with the OIG's findings and recommendations on the effect of the change to set FULs on average manufacturer prices (AMPs). We find that the analysis is deficient in numerous ways and such deficiencies lead to flawed results and misleading conclusions. Specifically, we find that the analysis is deficient in the following ways:

- The AMPs used in the OIG's analysis are lower than appropriate because they fail to account for the deletion of customary prompt pay discounts required under the DRA. Our most current analysis based on the use of the monthly AMP data shows that adequate reimbursement may be achieved with FULs based on AMP.
- The acquisition costs used in the OIG's analysis are higher than appropriate because they do not fully account for discounts provided to pharmacies.
- The comparison, between pre-DRA FULs and the DRA FULs, is improper because the pre-DRA FULs are often inflated such that nearly all States (43) have maximum allowable cost (MAC) programs that pay far less than the FUL.
- The weighted average AMP used in the OIG's analysis as the benchmark to set the FUL is inconsistent with the legal requirement to use the lowest AMP and reflects the current incentive for pharmacies to purchase drugs which yield the greatest profit, rather than the most cost-effective drug.
- The mitigating effects of applying the FULs in the aggregate are ignored.

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Each of these flaws has the effect of exaggerating the reduction in pharmacy payment and collectively results in a severe distortion of the effects of the DRA revisions. We requested that the OIG revise its analysis to address these issues. While the OIG acknowledged the merit of these concerns, we understand that time pressures made further analyses impossible. We consider this “rush to report” harmful to the policy debate and regret that the OIG, which had been so instrumental in raising the policy concern of Medicaid’s high drug reimbursement rates, would issue this report in light of its inadequacies and misleading conclusions.

Our analysis, and that of several State Medicaid agencies, shows that adequate reimbursement can be achieved with FULs based on AMP. We suggest that the OIG wait until the final regulation which defines AMP is promulgated, before trying to assess its impact. It is only after a final definition of AMP has been issued that an accurate analysis of the impact of DRA can be conducted. We believe that an analysis that considers the actual AMPs used to determine the FULs, rather than a flawed proxy, would yield substantially different results from those presented in this report.

A fuller discussion of the OIG findings and recommendations and the CMS responses is attached.

Office of Inspector General’s Draft Report: “Deficit Reduction Act of 2005: Impact on the Medicaid Federal Upper Limit Program,” (OEI-03-06-00400)

This report provides a preliminary assessment of how the change in methodology for calculating the Medicaid Federal Upper Limit under the Deficit Reduction Act of 2005 may change reimbursement to pharmacy providers. The DRA requires the FUL to be set at 250 percent of the lowest average manufacturer price (computed without regard to customary prompt pay discounts extended to wholesalers). The previous FUL, or pre-DRA FUL, was calculated at 150 percent of the lowest published compendia price for the least costly therapeutically equivalent drug within an ingredient group.

To analyze the effect of the draft FUL, the OIG compared the draft FUL to the pre-DRA FUL for all drugs in FUL groups and also the draft FUL of 25 high-expenditure drugs to estimates of average acquisition cost. Five drug distributors provided pricing data for these 25 drugs to the OIG.

OIG Findings

The OIG estimates, using second quarter 2006 drug pricing data for all drugs with a FUL during that quarter, that FUL reimbursement amounts will decrease by a median of 61 percent under the new criteria. Overall, FUL amounts for 94 percent of such drugs will be reduced.

According to the OIG study, for 19 out of 25 high-expenditure drugs that were reviewed, the OIG found that average pharmacy acquisition cost would have exceeded the draft FUL. In other

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words, according to this study, only 6 of the 25 drugs reviewed would have an estimated average pharmacy acquisition cost below the estimated draft FUL.

Further, for 14 percent of the drugs on the FUL list, the lowest AMP was more than 60 percent below the second-lowest AMP. And, for 29 percent of reviewed drugs, the lowest AMP was more than 60 percent less than the volume-weighted AMP.

CMS Follow-up with the OIG

At CMS' request, the OIG provided us the raw data from the five distributors which identified the individual prices of these drugs. The OIG also met with us in response to our further analysis of this data and agreed to make certain changes in their final report. We requested that they conduct further analysis, in particular, to compare the average prices paid by Medicaid for the drugs in the quarter to the estimated acquisition cost. We also asked that they compare the draft FUL to the lowest acquisition cost. Due to time and data constraints, the OIG did not agree to these further analyses, but did agree to revise the draft report to provide more context to their findings. In particular, the OIG agreed to:

- State that drugs subject to a FUL account for a limited subset of Medicaid drug expenditures. For example, 4Q2005 data showed that only about 8.3 percent of Medicaid drug expenditures were for drugs subject to a FUL;
- Highlight the comparison of FULs calculated using the pre-DRA method to pharmacy acquisition costs to show the extent to which Medicaid may have overpaid for these drugs with the pre-DRA FUL and to add a chart to illustrate this point;
- Make note of the fact that the reduction in FUL amounts was directed by the DRA in order to save money; and,
- Rephrase parts of the recommendation to note that the FUL needed to be changed so that Medicaid did not overpay for drugs, note that most of the AMPs that resulted in the draft FULs being lower than the estimated acquisition cost were caused by "outlier" AMPs (AMPs with very low values that appear questionable as to their accuracy), and add information to stress that accurate manufacturer reporting of AMPs is critical for FULs when used for payment.

CMS Response

Based on the information provided and the methodology used, we do not concur with the OIG findings that the AMP-based FULs will be less than acquisition costs under the draft criteria established by the DRA.

As this report prominently notes, numerous prior OIG reports found that the published prices used to set FUL amounts often greatly exceeded prices available in the marketplace. The OIG

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outlined the need for reform in Medicaid pharmacy reimbursement and recognized that the DRA changes were based in part on their work. The pre-DRA FUL amounts often greatly exceeded pharmacy acquisition costs, and thus, may have resulted in increased costs to the States and Federal Government. This study acknowledges that pre-DRA FULs often far exceeded acquisition costs. Specifically, the OIG found that for 23 of the 25 high-expenditure drugs reviewed in this study, pre-DRA FUL amounts were more than double the average pharmacy acquisition cost. In 13 cases, the pre-DRA FUL amounts were at least 5 times higher than average acquisition costs.

Further, when the lowest pharmacy acquisition cost is used as the point of comparison, the pre-DRA FUL amounts were from one and one-half times to more than 52 times higher than that cost. In fact, the pre-DRA FUL was more than 13 times higher than the lowest pharmacy acquisition cost on average. These findings bolster OIG's previous findings that reiterate the need for reform in Medicaid pharmacy reimbursement.

However, we believe that the OIG's analysis is flawed in analyzing the draft FULs in several important ways and that each of these flaws exaggerates the impact of the draft FULs on pharmacies.

We believe the purpose of revising the FULs is to provide an incentive for pharmacies to buy the lowest price drug among competing generics. Therefore, the OIG's use of the average acquisition cost as the comparison point to the draft FULs does not recognize that pharmacies may seek out the lowest cost drugs to the extent that Medicaid reimbursement is reduced.

Accordingly, we believe that OIG's findings would represent a more accurate evaluation if the lowest price were used as a point of comparison for the DRA FUL. See Attachment A for a comparison by drug. Our analysis shows that by using the lowest pharmacy acquisition cost as the price comparison, using the OIG reported second quarter 2006 quarterly AMP basis for the DRA FUL, 15 (rather than 6) of the 25 drugs reviewed would have an estimated pharmacy acquisition cost below or equal to the estimated draft FUL. Using the February 2007 monthly AMP as the basis for the DRA FUL, 20 of the 25 drugs reviewed would have an estimated pharmacy acquisition cost below the estimated draft FUL.

Further, the majority of wholesalers/distributors (three of five) did not report prices net of rebates or price concessions that lower provider acquisition costs. This failure to include rebates or concessions inflates the estimated pharmacy acquisition costs used in the OIG's analysis. If the lowest distributor price is not net of discounts or rebates, we believe that the OIG should have imputed a discount and subtracted it from the price reported to estimate the true acquisition cost to the pharmacy.

We believe that the OIG's use of current market volume is also not indicative of a drug product's national availability. In volume weighting both the AMPs and the average pharmacy acquisition costs, the OIG implies that a lower priced drug with a low market volume in the data reviewed may be an indication that this drug is not nationally available. The OIG presents no evidence to

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substantiate this premise. We believe that it is important to understand that pharmacies benefited substantially by buying the generic drug with the greatest spread between actual acquisition cost and reported price. The market incentive was not to purchase the least costly drug, but rather the drug with the most inflated price. The intent of the DRA was to restore an efficient market incentive that would make purchase of the lowest price drug the most financially rewarding. Further analysis needs to be done to determine the influence this spread had on purchasing choices.

The FULs have been so high in the past that many States use State Maximum Allowable Cost programs that reimburse pharmacies far below the current FUL. Currently, 43 States have established MAC programs. CMS believes that the impact of these existing State cost-containment programs should have been included in the OIG analysis. The decreased FUL reimbursement amounts will not impact actual reimbursement to providers where current reimbursement amounts are based on lower State MAC reimbursement amounts in the vast majority of States.

This study also fails to note that Medicaid policy allows States to pay above the FUL as long as total expenditures for FUL drugs do not exceed the aggregate FUL amount. We have proposed to continue the policy that States have the ability to make payment at levels above the specific FUL for some drugs, provided that the State pays below the FUL for other drugs. In fact, CMS' analysis (see attachment A) shows that if the lowest pharmacy acquisition cost were used, the second quarter 2006 quarterly AMP based DRA FULs would exceed that pharmacy acquisition cost by nearly \$8 million for these drugs. If the February 2007 AMP DRA FULs are used, that FUL would exceed that pharmacy acquisition cost by nearly \$39 million. In fact, the February 2007 AMP based FULs exceed even the average pharmacy acquisition cost by over \$21 million. (We note that while the February 2007 AMPs are for a different time period than the acquisition cost data the OIG obtained, this was the only comparison we could make based on the available OIG data. As noted elsewhere in this report, we believe the OIG should delay this report until it can re-examine not only the more current monthly AMPs, but the effect of the final regulation.)

If Medicaid expenditures for these drugs using the old FULs of \$212 million are compared to the cost using the lowest pharmacy acquisition cost of \$37 million, States would overpay pharmacies by nearly \$175 million, or nearly six times the cost of the lowest pharmacy acquisition cost.

Additionally, this analysis did not address dispensing fees that Medicaid pays to pharmacies in addition to reimbursing for drug product costs. CMS recognizes that these fees are an important part of pharmacy reimbursement. We encourage States to review these fees in conjunction with changes States may consider for drug reimbursement.

As noted in this report, the OIG study uses a different AMP from what will be used to set the draft FULs, thereby underestimating the FULs. The DRA revises the definition of AMP, effective January 1, 2007, to exclude customary prompt pay discounts to wholesalers and requires drug manufacturers to include sales of authorized generics when they report their

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AMPs. Because prompt pay discounts decrease AMPs, their exclusion would increase the AMP and subsequently increase the FULs. Further, the proposed changes in the AMP calculation in the CMS proposed regulation, yet to be finalized, may also have an effect on the manufacturer submitted price. CMS has also proposed that the AMP of a terminated national drug code will not be used to set the FUL, beginning with the first day of the month after the actual termination date reported by the manufacturer to CMS. The OIG report does not address this proposed exclusion of AMPs in its analysis.

Since the release of the draft report, CMS has had the opportunity to analyze the monthly AMP data, submitted by the manufacturers per the provisions of the DRA, and the subsequent FUL calculations for the 25 high expenditure drugs in the OIG study. We have found that, using the February 2007 monthly AMP data, and applying the proposed outlier policy of eliminating the AMP of the lowest priced therapeutically and pharmaceutically equivalent drug that is not less than 30 percent of the next highest AMP, there are only 5 ingredient groups out of the 25 high expenditure ingredient groups in the review, whose lowest acquisition cost exceeds the draft FUL. (See attachment A)

OIG Recommendation

The OIG recommends that the CMS should monitor the new FUL amounts closely during initial implementation of the DRA provisions to ensure pharmacies receive adequate reimbursement. It also recommends that the CMS should take steps to identify when a new FUL amount may not be representative of a drug's true cost to pharmacies. These recommendations include issuing a final regulation that would focus on situations when the lowest AMP is significantly lower than the volume-weighted AMP for a drug, contacting manufacturers to validate reported data, examining utilization data to determine that the product on which the FUL is based is commonly prescribed in the marketplace, and providing pharmacists an opportunity to communicate when a drug is not available nationally at the FUL price. The OIG notes that the drug manufacturers are duly responsible to report accurate and verified AMPs.

Finally, the OIG recommends that the CMS work with the Congress to determine the proper course of action in situations in which 250 percent of the AMP may not be sufficient to cover pharmacy costs.

CMS Response

In our proposed rule, we invited comments from the public on how to implement the new FUL and invited suggestions on how to accomplish the goal of ensuring that the use of AMP in calculating the FUL will ensure that a drug is available nationally at the FUL price. CMS is evaluating the comments submitted on the proposed rule, CMS-2238-P, to ensure that all reasonable options are considered. CMS expects to issue this rule by July 1, 2007, as required by the DRA.

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We concur with the OIG recommendation that new FUL amounts should be monitored closely to ensure that reimbursement to pharmacies is adequate to cover acquisition costs. We also strongly agree with the OIG that the drug manufacturers have an important role to play in this regard. For a FUL based on AMP to work as intended, drug manufacturers must accurately report the AMPs for their drugs. The OIG is well positioned to evaluate the accuracy of manufacturers' submitted AMPs and to advise us of policies that might effect the proper reporting of such AMPs under the law.

We note that the Congress provided the OIG a role in advising CMS on how to clarify AMP. We appreciate the previous and ongoing OIG work in this area and we will give every consideration to the OIG's comments in the future as we did with the comments they provided prior to our development of our notice of proposed rulemaking. We hope to continue to work collaboratively with the OIG to ensure that the new methodology for FULs will be more than adequate to cover pharmacies' acquisition costs.

We appreciate the OIG analysis of how low AMPs may result in FULs that are lower than average acquisition cost. We agree with the OIG that the FULs in aggregate must be sufficient to cover the cost of the lowest priced drug that a pharmacy can obtain. To that end, we will continue to closely analyze the AMPs that are reported under the DRA and OIG's suggested approaches to monitoring the FULs. However, contrary to the OIG's recommendation for further legislation in this area, we believe the current law provides sufficient flexibility to provide supportable FULs.

In conclusion, the use of AMP to set FUL reimbursement for multiple source drugs, and making these AMPs available to the public, provides transparency in drug pricing. The prior lack of transparency leads to Medicaid paying too much for drugs. The AMPs are specific prices for individual drugs received by manufacturers from sales in the marketplace. Drug manufacturers submit AMPs to CMS under penalty of law for false reporting. We believe these changes will help capture the most accurate pricing data possible to assure that the Federal Government and State Medicaid programs are paying appropriately for generic drugs. We believe that this drug pricing transparency will lead to more equitable and appropriate reimbursement for prescription drugs as States will be more aware about the true market price of prescription drugs.

We appreciate the OIG follow-up information and that the OIG could not provide further analyses due to time and data constraints. Because we believe that setting the FULs appropriately is an important part of the Medicaid drug program and the DRA AMPs are, we request that the OIG consider our earlier discussions and review this response to work collaboratively with us and delay issuing this report in final.

Attachment A

Drug	A. OIG Q2 Reimbursed Units	B. CMS Current FUL	C. Q2 Expenditure using Current FUL	D. Lowest Pharmacy Acquisition Cost	E. Q2 Expenditure using Lowest Pharmacy Acquisition Cost	F. OIG Reported Average Pharmacy Acquisition Cost	G. Q2 Expenditure using Average Pharmacy Acquisition Cost	H. OIG Reported Q2Y06 New FUL	I. Q2 Expenditure using Q2 New FUL	J. February 2007 Monthly FUL	K. Q2 Expenditure using February 2007 FUL
Acetaminophen/Hydrocodone											
Bicarbonate 500MG-5MG Tablet	35,572,197	\$0.0833	\$2,963,164.04	0.030	\$1,087,185.92	\$0.032	\$1,138,310.32	\$0.039	\$1,387,315.70	0.065	\$2,312,192.83
Acetaminophen/Propoxyphene Napsylate 650MG-100MG Tablet	15,578,413	\$0.1800	\$2,804,114.34	0.030	\$487,352.39	\$0.049	\$763,342.24	\$0.024	\$373,881.91	0.066	\$1,028,175.26
Albuterol .08MG/Actuation Aerosol Solid (Inhaler)	22,689,434	\$0.4357	\$9,908,475.92	0.280	\$6,353,041.58	\$0.335	\$7,600,960.46	\$0.767	\$17,402,786.04	0.713	\$16,177,566.59
Albuterol Sulfate 0.83% Solution	86,002,930	\$0.1150	\$9,890,336.93	0.030	\$2,580,087.90	\$0.041	\$3,526,120.12	\$0.011	\$946,032.23	0.111	\$9,546,325.21
Gabapentin 300MG Capsule	19,704,055	\$1.3083	\$25,778,814.88	0.100	\$1,970,405.48	\$0.157	\$3,093,536.60	\$0.108	\$2,128,037.92	0.053	\$1,044,314.90
Gabapentin 400MG Capsule	4,107,344	\$1.5896	\$6,446,887.79	0.030	\$123,220.30	\$0.203	\$833,790.92	\$0.030	\$123,220.33	0.044	\$180,723.15
Gabapentin 600MG Tablet	9,880,423	\$2.4704	\$24,408,587.10	0.360	\$3,556,952.30	\$0.447	\$4,416,549.10	\$0.476	\$4,703,081.37	0.258	\$2,549,149.15
Gabapentin 800MG Tablet	2,830,053	\$2.9886	\$8,372,995.35	0.430	\$1,216,922.87	\$0.573	\$1,621,620.48	\$0.669	\$1,893,305.58	0.172	\$486,769.15
Glimepiride 4MG Tablet	2,366,105	\$0.4100	\$970,103.05	0.080	\$189,288.40	\$0.083	\$196,366.72	\$0.077	\$182,190.09	0.029	\$68,617.05
Glyburide 5MG Tablet	8,645,295	\$0.2831	\$2,447,482.88	0.040	\$345,811.78	\$0.069	\$596,525.32	\$0.031	\$268,004.13	0.064	\$553,298.85
Glyburide/Metformin Hydrochloride 5MG-500MG Tablet	4,826,816	\$1.0026	\$4,839,365.72	0.110	\$530,949.76	\$0.142	\$685,407.87	\$0.105	\$506,815.68	0.166	\$801,251.46
Lorazepam 1MG Tablet	23,463,589	\$0.5718	\$13,418,479.95	0.030	\$703,907.66	\$0.040	\$938,543.54	\$0.033	\$774,298.42	0.061	\$1,431,278.90
Metformin Hydrochloride 1000MG Tablet	11,434,045	\$0.4597	\$5,256,230.54	0.020	\$228,680.90	\$0.091	\$1,040,498.11	\$0.005	\$57,170.23	0.013	\$148,642.59
Metformin Hydrochloride 500MG Tablet	25,923,915	\$0.3557	\$9,221,136.56	0.010	\$259,239.15	\$0.055	\$1,425,815.32	\$0.026	\$674,021.79	0.034	\$881,413.11
Onepazole 20MG Enteric Coated Tablet	1,701,502	\$3.9790	\$6,770,275.91	0.430	\$731,645.80	\$0.638	\$1,085,588.19	\$0.299	\$508,749.06	0.643	\$1,094,065.70
Oxycodone Hydrochloride 20MG Tablet Extended Release	2,468,706	\$1.8374	\$4,536,000.40	0.730	\$1,802,155.38	\$0.875	\$2,160,117.75	\$0.080	\$197,496.48	1.857	\$4,584,387.04
Oxycodone Hydrochloride 40MG Tablet Extended Release	3,151,038	\$3.2601	\$10,272,700.35	1.290	\$4,064,839.56	\$1.445	\$4,553,250.52	\$0.191	\$601,848.34	1.439	\$4,534,344.29
Oxycodone Hydrochloride 80MG Tablet Extended Release	2,649,261	\$6.1175	\$16,206,854.17	2.470	\$6,543,674.67	\$2.633	\$6,975,504.21	\$2.719	\$7,203,340.66	8.211	\$21,753,082.07
Paroxetine Hydrochloride 20MG Tablet	5,087,333	\$2.5200	\$12,820,078.91	0.200	\$1,017,466.58	\$0.445	\$2,263,863.14	\$0.025	\$127,183.32	0.281	\$1,429,540.55
Paroxetine Hydrochloride 40MG Tablet	2,678,903	\$2.7000	\$7,233,038.72	0.330	\$884,038.07	\$0.517	\$1,384,992.97	\$0.158	\$423,266.71	0.434	\$1,162,644.00
Potassium Chloride 20MEG Tablet Extended Release	8,480,565	\$0.4625	\$3,922,261.16	0.010	\$84,805.65	\$0.121	\$1,026,148.33	\$0.086	\$729,328.56	0.045	\$381,625.41
Ranitidine Hydrochloride 150MG Tablet	19,023,740	\$0.1088	\$2,069,782.91	0.010	\$190,237.40	\$0.030	\$570,712.20	\$0.042	\$798,997.08	0.021	\$399,498.54
Ribavirin 200MG Capsule	1,228,663	\$7.5764	\$9,308,838.57	0.400	\$491,465.00	\$2.304	\$2,830,838.40	\$0.400	\$491,465.00	1.813	\$2,227,565.11
Tramadol Hydrochloride 50MG Tablet	28,970,114	\$0.3068	\$8,774,430.82	0.010	\$269,701.14	\$0.049	\$1,321,535.56	\$0.027	\$728,193.06	0.031	\$836,073.52
Zonisamide 100MG Capsule	3,704,845	\$1.1742	\$4,350,229.27	0.350	\$1,296,695.83	\$0.657	\$2,434,062.32	\$0.405	\$1,500,462.32	0.045	\$166,718.04
TOTAL			\$212,488,676		\$36,969,751		\$54,484,012		\$44,730,502		\$75,779,262



A C K N O W L E D G M E N T S

This report was prepared under the direction of Robert A. Vito, Regional Inspector General for Evaluation and Inspections in the Philadelphia regional office, and David E. Tawes, Director of the Medicare and Medicaid Prescription Drug Unit.

Other principal Office of Evaluation and Inspections staff from the Philadelphia regional office who contributed include Lauren McNulty and Jessica Demko. Central office staff who contributed include Sarah Craren, Cynthia Thomas, and Gina Maree.